REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: 102000007779

Product name(s): Flufenacet SC 508.8 G

Chemical active substance(s):

Flufenacet 508.8 g/L

Central Zone

Zonal Rapporteur Member State:Poland

CORE ASSESSMENT

(Authorisation)

Applicant: Bayer Crop Science Division

Submission date: 30 June 2021, updated December 2022

MS Finalisation date: March 2023 (initial Core Assessment)

June 2023 (final Core Assessment)

Version history

When	What
June 2021	Original Bayer Crop Science Division submission
December 2022	Bayer submission with additional studies for non-target arthropods and soil organisms This document is an updated version of the draft Registration Report M-771029-01-1 prepared by the applicant to include new studies for the risk assessment for non-target arthropods and soil organisms. Additions to the original document are highlighted in yellow; deletions are crossed out and marked green.
March 2023	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
June 2023	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow. Information no longer relevant ~~is struck through and shaded~~.

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
29	POL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage									
30	POL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage									
31	POL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage									
32	POL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage									
33	POL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage									
34	POL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage									

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
35	POL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
36	POL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
37	POL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
38	POL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
39	POL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
40	POL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
89	POL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
90	POL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
91	POL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
92	POL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
93	POL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
94	POL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
95	POL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
96	POL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
129	POL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
130	POL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
131	POL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
132	POL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
53	SVK	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
54	SVK	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
55	SVK	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
56	SVK	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
57	SVK	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
58	SVK	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
59	SVK	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
60	SVK	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
61	SVK	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
62	SVK	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
63	SVK	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
64	SVK	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
97	SVK	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
98	SVK	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
99	SVK	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
100	SVK	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
101	SVK	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
102	SVK	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
103	SVK	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
104	SVK	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
133	SVK	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
134	SVK	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								

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135	SVK	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
136	SVK	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
65	BEL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
66	BEL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
67	BEL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
68	BEL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
69	BEL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
70	BEL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
71	BEL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
72	BEL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								

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73	BEL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
74	BEL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
75	BEL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
76	BEL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
105	BEL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
106	BEL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
107	BEL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
108	BEL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
109	BEL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
110	BEL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								

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112	BEL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
137	BEL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
138	BEL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
139	BEL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
140	BEL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
77	IRL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
78	IRL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
79	IRL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
80	IRL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
81	IRL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
82	IRL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
83	IRL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
84	IRL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
85	IRL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
86	IRL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
87	IRL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
88	IRL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
113	IRL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
114	IRL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
115	IRL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
116	IRL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
117	IRL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
118	IRL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
119	IRL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
120	IRL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
141	IRL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
142	IRL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage								
143	IRL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								
144	IRL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage								

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 "Conclusion"

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of application possible under practical conditions of use must be provided
(9) Minimum interval (in days) between applications of the same product.
(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions

9.1.1 Overall conclusions

zRMS comments:

Conclusions presented in points 9.1.1.1 to 9.1.1.7 below were checked by the zRMS and amended where necessary.

9.1.1.1 Effects on birds (KCP 10.1.1),Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

The risk assessment for effects on birds and other terrestrial vertebrates was carried out for the use patterns of the product FFA SC 508.8 G supported in the zone.

The risk birds and mammals from dietary exposure after the uses supported for the product FFA SC 508.8 G is acceptable. Furthermore, the assessment of the effects of exposure via drinking water and secondary poisoning indicate acceptable risk. Overall, it can be concluded that the risk associated with the recommended use of FFA SC 508.8 G is low for birds and other terrestrial vertebrates.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

The risk for aquatic organisms based on refined risk assessment is considered acceptable provided that the following risk mitigation measures are applied:

~~For use group A & B (application rate of 1 x 0.48 L prod./ha on winter cereals pre- and post-emergence at BBCH 00-09 and BBCH 10-13) the necessary mitigation measures include a 20 m no spray buffer zone + a 20 m vegetated strip and the product should not be used on artificially drained soil.~~
~~For use group C & D (application rate of 1 x 0.24 L prod./ha on winter cereals pre- and post-emergence at BBCH 00-09 and BBCH 10-13) the necessary mitigation measures include a 10 m no spray buffer zone + a 10 m vegetated strip and the product should not be used on artificially drained soil.~~
~~Depending on country specific requirements, some member states might have less stringent mitigation measures.~~

Group use A
Winter cereals, BBCH 00-09, pre-emergence, autumn - 1×244.2 g a.s./ha, (1 x 0.48 L/ha)

- scenarios D3, D4, D5, R1 (pond): acceptable risk with no need for risk mitigation measures
- scenarios: R1 (stream), R3, R4: acceptable risk with 20 m VFS
- scenarios D1, D2, D6: the risk unresolved with 20 m VFS

Group use B
Winter cereals, BBCH 10-13, early post emergence, 1 x 244.2 kg a.s./ha, (1 x 0.48 L/ha)

- scenarios D3, D4, D5, R1 (pond), R4: acceptable risk with no need for risk mitigation measures
- scenarios: R1 (stream), R3: acceptable risk with 20 m VFS
- scenarios D1, D2, D6: the risk unresolved with 20 m VFS

Group use C
Winter cereals, BBCH 00-09, pre-emergence, 1 x 0.1221 kg a.s./ha, (1 x 0.24 L/ha)

- scenarios D3, D4, D5, R1 (pond), D1 (stream), D6: acceptable risk with no need for risk mitigation measures
- scenarios: R1, R3, R4: acceptable risk with 10 m VFS
- scenarios D1 (ditch), D2: the risk unresolved with 20 m VFS

Group use D
Winter cereals, BBCH 10-13, post - emergence, 1×0.1221 g a.s./ha, (1 x 0.24 L/ha)
- scenarios D3, D4, D5, R1 (pond), R4: acceptable risk with no need for risk mitigation measures
- scenarios: R1, R3: acceptable risk with 10 m VFS
- scenarios D1, D2, D6: the risk unresolved with 20 m VFS

Concerned Member States must decide on applicability of indicated risk mitigation measures in their countries at the product authorization.
Please note that additional aquatic risk assessment may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.
The risk for metabolites is covered by the active substance-flufenacet.

9.1.1.3 Effects on bees (KCP 10.3.1)

The hazard quotients for both contact and oral exposure are below the trigger of concern (QH ≤ 50) for the active ingredient and the formulation. Therefore, it can be concluded that no unacceptable risk to bees is expected using the product according to the proposed use pattern at a maximal application rate of 0.480 L product/ha in winter cereals.
It should be noted that the EPPO 2010 scheme does not recommend a chronic assessment for adults for foliar spray applications. Therefore, consideration of the chronic risk is left at MSs level.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

The NTA risk assessment indicates that no unacceptable adverse effects for non-target arthropods are to be expected for the application of FFA SC 508.8 G at a maximum application rate of 0.48 L/ha (=244.2 g a.s./ha) for the in- or off-field habitats following the use of the product according to the proposed use pattern. No mitigation measures are required.

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

Based on the risk assessment findings no ecologically adverse effects on earthworms and other soil non-target macro-organisms can be concluded for the maximum intended application rate of up to 0.48 L/ha FFA SC 508.8 G in cereals (use group A).

The risk assessment indicates that no adverse effects on soil micro-organisms are to be expected when the product is applied according to the proposed use pattern. Effects on non-target terrestrial plants (KCP 10.6)

9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)

Based on the probabilistic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields and that no mitigation measures are necessary for the intended use rate.
Based on the deterministic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:
o 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for application rate 1 x 0.48 L/ha (correspond to 1 x 244.2 g a.s./ha)
o 5 m buffer zone, or alternatively 50% drift reducing spray nozzles for application rate 1 x 0.24 L product/ha (correspond to 122.1 g a.s./ha)
The final decision of risk mitigation measures should be decided at MSs level.

9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

No further information is available or considered to be necessary.

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

Table 9.1-2: Critical use pattern of FFA SC 508.8 G grouped according to crop

Grouping according to crop			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
Use group A*	Use no. 1, Winter cereals, BBCH 00-09, 244.2 g/ha (pre-emergence)	BBCH range and application rate	BBCH range and application rate
Use group B**	Use no. 2, Winter cereals, BBCH 10-13, 244.2 g/ha (early post-emergence)	BBCH range and application rate	BBCH range and application rate
Use group C***	Use no. 3, Winter cereals, BBCH 00-09, 122.1 g/ha (pre-emergence)	BBCH range and application rate	BBCH range and application rate
Use group D****	Use no. 4, Winter cereals, BBCH 10-13, 122.1 g/ha (early post-emergence)	BBCH range and application rate	BBCH range and application rate

* Use group A 29;33;37;89;93;129;53;57;61;97;101;133;65;69;73;105;109137;77;81; 85;113;117;141

** Use group B 30;34;38;90;94;130;54;58;62;98;102;134;66;70;74;106;110;138;78;82;86;114;118;142

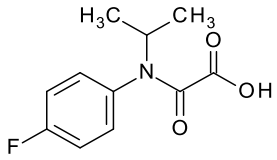
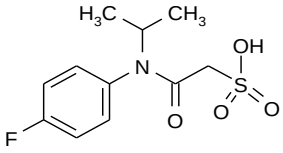
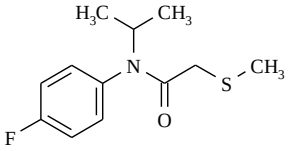
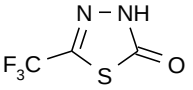
*** Use group C 31;35;39;91;95;131;55;59;63;99;103;135;67;71;75;107;111;139;79;83;87;115;119;143

**** Use group D 31;35;39;91;95;131;55;59;63;99;103;135;67;71;75;107;111;139;79;83;87;115;119;143

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of FFA SC 508.8 G is indicated in the table.

Table 9.1-3 Metabolites of flufenacet

Metabolite[1]	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Risk assessment required?
FOE oxalate (M1)	225.2 g/mol		Soil 15.6% (aerobic)	Yes, aquatic and soil organisms
FOE sulfonic acid (M2)	275.3 g/mol		Soil 26.3% (aerobic)	Yes, aquatic and soil organisms
FOE methylsulfide (M5)	241.3 g/mol		Water/sediment: 11.5% entire system	Yes, aquatic organisms
FOE-thiadone (Thiadone, M9)	170.1 g/mol		Water/sediment: 84.3% entire system	Yes, aquatic organisms

[1] The structures and report names of degradation products identified in e-fate studies reflect in general their neutral (uncharged) species. The degradation product FOE sulfonic acid has a pKa-value < 2 and hence, is deprotonated under environmental conditions. Therefore, the environmental relevant deprotonated species was used for all studies which were conducted to elucidate the toxicological and ecotoxicological properties of this degradation product as well as its fate in the environment, plants and animals.

zRMS comments:

Metabolites relevant for soil and water compartment listed in Table 9.1-3 are the same as indicated in EC review report 7469/VI/98-Final (2003).
The maximum occurrence is relevant for exposure evaluation, for mor information agreed in this area please refer to the Core Assessment, Part B, Section 8, where all respective data are provided and used in calculation of PECsoil and PECsw/sed values, considered further in the risk assessment.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with flufenacet and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents. Effects on birds of FFA SC 508.8 G were not evaluated as part of the EU assessment of flufenacet.
Studies and endpoints used for the risk assessment are in line with the endpoints listed for the EU review of the concerned active substance. Justifications are provided below.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Bobwhite quail *Colinus virginianus*	Flufenacet	Oral Acute	LD_{50} = 1608 mg a.s./kg bw	EC review report 7469/VI/98-Final (2003)
Mallard duck *Anas platyrhynchos*	Flufenacet	5-day dietary	LC_{50} > 4970 ppm LC_{50} > 949 mg a.s./kg bw	EC review report 7469/VI/98-Final (2003)
Colinus virginianus	Flufenacet	5-day dietary	LC_{50} > 5317 ppm **LDD_{50} > 755 mg a.s./kg bw** [1)]	EC review report 7469/VI/98-Final (2003)
Mallard duck M-429545-01-1 *Anas platyrhynchos*	Flufenacet	Dietary Reproductive toxicity	NOEC = 88 ppm NOEL = **9.4** mg a.s./kg bw	EC review report 7469/VI/98-Final (2003)
			~~NOAEL = 9.87 mg /kg bw/d~~	~~See justification~~

1) Since the dietary LC_{50} is lower than the acute LD_{50} and mortalities were observed at the two highest concentrations in the dietary study, the $LC_{50} \succeq$ 755 mg/kg bw is used for the acute risk assessment (EFSA, 2009).

zRMS comments:

Avian toxicity data for flufenacet are in line with the EU agreed endpoints reported in the EC review report 7469/VI/98-Final (2003). Since the dietary LC_{50} is lower than the acute LD_{50}, zRMS agrees with the LC_{50} of 755 mg/kg bw used for the acute risk assessment.

Metabolites of flufenacet

To determine the residue behaviour of flufenacet in plants, trials were conducted in cereals, corn, sunflower, and soybean. The results show that no flufenacet residues above the LOQ of 0.05 mg/kg were determined (Monograph Annex IIA, Point 6). Therefore, it can be concluded that a risk from residues of flufenacet and/or its metabolites in plants to birds is not to be expected. In addition, flufenacet metabolites have been detected in laying hen (see Monograph Annex IIA, Point 5.1.2.2). Flufenacet (fluorophenyl label) in poultry appeared to involve the mercapturic acid pathway resulting in a wide range of methylsulfinyl and methylsulfonyl containing metabolites produced from further metabolisation of the cysteine or mercapturic acid conjugates. Flufenacet (thia-diazole label) was rapidly cleaved at the ether bond yielding thiadone. Its glucuronic acid conjugate (M24) was detected in liver.

9.2.1.1 Justification for new endpoints

Table 9.2-2: Justification for new endpoints.

Species	Substance	Exposure System	Results	Justification
Mallard duck	Flufenacet	Dietary Reproductive toxicity 21 w	NOAEL = 9.87 mg a.s./kg bw/d	The NOEC of 88 ppm was converted into a dose (mg a.s./kg bw/d) based on on body weight effects seen only in female birds at 211 ppm, whereas in males no significant body weight effects were recorded up to the highest does level (544 ppm): Mean body weight of female birds (n= 6) during week 1 – 8 = 1114 g Mean food consumption = 125 g/bird/day; Resulting food consumption per kg bird = 112.2 g. At a dietary concentration of 88 mg/kg diet (ppm), this corresponds to a dose level of 9.87 mg/kg bw/day.

The endpoint has been recalculated using information from the actual study and not with default values (correction by a factor 0.1 according to EFSA Birds &Mammals GD (2009)).

zRMS comments:

zRMS disagrees with conversion of NOEC to NOAEL = 9.87 mg a.s./kg bw/d value presented in Table 9.2-2 above.
Based on the study results presented in the DAR, an average daily feed consumption of 125 g/bird/d and an average body weight of 1173.38 g a daily dose of 9.4 mg a.s./kg bw/d was determined (according to EFSA GD for birds and mammals, 2009) by zRMS. It should be indicated that this value was peer reviewed in the ongoing process of renewal of a.s.-flufenacet and considered acceptable.
Therefore, NOEL = **9.4 mg a.s./kg bw** should be used in the risk assessment.

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Screening assessment

Table 9.2-3: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FFA SC 508.8 in cereals (use group A)

Intended use	Cereals, BBCH 00-09				
Active substance/product	Flufenacet				
Application rate (kg/ha)	1 × 0.2442				
Acute toxicity (mg/kg bw)	>755				
TER criterion	10				
Crop scenario Growth stage	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bare soils	Small granivorous bird	24.7	1.0	6.03	>125
Reprod. toxicity (mg/kg bw/d)	9.4~~9.87~~				
TER criterion	5				
Crop scenario Growth stage	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bare soils	Small granivorous bird	11.4	1.0 × 0.53	1.48	6.35~~6.69~~

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-4: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FFA SC 508.8 in cereals (use group B)

Intended use	Cereals, BBCH 10-13				
Active substance/product	Flufenacet				
Application rate (kg/ha)	1 × 0.2442				
Acute toxicity (mg/kg bw)	>755				
TER criterion	10				
Crop scenario Growth stage	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals	Small omnivorous bird	158.8	1.0	38.8	>19.5
Reprod. toxicity (mg/kg bw/d)	9.4~~9.87~~				
TER criterion	5				
Crop scenario Growth stage	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals	Small omnivorous bird	64.8	1.0 × 0.53	8.39	**1.12**~~1.18~~

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-5: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FFA SC 508.8 in cereals (use group C)

Intended use	Cereals, BBCH 00-09				
Active substance/product	Flufenacet				
Application rate (kg/ha)	1 × 0.1221				
Acute toxicity (mg/kg bw)	>755				
TER criterion	10				
Crop scenario Growth stage	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bare soils	Small granivorous bird	24.7	1.0	3.02	>250

Reprod. toxicity (mg/kg bw/d)	9.4~~9.87~~				
TER criterion	5				
Crop scenario Growth stage	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bare soils	Small granivorous bird	11.4	1.0 × 0.53	0.738	12.73 ~~13.4~~

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-6: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FFA SC 508.8 in cereals (use group D)

Intended use	Cereals, BBCH 10-13				
Active substance/product	Flufenacet				
Application rate (kg/ha)	1 × 0.1221				
Acute toxicity (mg/kg bw)	>755				
TER criterion	10				
Crop scenario Growth stage	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals	Small omnivorous bird	158.8	1.0	19.4	>38.9
Reprod. toxicity (mg/kg bw/d)	9.4~~9.87~~				
TER criterion	5				
Crop scenario Growth stage	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals	Small omnivorous bird	64.8	1.0 × 0.53	4.19	**2.24** ~~2.35~~

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comments:

Screening step in the risk assessment

The acute screening step risk assessment for flufenacet is validated by zRMS.
TER_A values for the exposure to flufenacet for all use groups are above the trigger of 10, indicating acceptable risk for birds.
It should be noted that the long-term risk was performed by the Applicant with consideration NOEAL of 9.87 mg a.s./kg bw value, while the NOEL of 9.4 mg a.s./kg bw value should be used (please see in the commenting boxes under Table 9.2.1.1.).
The evaluations presented in Table 9.2-3 to Table 9.2-6 above were amended accordingly with consideration of the NOEL = 9.4 mg pm/kg bw/d.
Based on the results for use groups A and C (pre-emergence application at rates 1 x 0.1221 and 1 x 0.244.2 kg a.s./ha) the acceptable risk has been indicated while for use groups B and D (post emergence application at rates 1 x 0.1221 and 1 x 0.244.2 kg a.s./ha) the Tier 1 risk assessment is required.

First-tier assessment

Table 9.2-7: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of FFA SC 508.8 in cereals (use group B)

Intended use	Cereals, BBCH 10-13				
Active substance/product	Flufenacet				
Application rate (kg/ha)	1 × 0.2442				
Acute toxicity (mg/kg bw)	>755				
TER criterion	10				
Crop scenario Growth stage	**Generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird “goose”	30.5	1.0	7.45	>101
Cereals BBCH 10–29	Small omnivorous bird “lark”	24.0	1.0	5.86	>129
Reprod. toxicity (mg/kg bw/d)	9.4~~9.87~~				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird “goose”	16.2	1.0 × 0.53	2.10	**4.47** ~~4.71~~
Cereals BBCH 10–29	Small omnivorous bird “lark”	10.9	1.0 × 0.53	1.41	6.66 ~~7.00~~

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-8: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of FFA SC 508.8 in cereals (use group D)

Intended use	Cereals, BBCH 10-13				
Active substance/product	Flufenacet				
Application rate (kg/ha)	1 × 0.1221				
Acute toxicity (mg/kg bw)	>755				
TER criterion	10				
Crop scenario Growth stage	**Generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird “goose”	30.5	1.0	3.72	>203
Cereals BBCH 10–29	Small omnivorous bird “lark”	24.0	1.0	2.93	>258
Reprod. toxicity (mg/kg bw/d)	9.4~~9.87~~				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird “goose”	16.2	1.0 × 0.53	1.05	8.95 ~~9.41~~
Cereals	Small omnivorous bird “lark”	10.9	1.0 × 0.53	0.705	13.3

BBCH 10–29					14.0

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comments:

Based on the calculations at Tier 1 risk assessment further refinement is still required for use group C (post-emergence application at rate 1 x 0.2442 kg a.s/ha) for generic focal species Large herbivorous bird "goose" at BBCH 10-13.

9.2.2.2 Higher-tier risk assessment

Large herbivorous bird "goose"

Additional refinement potential can be employed by incorporating a PT value for greylag geese in cereals (autumn and winter application) as reported in xxx (2010, M-429545-01-1, Appendix 2): 90th percentile PT for greylag geese in cereals: 0.8 (consumer goose).

For illustration, below the screenshot of Table 17 on page 19 of xxx (2010), providing highly conservative PT – value recommendations for greylag geese in cereals is included.

Screenshot Table 17 on page 19 of xxx (2010):

Table 17 PT values for greylag geese – consumer goose-days only. The figures in bold highlight those scenarios where the upper confidence limit is 1.00, which is the maximum value for PT.

Season	Crop	No. of goose-days	No. of birds contributing goose-days	90th percentile PT value (95% CLs)	95th percentile PT value (95% CLs)
Spring (March – May)	Cereal	25	6	0.58 (0.50 – 0.70)	0.66 (0.57 – 0.78)
	All crops	27	6	0.57 (0.48 – 0.68)	0.65 (0.55 – 0.76)
Summer (June – August)*	All crops	11	5	0.79 (0.57 – 0.98)	**0.88 (0.67 – 1.00)**
Autumn (September – November)	Cereal	39	6	0.80 (0.64 – 1.00)	**1.00 (0.78 – 1.00)**
	All crops	54	6	**1.00 (1.00 – 1.00)**	**1.00 (1.00 – 1.00)**
Winter (December – February)	Cereal	27	2	0.67 (0.59 – 0.77)	0.74 (0.66 – 0.84)
	All crops	27	2	0.67 (0.59 – 0.76)	0.74 (0.65 – 0.83)

Table 9.2-9: Higher-tier assessment of the long-term/reproductive risk due to the use of FFA SC 508.8. in cereals (use group B) – refined parameter (*) are further described and justified in the text above

Intended use	Cereals, BBCH 10-13					
Active substance/product	Flufenacet					
Application rate (kg/ha)	1 × 0.2442					
Reprod. toxicity (mg/kg bw/d)	9.4~~0.87~~					
TER criterion	5					
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**PT**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose"	16.2	1.0 × 0.53	0.8*	1.67 ~~1.68~~	5.62 ~~5.9~~

zRMS comments:

zRMS agrees with refinement based on PT value for large herbivorous bird.
According to bird bible[1], the most relevant species for cereal BBCH of 10-13 is the Brent Goose as it is a winter visitor and so corresponds to the application timing of FFA SC 508.8 G. According to the 'Consolidation of bird and mammal PT data for use in risk assessment' (xxx, 2010), the PT for Graylag geese in cereals (consumers goose days only, 90th percentile) is 0.80 from September to November and 0.67 from December to February. zRMS considered that the PT value of 0.8 for Graylag geese could be used to Brent geese and thus can be used in the refined risk assessment for herbivorous birds.

Overall, based on Applicants' and zRMS calculations, acceptable risk to birds from compounds active substance flufenacet may be concluded from the intended uses of FFA SC 508.8 G.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario
Since FFA SC 508.8 G is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario
Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With an arithmetic mean K(f)oc of 201, flufenacet belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for birds from all other intended uses (see 9.1.2).

[1] J.M. Buxton, D.R. Crocker & J.A. Pascual , MILESTONE REPORT Birds and farming: information for risk assessement, 1998 Update CONTRACT PN0919, CSL Project No. M37

Flufenacet:

Effective application rate (g/ha) =	244.2		
Acute toxicity (mg/kg bw) =	755	quotient =	0.32
Reprod. toxicity (mg/kg bw/d) =	9.4 ~~9.87~~	quotient =	25.97 ~~24.7~~

zRMS comments:

No unacceptable risk to birds is identified from drinking water exposure.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of flufenacet (log P_{ow} = 3.2) exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is required for flufenacet. Bioconcentration studies were conducted with active substances. The BCF values resulted in in 71.4 for flufenacet (EC review report, 2003).

The metabolites of flufenacet: FOE sulfonic acid, FOE oxalate, FOE-thiadone, and FOE methylsulfide have a log P_{ow} value of respectively -2.75 (all pH), -2.2 (pH 7), of 0.62 (pH 7) and 2.6 (pH 7). Therefore, it is not necessary to consider the risk from secondary poisoning for these metabolites.

Risk assessment for earthworm-eating birds via secondary poisoning
According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g, resulting in FIR/bw = 1.05 for earthworm eating birds. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for birds from all other intended uses (see 9.1.2).

Table 9.2-10: Assessment of the risk for earthworm-eating birds due to exposure to flufenacet via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals (use group A)

Parameter	Flufenacet	comments
PECsoil (twa = 21 d) (mg/kg soil)	0.285	See section B8 (Chapter 8.7.2) PEC_{soil} (twa = 21 d) + $PEC_{soil,plateau}$ (<0.001 mg/kg, 20 cm mixing depth)
log Pow / Pow	3.2 / 1600	EC review report 7469/VI/98-Final (2003)
Koc	202.4	Arithmetic mean (n = 5)
Foc	0.02	Default
BCFworm	4.951	$BCF_{worm/soil}$ = ($PEC_{worm,ww}/PEC_{soil,dw}$) = $(0.84 + 0.012 \times P_{ow}) / f_{oc} \times K_{oc}$
PECworm	1.411	PECworm = PECsoil × BCFworm/soil
Daily dietary dose (mg/kg bw/d)	1.481	DDD = PECworm × 1.05
NOAEL (mg/kg bw/d)	9.4 ~~9.87~~	
TER_{lt}	6.34 ~~6.6~~	

TER values shown in bold fall below the relevant trigger.

TER_{mix} is with a value of 6.6 above the respective trigger of 5 and therefore shows an acceptable risk for earthworm-eating birds due to exposure to flufenacet via bioaccumulation in earthworms.

Risk assessment for fish-eating birds via secondary poisoning
According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body

weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for use group A also covers the risk for birds from all other intended uses for flufenacet (see 9.1.2).

Table 9.2-11: Assessment of the risk for fish-eating birds due to exposure to flufenacet via bioaccumulation in fish (secondary poisoning) for the intended use in crop (A group)

Parameter	Flufenacet	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.0572	Maximum PEC_{sw} (twa = 21 d) value resulting from Step1 (see Part B8, chapter 8.9.2).
BCF_{fish}	71.4	EC review report 7469/VI/98-Final (2003)
BMF	Not relevant	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	4.084	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.649	$DDD = PEC_{fish} \times 0.159$
NOAEL (mg/kg bw/d)	9.4 ~~9.87~~	
TER_{lt}	14.48 ~~15.2~~	

TER values shown in bold fall below the relevant trigger.

TER_{mix} is with a value of 15.2 above the respective trigger of 5 and therefore shows an acceptable risk for fish-eating birds due to exposure to flufenacet via bioaccumulation in fish.

zRMS comments:

The Applicants' approach in evaluation of the risk of secondary poisoning is in line with EFSA (2009). Compounds selected for this assessment are agreed by the zRMS.
Evaluation was not triggered for remaining metabolites of active substance due to their log Pow <3.

Some additional corrections were added in tables above in case NOEL of 9.4 mg a.s./kg bw value according to zRMS's evaluation.

Despite all corrections of the zRMS, acceptable risk of secondary exposure from all relevant compounds could be concluded for birds.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

The risk for birds from dietary exposure after the uses supported for the product FFA SC 508.8 is acceptable. Furthermore, the assessment of the effects of exposure via drinking water and secondary poisoning indicate acceptable risk. Overall, it can be concluded that the risk associated with the recommended use of FFA SC 508.8 is low for birds.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with flufenacet. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of FFA SC 508.8 G were not evaluated as part of the EU assessment of the active substance flufenacet. New data submitted with this application are listed in Appendix 1 and summarised in Section 6 (Mammalian Toxicology).

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Flufenacet	Oral Acute	$LD_{50\ female}$ = 589 mg a.s./kg bw	EC review report 7469/VI/98-Final (2003)
Rat, Rabbit	Flufenacet	Oral Developmental toxicity (rat , rabit)	NOAEL = 25 mg a.s./kg bw/d	EC review report 7469/VI/98-Final (2003)

zRMS comments:

Mammalian toxicity data for flufenacet are in line with the EU agreed endpoints reported in the EC review report 7469/VI/98-Final (2003).

9.3.1.1 Justification for new endpoints

No deviation to EU agreed endpoints.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for mammals from all other intended uses (see 9.1.2).

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Screening assessment

Table 9.3-2: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FFA SC 508.8 in cereals (use group A)

Intended use	Cereals, BBCH 00-09				
Active substance/product	Flufenacet				
Application rate (kg/ha)	1 × 0.2442				
Acute toxicity (mg/kg bw)	589				
TER criterion	10				
Crop scenario Growth stage	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bare soils	Small granivorous mammal	14.4	1.0	3.52	167
Reprod. toxicity (mg/kg bw/d)	25				
TER criterion	5				
Crop scenario Growth stage	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bare soils	Small granivorous mammal	6.6	1.0 × 0.53	0.854	29.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-3: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FFA SC 508.8 in cereals (use group B)

Intended use	Cereals, BBCH 10-13				
Active substance/product	Flufenacet				
Application rate (kg/ha)	1 × 0.2442				
Acute toxicity (mg/kg bw)	589				
TER criterion	10				
Crop scenario Growth stage	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals	Small herbivorous mammal	118.4	1.0	28.9	20.4
Reprod. toxicity (mg/kg bw/d)	25				
TER criterion	5				
Crop scenario Growth stage	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals	Small herbivorous mammal	48.3	1.0 × 0.53	6.25	**4.00**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-4: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FFA SC 508.8 in cereals (use group C)

Intended use	Cereals, BBCH 00-09				
Active substance/product	Flufenacet				
Application rate (kg/ha)	1 × 0.1221				
Acute toxicity (mg/kg bw)	589				
TER criterion	10				
Crop scenario Growth stage	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bare soils	Small granivorous mammal	14.4	1.0	1.76	335
Reprod. toxicity (mg/kg bw/d)	25				
TER criterion	5				
Crop scenario Growth stage	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bare soils	Small granivorous mammal	6.6	1.0 × 0.53	0.427	58.5

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-5: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FFA SC 508.8 in cereals (use group D)

Intended use	Cereals, BBCH 10-13				
Active substance/product	Flufenacet				
Application rate (kg/ha)	1 × 0.1221				
Acute toxicity (mg/kg bw)	589				
TER criterion	10				
Crop scenario Growth stage	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals	Small herbivorous mammal	118.4	1.0	14.5	40.7
Reprod. toxicity (mg/kg bw/d)	25				
TER criterion	5				
Crop scenario Growth stage	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals	Small herbivorous mammal	48.3	1.0 × 0.53	3.13	8.00

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comments:

The screening step risk assessment for flufenacet is agreed by the zRMS.

Acceptable acute and long-term risk may be concluded for mammals exposed to flufenacet in FFA SC 508.8 except use group B for which Tier 1 long-term risk is required for small herbivorous mammal.

First-tier assessment

Table 9.3-6: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of FFA SC 508.8 in cereals (use group B)

Intended use	Cereals, BBCH 10-13				
Active substance/product	Flufenacet				
Application rate (kg/ha)	1 × 0.2442				
Acute toxicity (mg/kg bw)	589				
TER criterion	10				
Crop scenario Growth stage	**Generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals BBCH 10 - 19	Small insectivorous mammal "shrew"	7.6	1.0	1.86	317
Cereals Early (shoots)	Large herbivorous mammal "lagomorph"	42.1	1.0	10.3	57.3
Cereals BBCH 10-29	Small omnivorous mammal "mouse"	17.2	1.0	4.20	140
Reprod. toxicity (mg/kg bw/d)	25				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals BBCH 10 - 19	Small insectivorous mammal "shrew"	4.2	1.0 × 0.53	0.544	46.0
Cereals Early (shoots)	Large herbivorous mammal "lagomorph"	22.3	1.0 × 0.53	2.89	8.66
Cereals BBCH 10-29	Small omnivorous mammal "mouse"	7.8	1.0 × 0.53	1.01	24.8

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comments:

The Tier 1 risk assessment for flufenacet is validated by the zRMS.

Overall, acceptable acute and long-term risk may be concluded for mammals exposed to flufenacet in FFA SC 508.8.

9.3.2.2 Higher-tier risk assessment

Not needed.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario
Since FFA SC 508.8 G is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario
Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With an arithmetic mean K(f)oc of 201, flufenacet belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for mammals from all other intended uses (see 9.1.2).

Flufenacet

Effective application rate (g/ha)	=	244.2		
Acute toxicity (mg/kg bw)	=	589	quotient =	0.42
Reprod. toxicity (mg/kg bw/d)	=	25	quotient =	9.77

zRMS comments:

No unacceptable risk to mammals is identified from drinking water exposure.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of flufenacet (log P_{ow} = 3.20) exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required for flufenacet. Bioconcentration studies were conducted with flufenacet. The BCF values resulted in 71.4 for flufenacet (EC review report, 2003).

The metabolites of flufenacet: FOE sulfonic acid, FOE oxalate, FOE-thiadone, and FOE methylsulfide have a log P_{ow} value of respectively -2.75 (all pH), -2.2 (pH 7), of 0.62 (pH 7) and 2.6 (pH 7). Therefore, it is not necessary to consider the risk from secondary poisoning for these metabolites.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for use group A also covers the risk for mammals from all other intended uses for flufenacet (see 9.1.2).

Risk assessment for earthworm-eating mammals via secondary poisoning
According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g, resulting in FIR/bw = 1.28. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for use group A also covers the risk for mammals from all other intended uses for flufenacet (see 9.1.2).

Table 9.3-7: Assessment of the risk for earthworm-eating mammals due to exposure to flufenacet via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals (use group A)

Parameter	Flufenacet	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.285	See section B8 (Chapter 8.7.2) PEC_{soil} (twa = 21 d) + $PEC_{soil,plateau}$ (<0.001 mg/kg, 20 cm mixing depth)
log P_{ow} / P_{ow}	3.2 / 1600	EC review report 7469/VI/98-Final (2003)
K_{oc}	202.4	Arithmetic mean (n = 5)
f_{oc}	0.02	Default
BCF_{worm}	4.951	$BCF_{worm/soil}$ = ($PEC_{worm,ww}/PEC_{soil,dw}$) = $(0.84 + 0.012 \times P_{ow}) / f_{oc} \times K_{oc}$
PEC_{worm}	1.411	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	1.481	$DDD = PEC_{worm} \times 1.28$
NOAEL (mg/kg bw/d)	25	
TER_{lt}	16.9	

TER values shown in bold fall below the relevant trigger.

TER_{mix} is with a value of 16.9 above the respective trigger of 5 and therefore shows an acceptable risk for earthworm-eating mammals due to exposure to flufenacet via bioaccumulation in earthworms.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g, resulting in FIR/bw = 0.142. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for use group A also covers the risk for mammals from all other intended uses for flufenacet (see 9.1.2).

Table 9.3-8: Assessment of the risk for fish-eating mammals due to exposure to flufenacet via bioaccumulation in fish (secondary poisoning) for the intended use in cereals (use group A)

Parameter	Flufenacet	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.0572	Maximum PEC_{sw} (twa = 21 d) value resulting from drainage entry (see Part B8, chapter 8.9.2).
BCF_{fish}	71.4	EC review report 7469/VI/98-Final (2003)
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	4.084	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.649	$DDD = PEC_{fish} \times 0.142$
NOAEL (mg/kg bw/d)	25	
TER_{lt}	38.5	

TER values shown in bold fall below the relevant trigger.

TER_{mix} is with a value of 38.5 above the respective trigger of 5 and therefore shows an acceptable risk for fish-eating mammals due to exposure to flufenacet via bioaccumulation in fish.

zRMS comments:

The Applicants' approach in evaluation of the risk of secondary poisoning is in line with EFSA (2009). Compounds selected for this assessment are agreed by the zRMS. Evaluation was not triggered for remaining metabolites of active substance due to their log Pow <3.

Overall, acceptable risk of secondary exposure from all relevant compounds could be concluded for birds.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

The risk for terrestrial vertebrates other than birds from dietary exposure after the uses supported for the product FFA SC 508.8 is acceptable. Furthermore, the assessment of the effects of exposure via drinking water and secondary poisoning indicate acceptable risk. Overall, it can be concluded that the risk associated with the recommended use of FFA SC 508.8 is low for terrestrial vertebrates other than birds.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Regarding the assessment of potential effects on reptiles and amphibians neither guidance documents nor testing guidelines are available at present. Therefore, no additional data on terrestrial vertebrate wildlife is presented here.

zRMS comments:

As currently there are no agreed rules or criteria for evaluation of the risk to other terrestrial vertebrates like reptiles and amphibians, this issue should be addressed once respective guidance is available and EU agreed endpoints concluded.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with flufenacet and relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents, as well as in Appendix 2 of this document when new studies are submitted.
Effects on aquatic organisms of FFA SC 508.8 G were not evaluated as part of the EU assessment of flufenacet. Any data submitted with this application in this core dossier are listed in Appendix 1 and summarised in Appendix 2.
Where the selection of studies and endpoints for the risk assessment deviates from the results of the EU review process, justifications are provided below.

Flufenacet and relevant metabolites

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – flufenacet and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Lepomis macrochirus	Flufenacet	96 h, ss	LC_{50} = **2.13** mg a.s./L $_{mm}$	EC review report 7469/VI/98-Final (2003)
Oncorhynchus mykiss	Flufenacet	97 d, (ELS), f	$NOEC_{growth\ (fry\ length)}$ = **0.179**~~2~~ mg a.s./L $_{mm}$	EC review report 7469/VI/98-Final (2003)
Daphnia magna	Flufenacet	48 h, s	EC_{50} = **30.9** mg a.s./L $_{mm}$	EC review report 7469/VI/98-Final (2003)
Daphnia magna	Flufenacet	21 d, ss	NOEC = **3.26** mg a.s./L $_{mm}$	EC review report 7469/VI/98-Final (2003)
Pseudokirchneriella subcapitata	Flufenacet	5 d, s	96h-E_rC_{50}: 0.0031 mg a.s./L (im) 96h-E_bC_{50}: 0.00182 mg a.s./L 120h-E_rC_{50}: 0.00452 mg a.s./L 120h-E_bC_{50}: 0.00245 mg a.s./L	EC review Report 7469/VI/98-Final (2003) Bowers (1995) M-002348-02-1 recalculated by Dorgerloh (1998) M-086475-01-1
Pseudokirchneriella subcapitata	Flufenacet	96 h, s	E_rC_{50} = 0.00699 mg a.s./L $_{nom}$	Monograph AII, 8.2.6 Anderson (1997) See justification
Pseudokirchneriella subcapitata	Flufenacet	72 h, s	E_rC_{50} = 0.138 mg a.s./L $_{mm}$ E_bC_{50} = 0.00669 mg a.s./L $_{mm}$	Bruns (2010) M-363891-04-1 See justification
~~*Pseudokirchneriella subcapitata*~~	~~Flufenacet~~	~~Geometric mean (n=3)~~	~~E_rC_{50} (geomean) = **0.0144** mg a.s./L $_{mm}$ 1)~~	~~See justification~~
Lemna gibba	Flufenacet	14 d, s	14 d-EC_{50} = 0.00243 mg a.s./L $_{nom}$ 7d-E_rC_{50} = 0.0318 mg a.s./L $_{nom}$	EC review report 7469/VI/98-Final (2003) Hughes & Alexander (1993) M-002418-02-1 recalculated: Dorgerloh (1998) M-086479-01-1

Species	Substance	Exposure System	Results	Reference
				See justification
Lemna gibba	Flufenacet	7 d, s	E_rC_{50}, frond no = 0.0161 mg a.s./L nom $E_rC_{50,frond\ area}$ = **0.0139** mg a.s./L nom	Bruns (2013)[1] M-451198-01-1 See justification
Pseudokirchneriella subcapitata	FOE-oxalate	72 h, s	E_bC_{50} > 100 mg p.m./L nom E_rC_{50} > 100 mg p.m./L nom	Bruns (2009) [2] M-358823-01-1 See justification
Lemna gibba	FOE-oxalate	7 d, s	E_rC_{50} > 100 mg p.m./L nom	Bruns (2009) [2] M-359515-02-1 See justification
Oncorhynchus mykiss	FOE Sulfonic acid	96 h, s	LC_{50} > 86.7 mg p.m./L nom	EC review report 7469/VI/98-Final (2003)
Daphnia magna	FOE Sulfonic acid	48 h, s	EC_{50} > 87.3 mg p.m./L nom	EC review report 7469/VI/98-Final (2003)
Desmodesmus subspicatus	FOE Sulfonic acid	72 h, s	E_rC_{50} > 86.7 mg p.m./L nom	EC review report 7469/VI/98-Final (2003)
Lemna gibba	FOE Sulfonic acid	14 d, s	EC_{50} > 86.7 mg p.m./L nom	EC review report 7469/VI/98-Final (2003)
Pseudokirchneriella subcapitata	FOE Methylsulfide	72 h, s	E_rC_{50} = 83.8 mg p.m./L nom	EC review report 7469/VI/98-Final (2003)
Oncorhynchus mykiss	FOE-Thiadone	96 h, s	LC_{50} = 9.1 mg p.m./L mm	EC review report 7469/VI/98-Final (2003)
Daphnia magna	FOE-Thiadone	48 h, s	EC_{50} = 31.7 mg p.m./L mm	EC review report 7469/VI/98-Final (2003)
Pseudokirchneriella subcapitata	FOE-Thiadone	72 h, s	72h-E_bC_{50} = 4.1 mg p.m./L mm 72h-E_rC_{50} = 15.0 mg p.m./L mm	EC review report 7469/VI/98-Final (2003)
Higher-tier studies (micro- or mesocosm studies)				
Macrophytes & periphyton	Flufenacet WG 60	84 d, s	NOEC = 1 x 0.012 mg a.s./L nom [3]	Review Report 7469/VI/98-Final (2003)

Bold: parent endpoints used for risk assessment.
s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations
[1] Geometric mean of 72h-ErC_{50} = 0.138 (Bruns, 2010), E_rC_{50} = 0.00699 (Anderson, 1997) and 96h-E_rC_{50} = 0.0031 (Dorgerloh, 1998) (see explanations below)
[2] New studies. Not assessed yet (see part "justification for new endpoints")
[3] The NOEC can be used in the refined risk assessment with a safety factor of 5 (RAC = 0.0024 mg as/L)

zRMS comments:

The toxicity endpoints validated during the original evaluation of flufenacet are considered to be still in force. For this reason these endpoints were not re-evaluated by zRMS at zonal authorisation of the product FFA SC 508.8.
Therefore, agreeded enpoints at EU level were used in the risk assessment and will be updated only after the re-approval of flufenacet. In reference to **new studies** for the active substance provided for the current core dossier only studies validated by RMS (PL) during the peer-review of a.s.- flufenacet are considered as relible for the current risk assessment, if necessary.

Mesocosm study with NOEC = 0.012 mg a.s./L is currently the EU agreed higher-tier endpoint for risk assessment on algae and plants. AF of 5 is proposed for this study as additional safety factor due to uncertainty of study endpoint reliability following EFSA AGD 2013 evaluation scheme, due to the few available species with an appropriate MDD value and low representation of planktonic algae. It should be noted that at zonal authorisation of the product zRMS should not does the re-evaluation of EU agreed endpoints/conclusions and endpoints indicated in SANCO report 7469/VI/98-Final 3 July 2003 which is currently the EU agreed endpoints. Flufenacet is currently ongoing a renewal procedure and zRMS-PL (also being RMS to a.s.-flufenacet) should not discard this endpoint before the renewal of flufenacet and till the new endpoints are anticipated.
The AF of 5 seems like an acceptable option to add some safety factor and until the renewal process if finalised zRMS-PL accepts the **RAC of 2.4 µg/L.**

Metabolites of flufenacet

Aquatic organisms may be exposed to the major metabolites FOE-sulfonic acid, FOE-thiadone, FOE-methylsulfide and FOE oxalate. Therefore, their risk to aquatic organisms should also be assessed.
However, considering the ecotoxicity profile for FOE-sulfonic acid, FOE-thiadone, FOE-methylsulfide and FOE-oxalate, it can be assumed that none is likely to be ecologically relevant as they have clearly a lower toxicity than the parent compound (especially to green algae and aquatic plant, the most sensitive species). Therefore, a risk assessment for aquatic organisms with these metabolites is not deemed necessary.
However, for reasons of completeness, a risk assessment for metabolites is presented below (see point 9.5.2.2 to 9.5.2.5) for the worst-case use pattern (i.e. use group A) as a risk envelope.

zRMS comments:

The aquatic organisms may be exposed to the major metabolites FOE-sulfonic acid, FOE-thiadone, FOE-methylsulfide and FOE oxalate. The toxicity of metabolites was tested on the most sensitive organism, primary producers, and the results of studies on the metabolites show that the toxicity of all metabolites are less than the parent compound.

Therefore, in zRMS's opinion it can be concluded, that the potential risk metabolites of flufenacet are covered by the risk assessment for the active substance and calculations PEC/RAC ratio with the metabolites is not necessary as covered by the one for the active substance.

Geometric mean calculation for algae

Three studies with the same algal species (*Pseudokirchneriella subcapitata*, the most susceptible freshwater alga) are available. According to the EFSA Guidance, (EFSA Journal 2013;11(7):3290) endpoints of these studies should be combined and the geometric mean be used in the risk assessment. Two studies are clearly suitable for this combination, Bowers (1995, M-002348-02-1, Monograph (1997), B.8.2.8) and Bruns (2013, M-363891-04-1, Appendix 2, A 2.2.1.3). A third study (Anderson 1997, M-002343-01-1, Monograph (1997)) deviated in terms of design, as it used pre-exposed algal cells to demonstrate that exposure does not limit the potential for recovery (i.e. flufenacet is algistatic and not algicidal). However, as the study also generated a low-end point and the geometric mean based on all three studies is lower than the one based on the two standard studies, the former approach was chosen as the more conservative one. Consequently, the risk assessment will be performed using the geomean E_rC_{50} of 14.4 µg a.s./L for algae.

zRMS comments:

The proposed geometric mean for algae species Selenastrum carpiconatum is considered as not acceptable by zRMS-PL.
The geometric mean value should be based on the endpoints obtained from the same study design and the same parameter tested.
Indeed, the time exposure of the three study is different (ranged to 72 hours to 5 days).
Moreover, the study Bruns (2010) was peer reviewed in ongoing process for flufenacet and considered not reliable in RAR 2018 (see zRMS comment in the study summary in Appendix 2 for the justification).
Therefore, the proposed geometric mean calculation is not considered relevant and was not used in the risk assessment by zRMS.

Relevant endpoint for *Lemna*

So far, the EU-agreed endpoint for aquatic plants is based on a 14-day *Lemna* study from 1993 (Hughes & Alexander). This study was done according to the FIFRA Guideline 123-2 and the endpoint was based on frond counts solely. In 1998, Dorgerloh recalculated a 7-day E_rC_{50} based on frond count out of this study with 31.8 µg/L. However, this study by Hughes & Alexander is considered to be not valid according to current guidelines (OECD 221, 2006) as a second endpoint like frond dry weight or frond area has not been determined.

To address this data requirement with a fully valid study, a new 7-day *Lemna* study (Bruns 2013; M-451198-01-1, Appendix 2, A 2.2.3) was performed. In this study, the two parameters frond number and frond area were assessed as required by the currently valid OECD 221 guideline. The determined endpoint relevant for risk assessment – the 7-day E_rC_{50} based on growth rates of frond area– was by more than a factor of 2 lower than the one recalculated by Dorgerloh (1998, AII; B.8.2.8/03 Evaluation table (2001) Doc.7468/VI/98 rev.10)) out of the 14-day study. In addition, the OECD guideline 221 states that growth related endpoints should be used for risk assessment purposes to allow comparison of sensitivity of different species. As in addition the no observed effect concentrations (NOECs) from both studies reveal that the test organisms were of equal sensitivity (0.44 and 0.658 µg/L from the old and new study, respectively) it is considered justified that the new fully valid and according to current state of the science performed 7-day Lemna-study supersedes the old 14-day Lemna study where the endpoint is based solely on the frond counts. Consequently, the risk assessment will be performed using the new 7-day E_rC_{50} of 13.9 µg a.s./L based on growth rate.

zRMS comments:

Generally, the toxicity endpoints validated during the original evaluation of flufenacet should be considered to be still in force.
However, in reference to Lemna gibba aquatic macropytes, the study by Hughes & Alexander with 14 d E_rC_{50}= 0.00243 mg a.s./L recalculated to 7d-E_rC_{50} = 0.0318 mg a.s./L based on one parameter tested can be superseded by new endpoint for this species which was considered valid and reliable by RMS-PL in RAR 2018.

Therefore, we agree in this case with 7 d E_rC_{50} = 0.0139 mg a.s./L value based on growth rate to use in the risk assessment.

FFA SC 508.8 G

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – FFA SC 508.8 G

Species	Substance	Exposure System	Results	Reference
Pseudokirchneriella subcapitata	FFA SC 500**	72 h, s	E_rC_{50} = 31 µg product/L $_{nom}$ E_rC_{50} = 13.6 µg a.s./L $_{nom}$ *	Appendix 2 Baetscher, 2001 M-055471-01-1
Lemna gibba	FFA SC 500**	7 d, s	E_rC_{50} = 110 µg product/L $_{mm}$ E_rC_{50} = 48.3 µg a.s./L $_{mm}$ *	Appendix 2 Baetscher, 2001 M-055476-01-1
Higher-tier studies (micro- or mesocosm studies)				
Not required				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations
* Re-calculation of the endpoint based on a.s. were performed by using the Flufenacet content within the formulation of 43.9%.
** By mistake a wrong name Cadou SC 500 (Flufenacet SC 500, 500 g/L) has been mentioned in several documents which have been submitted to authorities. However, in all submitted studies the a.i. content of Flufenacet was in a range which was valid for the SC 508.8 formulated product. The FAO tolerances for the a.i. content in a SC 508.8 g/L formulation are from 483.8 g/L to 533.8 g/L (508.8 ± 25 g/L). For more information please refer to the statement by Conrad (2013, M-470405-01-1, Appendix 2)

For the product FFA SC508.8, formulation studies on the most sensitive aquatic species of the active ingredient flufenacet are available (i.e. green alga *Pseudokirchneriella subcapitata* and aquatic macrophyte *Lemna gibba*).
P. subcapitata (worst-case E_rC_{50} (72 h) = 0.0031 mg FFA/L ~~and geomean E_rC_{50} =0.0144 mg FFA/L)~~ and *L. gibba* (E_rC_{50},frond area = 0.0139 mg FFA/L) are clearly by a factor > 10 more sensitive against flufenacet as fish (*L. macrochirus* LC_{50} = 2.13 mg FFA/L) and *D. magna* EC_{50}= 30.9 mg FFA/L).

For fish and *D. magna*, acute studies have been performed outside of Europe. The studies do not fully comply with the respective OECD guidelines (i.e. OECD TG 203 and 202) but can be used as supportive information. The acute fish study with *C. carpio* (Dae-Mang, Ha; 2015; M-508405-01-1) resulted in an endpoint of 43.5 mg product/L corresponding to approx. 19.1 mg a.s./L. The acute study on *D. magna* (Dae-Mang, Ha; 2015; M-508410-01-1) resulted in an endpoint of 63.1 mg product/L corresponding to approx. 27.7 mg a.s./L. The results of the product studies with FFA SC508.8 on fish and *D. magna* demonstrate that the formulated product is not acutely toxic to fish and aquatic invertebrates represented by daphnids.

Therefore, the available and valid product studies for *P. subcapitata* and *L. gibba* are covering the risk of the product for all other taxonomic groups.

In accordance with the latest EFSA technical report “Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology” from 2019 (EFSA Supporting publication 2019: EN-1673), a formulation should be considered more toxic than the active substance, if a difference of a factor of three was determined. *This means that when the endpoint of the PPP (expressed in terms of the active substance) is at least three times lower than the equivalent endpoint for the active substance, it should be considered to be more toxic.*

Formulation toxicity and active substance toxicity are compared in the following table:

Table 9.5-3: Difference between formulation toxicity and active substance toxicity

Organism group	Results from product testing	Most sensitive results from active substance testing	Difference of toxicity (a.s. EP / product based a.s. EP)
Algae	0.0136 mg a.s./L_{nom}	0.0031 mg a.s./L_{im} [1)]	0.228
Aquatic plant	0.0483 mg a.s./L_{mm}	0.0139 mg a.s./L_{nom} [2)]	0.288

[1)] Endpoint derived from Bowers, 1995, M-002348-02-1
[2)] Endpoint derived from Bruns, 2013, M-451198-01-1

For all aquatic organisms, the product FFA SC 508.8 G should be considered as being less toxic than the active substance under assessment.
Therefore, the risk assessment of the active substance is considered as being protective for the product and no additional assessment of the product FFA SC 508.8 G is necessary.

zRMS comments:

It should be noted that no toxicity was provided by the Applicant for the formulation to fish and daphnia. However, the formulation FFA SC 508.8 G is not more toxic than expected based on its content on the active substances for algae and aquatic plant, most sensitive species.
Therefore, zRMS considered that toxicity data on fish and daphnia with the formulation FFA SC 508.8 G are not necessary. Therefore, the risk assessment is based on active substance toxicity data.
In the LoEP 72 h E_bC_{50} = 0.00204 mg a.s./L for Pseudokirchneriella subcapitata was agreed at EU level. However, according to the current requirement E_rC_{50} value is more appropriate to use in the risk assessment. For this species **96 h E_rC_{50} of 0.0031 mg a.s./L** value from the same study as 72 h E_bC_{50} value (Bowers, 1995, M-002348-02-1), considered acceptable in the DAR for flufenacet during the first approval of a.s.-flufenacet was used in the risk assessment.

9.5.1.1 Justification for new endpoints

Table 9.5-4: Justification for new endpoints

Species	Substance	Exposure System	Endpoint	Justification	Reference
Pseudo-kirchneriella subcapitata	Flufenacet	96h, static	E_rC_{50} = 0.00699 mg a.s./L_{nom}	Additional study used for geomean calculation	Monograph AII, 8.2.6 Anderson (1997)
Pseudo-kirchneriella subcapitata	Flufenacet	72h, static	E_rC_{50} = 0.138 mg a.s./L_{mm}	Additional study used for geomean calculation	Appendix 2 Bruns (2013) M-363891-04-1
Pseudo-kirchneriella subcapitata	Flufenacet	72h-96h, static	Geomean (n=3): E_rC_{50} = 0.0144 mg a.s./L	Three studies with the same algal species (*P. subcapitata*, the most susceptible freshwater alga) are available. According to the EFSA Opinion Paper on additional species testing (EFSA 2005) endpoints of these studies should be combined and the geometric mean be used in the risk assessment. Two studies are clearly suitable for this combination, Bowers (1995) and Bruns (2010). A third study (Anderson 1997) deviated in terms of design, as it used pre-exposed algal cells to	Geomean of studies Bowers (1995); Anderson (1997) (Monograph annex II A point 8 and new study M-363891-04-1 (Bruns 2013)

Species	Substance	Exposure System	Endpoint	Justification	Reference
				~~demonstrate that exposure does not limit the potential for recovery (i.e. flufenacet is algistatic and not algicidal). However, as the study also generated a low end point and the geometric mean based on all three studies is lower than the one based on the two standard studies, the former approach was chosen as the more conservative one.~~	
Lemna gibba	Flufenacet	7d, s	E_rC_{50}, frond no = 0.016 mg a.s./L nom E_rC_{50}, frond area = 0.0139 mg a.s./L nom	Adverse data. Lowest endpoint for chronic exposure of aquatic plants based on frond area.	Appendix 2 Bruns (2013) M-451198-01-1
Pseudokirch-neriella subcapitata	FOE oxalate	72h, s	E_rC_{50} > 100 mg p.m./L nom	New study for metabolite.	Appendix 2 Bruns (2009) M-358823-01-1
Lemna gibba	FOE oxalate	7d, s	E_rC_{50} > 100 mg p.m./L nom	New study for metabolite.	Appendix 2 Bruns (2009) M-359515-02-1

zRMS comments:

zRMS disagree with justification of the new endpoints for active substance – flufenacet for algae.
The proposed geometric mean for species Selenastrum carpiconatum is considered as not acceptable by zRMS-PL. The geometric mean value should be based on the endpoints obtained from the same study design.
Indeed, the time exposure of the three studies is different (ranged to 72 hours to 5 days). Moreover, the study Bruns (2010) was peer reviewed in ongoing process for flufenacet and considered not reliable in RAR 2018 (see zRMS comment in the study summary in Appendix 2 for the justification).
Therefore, the proposed geometric mean calculation is not considered relevant and was not used in the risk assessment by zRMS.
The new studies for metabolite flufenacet-oxalate for algae and aquatic macrophyte Lemna gibba were submitted by the Applicant in the current dossier for zonal authorisation of the product.
These studies were not evaluated in the current dossier but they were considered valid and and reliable by RMS-PL in RAR 2018 in ongoing process for flufenacet.
However, flufenacet metabolites are less toxic than active substance. Therefore, in zRMS's opinion it can be concluded, that the potential risk metabolites of flufenacet are covered by the risk assessment for the active substance and calculations PEC_{sw}/RAC ratio with the metabolites is not necessary as covered by the one for the active substance.
In reference to the new study for Lemna gibba considered in RAR 2018 as a valid and reliable, in zRMS's opinion can superseded the old study for this species and 7 d E_rC_{50} = 0.0139 mg a.s./L value can be used now in the risk assessment as a refinement option for this species only.
However, as the old endpoint is still in force zRMS added it the risk assessment.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the Regulation (EC) No 284/2013 entitled "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS PEC_{SW} values used for the risk assessment covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the tables below.
For the parent compound, risk assessment is presented for all use groups except for Step 1+2. For the metabolites, a risk envelope is applied: the assessment for use group A covers the risk from all other intended uses in groups B, C and D (see 9.1.2)

In the following tables, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

9.5.2.1 Parent compound flufenacet

RQ calculations based on FOCUS Step 1+2

In the following tables, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group. For Step 1+2 use groups A and C cover also B and D.

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flufenacet for each organism group based on FOCUS Steps 1, 2 calculations for the use of FFA SC 508.8 G in Winter cereals (Use group A; modelling use winter cereals I -- autumn -- 1×244.2g a.s./ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	~~Algae~~	Algae	Aquatic plants	Aquatic plants	Higher-tier information
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	~~***Pseudokirchneriella subcapitata***~~	***Pseudokirchneriella subcapitata****	***Lemna gibba****	***Lemna gibba***	**Macrophytes and periphyton**
Endpoint		**LC_{50}**	**NOEC**	**EC_{50}**	**NOEC**	~~**E_rC_{50} (geomean)**~~	**E_rC_{50}**	**E_rC_{50}**	**E_rC_{50}**	**NOEC**
(µg/L)		**2130**	**200**	**30900**	**3260**	~~**14.4**~~	**3.1**	**2.43**	**13.9**	**12**
AF		**100**	**10**	**100**	**10**	~~**10**~~	**10**	**10**	**10**	**5**
RAC (µg/L)		**21.3**	**20**	**309**	**326**	~~**1.44**~~	**0.31**	**0.243**	**1.39**	**2.4**
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**									
Step 1										
- -	67.4	**3.16**	**3.37**	0.218	0.207	~~**46.8**~~	**217.42**	**277.37**	**48.5**	**28.1**
Step 2										
Northern Europe Oct. - Feb. (Autumn)	29.3	**1.38**	**1.47**	0.095	0.090	~~**20.4**~~	**94.52**	**120.58**	**21.1**	**12.2**
Southern Europe Oct. - Feb. (Autumn)	23.8	**1.12**	**1.19**	0.077	0.073	~~**16.6**~~	**76.77**	**97.94**	**17.2**	**9.93**

*Agreed endpoints at EU level (2003)

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flufenacet for each organism group based on FOCUS Steps 1, 2 calculations for the use of FFA SC 508.8 G in Winter cereals (Use group C; modelling use winter cereals II -- autumn -- 1×122.1g a.s./ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Algae	Aquatic plants	Aquatic plants	Higher-tier information
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	~~***Pseudokirchneriella subcapitata***~~	***Pseudokirchneriella subcapitata****	***Lemna gibba****	***Lemna gibba***	**Macrophytes and periphyton**
Endpoint		**LC_{50}**	**NOEC**	**EC_{50}**	**NOEC**	~~**E_rC_{50} (geomean)**~~	**E_rC_{50}**	**E_rC_{50}**	**E_rC_{50}**	**NOEC**
(µg/L)		**2130**	**200**	**30900**	**3260**	~~**14.4**~~	**3.1**	**2.43**	**13.9**	**12**
AF		**100**	**10**	**100**	**10**	~~**10**~~	**10**	**10**	**10**	**5**
RAC (µg/L)		**21.3**	**20**	**309**	**326**	~~**1.44**~~	**0.31**	**0.243**	**1.39**	**2.4**
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**									
Step 1										
- -	33.7	**1.58**	**1.69**	0.109	0.103	~~**23.4**~~	**108.71**	**138.68**	**24.2**	**14.0**
Step 2										
Northern Europe Oct. - Feb. (Autumn)	14.7	0.689	0.734	0.047	0.045	~~**10.2**~~	**47.42**	**60.49**	**10.6**	**6.11**
Southern Europe Oct. - Feb. (Autumn)	11.9	0.560	0.596	0.039	0.037	~~**8.28**~~	**38.39**	**48.97**	**8.58**	**4.97**

*Agreed endpoints at EU level (2003)

RQ calculations based on FOCUS Step 3

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flufenacet for each organism group based on FOCUS Steps 3 calculations for the use of FFA SC 508.8 G in Winter cereals (Use group A; modelling use winter cereals I -- pre-emg. -- 0.2442 kg a.s./ha)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	Algae	**Algae**	**Aquatic plants**	**Aquatic plants**	**Higher-tier information**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	~~*Pseudokirchneriella subcapitata*~~	***Pseudokirchneriella subcapitata****	***Lemna gibba****	***Lemna gibba***	**Macrophytes and periphyton**
Endpoint		**LC_{50}**	**NOEC**	**EC_{50}**	**NOEC**	~~E_rC_{50} (geomean)~~	**E_rC_{50}**	**E_rC_{50}**	**E_rC_{50}**	**NOEC**
(µg/L)		**2130**	**200**	**30900**	**3260**	~~14.4~~	**3.1**	**2.43**	**13.9**	**12**
AF		**100**	**10**	**100**	**10**	~~10~~	**10**	**10**	**10**	**5**
RAC (µg/L)		**21.3**	**20**	**309**	**326**	~~1.44~~	**0.31**	**0.243**	**1.39**	**2.4**
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**									
Step 3										
D1/Ditch	5.75	0.270	0.288	0.019	0.018	~~3.99~~	**18.55**	**23.66**	**4.14**	**2.40**
D1/Stream	3.67	0.172	0.184	0.012	0.011	~~2.55~~	**11.84**	**15.10**	**2.64**	**1.53**
D2/Ditch	17.0	0.800	0.852	0.055	0.052	~~11.8~~	**54.84**	**69.96**	**12.3**	**7.10**
D2/Stream	10.9	0.512	0.546	0.035	0.033	~~7.58~~	**35.16**	**44.86**	**7.85**	**4.55**
D3/Ditch	1.54	0.072	0.077	0.005	0.005	~~1.07~~	**4.97**	**6.34**	**1.11**	0.643
D4/Pond	0.484	0.023	0.024	0.002	0.001	~~0.336~~	**1.56**	**1.99**	0.348	0.202
D4/Stream	1.34	0.063	0.067	0.004	0.004	~~0.929~~	**4.32**	**5.51**	0.963	0.558
D5/Pond	0.542	0.025	0.027	0.002	0.002	~~0.376~~	**1.75**	**2.23**	0.390	0.226
D5/Stream	1.44	0.068	0.072	0.005	0.004	~~1.00~~	**4.65**	**5.93**	**1.04**	0.602
D6/Ditch	4.42	0.208	0.221	0.014	0.014	~~3.07~~	**14.26**	**18.19**	**3.18**	**1.84**
R1/Pond	0.163	0.008	0.008	0.001	0.001	~~0.113~~	0.53	0.67	0.117	0.068
R1/Stream	5.55	0.261	0.277	0.018	0.017	~~3.85~~	**17.90**	**22.84**	**3.99**	**2.31**

R3/Stream	8.54	0.401	0.427	0.028	0.026	5.93	**27.55**	**35.14**	**6.14**	**3.56**
R4/Stream	9.79	0.460	0.490	0.032	0.030	6.80	**31.58**	**40.29**	**7.05**	**4.08**

*Agreed endpoints at EU level (2003)

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flufenacet for each organism group based on FOCUS Steps 3 calculations for the use of FFA SC 508.8 G in Winter cereals (Use group B; modelling use winter cereals I -- early post-emg. -- 0.2442 kg a.s./ha)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Algae**	**Aquatic plants**	**Aquatic plants**	**Higher-tier information**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Pseudokirchneriella subcapitata****	***Lemna gibba****	***Lemna gibba***	**Macrophytes and periphyton**
Endpoint		**LC_{50}**	**NOEC**	**EC_{50}**	**NOEC**	**E_rC_{50} (geomean)**	**E_rC_{50}**	**E_rC_{50}**	**E_rC_{50}**	**NOEC**
(µg/L)		**2130**	**200**	**30900**	**3260**	**14.4**	**3.1**	**2.43**	**13.9**	**12**
AF		**100**	**10**	**100**	**10**	**10**	**10**	**10**	**10**	**5**
RAC (µg/L)		**21.3**	**20**	**309**	**326**	**1.44**	**0.31**	**0.243**	**1.39**	**2.4**
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**									
Step 3										
D1/Ditch	9.87	0.463	0.493	0.032	0.030	6.85	**31.84**	**40.62**	**7.10**	**4.11**
D1/Stream	6.18	0.290	0.309	0.020	0.019	4.29	**19.94**	**25.43**	**4.45**	**2.58**
D2/Ditch	21.0	0.984	**1.05**	0.068	0.064	14.5	**67.74**	**86.42**	**15.1**	**8.73**
D2/Stream	13.3	0.623	0.663	0.043	0.041	9.21	**42.90**	**54.73**	**9.54**	**5.53**
D3/Ditch	1.54	0.072	0.077	0.005	0.005	1.07	**4.97**	**6.34**	**1.11**	0.643
D4/Pond	1.20	0.056	0.060	0.004	0.004	0.831	**3.87**	**4.94**	0.860	0.498
D4/Stream	1.51	0.071	0.075	0.005	0.005	1.05	**4.87**	**6.21**	**1.09**	0.629
D5/Pond	1.30	0.061	0.065	0.004	0.004	0.904	**4.19**	**5.35**	0.937	0.543
D5/Stream	1.72	0.081	0.086	0.006	0.005	1.19	**5.55**	**7.08**	**1.24**	0.716
D6/Ditch	6.51	0.305	0.325	0.021	0.020	4.52	**21.00**	**26.79**	**4.68**	**2.71**
R1/Pond	0.115	0.005	0.006	<0.001	<0.001	0.080	0.37	0.47	0.083	0.048

R1/Stream	6.57	0.308	0.329	0.021	0.020	4.56	**21.19**	**27.04**	**4.73**	**2.74**
R3/Stream	8.56	0.402	0.428	0.028	0.026	5.94	**27.61**	**35.23**	**6.16**	**3.57**
R4/Stream	2.38	0.112	0.119	0.008	0.007	1.65	**7.68**	**9.79**	**1.71**	0.991

*Agreed endpoints at EU level (2003)

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flufenacet for each organism group based on FOCUS Steps 3 calculations for the use of FFA SC 508.8 G in Winter cereals (Use group C; modelling use winter cereals II -- pre-emg. -- 0.1221 kg a.s./ha)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Algae**	**Aquatic plants**	**Aquatic plants**	**Higher-tier information**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Pseudokirchneriella subcapitata***	***Lemna gibba****	***Lemna gibba***	**Macrophytes and periphyton**
Endpoint		**LC_{50}**	**NOEC**	**EC_{50}**	**NOEC**	**E_rC_{50} (geomean)**	**E_rC_{50}**	**E_rC_{50}**	**E_rC_{50}**	**NOEC**
(µg/L)		**2130**	**200**	**30900**	**3260**	**14.4**	**3.1**	**2.43**	**13.9**	**12**
AF		**100**	**10**	**100**	**10**	**10**	**10**	**10**	**10**	**5**
RAC (µg/L)		**21.3**	**20**	**309**	**326**	**1.44**	**0.31**	**0.243**	**1.39**	**2.4**
FOCUS Scenario	**$PEC_{gl\text{-}max}$ (µg/L)**									
Step 3										
D1/Ditch	2.84	0.133	0.142	0.009	0.009	1.97	**9.16**	**11.69**	**2.04**	**1.18**
D1/Stream	1.82	0.085	0.091	0.006	0.006	1.26	**5.87**	**7.49**	**1.31**	0.756
D2/Ditch	7.88	0.370	0.394	0.026	0.024	5.47	**25.42**	**32.43**	**5.67**	**3.28**
D2/Stream	5.07	0.238	0.254	0.016	0.016	3.52	**16.35**	**20.86**	**3.65**	**2.11**
D3/Ditch	0.772	0.036	0.039	0.002	0.002	0.536	**2.49**	**3.18**	0.555	0.322
D4/Pond	0.239	0.011	0.012	0.001	0.001	0.166	0.77	0.98	0.172	0.100
D4/Stream	0.669	0.031	0.033	0.002	0.002	0.465	**2.16**	**2.75**	0.481	0.279
D5/Pond	0.263	0.012	0.013	0.001	0.001	0.183	**0.85**	**1.08**	0.189	0.110
D5/Stream	0.722	0.034	0.036	0.002	0.002	0.501	**2.33**	**2.97**	0.519	0.301
D6/Ditch	1.82	0.085	0.091	0.006	0.006	1.26	**5.87**	**7.49**	**1.31**	0.757

R1/Pond	0.079	0.004	0.004	<0.001	<0.001	0.055	0.25	0.33	0.057	0.033
R1/Stream	2.69	0.126	0.134	0.009	0.008	1.87	**8.68**	**11.07**	**1.93**	**1.12**
R3/Stream	4.06	0.191	0.203	0.013	0.012	2.82	**13.10**	**16.71**	**2.92**	**1.69**
R4/Stream	4.71	0.221	0.236	0.015	0.014	3.27	**15.19**	**19.38**	**3.39**	**1.96**

*Agreed endpoints at EU level (2003)

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flufenacet for each organism group based on FOCUS Steps 3 calculations for the use of FFA SC 508.8 G in Winter cereals (Use group D; modelling use winter cereals II -- early post-emg. -- 0.1221 kg a.s./ha)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Algae**	**Aquatic plants**	**Aquatic plants**	**Higher-tier in-formation**
Test species		***Lepomis macro-chirus***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirch-neriella subcap-itata***	***Pseudokirchneriella subcapitata****	***Lemna gibba****	***Lemna gibba***	**Macrophytes and periphyton**
Endpoint		**LC_{50}**	**NOEC**	**EC_{50}**	**NOEC**	**E_rC_{50} (ge-omean)**	**E_rC_{50}**	**E_rC_{50}**	**E_rC_{50}**	**NOEC**
(µg/L)		**2130**	**200**	**30900**	**3260**	**14.4**	**3.1**	**2.43**	**13.9**	**12**
AF		**100**	**10**	**100**	**10**	**10**	**10**	**10**	**10**	**5**
RAC (µg/L)		**21.3**	**20**	**309**	**326**	**1.44**	**0.31**	**0.243**	**1.39**	**2.4**
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**									
Step 3										
D1/Ditch	4.32	0.203	0.216	0.014	0.013	3.00	**13.94**	**17.78**	**3.11**	**1.80**
D1/Stream	2.69	0.126	0.135	0.009	0.008	1.87	**8.68**	**11.07**	**1.94**	**1.12**
D2/Ditch	10.1	0.474	0.505	0.033	0.031	7.01	**32.58**	**41.56**	**7.27**	**4.21**
D2/Stream	6.29	0.295	0.314	0.020	0.019	4.37	**20.29**	**25.88**	**4.52**	**2.62**
D3/Ditch	0.771	0.036	0.039	0.002	0.002	0.535	**2.49**	**3.17**	0.555	0.321
D4/Pond	0.591	0.028	0.030	0.002	0.002	0.410	**1.91**	**2.43**	0.425	0.246
D4/Stream	0.722	0.034	0.036	0.002	0.002	0.501	**2.33**	**2.97**	0.519	0.301
D5/Pond	0.659	0.031	0.033	0.002	0.002	0.458	**2.13**	**2.71**	0.474	0.275
D5/Stream	0.873	0.041	0.044	0.003	0.003	0.606	**2.82**	**3.59**	0.628	0.364

D6/Ditch	3.37	0.158	0.168	0.011	0.010	~~2.34~~	**10.87**	**13.87**	**2.42**	**1.40**
R1/Pond	0.056	0.003	0.003	<0.001	<0.001	~~0.039~~	0.18	0.23	0.040	0.023
R1/Stream	3.14	0.147	0.157	0.010	0.010	~~2.18~~	**10.13**	**12.92**	**2.26**	**1.31**
R3/Stream	4.07	0.191	0.203	0.013	0.012	~~2.82~~	**13.13**	**16.75**	**2.93**	**1.69**
R4/Stream	1.23	0.058	0.062	0.004	0.004	~~0.856~~	**3.97**	**5.06**	0.886	0.513

*Agreed endpoints at EU level (2003)

RQ calculations based on FOCUS Step 4

For all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for macrophytes, algae and periphyton in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the long-term mesocosm RAC of 2.4 µg/L (NOEC =12 µg/L, AF = 5; covering macrophytes, algae and periphyton).

Table 9.5-11: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for flufenacet based on FOCUS Step 4 calculations and toxicity data for Aquatic plants with mitigation of spray drift and run-off for the use of FFA SC 508.8 G in Winter cereals (Use group A; modelling use winter cereals I -- pre-emg. -- 0.2442 kg a.s./ha)

Intended use		Winter cereals, BBCH 00 -09							
Active substance		flufenacet							
Application rate (g/ha)		244.2 g a.s./ha (0.480 L prod/ha)							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	None	10 m	20 m	
	No spray buffer (m)	0 m	2 m	5 m	10 m	20 m	10 m	20 m	
None	D1 Ditch	5.75	5.75	5.75	5.75	5.75	5.75	5.75	
50 %		5.75	5.75	5.75	5.75	5.75	5.75	5.75	
75 %		5.75	5.75	5.75	5.75	5.75	5.75	5.75	
90 %		5.75	5.75	5.75	5.75	5.75	5.75	5.75	
None	D1 Stream	3.67	3.67	3.67	3.67	3.67	3.67	3.67	
50 %		3.67	3.67	3.67	3.67	3.67	3.67	3.67	
75 %		3.67	3.67	3.67	3.67	3.67	3.67	3.67	
90 %		3.67	3.67	3.67	3.67	3.67	3.67	3.67	
None	D2 Ditch	17.0	17.0	17.0	17.0	17.0	17.0	17.0	
50 %		17.0	17.0	17.0	17.0	17.0	17.0	17.0	
75 %		17.0	17.0	17.0	17.0	17.0	17.0	17.0	
90 %		17.0	17.0	17.0	17.0	17.0	17.0	17.0	
None	D2 Stream	10.9	10.9	10.9	10.9	10.9	10.9	10.9	
50 %		10.9	10.9	10.9	10.9	10.9	10.9	10.9	
75 %		10.9	10.9	10.9	10.9	10.9	10.9	10.9	
90 %		10.9	10.9	10.9	10.9	10.9	10.9	10.9	
None	D3 Ditch	1.54	0.914	0.419	0.222	0.115	0.222	0.115	
50 %		0.772	0.457	0.209	0.111	0.058	0.111	0.058	
75 %		0.386	0.229	0.105	0.056	0.029	0.056	0.029	
90 %		0.154	0.091	0.042	0.022	0.012	0.022	0.012	
None	D4 Pond	0.484	0.486	0.482	0.480	0.477	0.480	0.477	
50 %		0.478	0.479	0.477	0.476	0.475	0.476	0.475	
75 %		0.475	0.476	0.475	0.474	0.474	0.474	0.474	
90 %		0.474	0.474	0.474	0.473	0.473	0.473	0.473	
None	D4 Stream	1.34	1.07	0.586	0.586	0.586	0.586	0.586	
50 %		0.669	0.586	0.586	0.586	0.586	0.586	0.586	
75 %		0.586	0.586	0.586	0.586	0.586	0.586	0.586	
90 %		0.586	0.586	0.586	0.586	0.586	0.586	0.586	
None	D5 Pond	0.542	0.544	0.541	0.539	0.537	0.539	0.537	
50 %		0.538	0.539	0.537	0.536	0.535	0.536	0.535	

75 %		0.535	0.536	0.535	0.535	0.534	0.535	0.534	
90 %		0.534	0.534	0.534	0.534	0.533	0.534	0.533	
None	D5 Stream	1.44	1.15	0.674	0.674	0.674	0.674	0.674	
50 %		0.722	0.674	0.674	0.674	0.674	0.674	0.674	
75 %		0.674	0.674	0.674	0.674	0.674	0.674	0.674	
90 %		0.674	0.674	0.674	0.674	0.674	0.674	0.674	
None	D6 Ditch	4.42	4.42	4.42	4.42	4.42	4.42	4.42	
50 %		4.42	4.42	4.42	4.42	4.42	4.42	4.42	
75 %		4.42	4.42	4.42	4.42	4.42	4.42	4.42	
90 %		4.42	4.42	4.42	4.42	4.42	4.42	4.42	
None	R1 Pond	0.163	0.172	0.157	0.146	0.138	0.075	0.042	
50 %		0.141	0.146	0.138	0.133	0.129	0.061	0.033	
75 %		0.131	0.133	0.129	0.126	0.124	0.055	0.029	
90 %		0.124	0.125	0.124	0.123	0.122	0.051	0.026	
None	R1 Stream	5.55	5.55	5.55	5.55	5.55	2.52	1.32	
50 %		5.55	5.55	5.55	5.55	5.55	2.52	1.32	
75 %		5.55	5.55	5.55	5.55	5.55	2.52	1.32	
90 %		5.55	5.55	5.55	5.55	5.55	2.52	1.32	
None	R3 Stream	8.54	8.54	8.54	8.54	8.54	3.89	2.04	
50 %		8.54	8.54	8.54	8.54	8.54	3.89	2.04	
75 %		8.54	8.54	8.54	8.54	8.54	3.89	2.04	
90 %		8.54	8.54	8.54	8.54	8.54	3.89	2.04	
None	R4 Stream	9.79	9.79	9.79	9.79	9.79	4.40	2.29	
50 %		9.79	9.79	9.79	9.79	9.79	4.40	2.29	
75 %		9.79	9.79	9.79	9.79	9.79	4.40	2.29	
90 %		9.79	9.79	9.79	9.79	9.79	4.40	2.29	
RAC (µg/L)	2.4	PEC / RAC ratio							
None	D1 Ditch	**2.40**	**2.40**	**2.40**	**2.40**	**2.40**	**2.40**	**2.40**	
50 %		**2.40**	**2.40**	**2.40**	**2.40**	**2.40**	**2.40**	**2.40**	
75 %		**2.40**	**2.40**	**2.40**	**2.40**	**2.40**	**2.40**	**2.40**	
90 %		**2.40**	**2.40**	**2.40**	**2.40**	**2.40**	**2.40**	**2.40**	
None	D1 Stream	**1.53**	**1.53**	**1.53**	**1.53**	**1.53**	**1.53**	**1.53**	
50 %		**1.53**	**1.53**	**1.53**	**1.53**	**1.53**	**1.53**	**1.53**	
75 %		**1.53**	**1.53**	**1.53**	**1.53**	**1.53**	**1.53**	**1.53**	
90 %		**1.53**	**1.53**	**1.53**	**1.53**	**1.53**	**1.53**	**1.53**	
None	D2 Ditch	**7.10**	**7.10**	**7.10**	**7.10**	**7.10**	**7.10**	**7.10**	
50 %		**7.10**	**7.10**	**7.10**	**7.10**	**7.10**	**7.10**	**7.10**	
75 %		**7.10**	**7.10**	**7.10**	**7.10**	**7.10**	**7.10**	**7.10**	
90 %		**7.10**	**7.10**	**7.10**	**7.10**	**7.10**	**7.10**	**7.10**	
None	D2 Stream	**4.55**	**4.55**	**4.55**	**4.55**	**4.55**	**4.55**	**4.55**	
50 %		**4.55**	**4.55**	**4.55**	**4.55**	**4.55**	**4.55**	**4.55**	
75 %		**4.55**	**4.55**	**4.55**	**4.55**	**4.55**	**4.55**	**4.55**	
90 %		**4.55**	**4.55**	**4.55**	**4.55**	**4.55**	**4.55**	**4.55**	
None	D3 Ditch	0.643	0.381	0.174	0.093	0.048	0.093	0.048	
50 %		0.322	0.191	0.087	0.046	0.024	0.046	0.024	
75 %		0.161	0.095	0.044	0.023	0.012	0.023	0.012	

90 %		0.064	0.038	0.017	0.009	0.005	0.009	0.005	
None	D4 Pond	0.202	0.203	0.201	0.200	0.199	0.200	0.199	
50 %		0.199	0.200	0.199	0.198	0.198	0.198	0.198	
75 %		0.198	0.198	0.198	0.198	0.197	0.198	0.197	
90 %		0.197	0.197	0.197	0.197	0.197	0.197	0.197	
None	D4 Stream	0.558	0.445	0.244	0.244	0.244	0.244	0.244	
50 %		0.279	0.244	0.244	0.244	0.244	0.244	0.244	
75 %		0.244	0.244	0.244	0.244	0.244	0.244	0.244	
90 %		0.244	0.244	0.244	0.244	0.244	0.244	0.244	
None	D5 Pond	0.226	0.227	0.225	0.224	0.224	0.224	0.224	
50 %		0.224	0.224	0.224	0.223	0.223	0.223	0.223	
75 %		0.223	0.223	0.223	0.223	0.223	0.223	0.223	
90 %		0.223	0.223	0.222	0.222	0.222	0.222	0.222	
None	D5 Stream	0.602	0.480	0.281	0.281	0.281	0.281	0.281	
50 %		0.301	0.281	0.281	0.281	0.281	0.281	0.281	
75 %		0.281	0.281	0.281	0.281	0.281	0.281	0.281	
90 %		0.281	0.281	0.281	0.281	0.281	0.281	0.281	
None	D6 Ditch	**1.84**	**1.84**	**1.84**	**1.84**	**1.84**	**1.84**	**1.84**	
50 %		**1.84**	**1.84**	**1.84**	**1.84**	**1.84**	**1.84**	**1.84**	
75 %		**1.84**	**1.84**	**1.84**	**1.84**	**1.84**	**1.84**	**1.84**	
90 %		**1.84**	**1.84**	**1.84**	**1.84**	**1.84**	**1.84**	**1.84**	
None	R1 Pond	0.068	0.072	0.065	0.061	0.057	0.031	0.017	
50 %		0.059	0.061	0.058	0.055	0.054	0.026	0.014	
75 %		0.054	0.055	0.054	0.053	0.052	0.023	0.012	
90 %		0.052	0.052	0.051	0.051	0.051	0.021	0.011	
None	R1 Stream	**2.31**	**2.31**	**2.31**	**2.31**	**2.31**	**1.05**	0.550	
50 %		**2.31**	**2.31**	**2.31**	**2.31**	**2.31**	**1.05**	0.550	
75 %		**2.31**	**2.31**	**2.31**	**2.31**	**2.31**	**1.05**	0.550	
90 %		**2.31**	**2.31**	**2.31**	**2.31**	**2.31**	**1.05**	0.550	
None	R3 Stream	**3.56**	**3.56**	**3.56**	**3.56**	**3.56**	**1.62**	0.851	
50 %		**3.56**	**3.56**	**3.56**	**3.56**	**3.56**	**1.62**	0.851	
75 %		**3.56**	**3.56**	**3.56**	**3.56**	**3.56**	**1.62**	0.851	
90 %		**3.56**	**3.56**	**3.56**	**3.56**	**3.56**	**1.62**	0.851	
None	R4 Stream	**4.08**	**4.08**	**4.08**	**4.08**	**4.08**	**1.83**	0.955	
50 %		**4.08**	**4.08**	**4.08**	**4.08**	**4.08**	**1.83**	0.955	
75 %		**4.08**	**4.08**	**4.08**	**4.08**	**4.08**	**1.83**	0.955	
90 %		**4.08**	**4.08**	**4.08**	**4.08**	**4.08**	**1.83**	0.955	

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-12: **Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for flufenacet based on FOCUS Step 4 calculations and toxicity data for Aquatic plants with mitigation of spray drift and run-off for the use of FFA SC 508.8 G in Winter cereals (Use group B; modelling use winter cereals I -- early post-emg. -- 0.2442 kg a.s./ha)**

Intended use		Winter cereals, BBCH 10-13							
Active substance		flufenacet							
Application rate (g/ha)		244.s g a.s./ha (0.480 L prod/ha)							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	None	10 m	20 m	
	No spray buffer (m)	0 m	2 m	5 m	10 m	20 m	10 m	20 m	
None	D1 Ditch	9.87	9.87	9.87	9.87	9.87	9.87	9.87	
50 %		9.87	9.87	9.87	9.87	9.87	9.87	9.87	
75 %		9.87	9.87	9.87	9.87	9.87	9.87	9.87	
90 %		9.87	9.87	9.87	9.87	9.87	9.87	9.87	
None	D1 Stream	6.18	6.18	6.18	6.18	6.18	6.18	6.18	
50 %		6.18	6.18	6.18	6.18	6.18	6.18	6.18	
75 %		6.18	6.18	6.18	6.18	6.18	6.18	6.18	
90 %		6.18	6.18	6.18	6.18	6.18	6.18	6.18	
None	D2 Ditch	21.0	21.0	21.0	21.0	21.0	21.0	21.0	
50 %		21.0	21.0	21.0	21.0	21.0	21.0	21.0	
75 %		21.0	21.0	21.0	21.0	21.0	21.0	21.0	
90 %		21.0	21.0	21.0	21.0	21.0	21.0	21.0	
None	D2 Stream	13.3	13.3	13.3	13.3	13.3	13.3	13.3	
50 %		13.3	13.3	13.3	13.3	13.3	13.3	13.3	
75 %		13.3	13.3	13.3	13.3	13.3	13.3	13.3	
90 %		13.3	13.3	13.3	13.3	13.3	13.3	13.3	
None	D3 Ditch	1.54	0.914	0.418	0.222	0.115	0.222	0.115	
50 %		0.771	0.457	0.209	0.111	0.058	0.111	0.058	
75 %		0.386	0.228	0.105	0.056	0.029	0.056	0.029	
90 %		0.154	0.091	0.042	0.022	0.012	0.022	0.012	
None	D4 Pond	1.20	1.20	1.19	1.19	1.19	1.19	1.19	
50 %		1.19	1.19	1.19	1.19	1.18	1.19	1.18	
75 %		1.18	1.19	1.18	1.18	1.18	1.18	1.18	
90 %		1.18	1.18	1.18	1.18	1.18	1.18	1.18	
None	D4 Stream	1.51	1.51	1.51	1.51	1.51	1.51	1.51	
50 %		1.51	1.51	1.51	1.51	1.51	1.51	1.51	
75 %		1.51	1.51	1.51	1.51	1.51	1.51	1.51	
90 %		1.51	1.51	1.51	1.51	1.51	1.51	1.51	
None	D5 Pond	1.30	1.31	1.30	1.30	1.29	1.30	1.29	
50 %		1.30	1.30	1.29	1.29	1.29	1.29	1.29	
75 %		1.29	1.29	1.29	1.29	1.29	1.29	1.29	
90 %		1.29	1.29	1.29	1.29	1.29	1.29	1.29	
None	D5 Stream	1.72	1.72	1.72	1.72	1.72	1.72	1.72	
50 %		1.72	1.72	1.72	1.72	1.72	1.72	1.72	
75 %		1.72	1.72	1.72	1.72	1.72	1.72	1.72	
90 %		1.72	1.72	1.72	1.72	1.72	1.72	1.72	

None	D6 Ditch	6.51	6.51	6.51	6.51	6.51	6.51	6.51	
50 %		6.51	6.51	6.51	6.51	6.51	6.51	6.51	
75 %		6.51	6.51	6.51	6.51	6.51	6.51	6.51	
90 %		6.51	6.51	6.51	6.51	6.51	6.51	6.51	
None	R1 Pond	0.115	0.125	0.109	0.098	0.089	0.056	0.033	
50 %		0.093	0.098	0.090	0.084	0.080	0.042	0.023	
75 %		0.082	0.084	0.080	0.078	0.075	0.035	0.019	
90 %		0.075	0.076	0.074	0.073	0.072	0.031	0.016	
None	R1 Stream	6.57	6.57	6.57	6.57	6.57	2.95	1.53	
50 %		6.57	6.57	6.57	6.57	6.57	2.95	1.53	
75 %		6.57	6.57	6.57	6.57	6.57	2.95	1.53	
90 %		6.57	6.57	6.57	6.57	6.57	2.95	1.53	
None	R3 Stream	8.56	8.56	8.56	8.56	8.56	3.86	2.02	
50 %		8.56	8.56	8.56	8.56	8.56	3.86	2.02	
75 %		8.56	8.56	8.56	8.56	8.56	3.86	2.02	
90 %		8.56	8.56	8.56	8.56	8.56	3.86	2.02	
None	R4 Stream	2.38	2.38	2.38	2.38	2.38	1.07	0.561	
50 %		2.38	2.38	2.38	2.38	2.38	1.07	0.561	
75 %		2.38	2.38	2.38	2.38	2.38	1.07	0.561	
90 %		2.38	2.38	2.38	2.38	2.38	1.07	0.561	
RAC (µg/L)	2.4	PEC / RAC ratio							
None	D1 Ditch	**4.11**	**4.11**	**4.11**	**4.11**	**4.11**	**4.11**	**4.11**	
50 %		**4.11**	**4.11**	**4.11**	**4.11**	**4.11**	**4.11**	**4.11**	
75 %		**4.11**	**4.11**	**4.11**	**4.11**	**4.11**	**4.11**	**4.11**	
90 %		**4.11**	**4.11**	**4.11**	**4.11**	**4.11**	**4.11**	**4.11**	
None	D1 Stream	**2.58**	**2.58**	**2.58**	**2.58**	**2.58**	**2.58**	**2.58**	
50 %		**2.58**	**2.58**	**2.58**	**2.58**	**2.58**	**2.58**	**2.58**	
75 %		**2.58**	**2.58**	**2.58**	**2.58**	**2.58**	**2.58**	**2.58**	
90 %		**2.58**	**2.58**	**2.58**	**2.58**	**2.58**	**2.58**	**2.58**	
None	D2 Ditch	**8.73**	**8.73**	**8.73**	**8.73**	**8.73**	**8.73**	**8.73**	
50 %		**8.73**	**8.73**	**8.73**	**8.73**	**8.73**	**8.73**	**8.73**	
75 %		**8.73**	**8.73**	**8.73**	**8.73**	**8.73**	**8.73**	**8.73**	
90 %		**8.73**	**8.73**	**8.73**	**8.73**	**8.73**	**8.73**	**8.73**	
None	D2 Stream	**5.53**	**5.53**	**5.53**	**5.53**	**5.53**	**5.53**	**5.53**	
50 %		**5.53**	**5.53**	**5.53**	**5.53**	**5.53**	**5.53**	**5.53**	
75 %		**5.53**	**5.53**	**5.53**	**5.53**	**5.53**	**5.53**	**5.53**	
90 %		**5.53**	**5.53**	**5.53**	**5.53**	**5.53**	**5.53**	**5.53**	
None	D3 Ditch	0.643	0.381	0.174	0.092	0.048	0.092	0.048	
50 %		0.321	0.190	0.087	0.046	0.024	0.046	0.024	
75 %		0.161	0.095	0.044	0.023	0.012	0.023	0.012	
90 %		0.064	0.038	0.017	0.009	0.005	0.009	0.005	
None	D4 Pond	0.498	0.500	0.498	0.496	0.495	0.496	0.495	
50 %		0.495	0.496	0.495	0.494	0.493	0.494	0.493	
75 %		0.493	0.494	0.493	0.493	0.493	0.493	0.493	
90 %		0.493	0.493	0.492	0.492	0.492	0.492	0.492	
None	D4 Stream	0.629	0.629	0.629	0.629	0.629	0.629	0.629	

50 %		0.629	0.629	0.629	0.629	0.629	0.629	0.629	
75 %		0.629	0.629	0.629	0.629	0.629	0.629	0.629	
90 %		0.629	0.629	0.629	0.629	0.629	0.629	0.629	
None	D5 Pond	0.543	0.544	0.542	0.540	0.539	0.540	0.539	
50 %		0.540	0.540	0.539	0.539	0.538	0.539	0.538	
75 %		0.538	0.539	0.538	0.538	0.538	0.538	0.538	
90 %		0.538	0.538	0.537	0.537	0.537	0.537	0.537	
None	D5 Stream	0.716	0.716	0.716	0.716	0.716	0.716	0.716	
50 %		0.716	0.716	0.716	0.716	0.716	0.716	0.716	
75 %		0.716	0.716	0.716	0.716	0.716	0.716	0.716	
90 %		0.716	0.716	0.716	0.716	0.716	0.716	0.716	
None	D6 Ditch	**2.71**	**2.71**	**2.71**	**2.71**	**2.71**	**2.71**	**2.71**	
50 %		**2.71**	**2.71**	**2.71**	**2.71**	**2.71**	**2.71**	**2.71**	
75 %		**2.71**	**2.71**	**2.71**	**2.71**	**2.71**	**2.71**	**2.71**	
90 %		**2.71**	**2.71**	**2.71**	**2.71**	**2.71**	**2.71**	**2.71**	
None	R1 Pond	0.048	0.052	0.045	0.041	0.037	0.023	0.014	
50 %		0.039	0.041	0.037	0.035	0.033	0.018	0.010	
75 %		0.034	0.035	0.033	0.032	0.031	0.015	0.008	
90 %		0.031	0.032	0.031	0.031	0.030	0.013	0.007	
None	R1 Stream	**2.74**	**2.74**	**2.74**	**2.74**	**2.74**	**1.23**	0.639	
50 %		**2.74**	**2.74**	**2.74**	**2.74**	**2.74**	**1.23**	0.639	
75 %		**2.74**	**2.74**	**2.74**	**2.74**	**2.74**	**1.23**	0.639	
90 %		**2.74**	**2.74**	**2.74**	**2.74**	**2.74**	**1.23**	0.639	
None	R3 Stream	**3.57**	**3.57**	**3.57**	**3.57**	**3.57**	**1.61**	0.840	
50 %		**3.57**	**3.57**	**3.57**	**3.57**	**3.57**	**1.61**	0.840	
75 %		**3.57**	**3.57**	**3.57**	**3.57**	**3.57**	**1.61**	0.840	
90 %		**3.57**	**3.57**	**3.57**	**3.57**	**3.57**	**1.61**	0.840	
None	R4 Stream	0.991	0.991	0.991	0.991	0.991	0.447	0.234	
50 %		0.991	0.991	0.991	0.991	0.991	0.447	0.234	
75 %		0.991	0.991	0.991	0.991	0.991	0.447	0.234	
90 %		0.991	0.991	0.991	0.991	0.991	0.447	0.234	

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-13: **Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for flufenacet based on FOCUS Step 4 calculations and toxicity data for Aquatic plants with mitigation of spray drift and run-off for the use of FFA SC 508.8 G in Winter cereals (Use group C; modelling use winter cereals II -- pre-emg. -- 0.1221 kg a.s./ha)**

Intended use		Winter cereals, BBCH 00 -09							
Active substance		flufenacet							
Application rate (g/ha)		122.1 g a.s./ha (0.240 L prod/ha)							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	None	10 m	20 m	
	No spray buffer (m)	0 m	2 m	5 m	10 m	20 m	10 m	20 m	
None	D1 Ditch	2.84	2.84	2.84	2.84	2.84	2.84	2.84	
50 %		2.84	2.84	2.84	2.84	2.84	2.84	2.84	
75 %		2.84	2.84	2.84	2.84	2.84	2.84	2.84	
90 %		2.84	2.84	2.84	2.84	2.84	2.84	2.84	
None	D1 Stream	1.82	1.82	1.82	1.82	1.82	1.82	1.82	
50 %		1.82	1.82	1.82	1.82	1.82	1.82	1.82	
75 %		1.82	1.82	1.82	1.82	1.82	1.82	1.82	
90 %		1.82	1.82	1.82	1.82	1.82	1.82	1.82	
None	D2 Ditch	7.88	7.88	7.88	7.88	7.88	7.88	7.88	
50 %		7.88	7.88	7.88	7.88	7.88	7.88	7.88	
75 %		7.88	7.88	7.88	7.88	7.88	7.88	7.88	
90 %		7.88	7.88	7.88	7.88	7.88	7.88	7.88	
None	D2 Stream	5.07	5.07	5.07	5.07	5.07	5.07	5.07	
50 %		5.07	5.07	5.07	5.07	5.07	5.07	5.07	
75 %		5.07	5.07	5.07	5.07	5.07	5.07	5.07	
90 %		5.07	5.07	5.07	5.07	5.07	5.07	5.07	
None	D3 Ditch	0.772	0.457	0.209	0.111	0.058	0.111	0.058	
50 %		0.386	0.229	0.105	0.056	0.029	0.056	0.029	
75 %		0.193	0.114	0.052	0.028	0.014	0.028	0.014	
90 %		0.077	0.046	0.021	0.011	0.006	0.011	0.006	
None	D4 Pond	0.239	0.240	0.238	0.237	0.235	0.237	0.235	
50 %		0.236	0.237	0.236	0.235	0.234	0.235	0.234	
75 %		0.235	0.235	0.234	0.234	0.234	0.234	0.234	
90 %		0.234	0.234	0.234	0.234	0.233	0.234	0.233	
None	D4 Stream	0.669	0.534	0.281	0.281	0.281	0.281	0.281	
50 %		0.335	0.281	0.281	0.281	0.281	0.281	0.281	
75 %		0.281	0.281	0.281	0.281	0.281	0.281	0.281	
90 %		0.281	0.281	0.281	0.281	0.281	0.281	0.281	
None	D5 Pond	0.263	0.264	0.263	0.262	0.261	0.262	0.261	
50 %		0.261	0.262	0.261	0.260	0.260	0.260	0.260	
75 %		0.260	0.260	0.260	0.259	0.259	0.259	0.259	
90 %		0.259	0.259	0.259	0.259	0.259	0.259	0.259	
None	D5 Stream	0.722	0.576	0.315	0.315	0.315	0.315	0.315	
50 %		0.361	0.315	0.315	0.315	0.315	0.315	0.315	
75 %		0.315	0.315	0.315	0.315	0.315	0.315	0.315	
90 %		0.315	0.315	0.315	0.315	0.315	0.315	0.315	
None	D6 Ditch	1.82	1.82	1.82	1.82	1.82	1.82	1.82	

50 %		1.82	1.82	1.82	1.82	1.82	1.82	1.82	
75 %		1.82	1.82	1.82	1.82	1.82	1.82	1.82	
90 %		1.82	1.82	1.82	1.82	1.82	1.82	1.82	
None	R1 Pond	0.079	0.084	0.077	0.071	0.067	0.037	0.021	
50 %		0.069	0.071	0.067	0.065	0.062	0.030	0.016	
75 %		0.063	0.065	0.063	0.061	0.060	0.027	0.014	
90 %		0.060	0.061	0.060	0.059	0.059	0.025	0.013	
None	R1 Stream	2.69	2.69	2.69	2.69	2.69	1.22	0.638	
50 %		2.69	2.69	2.69	2.69	2.69	1.22	0.638	
75 %		2.69	2.69	2.69	2.69	2.69	1.22	0.638	
90 %		2.69	2.69	2.69	2.69	2.69	1.22	0.638	
None	R3 Stream	4.06	4.06	4.06	4.06	4.06	1.85	0.973	
50 %		4.06	4.06	4.06	4.06	4.06	1.85	0.973	
75 %		4.06	4.06	4.06	4.06	4.06	1.85	0.973	
90 %		4.06	4.06	4.06	4.06	4.06	1.85	0.973	
None	R4 Stream	4.71	4.71	4.71	4.71	4.71	2.12	1.10	
50 %		4.71	4.71	4.71	4.71	4.71	2.12	1.10	
75 %		4.71	4.71	4.71	4.71	4.71	2.12	1.10	
90 %		4.71	4.71	4.71	4.71	4.71	2.12	1.10	
RAC (µg/L)	2.4	PEC / RAC ratio							
None	D1 Ditch	**1.18**	**1.18**	**1.18**	**1.18**	**1.18**	**1.18**	**1.18**	
50 %		**1.18**	**1.18**	**1.18**	**1.18**	**1.18**	**1.18**	**1.18**	
75 %		**1.18**	**1.18**	**1.18**	**1.18**	**1.18**	**1.18**	**1.18**	
90 %		**1.18**	**1.18**	**1.18**	**1.18**	**1.18**	**1.18**	**1.18**	
None	D1 Stream	0.756	0.756	0.756	0.756	0.756	0.756	0.756	
50 %		0.756	0.756	0.756	0.756	0.756	0.756	0.756	
75 %		0.756	0.756	0.756	0.756	0.756	0.756	0.756	
90 %		0.756	0.756	0.756	0.756	0.756	0.756	0.756	
None	D2 Ditch	**3.28**	**3.28**	**3.28**	**3.28**	**3.28**	**3.28**	**3.28**	
50 %		**3.28**	**3.28**	**3.28**	**3.28**	**3.28**	**3.28**	**3.28**	
75 %		**3.28**	**3.28**	**3.28**	**3.28**	**3.28**	**3.28**	**3.28**	
90 %		**3.28**	**3.28**	**3.28**	**3.28**	**3.28**	**3.28**	**3.28**	
None	D2 Stream	**2.11**	**2.11**	**2.11**	**2.11**	**2.11**	**2.11**	**2.11**	
50 %		**2.11**	**2.11**	**2.11**	**2.11**	**2.11**	**2.11**	**2.11**	
75 %		**2.11**	**2.11**	**2.11**	**2.11**	**2.11**	**2.11**	**2.11**	
90 %		**2.11**	**2.11**	**2.11**	**2.11**	**2.11**	**2.11**	**2.11**	
None	D3 Ditch	0.322	0.191	0.087	0.046	0.024	0.046	0.024	
50 %		0.161	0.095	0.044	0.023	0.012	0.023	0.012	
75 %		0.080	0.048	0.022	0.012	0.006	0.012	0.006	
90 %		0.032	0.019	0.009	0.005	0.002	0.005	0.002	
None	D4 Pond	0.099	0.100	0.099	0.099	0.098	0.099	0.098	
50 %		0.098	0.099	0.098	0.098	0.098	0.098	0.098	
75 %		0.098	0.098	0.098	0.098	0.097	0.098	0.097	
90 %		0.097	0.097	0.097	0.097	0.097	0.097	0.097	
None	D4 Stream	0.279	0.223	0.117	0.117	0.117	0.117	0.117	
50 %		0.139	0.117	0.117	0.117	0.117	0.117	0.117	

75 %		0.117	0.117	0.117	0.117	0.117	0.117	0.117	
90 %		0.117	0.117	0.117	0.117	0.117	0.117	0.117	
None	D5 Pond	0.110	0.110	0.109	0.109	0.109	0.109	0.109	
50 %		0.109	0.109	0.109	0.108	0.108	0.108	0.108	
75 %		0.108	0.108	0.108	0.108	0.108	0.108	0.108	
90 %		0.108	0.108	0.108	0.108	0.108	0.108	0.108	
None	D5 Stream	0.301	0.240	0.131	0.131	0.131	0.131	0.131	
50 %		0.150	0.131	0.131	0.131	0.131	0.131	0.131	
75 %		0.131	0.131	0.131	0.131	0.131	0.131	0.131	
90 %		0.131	0.131	0.131	0.131	0.131	0.131	0.131	
None	D6 Ditch	0.757	0.757	0.757	0.757	0.757	0.757	0.757	
50 %		0.757	0.757	0.757	0.757	0.757	0.757	0.757	
75 %		0.757	0.757	0.757	0.757	0.757	0.757	0.757	
90 %		0.757	0.757	0.757	0.757	0.757	0.757	0.757	
None	R1 Pond	0.033	0.035	0.032	0.030	0.028	0.015	0.009	
50 %		0.029	0.030	0.028	0.027	0.026	0.012	0.007	
75 %		0.026	0.027	0.026	0.026	0.025	0.011	0.006	
90 %		0.025	0.025	0.025	0.025	0.025	0.010	0.005	
None	R1 Stream	**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	0.508	0.266	
50 %		**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	0.508	0.266	
75 %		**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	0.508	0.266	
90 %		**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	0.508	0.266	
None	R3 Stream	**1.69**	**1.69**	**1.69**	**1.69**	**1.69**	0.773	0.405	
50 %		**1.69**	**1.69**	**1.69**	**1.69**	**1.69**	0.773	0.405	
75 %		**1.69**	**1.69**	**1.69**	**1.69**	**1.69**	0.773	0.405	
90 %		**1.69**	**1.69**	**1.69**	**1.69**	**1.69**	0.773	0.405	
None	R4 Stream	**1.96**	**1.96**	**1.96**	**1.96**	**1.96**	0.882	0.460	
50 %		**1.96**	**1.96**	**1.96**	**1.96**	**1.96**	0.882	0.460	
75 %		**1.96**	**1.96**	**1.96**	**1.96**	**1.96**	0.882	0.460	
90 %		**1.96**	**1.96**	**1.96**	**1.96**	**1.96**	0.882	0.460	

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-14: **Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for flufenacet based on FOCUS Step 4 calculations and toxicity data for Aquatic plants with mitigation of spray drift and run-off for the use of FFA SC 508.8 G in Winter cereals (Use group D; modelling use winter cereals II -- early post-emg. -- 0.1221 kg a.s./ha)**

Intended use		Winter cereals, BBCH 10-13							
Active substance		flufenacet							
Application rate (g/ha)		122.1 g a.s./ha (0.240 L prod/ha)							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	None	10 m	20 m	
	No spray buffer (m)	0 m	2 m	5 m	10 m	20 m	10 m	20 m	
None	D1 Ditch	4.32	4.32	4.32	4.32	4.32	4.32	4.32	
50 %		4.32	4.32	4.32	4.32	4.32	4.32	4.32	
75 %		4.32	4.32	4.32	4.32	4.32	4.32	4.32	
90 %		4.32	4.32	4.32	4.32	4.32	4.32	4.32	
None	D1 Stream	2.69	2.69	2.69	2.69	2.69	2.69	2.69	
50 %		2.69	2.69	2.69	2.69	2.69	2.69	2.69	
75 %		2.69	2.69	2.69	2.69	2.69	2.69	2.69	
90 %		2.69	2.69	2.69	2.69	2.69	2.69	2.69	
None	D2 Ditch	10.1	10.1	10.1	10.1	10.1	10.1	10.1	
50 %		10.1	10.1	10.1	10.1	10.1	10.1	10.1	
75 %		10.1	10.1	10.1	10.1	10.1	10.1	10.1	
90 %		10.1	10.1	10.1	10.1	10.1	10.1	10.1	
None	D2 Stream	6.29	6.29	6.29	6.29	6.29	6.29	6.29	
50 %		6.29	6.29	6.29	6.29	6.29	6.29	6.29	
75 %		6.29	6.29	6.29	6.29	6.29	6.29	6.29	
90 %		6.29	6.29	6.29	6.29	6.29	6.29	6.29	
None	D3 Ditch	0.771	0.457	0.209	0.111	0.058	0.111	0.058	
50 %		0.386	0.228	0.105	0.056	0.029	0.056	0.029	
75 %		0.193	0.114	0.052	0.028	0.014	0.028	0.014	
90 %		0.077	0.046	0.021	0.011	0.006	0.011	0.006	
None	D4 Pond	0.591	0.593	0.590	0.588	0.586	0.588	0.586	
50 %		0.587	0.588	0.586	0.585	0.584	0.585	0.584	
75 %		0.585	0.585	0.585	0.584	0.584	0.584	0.584	
90 %		0.584	0.584	0.583	0.583	0.583	0.583	0.583	
None	D4 Stream	0.722	0.722	0.722	0.722	0.722	0.722	0.722	
50 %		0.722	0.722	0.722	0.722	0.722	0.722	0.722	
75 %		0.722	0.722	0.722	0.722	0.722	0.722	0.722	
90 %		0.722	0.722	0.722	0.722	0.722	0.722	0.722	
None	D5 Pond	0.659	0.660	0.658	0.656	0.655	0.656	0.655	
50 %		0.655	0.656	0.655	0.654	0.653	0.654	0.653	
75 %		0.653	0.654	0.653	0.653	0.652	0.653	0.652	
90 %		0.652	0.652	0.652	0.652	0.652	0.652	0.652	
None	D5 Stream	0.873	0.873	0.873	0.873	0.873	0.873	0.873	
50 %		0.873	0.873	0.873	0.873	0.873	0.873	0.873	
75 %		0.873	0.873	0.873	0.873	0.873	0.873	0.873	
90 %		0.873	0.873	0.873	0.873	0.873	0.873	0.873	

None	D6 Ditch	3.37	3.37	3.37	3.37	3.37	3.37	3.37	
50 %		3.37	3.37	3.37	3.37	3.37	3.37	3.37	
75 %		3.37	3.37	3.37	3.37	3.37	3.37	3.37	
90 %		3.37	3.37	3.37	3.37	3.37	3.37	3.37	
None	R1 Pond	0.056	0.061	0.053	0.048	0.043	0.027	0.016	
50 %		0.045	0.047	0.043	0.041	0.039	0.020	0.011	
75 %		0.039	0.040	0.039	0.038	0.037	0.017	0.009	
90 %		0.037	0.037	0.037	0.037	0.036	0.015	0.008	
None	R1 Stream	3.14	3.14	3.14	3.14	3.14	1.41	0.732	
50 %		3.14	3.14	3.14	3.14	3.14	1.41	0.732	
75 %		3.14	3.14	3.14	3.14	3.14	1.41	0.732	
90 %		3.14	3.14	3.14	3.14	3.14	1.41	0.732	
None	R3 Stream	4.07	4.07	4.07	4.07	4.07	1.84	0.958	
50 %		4.07	4.07	4.07	4.07	4.07	1.84	0.958	
75 %		4.07	4.07	4.07	4.07	4.07	1.84	0.958	
90 %		4.07	4.07	4.07	4.07	4.07	1.84	0.958	
None	R4 Stream	1.23	1.23	1.23	1.23	1.23	0.556	0.290	
50 %		1.23	1.23	1.23	1.23	1.23	0.556	0.290	
75 %		1.23	1.23	1.23	1.23	1.23	0.556	0.290	
90 %		1.23	1.23	1.23	1.23	1.23	0.556	0.290	
RAC (µg/L)	2.4	PEC / RAC ratio							
None	D1 Ditch	**1.80**	**1.80**	**1.80**	**1.80**	**1.80**	**1.80**	**1.80**	
50 %		**1.80**	**1.80**	**1.80**	**1.80**	**1.80**	**1.80**	**1.80**	
75 %		**1.80**	**1.80**	**1.80**	**1.80**	**1.80**	**1.80**	**1.80**	
90 %		**1.80**	**1.80**	**1.80**	**1.80**	**1.80**	**1.80**	**1.80**	
None	D1 Stream	**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	
50 %		**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	
75 %		**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	
90 %		**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	**1.12**	
None	D2 Ditch	**4.21**	**4.21**	**4.21**	**4.21**	**4.21**	**4.21**	**4.21**	
50 %		**4.21**	**4.21**	**4.21**	**4.21**	**4.21**	**4.21**	**4.21**	
75 %		**4.21**	**4.21**	**4.21**	**4.21**	**4.21**	**4.21**	**4.21**	
90 %		**4.21**	**4.21**	**4.21**	**4.21**	**4.21**	**4.21**	**4.21**	
None	D2 Stream	**2.62**	**2.62**	**2.62**	**2.62**	**2.62**	**2.62**	**2.62**	
50 %		**2.62**	**2.62**	**2.62**	**2.62**	**2.62**	**2.62**	**2.62**	
75 %		**2.62**	**2.62**	**2.62**	**2.62**	**2.62**	**2.62**	**2.62**	
90 %		**2.62**	**2.62**	**2.62**	**2.62**	**2.62**	**2.62**	**2.62**	
None	D3 Ditch	0.321	0.190	0.087	0.046	0.024	0.046	0.024	
50 %		0.161	0.095	0.044	0.023	0.012	0.023	0.012	
75 %		0.080	0.048	0.022	0.012	0.006	0.012	0.006	
90 %		0.032	0.019	0.009	0.005	0.002	0.005	0.002	
None	D4 Pond	0.246	0.247	0.246	0.245	0.244	0.245	0.244	
50 %		0.244	0.245	0.244	0.244	0.244	0.244	0.244	
75 %		0.244	0.244	0.244	0.243	0.243	0.243	0.243	
90 %		0.243	0.243	0.243	0.243	0.243	0.243	0.243	
None	D4 Stream	0.301	0.301	0.301	0.301	0.301	0.301	0.301	

50 %		0.301	0.301	0.301	0.301	0.301	0.301	0.301	
75 %		0.301	0.301	0.301	0.301	0.301	0.301	0.301	
90 %		0.301	0.301	0.301	0.301	0.301	0.301	0.301	
None	D5 Pond	0.274	0.275	0.274	0.273	0.273	0.273	0.273	
50 %		0.273	0.273	0.273	0.272	0.272	0.272	0.272	
75 %		0.272	0.272	0.272	0.272	0.272	0.272	0.272	
90 %		0.272	0.272	0.272	0.272	0.272	0.272	0.272	
None	D5 Stream	0.364	0.364	0.364	0.364	0.364	0.364	0.364	
50 %		0.364	0.364	0.364	0.364	0.364	0.364	0.364	
75 %		0.364	0.364	0.364	0.364	0.364	0.364	0.364	
90 %		0.364	0.364	0.364	0.364	0.364	0.364	0.364	
None	D6 Ditch	**1.40**	**1.40**	**1.40**	**1.40**	**1.40**	**1.40**	**1.40**	
50 %		**1.40**	**1.40**	**1.40**	**1.40**	**1.40**	**1.40**	**1.40**	
75 %		**1.40**	**1.40**	**1.40**	**1.40**	**1.40**	**1.40**	**1.40**	
90 %		**1.40**	**1.40**	**1.40**	**1.40**	**1.40**	**1.40**	**1.40**	
None	R1 Pond	0.023	0.025	0.022	0.020	0.018	0.011	0.007	
50 %		0.019	0.020	0.018	0.017	0.016	0.009	0.005	
75 %		0.016	0.017	0.016	0.016	0.015	0.007	0.004	
90 %		0.015	0.016	0.015	0.015	0.015	0.006	0.003	
None	R1 Stream	**1.31**	**1.31**	**1.31**	**1.31**	**1.31**	0.585	0.305	
50 %		**1.31**	**1.31**	**1.31**	**1.31**	**1.31**	0.585	0.305	
75 %		**1.31**	**1.31**	**1.31**	**1.31**	**1.31**	0.585	0.305	
90 %		**1.31**	**1.31**	**1.31**	**1.31**	**1.31**	0.585	0.305	
None	R3 Stream	**1.69**	**1.69**	**1.69**	**1.69**	**1.69**	0.765	0.399	
50 %		**1.69**	**1.69**	**1.69**	**1.69**	**1.69**	0.765	0.399	
75 %		**1.69**	**1.69**	**1.69**	**1.69**	**1.69**	0.765	0.399	
90 %		**1.69**	**1.69**	**1.69**	**1.69**	**1.69**	0.765	0.399	
None	R4 Stream	0.513	0.513	0.513	0.513	0.513	0.232	0.121	
50 %		0.513	0.513	0.513	0.513	0.513	0.232	0.121	
75 %		0.513	0.513	0.513	0.513	0.513	0.232	0.121	
90 %		0.513	0.513	0.513	0.513	0.513	0.232	0.121	

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

9.5.2.2 Metabolite FOE sulfonic acid

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for FOE sulfonic acid for each organism group based on FOCUS Steps 1, 2 calculations for the use of FFA SC 508.8 G in Winter cereals (Use group A; modelling use winter cereals I -- autumn -- 1×244.2g a.s./ha)

Group		Fish acute	Inverteb. acute	Algae	Aquatic plants						
Test species		*Oncorhyn-chus mykiss*	*Daphnia magna*	*Desmodesmus subspicatus*	*Lemna gibba*						
Endpoint (µg/L)		LC_{50} **> 86700**	EC_{50} **> 87300**	E_rC_{50} **> 86700**	EC_{50} **> 86700**						
AF		**100**	**100**	**10**	**10**						
RAC (µg/L)		**> 867**	**> 873**	**> 8670**	**> 8670**						
FOCUS Scenario	PEC $_{gl\text{-}max}$ (µg/L)										
Step 1											
- -	16.0	> 0.018	> 0.018	> 0.002	> 0.002						
Step 2											
Northern Europe Oct. - Feb. (Autumn)	7.84	> 0.009	> 0.009	> 0.001	> 0.001						
Southern Europe Oct. - Feb. (Autumn)	6.27	> 0.007	> 0.007	> 0.001	> 0.001						

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

9.5.2.3 Metabolite FOE oxalate

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for FOE oxalate for each organism group based on FOCUS Steps 1, 2 calculations for the use of FFA SC 508.8 G in Winter cereals (Use group A; modelling use winter cereals I -- autumn -- 1×244.2g a.s./ha)

Group		**~~Algae~~**	**~~Aquatic plants~~**								
Test species		***~~Pseudokirch-neriella sub-capitata~~***	***~~Lemna gibba~~***								
Endpoint (µg/L)		**E_rC_{50} > 100000**	**E_rC_{50} > 100000**								
AF		**10**	**10**								
RAC (µg/L)		**> 10000**	**> 10000**								
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**										
Step 1											
- -	7.76	> 0.001	> 0.001								
Step 2											
Northern Europe Oct. - Feb. (Autumn)	2.94	<0.001	<0.001								
Southern Europe Oct. - Feb. (Autumn)	2.35	<0.001	<0.001								

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

9.5.2.4 Metabolite FOE methylsulfide

Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for FOE methylsulfide for each organism group based on FOCUS Steps 1, 2 calculations for the use of FFA SC 508.8 G in Winter cereals (Use group A; modelling use winter cereals I -- autumn -- 1×244.2g a.s./ha)

Group		**Algae**									
Test species		***Pseudokirch-neriella sub-capitata***									
Endpoint (µg/L)		**E_rC_{50} 83800**									
AF		**10**									
RAC (µg/L)		**8380**									
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**										
Step 1											
- -	3.09	<0.001									
Step 2											
Northern Europe Oct. - Feb. (Autumn)	1.33	<0.001									
Southern Europe Oct. - Feb. (Autumn)	1.08	<0.001									

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

9.5.2.5 Metabolite FOE thiadone

Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for FOE thiadone for each organism group based on FOCUS Steps 1, 2 calculations for the use of FFA SC 508.8 G in Winter cereals (Use group A; modelling use winter cereals I -- autumn -- 1×244.2g a.s./ha)

Group		Fish acute	Inverteb. acute	Algae							
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella subcapitata***							
Endpoint (µg/L)		**LC_{50} 9100**	**EC_{50} 31700**	**E_rC_{50} 15000**							
AF		**100**	**100**	**10**							
RAC (µg/L)		**91**	**317**	**1500**							
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**										
Step 1											
- -	31.3	0.344	0.099	0.021							
Step 2											
Northern Europe Oct. - Feb. (Autumn)	13.7	0.151	0.043	0.009							
Southern Europe Oct. - Feb. (Autumn)	11.1	0.122	0.035	0.007							

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

For all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for macrophytes, algae and periphyton in several FOCUS Steps 1-3 scenarios.
Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the long-term mesocosm RAC of 2.4 µg/L (NOEC =12 µg/L, AF = 5; covering macrophytes, algae and periphyton).

Based on the performed calculations with the following conclusions may be derived:

Group use A
Winter cereals, BBCH 00-09, pre-emergence, autumn - 1×244.2 g a.s./ha, (1 x 0.48 L/ha)

- scenarios D3, D4, D5, R1 (pond): acceptable risk with no need for risk mitigation measures
- scenarios: R1 (stream), R3, R4: acceptable risk with 20 m VFS
- scenarios D1, D2, D6: the risk unresolved with 20 m VFS

Group use B
Winter cereals, BBCH 10-13, early post emergence, 1 x 244.2 kg a.s./ha, (1 x 0.48 L/ha)

- scenarios D3, D4, D5, R1 (pond), R4: acceptable risk with no need for risk mitigation measures
- scenarios: R1 (stream), R3: acceptable risk with 20 m VFS
- scenarios D1, D2, D6: the risk unresolved with 20 m VFS

Group use C
Winter cereals , BBCH 00-09, pre-emergence, 1 x 0.1221 kg a.s./ha, (1 x 0.24 L/ha)

- scenarios D3, D4, D5, R1 (pond), D1 (stream), D6: acceptable risk with no need for risk mitigation measures
- scenarios: R1, R3, R4: acceptable risk with 10 m VFS
- scenarios D1 (ditch), D2: the risk unresolved with 20 m VFS

Group use D
Winter cereals BBCH 10-13, post - emergence, 1×0.1221 g a.s./ha, (1 x 0.24 L/ha)

- scenarios D3, D4, D5, R1 (pond), R4: acceptable risk with no need for risk mitigation measures
- scenarios: R1, R3, acceptable risk with 10 m VFS
- scenarios D1, D2, D6 the risk unresolved with 20 m VFS

Concerned Member States must decide on applicability of indicated risk mitigation measures in their countries at the product authorization.
Please note that additional aquatic risk assessment may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations. The risk for metabolites is covered by the active substance-flufenacet.

9.5.3 Overall conclusions

For the active substance flufenacet the PEC/RAC ratios using worst-case PEC_{sw} values for pre- and post-emergence application exceeded the trigger value of 1 in several FOCUS Step 3 scenarios.
Therefore, refined risk assessments based on FOCUS Step 4 PEC_{sw} values considering reduced exposure of surface water bodies and the higher tier mesocosm RAC of 2.4 µg a.s./L for flufenacet were conducted.

The following risk mitigation measures are recommended.

For use group A&B (application rate of 1 x 0.48 L prod./ha on winter cereals pre- and post-emergence at BBCH 00-09 and BBCH 10-13) the necessary mitigation measures include a 20 m no spray buffer zone + a 20 m vegetated strip and the product should not be used on artificially drained soil.

For use group C&D (application rate of 1 x 0.24 L prod./ha on winter cereals pre- and post-emergence at BBCH 00-09 and BBCH 10-13) the necessary mitigation measures include a 10 m no spray buffer zone + a 10 m vegetated strip and the product should not be used on artificially drained soil.

Please note that mitigation measures may vary depending on the member states' specific scenario requirements.

zRMS comments:

Conclusions above were amended accordingly with consideration of the outcome of the performed risk assessment.

Please note that Additional calculations may be required by cMS that do not accept surface water exposure derived using FOCUS models.

The acceptability and applicability of the indicated risk mitigation measures has to be confirmed at the cMS level.

The following text is added due to agreements during the Central Zone harmonization meetings. It should be noted that this text has no impact on the outcome of zonal evaluation of formulation FFA SC 508.8 G, which was performed in line with the EU agreed methodology.

"The endpoint E_rC_{50} is selected in this Core Assessment but there are some uncertainties regarding the level of protection reached for primary producers. This is indicated for macrophytes in the aquatic Guidance Document (EFSA Journal 2013;11(7):3290) that recommends: "... a proper calibration between different tiers (higher and lower tier data) for macrophytes should be performed in the future". Such calibration should be extended to algae. Until available relevant information on the level of protection reached is considered at EU level, it is recommended to address this uncertainty at each Member State level in the National Addendum if considered necessary, although it would be highly appreciated to have a harmonized approach in the Central zone."

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with flufenacet. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document when new studies are submitted.
Effects on bees of FFA SC 508.8 G were not evaluated as part of the EU assessment of flufenacet. New data submitted with this application in the core dossier are listed in Appendix 1 and summarised in Appendix 2.
The selection of studies and endpoints for the risk assessment is in line the results of the EU review process. Where the selection of studies and endpoints for the risk assessment deviates from the results of the EU review process, justifications are provided below.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Flufenacet	Acute, oral	LD_{50} > 109.2 ~~170~~ µg a.s./bee ~~nominal value LD_{50} = 175.56~~	EC review report (2003)
		Acute, contact	LD_{50} > 100 ~~194~~ µg a.s./bee	EC review report (2003)
Apis mellifera	Flufenacet	10 d chronic adult feeding	NOEC = ≥ 120 mg a.s./kg diet LC_{50} > 120 mg a.s./kg diet NOEDD = ≥ 4.4 µg a.s./bee/day LDD50 > 4.4 µg a.s./bee/day	Kling (2014) M-477339-01-2 See justification
Apis mellifera larvae	Flufenacet	Larvae, repeated exposure (22 d)	ED_{10} = 2.8 µg a.s./larva ED_{50} > 75 µg a.s./larva EC_{50} > 470 µg a.s./larva NOED = 75 µg a.s./larva NOEC = 470 µg a.s./larva	Rathjen (2018) M-615473-01-1 See justification
Apis mellifera	FFA SC 500*	Acute, oral	LD_{50} >228.0 µg a.s./bee	Schmitzer (2001) M-136977-01-1 Appendix 2
		Acute, contact	LD_{50} > 200 µg a.s./bee	
Apis mellifera	FFA SC 508.8	Acute, oral	LD_{50} >224.0 µg a.s./bee	Sekine (2019) M-671405-01-1 Appendix 2
		Acute, contact	LD_{50} > 200 µg a.s./bee	
Higher-tier studies (tunnel test, field studies)				
Apis mellifera	Flufenacet SC 508.8	Honey bee brood feeding (Oomen et al., 1992)	No adverse effects on mortality, bee brood development (eggs, young larvae, old larvae, pupae) and colony development by feeding honey bee colonies sugar syrup with a flufenacet-concentration typical for/exceeding the concentration of flufenacet in the spray tank (1500 ppm or 1.5 g a.s./L diet)	Kimmel (2018) M-456504-03-1 See justification
Apis mellifera	Flufenacet SC 508.8	Semi-field honey bee brood study (according to OECD 75; forced exposure conditions) in *Phacelia*; application during full-bloom and bees actively foraging	No effects on the survival of adult bees and honeybee pupae, foraging activity, behaviour, colony development and colony strength as well as on the bee brood at 240 g a.s./ha	Taenzler (2016) M-553011-01-1 See justification

* By mistake a wrong name Cadou SC 500 (Flufenacet SC 500, 500 g/L) has been mentioned in several documents which have been submitted to authorities. However, in all submitted studies the a.s. content of Flufenacet was in a range which was valid

for the SC 508.8 formulated product. The FAO tolerances for the a.s. content in a SC 508.8 g/L formulation are from 483.8 g/L to 533.8 g/L (508.8 ± 25 g/L). For more information please refer to the statement by Conrad (2013, M-470405-01-1, Appendix 2)

zRMS comments:

The bee acute toxicity data for flufenacet presented in Table 9.6-1 are in line with the EU agreed endpoints reported in EC review report (2003).
Studies on acute effects of the formulated product to bees listed in Table 9.6 - 1 were evaluated by the zRMS and considered acceptable. The reported endpoints are confirmed.
Summary of the performed studies together with zRMS evaluation may be found in Appendix 2.
It is noted that in order to fulfil the data requirements as set by Commission Regulation (EU) No 284/2013, studies on chronic and larvae bee toxicity should be performed with the formulated product.
However, the adult and larvae chronic bees studies were performed only for active substance - flufenacet.
In addition, the two higher tier studies for bees were performed for formulation Flufenacet SC 508.8.

9.6.1.1 Justification for new endpoints

Table 9.6-2: Justification for new endpoints

Species	Substance	Exposure System	Endpoint	Justification	Reference
Apis mellifera	Flufenacet	10 d chronic adult feeding	NOEC = ≥ 120 mg a.s./kg diet LC_{50} > 120 mg a.s./kg diet NOEDD = ≥ 4.4 µg a.s./bee/day LDD50 > 4.4 µg a.s./bee/day	Further data has been generated in order to complete the data set and the knowledge on chronic effects on honey bees. The study is under evaluation at EU level in the context of the AIR process.	Appendix 2 Kling (2014) M-477339-01-2
Apis mellifera larvae	Flufenacet	Larvae, repeated exposure (22 d)	ED_{10} = 2.8 µg a.s./larva ED_{50} > 75 µg a.s./larva EC_{50} > 470 µg a.s./larva NOED = 75 µg a.s./larva NOEC = 470 µg a.s./larva	Further data has been generated in order to complete the data set and the knowledge on effects on developmental stages of honey bees. The study is under evaluation at EU level in the context of the AIR process.	Appendix 2 Rathjen (2018) M-615473-01-1
Apis mellifera	Flufenacet SC 500	Acute oral and contact test	LD_{50} > 228.0 µg a.s./bee LD_{50} > 200 µg a.s./bee	Submission of new data to address the data requirement for the plant protection product laid down in Regulation (EC) No. 284/2013.	Appendix 2 Schmitzer (2001) M-136977-01-1
Apis mellifera	Flufenacet SC 508.8	Acute oral and contact test	LD_{50} > 224.0 µg a.s./bee LD_{50} > 200 µg a.s./bee	Submission of new data to address the data requirement for the plant protection product laid down in Regulation (EC) No. 284/2013.	Appendix 2 Sekine (2019) M-671405-01-1
Apis mellifera	Flufenacet SC 508.8	Honey bee brood feeding (Oomen et al., 1992)	No adverse effects on mortality, bee brood development (eggs, young larvae, old larvae, pupae) and colony development by feeding	Submission of new data to address the data requirement for the plant protection product laid down in Regulation (EC) No. 284/2013.	Appendix 2 Kimmel (2018) M-456504-03-1

Species	Substance	Exposure System	Endpoint	Justification	Reference
			honey bee colonies sugar syrup with a flufenacet-concentration typical for/ exceeding the concentration of flufenacet in the spray tank (1500 ppm or 1.5 g a.s.-L diet)	The study is under evaluation at EU level in the context of the AIR process.	
Apis mellifera	Flufenacet SC 508.8	Semi-field honey bee brood study (according to OECD 75; forced exposure conditions) in *Phacelia*; application during full-bloom and bees actively foraging	No effects on the survival of adult bees and honeybee pupae, foraging activity, behaviour, colony development and colony strength as well as on the bee brood at 240 g a.s./ha	Submission of new data to address the data requirement for the plant protection product laid down in Regulation (EC) No. 284/2013 The study is under evaluation at EU level in the context of the AIR process	Appendix 2 Taenzler (2016) M-553011-01-1

zRMS comments:

The new chronic active substance data provided in the Table 9.6-2 were not evaluated in the current dossier by zRMS but they were considered acceptable in the ongoing renewal process of flufenacet.

In reference to higher tier studies one tunnel test study by Taenzler, V.; (2016) and honey bee breed feed study by Kimmel 2018 were performed for formulation Flufenacet 508.8.

In the tunnel study by Taenzler, 2016, to assess the potential effects of Flufenacet SC 508.8 on honey bee colonies including brood development, 467.3 mL product in 400 L tap water/ha (240 g a.s./ha), was applied to a full-flowering and highly bee-attractive crop (i.e. Phacelia tanacetifolia) under semi-field (tunnel) conditions during bee-flight. No adverse effects on mortality of worker bees or pupae were observed. Foraging activity, behaviour, nectar- and pollen storage as well as queen survival was not affected. No effects on colony development, colony strength or bee brood were observed.

Based on the results of this study, it can be concluded that Flufenacet SC 508.8 does not adversely affect honey bees and honey bee brood when applied at a rate of 240 g a.s./ha.
In addition, the honey bee brood feeding study by Kimmel 2018 was submitted with formulation Flufenacet SC 508.8. No adverse effects on mortality, bee brood development (eggs, young larvae, old larvae, pupae) and colony development by feeding honey bee colonies sugar syrup with a flufenacet - concentration typical for/exceeding the concentration of flufenacet in the spray tank (1500 ppm) was noted.

It should be noted that these two higher tier studies were peer reviewed in ongoing renewal process of flufenacet in RAR 2018 and was considered acceptable.

Therefore, the studies were not re-evaluated by zRMS again in the current dossier.

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

To achieve a concise risk assessment, the risk envelope approach is applied as presented in 9.1.2 and the assessment for group A covers the risk for bees from all other intended uses.

9.6.2.1 Hazard quotients for bees

Table 9.6-3: First-tier assessment of the risk for bees due to the use of FFA SC 508.8 G in cereals (use group A)

Intended use	Cereals, 1 × 0.48 L product/ha		
Product	FFA SC 508.8 G		
Application rate (g/ha)	1 × 244.2		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>224	244.2	<1.09
Contact toxicity	>200		<1.22

QHO, QHC: Hazard quotients for oral and contact exposure. QH values shown in bold breach the relevant trigger.
Product density = 1.213 kg/L.

Further considerations for the risk assessment

The active substance flufenacet is of low toxicity to bees. The technical material exhibits acute LD_{50} contact values for adult bees of >194 µg a.s./bee. For oral routes of administration, the observed endpoint for technical flufenacet is >170 µg a.s./bee. The formulated product (FFA SC 508.8) is of low toxicity as well, with acute oral and contact LD_{50} values for adult bees in excess of > 200 µg a.s./bee. HQ values based on the use in winter cereals for both the active substance and the formulated product FFA SC 508.8 are considerably lower than the levels regarded to indicate a risk to bees. As per the GAP, a maximum of one spray application of the formulated product is intended in winter cereals at pre-emergence (BBCH 00 – 09) or early post-emergence (BBCH 10 – 13). As winter cereals are not nectariferous and not strongly attractive to bees for pollen collection, and as the application of this herbicide is intended to occur in autumn, the probability of chronic exposure to the formulated product for either honey bee adults or larvae is considered to be low. Nevertheless, the applicant has performed a chronic oral toxicity test (10-day feeding) as well as a chronic larvae laboratory study (repeated exposure) as per OECD Guidance Document No. 239 to address potential chronic toxicity to honey bees and effects on honey bee development and other honey bee life stages, respectively, in accordance with the data requirements as set out in Commission Regulation (EU) No. 283/2013. The findings of these studies are described below.

Chronic adult toxicity/effects
A 10-day laboratory feeding study investigating the effects of flufenacet was conducted to assess chronic toxicity to honey bees. The study was carried out prior to the adoption of OECD Guideline No. 245, and thus, some deviations may be encountered. The test comprised a single test item treatment group with nominal concentration level of 120 mg a.s./kg diet. The study concluded that continuous *ad libitum* feeding at 120 mg a.s./kg diet (corresponding to 4.4 µg a.s./bee/day) over a period of 10 days led to 3% mortality. Thus, the LDD_{50} was determined as > 4.4 µg a.s./bee/day. Daily dosing with 4.4 µg a.s./bee/day over 10 days (total dose of 44 µg a.s./bee) thus did not induce higher mortality compared to a single acute oral exposure at 170 µg a.s./bee. Study results therefore do not indicate delayed or cumulative toxicity effects following chronic exposure to flufenacet compared with acute testing.

Chronic larval toxicity/effects on brood
A honey bee larval toxicity test assessing the effect of flufenacet on adult emergence following repeated feeding exposure was conducted to address effects on immature honey bee life stages and their development. The 22-day laboratory dose-response test assessed larval and pupal survival as well as adult emergence, following exposure to nominal concentrations of 470, 160, 52, 18, and 5.8 mg a.s./kg diet. The matching cumulative doses were 75, 25, 8.3, 2.8, and 0.93 µg a.s./larva. The 22-day NOED (emergence) was determined to be 75 µg a.s./larva, indicating no risk to honey bee development.

9.6.3 Higher-tier risk assessment for bees (tunnel test, field studies)

Although the findings of the laboratory toxicity tests and the tier I risk assessment based on acute tests did not indicate a risk to bees due to the use of flufenacet or the formulated product FFA SC 508.8 in winter cereals, further consideration of the chronic risk to adult bees and larvae can be achieved by use of the findings from higher tier studies performed under tunnel test conditions with application made during bee activity onto a flowering crop or as a result of feeding colonies with 1.5 g a.s./L (corresponding to 2.89 ml FFA SC 508.8/L).

Flufenacet SC 508.8 was tested under semi-field conditions at 240 g a.s./ha (Taenzler, V.; 2016; M-553011-01-1). In this test, adult bees and bee brood were exposed for at least 7 days to pollen and nectar containing residues of flufenacet given that the application was conducted at full flowering while foragers bees were actively foraging. The results indicated no unacceptable effects on the survival of adult bees and honeybee pupae, foraging activity, behaviour, colony development and colony strength as well as on the bee brood.

A honeybee brood feeding study according to Oomen *et al.* (1992) (Kimmel, S.; 2018; M-456504-03-1) was used to evaluate the effect of FFA SC 508.8 on brood development and mortality of adult worker bees. The colonies were free-flying with access to natural nectar and pollen sources, however, the study was conducted at a time without mass flowering plants/agricultural crops in the study region. The consumption of the test item by honey bee colonies at a concentration of 1.5 g a.s./L, corresponding to 2.89 mL Flufenacet SC 508.8 in 1 L 50 % (w/v) aqueous sucrose solution, had no adverse effects on the colony conditions and survival of honeybee developmental stages (eggs, young larvae and old larvae). Furthermore, the test item had no adverse effects on the survival of the exposed adult worker bees. Based on the results of this study, it can be concluded that Flufenacet SC 508.8 does not adversely affect honey bee colonies or bee brood development.

zRMS comments:

It is noted that no chronic and larvae toxicity studies were performed with Flufenacet SC 508.8 G in line with the Commission Regulation (EU) No 284/2013. It should be noted that chronic studies to bees from exposure to flufenacet are available. They were peer reviewed in ongoing renewal process of flufenacet in RAR 2018 and was considered acceptable. However, the new data for the active substance cannot be used until the renewal process is finalised.
The chronic studies for formulation could be potentially replaced by respective field or semi-field or field studies for formulation.
Therefore, the tunnel study with Flufenacet SC 508.8 (Taenzler, V.; 2016) was used by zRMS in higher tier risk assessment for bees. The study summary may be found in Appendix 2.

Based on the results no unacceptable effects on the survival of adult bees and honeybee pupae, foraging activity, behaviour, colony development and colony strength as well as on the bee brood up to 240 g a.s./ha.

It should be indicated that the application dose in the tunnel studies 1 x (240 g a.s./ha) is slight below than the max application rate 1 x 244.2 g a.s./ha in the GAP.
The intended use in winter cereals at BBCH 00-13 at application rate of 244.2 g a.s./ha (pre- and post-emergence) which is well before flowering occurs at BBCH 61-69, is highly unlikely to result in potential residues from treated cereal crops to be carried through into nectar or pollen.

In the most uses included in the GAP it is autumn application, also presence of flowering weeds is less likely as well as bee activity but exposure from flowering weeds cannot be ruled out completely.

Generally, based all available information acceptable chronic risk to bees from exposure of Flufenacet SC 508.8 can be concluded up to 240 g a.s/ha.

The EPPO 2010 scheme does not recommend a chronic assessment for adults for foliar spray applications. Therefore, further consideration of the chronic risk is left at the MSs level.

To fulfil criteria of EU Reg 284/2009 the applicant should submit the chronic studies for adult and larvae bees for formulation.

9.6.4 Effects on bumble bees

Not relevant. There are no testing requirements for any bee other than the honey bee within the currently implemented Regulation (EC) No. 1107/2009.

9.6.5 Effects on solitary bees

Not relevant. There are no testing requirements for any bee other than the honey bee within the currently implemented Regulation (EC) No. 1107/2009.

9.6.6 Overall conclusions

The hazard quotients for both contact and oral exposure are below the trigger of concern (QH ≤ 50) for the active ingredient and the formulation. Therefore, it can be concluded that no unacceptable risk to bees is expected using the product according to the proposed use pattern at a maximal application rate of 0.48 L product/ha in winter cereals.
It should be noted that the EPPO 2010 scheme does not recommend a chronic assessment for adults for foliar spray applications. Therefore, consideration of the chronic risk is left at MSs level.
To fulfil criteria of EU Reg 284/2009 the applicant should submit the chronic studies for adult and larvae bees for formulation.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Effects on non-target arthropods of FFA SC 508.8 G were not evaluated as part of the EU assessment of flufenacet. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

FFA SC 508.8 G[2] has been tested on the standard test species *Typhlodromus pyri* and *Aphidius rhopalosiphi* and the two additional species *Chrysoperla carnea* and *Aleochara bilineata*. The results of the extended laboratory tests indicate that *T. pyri* is clearly the most sensitive species concerning the exposure to flufenacet. ~~As indicated by the data for the FFA+TBA SC533 (see table below) *T. pyri* is clearly the most sensitive species concerning the exposure to flufenacet. Testing additional NTA species with flufenacet SC508.8 (e.g. *Chrysoperla carnea* and *Aleochara bilineata*) would not provide additional useful information.~~ ~~The~~ Therefore the refined risk assessment ~~for the most sensitive species, *Typhlodromus pyri*,~~ is based on an aged residue study with *T. pyri*, which ~~were~~ was performed with FFA SC 508.8 G. ~~The studies based on FFA+TBA SC533 are only used as supplementary information and are not used for the risk assessment.~~

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri	FFA SC 500*	Laboratory, glass plates	LR_{50} = 9.6 g a.s./ha	Appendix 2 Loose (2003) M-075227-01-1
Aphidius rhopalosiphi	FFA SC 500*	Extended laboratory test exposure on potted barley plants	LR_{50} > 600.0 g a.s./ha	Appendix 2 Vinall (2001) M-137160-02-1
Typhlodromus pyri	FFA SC 500*	Extended laboratory test exposure on detached maize leaves	LR_{50} = 51.5 g a.s./ha	Appendix 2 Wientjes (2001) M-074126-01-1
Chrysoperla carnea	FFA SC 508.8 G	Extended laboratory test Exposure on detached bean leaves	LR_{50} > 600 g a.s./ha ER_{50} > 600 g a.s./ha	Appendix 2 Röhlig (2022) M-814876-01-1
Aleochara bilineata	FFA SC 508.8 G	Extended laboratory test Exposure on sandy soil (LUFA 2.1)	ER_{50} > 600 g a.s./ha	Appendix 2 Röhlig (2022) M-816749-01-1
~~*Typhlodromus pyri*~~	~~FFA + TBA SC 533~~	~~Extended laboratory test exposure on detached maize leaves~~	~~LR_{50} = 619 mL prod./ha (124 g FFA/ha) ER_{50} > 693 mL prod./ha (>139 g FFA/ha)~~	~~Appendix 2 Roehlig (2005) M-255645-01-1~~
~~*Aphidius rhopalosiphi*~~	~~FFA + TBA SC 533~~	~~Extended laboratory test exposure on potted barley plants~~	~~LR_{50} > 3000 mL prod./ha (> 600 g FFA/ha) ER_{50} > 3000 mL prod./ha (> 600 g FFA/ha)~~	~~Appendix 2 Roehlig (2005) M-258796-01-1~~

Species	Substance	Exposure System	Results	Reference
~~*Chrysoperla carnea*~~	~~FFA + TBA SC 533~~	~~Extended laboratory test exposure on detached vine leaves~~	~~LR_{50} >2500 mL prod./ha (> 500 g FFA/ha) No effect on reproduction at all tested rates~~	~~Appendix 2 Moll (2013) M-444858-01-1~~
~~*Aleochara bilineata*~~	~~FFA + TBA SC 533~~	~~Extended laboratory test exposure on soil (LUFA 2.1)~~	~~ER_{50} >2500 mL prod./ha (>500 g FFA/ha)~~	~~Appendix 2 Schmitzer (2013) M-449144-01-1~~
Typhlodromus pyri	FFA SC 500*	Aged residue spray deposits on maize plants	No effect on mortality and reproduction at 614 g a.s./ha after aging period of 21 days	Appendix 2 Loose (2002) M-053185-01-1
Field or semi-field tests				
Not required.				

* By mistake a wrong name Cadou SC 500 (Flufenacet SC 500, 500 g/L) has been mentioned in several documents which have been submittedto authorities. However, in all submitted studies the a.i. content ofFlufenacet was in a range which was valid for the SC 508.8 formulated product. The FAO tolerances for the a.i. content in a SC 508.8 g/L formulation are from 483.8 g/L to 533.8 g/L (508.8 ± 25 g/L). For more information please refer to the statement by Conrad (2013, M-470405-01-1, Appendix 2)

zRMS comments:

Studies on toxicity of formulation Flufenacet SC 508.8 G to non-target arthropods were evaluated by zRMS and considered acceptable. For details of evaluation please refer to Appendix 2. Endpoints reported in Table 9.7-1 are confirmed to be correct.

9.7.1.1 Justification for new endpoints

Studies on non-target arthropods with the formulated product are needed to fulfil current requirements for plant protection product laid down in Regulation (EC) No. 284/2013.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for non-target arthropods from all other intended uses (see 9.1.2).

The non-target arthropod extended laboratory studies performed with FFA SC 508.8 ~~FFA+TBA SC533~~ demonstrate that *Typhlodromus pyri* is the most sensitive out of the four tested species. ~~For FFA+TBA SC533 the LR_{50} and ER_{50} of 124 g and >139 g FFA/ha, respectively, for *T. pyri* are clearly lower than the ecotoxicological endpoints for *Aphidius rhopalosiphi* (LR_{50} and ER_{50} >600 g FFA/ha), *Chrysoperla carnea* (LR_{50} and ER_{50} >500 g FFA/ha), and *Aleochara bilineata* (ER_{50} >500 g FFA/ha). Laboratory tests with FFA SC508 demonstrated that *T. pyri* is clearly more sensitive than *A. rhopalosiphi*. Considering the results from the existing laboratory studies it can be assumed that if FFA SC508 would have been tested as well on *Chrysoperla carnea* and *Aleochara bilineata* no different "most sensitive~~

~~species" would have been identified than identified with the FFA+TBA SC533 lab tests (where *T. pyri* was clearly the most sensitive species).~~ Hence, the presented aged residue study with *T. pyri* tested with FFA SC 508.~~8 FFA SC500~~ (effects < 50% at 1 x 614 g FFA/ha after 14 d aging period) is suitable for refining the in-crop risk assessment for FFA SC 508.8 ~~FFA SC500~~. The study demonstrated that the toxicity of FFA is reduced very fast after application and a field ~~applied~~ treated with FFA SC 508.8 ~~FFA SC500~~ could serve as habitat for non-target arthropods within an acceptable time frame after application (incl. species other than *T. pyri*).

Table 9.7.9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of Flufenacet in cereals (use group A)

Intended use	Cereals, 1 × 244.2 g a.s./ha		
Active substance/product	Flufenacet		
Application rate	1 × 244.2 g a.s./ha		
MAF	1.0		
Test species Tier 1	**LR_{50} (lab.) (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	9.6	244.2	**25.4**
Aphidius rhopalosiphi [1)]	-		-
Test species Higher-tier	**Rate with ≤ 50% effect* (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	51.5	244.2	**no**
Aphidius rhopalosiphi	>600		yes
Aleochara bilineata	>600		yes
Chrysoperla carnea	>600		yes
Test species Higher-tier	**Rate with ≤ 50% effect (g/ha) at 14 DALT**	**$PER_{in\text{-}field}$ (g/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	614 g a.s./ha, at 14 and 21 DALT	244.2	yes

MAF: multiple application factor; PER: predicted environmental rate; HQ: hazard quotient; DALT: days after last treatment. Criteria values shown in bold breach the relevant trigger.
* If an LR50 or ER50 from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.
1) a glass plate study with A. rhopalosiphi is not available, hence, for A. rhopalosiphi a tier 2 assessment is provided considering the extended laboratory study with FFA SC500.

For the most sensitive species *T. pyri* an LR_{50} value of 51.5 g a.s./ha has been determined, therefore initial effects on *T. pyri* or other NTA species in the in-field area with a similar sensitivity cannot be excluded. In case of initial effects, the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) requires that the potential for recovery within one year has to be demonstrated for the most sensitive species. To address the potential for recovery an aged residue study has been conducted with *T. pyri* with the formulation FFA SC 508.8. FFA SC 508.8 was applied with one application of 614 g a.s./ha covering the worst-case GAP of this product.
The study results indicated effects < 50% on mortality (i.e. corrected mortality: 8% and 0%) and no reduction of reproduction in the bioassays that were started on the day 14 and 21 days after the last application, respectively. Therefore, no unacceptable adverse effects on non-target arthropods are to be expected in the in-field area from the applications of FFA SC 508.8 according to the intended use pattern.

zRMS comments:

The risk assessment presented in Table 9.7-1 is validated by the zRMS.
Based on calculations performed with consideration of the laboratory data for Aphidius rhopalosiphi Aleochara bilineata and Chrysoperla carnea species aacceptable in - field risk to non-target arthropods from all intended uses of Flufenacet SC 508.8 may be concluded.

In case of most sensitive species T. pyri based on the results of laboratory and extended laboratory studies further refinement of in-field risk was required.
To address the potential for recovery an aged residue study was conducted with *T. pyri* with the formulation FFA SC 508.8 and considered as acceptable by zRMS for refined risk assessment.
FFA SC 508.8 applied with one application of 614 g a.s./ha covering the worst-case GAP of this product.
The study results indicated effects < 50% on mortality (i.e. corrected mortality: 8% and 0%) and no reduction of reproduction in the bioassays that were started on the day 14 and 21 days after the last application, respectively.

Overall, no unacceptable adverse effects on non-target arthropods are to be expected in the in-field area from the applications of FFA SC 508.8 according to the intended use pattern.

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for non-target arthropods from all other intended uses (see 9.1.2).

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Flufenacet in cereals (use group A)

Intended use	Cereals, 1 × 244.2 g a.s./ha
Active substance/product	Flufenacet
Application rate	1 × 244.2 g a.s./ha
MAF	1.0
VDF	10 (2D)* / 1 (3D) 5(2D)**

Test species Tier 1	**LR_{50} (lab.) (g/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	9.6	2.77	6.76 13.52**	10	0.7* 1.40**
Aphidius rhopalosiphi [1)]	-				-
Test species Higher-tier	**Rate with ≤ 50% effect* (g/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**corr. $PER_{off\text{-}field}$ with ≤ 50 % effect?**
Typhlodromus pyri	51.5	2.77	3.38 6.76**	5	Yes*/**
Aphidius rhopalosiphi	>600	2.77	33.8	5	Yes*/**
Aleochara bilineata	>600	2.77	3.38 6.76**	5	Yes*/**
Chrysoperla carnea	>600	2.77	3.38 6.76**	5	Yes*/**

MAF: multiple application factor; VDF: vegetation distribution factor; (corr.) PER: (corrected) predicted environmental rate, including a correction factor (10 for tier 1, and 5 for tier 2) and a vdf of 10; CF: conversion factor; HQ: hazard quotient. Criteria values shown in bold breach the relevant trigger.
* If an LR50 or ER50 from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.
** according to recommendation given in harmonization meeting in CZ
1) a glass plate study with A. rhopalosiphi is not available, hence, for A. rhopalosiphi a tier 2 assessment is provided considering the extended laboratory study with FFA SC500.

No unacceptable risk to non-target arthropods to off-field is to be expected based on the risk assessment as provided above.

zRMS comments:

The risk assessment presented in Table 9.7-2 is validated by the zRMS.
In addition, in the off-field risk assessment, as a worst case the VDF of 5 has been considered by zRMS, since available investigations indicate that VDF of 10 recommended by ESCORT 2 guidance document is not appropriate and may lead to underestimation of the exposure.

It should be, however, noted that according to EFSA Supporting publication 2019:EN-1673, VDF of 5 should be considered as the interim solution that will be reflected in the SANCO/10329/2002 rev 2 final with its implementation considered further.

Since use of VDF of 5 was not reflected in the current SANCO terrestrial guidance, its use is not yet mandatory. Nevertheless, the risk assessment performed with VDF of 5 is more protective and is thus was added and by the zRMS.
For this reason, zRMS amended the calculations in the Table 9.7-3.

Based on calculations performed with consideration of the laboratory data the acceptable off-field risk to non-target arthropods from all intended uses of Flufenacet SC 508.8 G may be concluded with no need for risk mitigation measures.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

The NTA risk assessment indicates that no unacceptable adverse effects for non-target arthropods are to be expected for the application of FFA SC 508.8 at a maximum application rate of 0.48 L/ha (=244.2 g a.s./ha) for the in- or off-field habitats following the use of the product according to the proposed use pattern. No mitigation measures are required.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with flufenacet and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of FFA SC 508.8 G were not evaluated as part of the EU assessment of flufenacet. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2. No studies for *Folsomia candida* or *Hypoaspis aculeifer* with FFA SC 508.8 G are available, therefore, results with DFF + FFA SC 600 are provided as a surrogate (assuming that in this formulation FFA is toxicological driver for soil organism). The composition of DFF+FFA SC 508.8 is very similar compared to FFA SC 508.8, however, it contains additionally the active substance diflufenican (DFF). As shown in detail in the statement of Ernst (2020; M-755443-01-1, see part C) DFF+FFA SC 600 contains the same co-formulants as FFA SC508.8. The content of flufenacet and the co-formulants do not differ more by a factor of two between both formulations. Hence, an additional safety factor of two is sufficient to cover the risk for soil organisms if the studies conducted with DFF+FFA SC 600 are used in the risk assessment for FFA SC 508.8.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
~~*Eisenia fetida*~~	~~Flufenacet~~	~~Mixed into substrate, 14 d, acute 10 % peat content~~	~~LC_{50} = 219 mg/kg dws~~ ~~$LC_{50,corr}$ = 109.5 mg/kg dws~~ ~~A~~	~~Review Report 7469/VI/98-Final (2003)~~
Eisenia fetida	Flufenacet (tested as FFA WG 60)	Overspray, 56 d, chronic 10 % peat content	NOEC ≥ 4.0 mg/kg dws	Review Report 7469/VI/98-Final (2003)
			$NOEC_{corr}$ = 1.2 mg/kg dws A	Appendix 2 Kratz (2011) M-004878-02-1 See justification
Eisenia fetida	FFA SC 500*	Mixed into substrate, 56 d, chronic 10 % peat content	NOEC = 48.0 mg prod./kg dws NOEC = 20 mg a.s./kg $NOEC_{corr}$ = 10 mg a.s./kg A EC_{10}= 47.2. mg product /kg dws (23.6 mg a.s/kg dws) **EC_{10} corr = 9.8 mg a.s./kg dws)A**	Appendix 2 Leicher (2007) M-294431-01-1
Eisenia fetida	FOE oxalate	Mixed into substrate, 14 d, acute 10 % peat content	LC_{50} > 1000 mg/kg dws	Review Report 7469/VI/98-Final (2003)
Eisenia fetida	FOE-sulfonic acid-Na-salt	Mixed into substrate, 14 d, acute 10 % peat content	LC_{50} > 1000 mg/kg dws	Review Report 7469/VI/98-Final (2003)
Folsomia candida	Flufenacet SC 508.8 G	Mixed into substrate, 28 d, chronic 5 % peat content	$NOEC_{repro}$ = 18 mg prod./kg dws $NOEC_{repro}$ = 7.63 mg a.s./kg dws B NOECrep.corr=3.81 mg a.s./kg dws A EC_{10} = 28 mg pood./kgdws	Appendix 2 Richter (2022) M-818073-01-1
Hypoaspis aculeifer	Flufenacet SC 508.8 G	Mixed into substrate, 14 d, chronic 5 % peat content	$NOEC_{repro}$ = 316 mg prod./kg dws $NOEC_{repro}$ = 134 mg a.s./kg dws B $NOEC_{reprocorr}$ = 67 mg a.s./kg dws A EC_{10} = 441 mg prod./kg dws	Appendix 2 Richter (2022) M-818456-01-1
Field studies				
Natural earthworm fauna	Flufenacet SC 500*	Field study 1 year, spray	NOEAER = 1.2 L prod./ha NOAER = 0.6 kg a.s./ha	Appendix 2 Leicher (2008) M-307211-01-1

A Corrected value derived by dividing the endpoint by a factor of 2 (log Pow >2)
B Endpoint recalculated based on 42.4% w/w flufenacet
* By mistake a wrong name Cadou SC 500 (Flufenacet SC 500, 500 g/L) has been mentioned in several documents which have been submittedto authorities. However, in all submitted studies the a.i. content of Flufenacet was in a range which was valid for the SC 508.8 formulated product. The FAO tolerances for the a.i. content in a SC 508.8 g/L formulation are from 483.8 g/L to 533.8 g/L (508.8 ± 25 g/L). For more information please refer to the statement by Conrad (2013, M-470405-01-1, Appendix 2)
~~** For flufenacet no EU agreed endpoints are available for soil macro organisms other than earthworms, therefore results derived with DFF + FFA SC 600 are provided as a surrogate (assuming that in this formulation FFA is toxicological driver for soil organism). Endpoints are calculated considering a FFA content of 32.6% flufenacet in DFF+FFA SC 600.~~

zRMS comments:

The toxicity data for flufenacet and its metabolites given in Table 9.8-1 are in line with the EU agreed endpoints reported in the Review Report 7469/VI/98-Final (2003).
The toxicity endpoints validated during the original evaluation of flufenacet are considered to be still in force.
These values can be used in the risk assessment and will be updated only after the reapproval of flufenacet
The new studies on toxicity of formulations Flufenacet SC 508.8 G to Folsomia candida and Hypoaspis aculeifer

were evaluated by zRMS and considered acceptable. For details of evaluation please refer to Appendix 2.
In addition, one higher tier study for earthworm for formulation Flufenacet SC 508.8 was performed.
This study was not used in the risk assessment due to the risk based on laboratory study was sufficient to concluded the acceptable risk for earthworms.

9.8.1.1 Justification for new endpoints

~~For flufenacet no EU agreed endpoints are available for soil macro organisms other than earthworms, therefore results derived with DFF + FFA SC 600 are provided as a surrogate (assuming that in this formulation FFA is toxicological driver for soil organism). Endpoints are calculated considering a FFA content of 32.6% flufenacet in DFF+FFA SC 600.~~

Table 9.8-2: Justification for new endpoints

Species	Substance	Exposure System	Endpoint	Justification	Reference
Eisenia fetida	Flufenacet (tested as FFA WG 60)	Overspray 56 d, chronic 10 % peat	$NOEC_{corr}$ = 1.2 mg/kg dw	New study performed by Heimbach (1997) which resulted in a lower endpoint of 1 kg test item/ha after recalculation of statistics by Kratz (2011). The revised NOEC, was re-calculated into 2.4 mg a.s./kg dws based on 605 g flufenacet/10000 m², size of test boxes = 198 cm² and 500 g dry weight substrate per test box. Due to log P_{ow} of flufenacet > 2 the NOEC is corrected to 1.2 mg/kg dw.	Appendix 2 Kratz (2011) M-004878-02-1

zRMS comments:

One study (Heimbach, 1997) on the reproductive toxicity of the active substance flufenacet (tested as Flufenacet WG 60) to earthworms was submitted for the first EU approval. The NOEC was estimated to be 3 kg a.s./ha corresponding to 4 mg a.s./kg soil dw. The new statistical analysis done by Kratz A. (1997) based on the original data from study Heimabach (1997) and NOEC of 1.2 mg a.s/kg dws was estimated.
It should be noted that formulation Flufenacet WG 60 is different than FFA SC 508.8 G.
Therfeore, it is zRMS opinion that if the chronic toxicity data are available for FFA SC 508.8 G it is more appropirate use it in the current risk assessment.

Therefore, the endpoint EC_{10} of 9.8 mg a.s./kg dws, slight lower than $NOEC_{corr}$= 10 mg a.s./kg dws value, obtained from the study results was used in the risk assessment by zRMS.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2. According to the assessment of environmental-fate data, multi-

annual accumulation in soil is considered for flufenacet.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2).

Table 9.8-3: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of FFA SC 508.8 G in cereals (use group A)

Intended use	Spray application on cereals (0.48 L prod./ha)		
Acute effects on earthworms			
Not required according to Regulation (EC) 1107/2009.			
Chronic effects on earthworms			
Product/active substance	**EC10/NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
~~Flufenacet~~	~~1.2~~ [A]	~~0.326~~ [B]	~~3.7~~
FFA SC 508.8 (Flufenacet a.s.)	9.8 [A,C] ~~20~~ [A]	0.326 [B]	30.06 ~~61~~
Chronic effects on other soil macro- and mesofauna			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Folsomia candida			
~~Flufenacet in DFF+FFA SC 600*~~	~~29~~ [A]	~~0.326~~ [B]	~~89~~
FFA SC 508.8 (Flufenacet a.s.)	3.81 [A,C] ~~7.63~~	0.326 [B]	11.68 ~~23~~
Hypoaspis aculeifer			
~~Flufenacet in DFF+FFA SC 600*~~	~~≥ 21.3~~	~~0.326~~ [B]	~~≥ 65~~
FFA SC 508.8 (Flufenacet a.s.)	67 [A,C] ~~134~~	0.326 [B]	205.52 ~~411~~

TER values shown in bold fall below the relevant trigger.
[A] Corrected value derived by dividing the endpoint by a factor of 2
[B] PECaccumulation = PECactual + PECsoil plateau calculated assuming a soil distribution into a depth of 5 cm.
[C] Endpoint recalculated based on 42.4% w/w flufenacet
~~* The NOEC from study conducted with DFF + FFA SC 600 expressed as mg active substance/kg (based on relative amounts of 32.6% flufenacet) is compared with the PEC_{soil} of the single active substance flufenacet.~~

All TER values exceed the critical TER trigger value of 5, except for the earthworm risk assessment active substance flufenacet earthworms. ~~A higher tier risk assessment is provided below.~~ The TER values of 11.63 ~~23~~ and 205.52 ~~4 11 89 and ≥ 65~~ for *Folsomia candida* and *Hypoaspis aculeifer* for the product ~~DFF+FFA SC 600~~ FFA SC 508.8 demonstrate a sufficient high margin of safety. ~~The remaining uncertainty from using tests with a different formulation (DFF+FFA SC 600 instead of FFA SC 508.8) is covered by an additional safety factor of 2 (see Ernst 2020; M-755443-01-1 see part C).~~

No unacceptable risk can be concluded for collembola and soil mites if FFA SC 508.8 is applied according to the recommended use pattern.

zRMS comments:

The calculations presented in the Table 9.8-3 for soil macro- and meso-fauna was amended by the zRMS.

All TER_{LT} values for soil meso- and macrofauna (other than earthworms) are greater than the trigger of 5, indicating an overall acceptable risk.

9.8.2.2 Higher-tier risk assessment

A one-year earthworm field study is available with Flufenacet SC 500 (Leicher, 2008; M-307211-01-1, Appendix 2). This study demonstrates that natural earthworm populations are not affected if Flufenacet SC 500 is applied on an arable field up to an application rate of 1.2 L/ha which is equivalent to 600 g Flufenacet/ha.
Thus, it can be concluded that earthworms are not at risk if flufenacet is applied up to 600 g/ha in arable fields indicating a safe use for all intended uses of FFA SC 508.8 (maximum intended application rate: 244.2 g a.s./ha).

zRMS comment:

Higher tier study for earthworm by Leicher 2008 for formulation Flufenacet SC 500 was performed.
This study was not used in the risk assessment due to that risk based on laboratory study was sufficient to concluded the acceptable risk for earthworms.

9.8.3 Overall conclusions

Based on the risk assessment findings no ecologically adverse effects on earthworms and other soil non-target macro-organisms can be concluded for the maximum intended application rate of up to 0.48 L/ha FFA SC 508.8 in cereals (use group A).

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document when new studies are submitted.
Effects on soil microorganisms of FFA SC 508.8 G were not evaluated as part of the EU assessment of flufenacet. Studies on the soil microbial activity have been carried out with the formulation DFF+FFA SC 600, which can be used in the risk assessment for FFA SC 508.8. New data submitted with this application in the core dossier are listed in Appendix 1 and summarised in Appendix 2.
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Flufenacet	28 d, 2 soils	No effects > 25% at 0.62 and 3.1 kg/ha (= 0.8 and 4.0 mg a.s./kg dws)	Review Report 7469/VI/98-Final (2003)
~~N-mineralisation~~	~~DFF + FFA SC 600*~~	~~28 d~~	~~No effects > 25% at 0.6 and 3 L product/ha (= 0.98 and 4.9 mg product/kg dws)** (= 0.31 and 1.6 mg a.s. (FFA)/kg dws)~~	~~Appendix 2 Frommholz (2009) M-357934-01-1~~
N-mineralisation	FFA SC 508.8 G	28 d, 1 soil	No effects > 25% at 2.5 and 12.5 mg product/kg dws (= 1.06 and 5.3 mg a.s./kg dws[A])	Appendix 2 Schulz (2022) M-821638-01-1

~~*For flufenacet no EU agreed endpoints are available for soil micro-organisms other than earthworms, therefore results derived with DFF+FFA SC SC 600 are provided as a surrogate (assuming that in this formulation FFA is toxicological driver for soil organism). Endpoints are calculated considering a FFA content of 32.1% w/w flufenacet in DFF+FFA SC 600.~~
~~** density: 1.229 g/mL~~
[A] Endpoint recalculated based on 42.4% w/w flufenacet

zRMS comments:

The toxicity data for flufenacet given in Table 9.9-1 are in line with the EU agreed endpoints reported in the Review Report 7469/VI/98-Final (2003).
The new study on toxicity of formulations Flufenacet SC 508.8 to microorganism was evaluated by zRMS and considered acceptable. For details of evaluation please refer to Appendix 2.

9.9.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8

(Environmental Fate), Chapter 8.7.2, and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for the soil microorganisms from all other intended uses (see 9.1.2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of FFA SC 508.8 G in cereals (use group A)

Intended use	FFA SC 508.8, Spray application on cereals (BBCH 00-09), 1 × 480 mL product/ha (equivalent to 244.4 g a.s./ha)		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Flufenacet	4.0 (at 28 d)	0.326 [A]	yes
FFA SC 508.8 (Flufenacet a.s.)	~~1.6~~ 5.3 (at 28 d)	0.326 [A]	yes
C-mineralisation			
Not required according to Regulation (EC) 1107/2009.			

[A] PECaccumulation = PECactual + PECsoil plateau calculated assuming a soil distribution into a depth of 5 cm.

zRMS comments:

The risk assessment presented in Table 9.9-2 above is agreed by the zRMS.

The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PECs for the maximum application rate of active substances and the product Flufenacet SC 508.8. G.

Overall, no unacceptable effects on soil microbial activity are expected following application of Flufenacet SC 508.8 G.

9.9.3 Overall conclusions

The risk assessment indicates that no adverse effects on soil micro-organisms are to be expected when the product is applied according to the proposed use pattern.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with all active substances and relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document when new studies are submitted.
Effects on non-target terrestrial plants of FFA SC 508.8 G were not evaluated as part of the EU assessment of flufenacet. New data submitted with this application in the core dossier are listed in Appendix 1 summarised in Appendix 2.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
Zea mays $_m$ [1)] *Avena sativa* $_m$ [2)] *Allium cepa* $_m$ [3)] *Lolium perenne* $_m$ [4)] *Sorghum bicolor* $_m$ [5)] *Brassica rapa* $_d$ [6)] *Beta vulgaris* $_d$ [7)] *Cucumis sativa* $_d$ [8)] *Lycopersicon esculentum* $_d$ [9)] *Glycine max* $_d$ [10)]	FFA SC 500*	21 d Seedling emergence	[1)] $ER_{50\ shoot\ fresh\ weight}$ = 477.9 g a.s./ha [2)] $ER_{50\ shoot\ fresh\ weight}$ = 80.9 g a.s./ha [3)] $ER_{50\ shoot\ fresh\ weight}$ = 53.3 g a.s./ha [4)] $ER_{50\ shoot\ fresh\ weight}$ = 11.5 g a.s./ha **[5)] $ER_{50\ shoot\ fresh\ weight}$ = 10.5 g a.s./ha** [6)] $ER_{50\ shoot\ fresh\ weight}$ = 282.7 g a.s./ha [7)] $ER_{50 shoot\ fresh\ weight}$ = 275.4 g a.s./ha [8)] $ER_{50\ shoot\ fresh\ weight}$ =101.1 g a.s./ha [9)] $ER_{50\ shoot\ fresh\ weight}$ = 93.6 g a.s./ha [10)] $ER_{50\ all\ parameters}$ > 600 g a.s./ha	Appendix 2 Friedrich (2005) M-248250-01-1
			HR_5 = 8.338 g a.s./ha	See calculations below
Zea mays $_m$ [1)] *Avena sativa* $_m$ [2)] *Allium cepa* $_m$ [3)] *Lolium perenne* $_m$ [4)] *Sorghum bicolor* $_m$ [5)] *Brassica rapa* $_d$ [6)] *Beta vulgaris* $_d$ [7)] *Cucumis sativa* $_d$ [8)] *Lycopersicon esculentum* $_d$ [9)] *Glycine max* $_d$ [10)]	FFA SC 500*	21 d vegetative vigour	[1)] $ER_{50\ all\ parameters}$ > 600 g a.s./ha [2)] $ER_{50\ shoot\ fresh\ weight}$ = 196 g a.s./ha [3)] $ER_{50\ shoot\ fresh\ weight}$ = 132 g a.s./ha **[4)] $ER_{50\ shoot\ fresh\ weight}$ = 17 g a.s./ha** [5)] $ER_{50\ shoot\ fresh\ weight}$ = 43 g a.s./ha [6)] $ER_{50\ shoot\ fresh\ weight}$ = 167 g a.s./ha [7)] $ER_{50\ shoot\ fresh\ weight}$ = 525 g a.s./ha [8)] $ER_{50\ shoot\ fresh\ weight}$ = 102 g a.s./ha [9)] $ER_{50\ all\ parameters}$ = >600 g a.s./ha [10)] $ER_{50\ shoot\ fresh\ weight}$ = 168 g a.s./ha	Appendix 2 Friedrich (2005) M-248251-01-1
			HR_5 = 19.170 g a.s./ha	See calculations below

m: monocotyledonous; d: dicotyledonous;
[1)-10)]: Numbers assign the plant species to the corresponding endpoint
* By mistake a wrong name Cadou SC 500 (Flufenacet SC 500, 500 g/L) has been mentioned in several documents which have been submitted to authorities. However, in all submitted studies the a.i. content of Flufenacet was in a range which was valid for the SC 508.8 formulated product. The FAO tolerances for the a.i. content in a SC 508.8 g/L formulation are from 483.8 g/L to 533.8 g/L (508.8 ± 25 g/L). For more information please refer to the statement by Conrad (2013, M-470405-01-1, Appendix 2)

zRMS comments:

The toxicity endpoints given in Table 9.8-1 based on the seedling emergence and vegetative vigor tests were were validated by zRMS.

It should be noted that these studies were also evaluated by RMS-PL in ongoing renewal process of flufenacet and were considered acceptable.

HR5 calculation

Studies with the formulation FFA SC 508.8 G were performed and are submitted with this application. For the risk assessment the endpoints from these studies were used.

The HR_5 is calculated according to the following equation (Aldenberg, T. & Jaworska, J.S.; 2000):

$$HR_5 = 10 \exp (avg - ks * std)$$

With
avg=mean of log10 transformed ER_{50} values
std=standard deviation of log10 transformed ER_{50} values
ks = extrapolation factor

The ER_{50}-levels obtained from the tests with Flufenacet SC 508.8 contain one and two "greater than"-figures for seedling emergence and vegetative vigour, respectively. For both study types there are at least six ER_{50} values available, as it is required to perform an SSD and calculate the HR_5. There is no common agreement whether to exclude these figures from the HR_5-calculation or to include them as "equal to"-figures. For example in the aquatic guidance document (EFSA Journal 2013;11(7):3290) it is concluded that under specific conditions that "greater than"-figures can be included. Therefore, both HR_5-calculations were conducted including and excluding "greater than"-figures. The inclusion of "greater than"-figures resulted in higher HR_5-values compared to excluding them. Thus, the lowest figure (excluding "greater than"-figures) was used as a conservative approach. In all species the ER_{50} based on fresh weight data was the lowest figure which was used to calculate the HR_5.

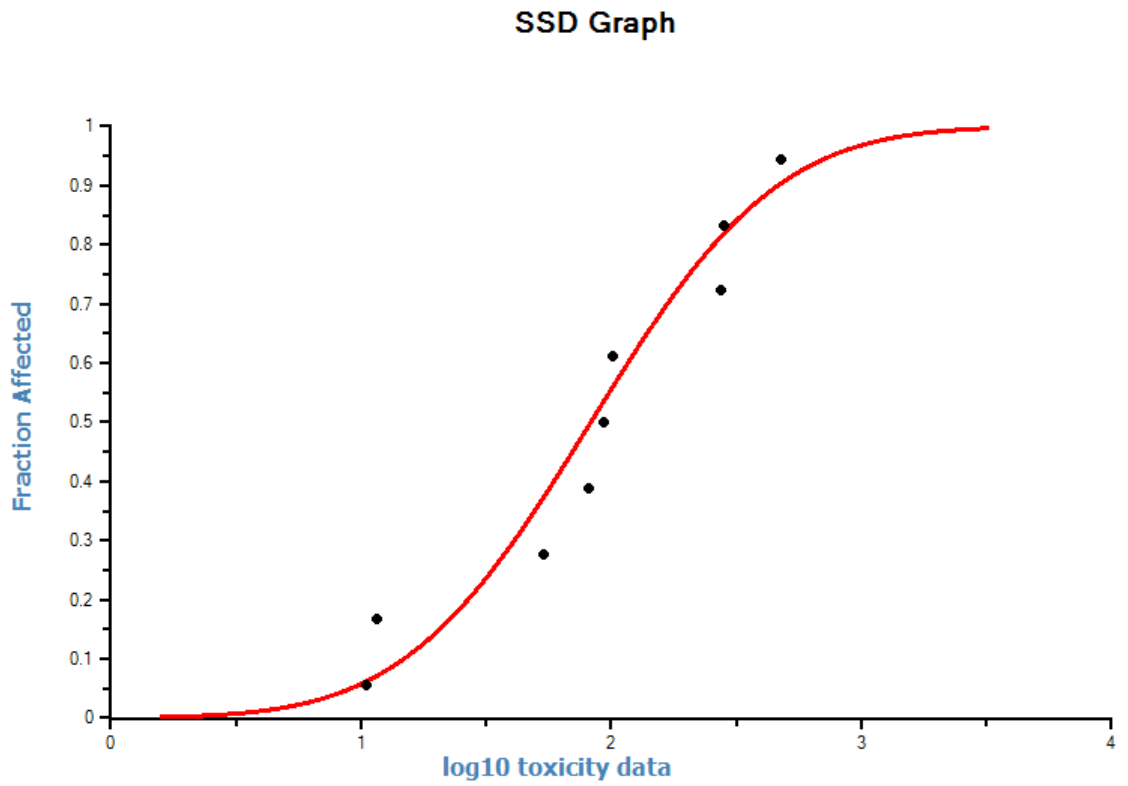
Table 9.10-2: HR_5-figures obtained from different calculation modes for seedling-emergence and vegetative vigour with FFA SC 508.8. Lowest figures are printed in bold

	Seedling emergence	**Vegetative vigour**
	fresh weight	fresh weight
HR_5 w/o > figures	**8.338 g a.s./ha**	19.170 g a.s./ha

Seedling-emergence

Table 9.10-3: Details on calculation of the lowest HR_5 based on the lowest endpoints without greater-than figures from the seedling-emergence study

Species	**Lowest ER_{50} (g a.s./ha)**
Zea mays	477.9
Avena sativa	80.9
Allium cepa	53.3
Lolium perenne	11.5
Sorghum bicolor	**10.5**
Brassica rapa	282.7
Beta vulgaris	275.4
Cucumis sativa	101.1
Lycopersicon esculentum	93.6
Glycine max	not included (> 600)
HR_5	**8.338**



Anderson-Darling test for normality				
Sign. level	Critical	Normal?		
0.1	0.631	Accepted	AD Statistic:	0.401
0.05	0.752	Accepted	n:	9
0.025	0.873	Accepted		
0.01	1.035	Accepted		

Kolmogorov-Smirnov test for normality				
Sign. level	Critical	Normal?		
0.1	0.819	Accepted	KS Statistic:	0.523
0.05	0.895	Accepted	n:	9
0.025	0.995	Accepted		
0.01	1.035	Accepted		

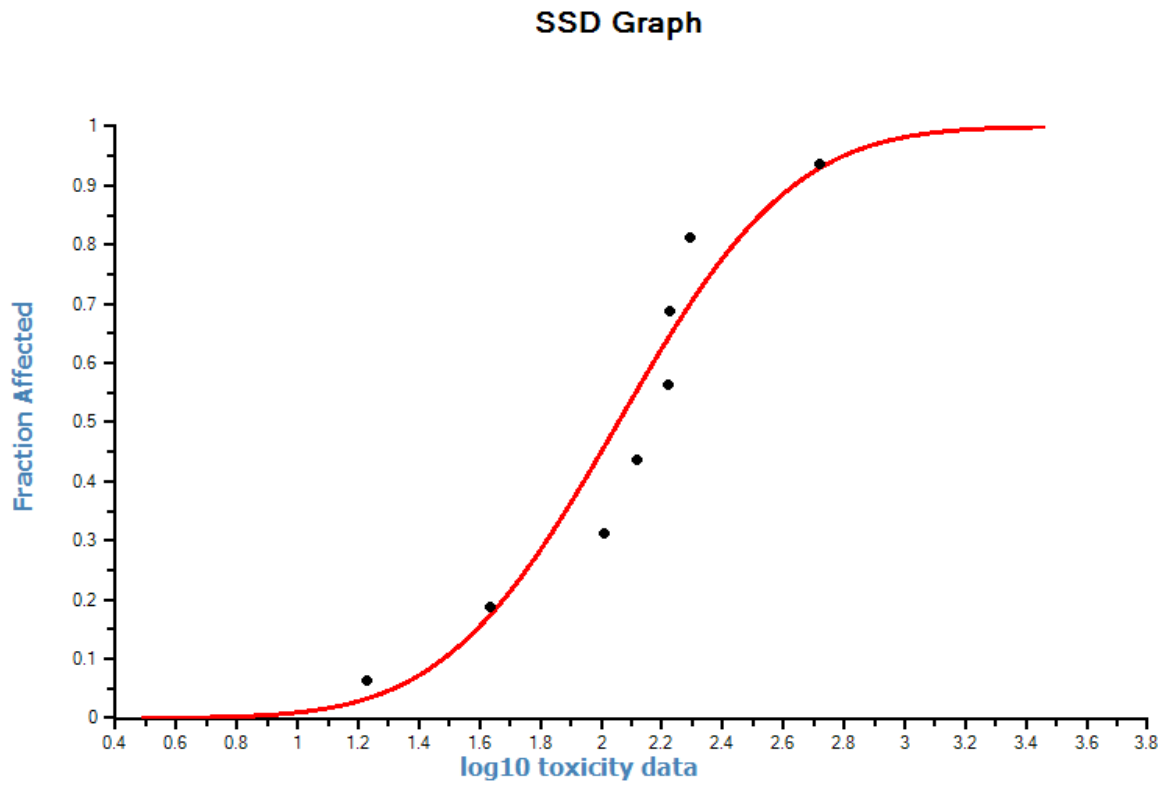
Cramer von Mises test for normality				
Sign. level	Critical	Normal?		
0.1	0.104	Accepted	CM Statistic:	0.046
0.05	0.126	Accepted	n:	9
0.025	0.148	Accepted		
0.01	0.179	Accepted		

Figure 9.10-1: SSD-Graph based on figures presented in table 10.10.1 compiled with ETX 2.0

Vegetative vigour

Table 9.10-4: Details on calculation of the lowest HR_5 based on the lowest endpoints without greater-than figures from the vegetative vigour study

Species	Lowest ER_{50} (g a.s./ha)
Zea mays	not included (> 600)
Avena sativa	196
Allium cepa	132
Lolium perenne	17
Sorghum bicolor	43
Brassica rapa	167
Beta vulgaris	525
Cucumis sativa	102
Lycopersicon esculentum	not included (>600)
Glycine max	168
HR_5	19.170



Anderson-Darling test for normality				
Sign. level	Critical	Normal?		
0.1	0.631	Accepted	AD Statistic:	0.408
0.05	0.752	Accepted	n:	8
0.025	0.873	Accepted		
0.01	1.035	Accepted		

Kolmogorov-Smirnov test for normality				
Sign. level	Critical	Normal?		
0.1	0.819	Accepted	KS Statistic:	0.647
0.05	0.895	Accepted	n:	8
0.025	0.995	Accepted		
0.01	1.035	Accepted		

Cramer von Mises test for normality				
Sign. level	Critical	Normal?		
0.1	0.104	Accepted	CM Statistic:	0.061
0.05	0.126	Accepted	n:	8
0.025	0.148	Accepted		
0.01	0.179	Accepted		

Figure 9.10-2: SSD-Graph based on figures presented in table 9.10-2 compiled with ETX 2.0

zRMS comments:

The calculations of both HR_5 values were validated by zRMS.

9.10.1.1 Justification for new endpoints

Not relevant.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A and C covers the risk for non-target terrestrial plants from all other intended uses (see 9.1.2).

The quantitative risk assessment presented here follows a stepwise approach. The first step is a deterministic risk assessment based on the lowest endpoints of the Tier-2 greenhouse studies. The second step is a probabilistic risk assessment based on the HR_5, which is derived from the species sensitivity distribution (SSD) analysis of the various species tested in the Tier-2 greenhouse studies.

Deterministic risk assessment

Table 9.10-5: Deterministic assessment of the risk for non-target plants due to the use of Flufenacet in cereals (use group A)

Intended use	Cereals, 1 × 244.2 g a.s./ha, BBCH 00-09 (use group A)			
product	Flufenacet			
Application rate (g a.s./ha)	1 × 244.2			
MAF	1.0 (single application)			
Test species	**ER_{50} (g a.s./ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5***
Sorgum bicolor -seedling emergence	10.5	2.77	6.8	**1.6**
Lolium perenne -vegetative vigour	17	2.77	6.8	**2.5**

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
* TER ≥ 5 for deterministic risk assessment based on ER_{50}

Table 9.10-6: Deterministic assessment of the risk for non-target plants due to the use of Flufenacet in cereals (use group C)

Intended use	Cereals, 1 × 122.1 g a.s./ha, BBCH 00-09 (use group C)			
product	Flufenacet			
Application rate (g a.s./ha)	1 × 122.1			
MAF	1.0 (single application)			
Test species	**ER_{50} (g a.s./ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5***
Sorgum bicolor -seedling emergence	10.5	2.77	3.4	**3.1**
Lolium perenne -vegetative vigour	17	2.77	3.4	5.0

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
* TER ≥ 5 for deterministic risk assessment based on ER_{50}

zRMS comment:

The above deterministic risk assessment has been checked and confirmed as correct.
For the highest intended rate, the trigger is met for vegetative vigour test however is not reached for seedling emergence.
In order to reduce the off-field exposure, risk mitigation measures can be implemented.
These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles.
The results of the lowest ER_{50} (seedling emergence) as well as typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following tables.

Table 9.10 5-1 : Risk mitigation measures based on deterministic assessment of the risk for non-target plants due to the use of Flufenacet in cereals (use group A)

Intended use		**Group A**			
Application rate (g a.s./ha)		1 × 244.2			
MAF		1.0			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL/ha)**	**$PER_{off\text{-}field}$ 50 % drift red. g a.s/ha)**	**$PER_{off\text{-}field}$ 75 % drift red. (g.a.s/ha)**	**$PER_{off\text{-}field}$ 90 % drift red. (g a.s /ha)**
no buffer	2.77	6.76	3.38	1.69	0.676
5 m	0.57	1.39	0.69	0.34	0.0139
10 m	0.29	0.70	0.35	0.17	0.007
Toxicity value		**TER**			
ER_{50} = 10.5 g a.s/ha		**criterion: TER ≥ 5**			
no buffer		1.55	3.11	**6.21**	**15.53**
5 m		**7.55**	**15.22**	**30.88**	**755.40**
10 m		**15.00**	**30.00**	**61.76**	**1500.00**

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

Table 9.10-7-1: Risk mitigation measured based on deterministic assessment of the risk for non-target plants due to the use of Flufenacet in cereals (use group C)

Intended use		**Group C**			
Application rate (g a.s./ha)		1 × 122.1			
MAF		1.0			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g a.s /ha)**	**$PER_{off-field}$ 50 % drift red. (g a.s./ha)**	**$PER_{off-field}$ 75 % drift red. (g a.s /ha)**	**$PER_{off-field}$ 90 % drift red. (g a.s /ha)**
no buffer	2.77	3.38	1.69	0.845	0.338
5 m	0.57	0.70	0.35	0.175	0.07
10 m	0.29	0.35	0.175	0.0875	0.035
Toxicity value		**TER**			
ER_{50} = 10.5 g a.s/ha		**criterion: TER ≥ 5**			
no buffer		3.11	**6.21**	**12.43**	**31.07**
5 m		**15.00**	**30.00**	**60.00**	**150.00**
10 m		**30.00**	**60.00**	**120.00**	**300.00**

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

Based on the deterministic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

- 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for application rate 1 x 0.48 L/ha (correspond to 1 x 244.2 g a.s./ha)
- 5 m buffer zone, or alternatively 50% drift reducing spray nozzles for application rate 1 x 0.24 L product/ha (correspond to 122.1 g a.s./ha)

In addition, the probabilistic risk assessment was performed by the Applicant based on the lowest HR_5 =10.5 g a.s./ha obtained from seedling emergence test (see below).

Probabilistic risk assessment

The Guidance Document on Terrestrial Ecotoxicology considers a probabilistic approach more suitable to achieve the environmental protection goal than the deterministic approach because the available data on the sensitivity of several species can be integrated simultaneously in the risk assessment. According to the Guidance Document on Terrestrial Ecotoxicology, the probabilistic method makes use of the species sensitivity distribution (SSD) in order to calculate an HR_5. The HR_5 is the rate below which less than 5% of the species will be harmed above the ER_{50} level. It is calculated using the ER_{50} values available from the seedling emergence studies and/or from the vegetative vigour study with the tested plant species. This approach is applicable if data for at least 6 species are available per study type. Details on how the HR_5 was derived for the formulation FFA SC 508.8 G are provided above (9.10.1).

Table 9.10-8: Probabilistic assessment of the risk for non-target plants due to the use of Flufenacet in cereals (use group A)

Intended use	Cereals, 1 × 244.2 g a.s./ha, BBCH 00-09 (use group A)			
product	Flufenacet			
Application rate (g a.s./ha)	1 × 244.2			
MAF	1.0 (single application)			
Test species	**HR_5 (g a.s./ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**criterion: TER ≥ 1***
HR_5 -seedling emergence	8.338	2.77	6.8	1.2
HR_5 -vegetative vigour	19.17	2.77	6.8	2.8

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
* TER ≥ 1 for probabilistic risk assessment based on HR_5

Table 9.10-9: Probabilistic assessment of the risk for non-target plants due to the use of Flufenacet in cereals (use group C)

Intended use	Cereals, 1 × 122.1 g a.s./ha, BBCH 00-09 (use group C)			
product	Flufenacet			
Application rate (g a.s./ha)	1 × 122.1			
MAF	1.0 (single application)			
Test species	**HR_5 (g a.s./ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**criterion: TER ≥ 1***
HR_5 -seedling emergence	8.338	2.77	3.4	2.5
HR_5 -vegetative vigour	19.17	2.77	3.4	5.7

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
* TER ≥ 1 for probabilistic risk assessment based on HR5

Conclusion: The trigger value of 1 is met for seedling emergence and vegetative vigour. The risk of the product FFA SC 508.8 G towards non-target terrestrial plants is acceptable for the intended uses.

zRMS comments:

Since Flufenacet SC 500 has stronger effects on seedling emergence than on the vegetative vigor of young plants seedling emergence data determine the risk assessment. Based on the probabilistic risk assessment for solo formulation (containing 42.4% a.s.-flufenacet), the risk for non-target terrestrial plants is considered acceptable with no buffer zone or drift reducing spraying equipment for all proposed uses in cereals.

It is the position of the zRMS-PL that a trigger value of 1 should be used in the probabilistic risk assessment with a HR_5 value; however, it is noted that this is not a Central Zone harmonised position and other member states may consider the use of a different trigger value at National Registration.

Based on the deterministic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

- 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for application rate 1 x 0.48 L/ha (correspond to 1 x 244.2 g a.s./ha)
- 5 m buffer zone, or alternatively 50% drift reducing spray nozzles for application rate 1 x 0.24 L product/ha (correspond to 122.1 g a.s./ha)

The risk mitigation measures should be considered at MSs level depending on their national requirements.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

Based on the probabilistic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields and that no mitigation measures are necessary for the intended use rate.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

No further information is available or considered to be necessary.

9.12 Monitoring data (KCP 10.8)

No further information is available or considered to be necessary.

9.13 Classification and Labelling

Hazard class(es), categories:	Chronic aquatic toxicity: Category 1 H410 Very toxic to aquatic life with long lasting effects

Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statement(s):	H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Precautionary statement(s):	P391 Collect spillage P501 Dispose of contents/container in accordance with local regulation
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

zRMS comments:

zRMS agrees with the final classification of product **H410.**

The following justification are provided below.

Classification of active substance

Item	Source	New classification	
		Category	H Code
Flufenacet	ATP1, Reg. (CE) 1272/2008	Aquatic acute 1	H400 Very toxic to aquatic life
		Aquatic chronic 1	H410 Very toxic to aquatic life with long lasting effects

Classification of the formulation FFA SC 508.8 G

Item	New classification	
	Category	H Code
FFA SC 508.8 G	Aquatic acute 1[1]	H400 Very toxic to aquatic life
	Aquatic chronic 1[2]	H410 Very toxic to aquatic life wiht long lasting effects

[1] Lowest E_rC_{50} is 0.031 mg formulation/L (correspond to 0.001361 mg a.s./L) for *P. subcapitata* (summation method induces the same classification).

[2] NOEC is 0.0063 mg formulation/L (correspond to 0.00277 mg a.s./L) for *P. subcapitata* (summation method induces the same classification).

Finally, the classification of the product is **H410.**

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP Section 10 / 01	Conrad, M.	2013	Statement about Cadou SC 508.8 - Flufenacet SC 508.8 (508.8 g/L) Report No.: M-470405-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: n.a. unpublished	No	Bayer
KCP 10.1.1.2 / 01	xxx	2010	Consolidation of bird and mammal PT data for use in risk assessment Report No.: M-429545-01-1 xxx GLP/GEP: n.a. unpublished	Yes	Bayer
KCP 10.2.1 / 03	Baetscher, R.	2001	Toxicity of flufenacet SC 500 to Pseudokirchneriella subcapitata (fornerly Selenastrum capricornutum in a 72-hour algal growth inhibition test Report No.: 796364, Edition Number: M-055471-01-1 RCC Ltd., Itingen, Switzerland GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.3 / 01	Bruns, E.	2013	Lemna gibba G3 - Growth inhibition test with flufenacet (technical substance) under static conditions Report No.: EBFON004, Edition Number: M-451198-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.3 / 03	Baetscher, R.	2001	Toxicity of flufenacet SC 500 to the aquatic higher plant Lemna gibba in a 7-day static growth inhibition test Report No.: 796342, Edition Number: M-055476-01-1 RCC Ltd., Itingen, Switzerland GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.1 / 01	Schmitzer, S.	2001	Effects of Flufenacet SC 500 (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory (limit test) Report No.: 9971036, Edition Number: M-136977-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	**Title** **Company Report No.** **Source** **GLP or GEP status** **published or not**	**Vertebrate study Y/N**	**Owner**
KCP 10.3.1.1 / 02	Sekine, T.	2019	Flufenacet SC 508.8 G: Effects (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory Report No.: 145951035, Edition Number: M-671405-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.3 / 02	Kimmel, S.	2018	Second amended report - Flufenacet SC 508.8: A honeybee brood feeding study to evaluate the effects on brood development of the honeybee, Apis mellifera L. (Hymenoptera: Apidae) Report No.: 20110057, Edition Number: M-456504-03-1 Innovative Environmental Services (IES) Ltd., Witterswil, Switzerland **... amended: 2018-12-17** GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.5 / 01	Taenzler, V.	2016	Flufenacet SC 508.8 G: Effects on honey bee brood (Apis mellifera L.) under semi-field conditions - Tunnel test Report No.: 87441033, Edition Number: M-553011-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.1 / 01	Loose, E. D.	2003	A laboratory dose-response study to evaluate the effects of Flufenacet SC 500 on survival reproduction of the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) Report No.: B110TPL, Edition Number: M-075227-01-1 MITOX Stichting Bevordering Duurzame Plaagbestrijding, Amsterdam, Netherlands GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 01	Vinall, S.	2001	An extended laboratory test to determine the effects of FOE 5043 500 SC on the parasitic wasp, Aphidius rhopalosiphi Report No.: BAY-01-12, Edition Number: M-137160-02-1 Mambo-Tox Ltd., Southampton, United Kingdom **... amended: 2001-08-29** GLP/GEP: Yes unpublished	No	Bayer
~~KCP 10.3.2.2 / 06~~	~~Schmitzer, S.~~	~~2013~~	~~Effects of flufenacet + terbuthylazine SC 533 (200 + 333 g/L) on the reproduction of rove beetles Aleochara bilineata – Extended laboratory study – Dose response test~~ ~~Report No.: 76542071, Edition Number: M-449144-01-1~~ ~~IBACON GmbH, Rossdorf, Germany~~ ~~GLP/GEP: Yes~~ ~~unpublished~~	~~No~~	~~Bayer~~

Data Point	Author(s)	Year	**Title** **Company Report No.** **Source** **GLP or GEP status** **published or not**	**Vertebrate study Y/N**	**Owner**
KCP 10.3.2.2 / 08	Roehlig, U.	2022	Toxicity to the green lacewing Chrysoperla carnea STEPH. (Neuroptera: Chrysopidae) using an extended laboratory test on bean; flufenacet SC 508.8 (508.8 g/L) Report No.: 22 48 NCE 0002, Edition Number: M-814876-01-1 BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 09	Röhlig, U.	2022	Toxicity to the rove beetle Aleochara bilineata GYLL. (Coleoptera: Staphylinidae) using an extended laboratory test onto sandy soil; flufenacet SC 508.8 (508.8 g/L) Report No.: 22 48 NKE 0002, Edition Number: M-816749-01-1 BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 07	Loose, E. D.	2002	Extended laboratory study to evaluate the effects of Flufenacet SC 500 on the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on corn plants -aged residue- Report No.: B108TPE, Edition Number: M-053185-01-1 MITOX BV, Amsterdam, Netherlands GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.1.1 / 01	Kratz, M. A.	2011	Influence of FOE 5043 WG 60 on the reproduction of earthworms (Eisenia fetida) Report No.: HBF/RG 251, Edition Number: M-004878-02-1 Bayer AG, Leverkusen, Germany **... amended: 2011-09-06** GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.1.1 / 02	Leicher, T.	2007	Flufenacet SC 500: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 % peat Report No.: LRT-RG-R-35/07, Edition Number: M-294431-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
~~KCP 10.4.1.2 / 01~~	~~Leicher, T.~~	~~2008~~	~~Flufenacet SC 500: effect on the earthworm fauna of a grassland area within one year~~ ~~Report No.: LRT/RG-F 4/08, Edition Number: M-307211-01-1~~ ~~Bayer CropScience AG, Monheim, Germany~~ ~~GLP/GEP: Yes~~ ~~unpublished~~	~~No~~	~~Bayer~~

Data Point	Author(s)	Year	**Title** **Company Report No.** **Source** **GLP or GEP status** **published or not**	**Vertebrate study Y/N**	**Owner**
KCP 10.4.2.1 / 02	Richter, A.	2022	Flufenacet SC 508.8 g/L: Influence on mortality and reproduction of the collembolan species Folsomia candida tested in artificial soil Report No.: E 314 05757-2, Edition Number: M-818073-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.2.1 / 03	Richter, A.	2022	Flufenacet SC 508.8 g/L: Influence on mortality and reproduction of the soil mite species Hypoaspis aculeifer tested in artificial soil Report No.: E 428 05758-9, Edition Number: M-818456-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.5 / 02	Schulz, L.	2022	Flufenacet SC 508.8 (508.8 g/L): Effects on the activity of soil microflora (nitrogen transformation test) Report No.: 22 48 SMN 0016, Edition Number: M-821638-01-1 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Machern OT Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.6.2 / 01	Friedrich, S.	2005	Flufenacet SC 500: seedling emergence and seedling growth test on terrestrial non-target plants Report No.: 041048104, Edition Number: M-248250-01-1 BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.6.2 / 02	Friedrich, S.	2005	Flufenacet SC 500: vegetative vigour test on non-target terrestrial plants Report No.: 041048105, Edition Number: M-248251-01-1 BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Please note that all data mentioned as part of DAR, RAR, or EFSA journals are considered as relied on.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1 / 01	Bruns, E.	2010	Pseudokirchneriella subcapitata growth inhibition test with flufenacet (tech.) Report No.: EBFOL150, Edition Number: M-363891-04-1 Bayer CropScience AG, Monheim, Germany **... amended: 2013-06-13** GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.1 / 02	Bruns, E.	2009	Pseudokirchneriella subcapitata growth inhibition test with flufenacet-oxalate Report No.: EBFOL137, Edition Number: M-358823-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.3 / 02	Bruns, E.	2009	Lemna gibba G3 Growth inhibition test with flufenacet-oxalate under static conditions Report No.: EBFOL138, Edition Number: M-359515-02-1 Bayer CropScience AG, Monheim, Germany **... amended: 2009-12-08** GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.2 / 01	Kling, A.	2014	Flufenacet (tech.) - Assessment of chronic effects to the honeybee, Apis mellifera L., in a 10 days continuous laboratory feeding limit test Report No.: S13-00145, Edition Number: M-477339-01-2 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP 10.3.1.3 / 01	Rathjen, K. A.	2018	Flufenacet: Honey bee (Apis mellifera L.) larval toxicity test, repeated exposure Report No.: 13798.6448, Edition Number: M-615473-01-1 Smithers Viscient, LLC, Snow Camp, NC, USA GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 02	Wientjes, J. C.	2001	An extended laboratory dose-response study to evaluate the effects of flufenacet SC 500 on survival and reproduction of the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on zea mays leaves Report No.: B076TPE, Edition Number: M-074126-01-1 MITOX Stichting Bevordering Duurzame Plaagbestrijding, Amsterdam, Netherlands GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 03	Roehlig, U.	2005	Dose-response toxicity (LR50) of flufenacet & terbuthylazin SC 200 + 333 to the predatory mite Typhlodromus pyri (Scheuten) under Extended laboratory conditions Report No.: 05 10 48 086, Edition Number: M-255645-01-1 BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 04	Roehlig, U.	2005	Dose-response toxicity (LR50) of Flufenacet & Terbuthylazine SC 200 + 333 to the parasitic wasp Aphidius rhopalosiphi (DESTEFANI-PEREZ) under extended laboratory conditions Report No.: 051048085, Edition Number: M-258796-01-1 BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 05	Moll, M.	2013	Effects of flufenacet + terbuthylazine SC 533 (200 + 333 g/L) on the lacewing Chrysoperla carnea, extended laboratory study - Dose response test Report No.: 76541047, Edition Number: M-444858-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.2.2 / 06	Schmitzer, S.	2013	Effects of flufenacet + terbuthylazine SC 533 (200 + 333 g/L) on the reproduction of rove beetles Aleochara bilineata - Extended laboratory study - Dose response test Report No.: 76542071, Edition Number: M-449144-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.1.2 / 01	Leicher, T.	2008	Flufenacet SC 500: effect on the earthworm fauna of a grassland area within one year Report No.: LRT/RG-F-4/08, Edition Number: M-307211-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.2.1 / 01	Frommholz, U.	2011	Diflufenican + flufenacet SC 600 (200+400) G: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil. Report No.: FRM-Coll-125/11, Edition Number: M-415903-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.5 / 01	Frommholz, U.	2009	Diflufenican + flufenacet SC 600 (200+400) G: determination of effects on nitrogen transformation in soil Report No.: FRM-N-121/09, Edition Number: M-357934-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the new studies

Comments of zRMS:	According to FAO formulations are considered to comply with the specification if the average analytical result lies within the tolerance range of the declared content. For formulated products with declared content above 500 g/L, the tolerance is ± 25 g/L. Therefore, the Applicant's statement is acceptable.

Reference:	**KCP Section 10/01**
Title:	Statement about Cadou SC 508.8 - Flufenacet SC 508.8 (508.8 g/L)
Report:	Conrad, M.; 2013; M-470405-01-1
Authority registration No:	
Guideline(s):	not specified
Deviations:	not specified
GLP/GEP:	not applicable
Acceptability:	Acceptable
Duplication (if vertebrate study)	

Bayer CropScience is selling the formulated product Cadou SC 508.8 (Flufenacet SC 508.8, 508.8 g/L). By mistake a wrong name Cadou SC 500 (Flufenacet SC 500, 500 g/L) has been mentioned in several documents which have been submitted to authorities.
However, in all submitted studies the a.s. content of Flufenacet was in a range which was valid for the SC 508.8 formulated product. The FAO tolerances for the a.s. content in a SC 508.8 g/L formulation are from 483.8 g/L to 533.8 g/L (508.8 ± 25 g/L).

Content of the pure active substance flufenacet

508.8 g/L flufenacet (declared)
Tolerances (FAO) min: 483.8 g/L max: 533.8 g/L

A table which compiles the Flufenacet a.s. contents of all submitted studies is provided in the full document and it can be shown that all a.s. contents are in the range of 483.8 g/L to 533.8 g/L.
It can be concluded that all submitted studies are valid for the formulated product Cadou SC 508.8 (Flufenacet SC 508.8, 508.8 g/L).

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

No additional studies are submitted.

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

Comments of zRMS:	zRMS accepted PT value.

Public literature

Reference:	**KCP 10.1.1.2/01**
Title:	Consolidation of bird and mammal PT data for use in risk assessment
Report:	xxx 2010; M-429545-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	not applicable
Acceptability:	
Duplication (if vertebrate study)	No

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

No additional studies are submitted.

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

No additional studies are submitted.

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

No additional studies are submitted.

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

A 2.2.1.1 Fish

No additional studies are submitted.

A 2.2.1.2 Aquatic invertebrates

No additional studies are submitted.

A 2.2.1.3 Effects on aquatic algae

Comments of zRMS:	The study was evaluated by the RMS in the course of the ongoing EU renewal process and during the 181 Experts' Meeting in June 2018 it was agreed to reject this study due to identified uncertainties in deriving the endpoints.

Reference:	**KCP 10.2.1/01**
Title:	Pseudokirchneriella subcapitata growth inhibition test with flufenacet (tech.)
Report:	Bruns, E.; 2010; EBFOL150; M-363891-04-1
Authority registration No:	
Guideline(s):	OECD Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test (March 23, 2006) US EPA OCSPP Guidline 850.4500
Deviations:	none
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process and rejected
Duplication (if vertebrate study)	

Objective

The aim of the study was to determine the influence of the test item on exponentially growing populations of *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and EC_x for growth rate of algal biomass (cells per volume).

Materials and methods

Flufenacet (tech.) analysed purity: 97.5% w/w was tested, specified by origin batch no.: K664078, customer order no.: TOX07969-01 and specification no.: 102000006978.

Pseudokirchneriella subcapitata (freshwater microalgae, formerly known as *Selenastrum capricornutum*) were exposed in a chronic multigeneration test for 3 days under static exposure conditions to nominal concentrations of 0.138, 0.416, 1.25, 3.71, 11.1, 34.4, 102, 322, 983, 3127 and 8605 µg active substance/L in comparison to a blank control and a solvent control. The pH values ranged from 7.8 to 8.5 in the controls and the incubation temperature ranged from 21.2°C to 22.5°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 8313 lux.
Quantitative amounts of flufenacet were measured in all treatment groups and in the control on day 0 and day 3 of the exposure period.

Results and discussions

Test conditions met all validity criteria, given by the mentioned guideline(s). Biomass increased in the control by more than 16-fold within the evaluation period, the mean percent coefficient of variation of sectional growth rates from day 0-1, day 1-2, and day 2-3 in the control did not exceed 35% and the mean percent coefficient of variation of sectional growth rates from day 0-1, day 1-2, and day 2-3 in the control did not exceed 7%.

The analytical findings of flufenacet in the treatment levels found on day 0 were 88% to 158% of nominal (average 110%). On day 3 analytical findings of 84% to 147% of nominal (average 113%) were found. Due to the analytical findings, all results are based on geometric mean measured test concentrations.

The static 72-hour algae growth inhibition test provided the following effects:

geometric mean measured concentration [µg a.s./L]	cell number after 72 h (means) per mL	(0-72h) average specific growth rates [days^{-1}]	inhibition of average specific growth rate [%]	doubling time of algae cells [days]
control	801 000	1.461	–	0.474
solvent control	837 000	1.475	–	0.470
pooled controls	819 000	1.468	–	0.472
0.138	791 000	1.457	0.8	0.476
0.416	751 000	1.440	1.9	0.481
1.25	712 000	1.421	3.2	0.488
3.71	601 000	1.364	7.1	0.508
11.1	117 000	0.819	44.2	0.846
34.4	67 000	0.632	57.0	1.10
102	65 000	0.623	57.5	1.11
322	61 000	0.602	59.0	1.15
983	56 000	0.574	60.9	1.21
3127	41 000	0.470	67.9	1.47
8605	37 000	0.434	70.4	1.60

test initiation with 10,000 cells/mL

Conclusion

The (0 – 72h) E_rC_{50} for flufenacet (tech.) is 138 µg a.s./L (95 % CI: 37.1 – 641 /L) and the (0 – 72h) – NOE_rC is 0.138 µg a.s./L. Endpoints are based on geometric mean measured concentrations.

*****

Comments of zRMS:	The study was evaluated and agreed by the RMS in the course of the ongoing EU renewal process with the following endpoints (based on nominal concentration): E_rC_{50} > 100 mg Flufenacet-oxalate/L $NOE_rC \geq$ 100 mg Flufenacet-oxalate /L E_bC_{50} > 100 mg Flufenacet-oxalate /L $NOE_bC \geq$ 100 mg Flufenacet-oxalate /L Although the renewal process is not finalised yet, no changes regarding the derived endpoints are expected. **The study was not used in the current risk assessment.**

Reference:	**KCP 10.2.1/02**
Title:	Pseudokirchneriella subcapitata growth inhibition test with flufenacet-oxalate
Report:	Bruns, E.; 2009; EBFOL137; M-358823-01-1
Authority registration No:	
Guideline(s):	OECD Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test (March 23, 2006)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process thus additional validation at the zonal level is deemed not necessary

Duplication (if vertebrate study)	

Objective

The aim of the study was to determine the influence of the test item on exponentially growing *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and EC_x for growth rate of algal biomass (cells per volume).

Material and methods

Test item: Flufenacet oxalate analysed purity: 95.3% was tested, specified by origin batch number: SES 10564-3-1, sample description: TOX08524-00 and LIMS number: 0910452.
Pseudokirchneriella subcapitata (freshwater microalgae, formerly known as *Selenastrum capricornutum*) were exposed in a chronic multigeneration test for 3 days under static exposure conditions to nominal concentrations of 6.25, 12.5, 25.0, 50.0 and 100 mg pure metabolite/L in comparison to the control (nutrient medium).
The pH values ranged from 7.9 to 8.2 in the controls and the incubation temperature ranged from 21.6°C to 21.9°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 7941 lux.
Morphological examination of cells using a microscope were made over the exposure period on each study day. Quantitative amounts of flufenacet oxalate (calculated from flufenacet-oxalate hydrate) were measured by HPLC-MS/MS in all treatment groups and in the control on day 0 and day 3 of the exposure period.

Results and discussions

Analytical findings:
The analytical findings of flufenacet oxalate (calculated from flufenacet-oxalate hydrate) in the treatment levels found on day 0 were 104% to 107% of nominal (average 105%). On day 3 analytical findings of 102% to 117% of nominal (average 107%) were found. All results are based on nominal test concentrations of pure metabolite.

Biological findings:
The static 72-hour algae growth inhibition test provided the following effects:

Nominal Concentration [mg p.m./L]	Cell Number after 72 h (means) per mL*	(0-72 h) Average Specific Growth Rates [$days^{-1}$]	Inhibition of Average Specific Growth Rate [%]	Doubling time of algae cells [days]
Control	920000	1.507	-	0.460
6.25	994000	1.533	-1.7	0.452
12.5	962000	1.522	-1.0	0.455
25.0	983000	1.529	-1.5	0.453
50.0	1003000	1.536	-1.9	0.451
100	985000	1.530	-1.5	0.453

* test initiation with 10,000 cells/mL
-% inhibition: increase in growth relative to the control

Morphological changes in algae were not observed in any of the test concentration.

Validity:
Test conditions met all validity criteria, given by the mentioned guideline(s). Biomass increased in the control by more than 16-fold within the evaluation period, the mean percent coefficient of variation of sectional growth rates from day 0-1, day 1-2, and day 2-3 in the control did not exceed 35% and the mean percent coefficient of variation of sectional growth rates from day 0-1, day 1-2, and day 2-3 in the control did not exceed 7%.

Conclusion

The (0-72 h) E_rC_{50} for flufenacet oxalate is > 100 mg p.m./L and the (0-72 h) NOE_rC is ≥ 100 mg p.m./L

based on nominal test concentrations.

Comments of zRMS:	The study was conducted in line with OECD 201 (1984) with no deviations. The mean measured concentrations of the active substance were maintained within 80-120% of nominal. The validity criterion was met and the study is considered acceptable with the following endpoints relevant for the risk assessment (based on nominal concentration): E_rC_{50} (growth) = 31 µg product/L NOE_rC = 6.3 µg product/L E_bC_{50} (biomass) = 13 µg product/L NOE_bC = 2.0 µg product/L

Reference:	**KCP 10.2.1/03**
Title:	Toxicity of flufenacet SC 500 to Pseudokirchneriella subcapitata (fornerly Selenastrum capricornutum in a 72-hour algal growth inhibition test
Report:	Baetscher, R.; 2001; 796364; M-055471-01-1
Authority registration No:	
Guideline(s):	OECD Guideline for Testing of Chemicals, No. 201: Alga, Growth Inhibition Test, 1984 –
Deviations:	None –
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication (if vertebrate study)	

Materials and methods

Test item: Flufenacet SC 500; specification: Batch No. 04402/0161 (0096); Tox. No. 5554-00; active ingredient Flufenacet; content of active ingredient 533.4 g/L; *Pseudokirchneriella subcapitata* (strain no. 61.81 SAG) was exposed under static conditions (stirring cultures) for 72 h. The following nominal test item concentrations were tested: 0.20, 0.63, 2.0, 6.3, 20, and 63 µg/L. The mean measured test item concentrations were in the range of 80 to 102% of the nominal values. Therefore, the calculations are based on nominal values.

The test design included three replicates per test concentration and six replicates of the control. The test was started (0 hours) by inoculation of 10,000 algal cells per ml test medium. Volumes of 15 ml algal suspension for each replicate were continuously stirred by magnetic stirrers in 50 ml Erlenmeyer flasks. The flasks were covered with glass dishes. They were incubated in a temperature-controlled water bath at a temperature of 21°C, and continuously illuminated at a measured light intensity of about 8800 Lux (mean value). At the start of the test, the pH values in the test media and the control ranged from 7.9 to 8.0 and at the end of the test, pH values between 8.0 and 8.3 were measured.

Small volumes of the test media and the control (1.0–2.0 ml) were taken out of all test flasks after 24, 48, and 72 hours exposure, and were not replaced. The algal cell densities in the samples were determined by counting with an electronic particle counter (Coulter Counter®, Model ZM), with at least two measurements per sample.

In addition, after 72 hours exposure, a sample was taken from the control and from a test concentration with reduced algal growth (nominal 6.3 µg/l). The shape of the algal cells was microscopically examined.

Dates of work: March 16, 2001 - May 15, 2001

Results and discussions

Growth rate related values are preferred because the validity criteria according to exponential algal growth are fulfilled.

The influence of the test item Flufenacet SC 500 on the growth of *Pseudokirchneriella subcapitata* is shown in Tables 1 and 2. The test item had a statistically significant inhibitory effect on the growth (i.e. biomass) of *Pseudokirchneriella subcapitata* after the exposure period of 72 hours at concentrations of 6.3 ug/l and above (results of Dunnett-Tests, one-sided, $\alpha = 0.05$). The growth rate r was statistically significantly reduced even first at the next higher test concentration of 20 ug/l.

In the control the cell density increased from nominal $N = 1 \times 10^4$ cells/ml at the start of the test (0 hours) to $N = 99 \times 10^4$ cells/ml (mean value) after 72 hours. Thus, the algal growth in the control was sufficiently high under the test conditions and the validity criterion of increase of cell density by at least a factor of 16 over the duration of the study was fulfilled.

The microscopic examination of the algal cells after 72 hours test period showed no difference between the algae growing in the test concentration of 6.3 ug/l and the algal cells in the control. The shape and size of the algal cells growing in test media containing the test item at up to this test concentration were obviously not affected. No remarkable observations were made concerning the appearance of the test media. All test media were clear solutions throughout the test period.

Effects on algal average growth rate

Test item	**Flufenacet SC 500**	
Test system	*Pseudokirchneriella subcapitata*	
Exposure	72 h, static	
results based upon:	product	a.s. *
E_rC_{50} (0-72 h) [µg/L]	31	13.61
Lowest observed effect concentration (0-72 h LOE_rC) [µg/L]	20	8.78
No observed effect concentration (0-72 h NOE_rC) [µg/L]	6.3	2.77

* recalculated on the basis of a content of 43.9% w/w of active ingredient within the test compound (as given in the report)

Conclusion

The 0-72h E_rC_{50} was 31 µg product/L (corresponding to 13.61 µg a.s./L) in a test on green algae (*P. sub-capitata*) under static exposure conditions.

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

No additional studies are submitted.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

Comments of zRMS:	The study was evaluated and agreed by the RMS in the course of the ongoing EU renewal process with the following endpoints (based on nominal concentration):

	0-7 d Frond number: Growth rate: E_rC_{50} = 16.1 µg s.a./L Growth rate: E_rC_{20} = 6.1 µg s.a./L Growth rate: E_rC_{10} = 3.91 µg s.a./L NOE_rC=0.658 µg s.a/L 0-7 d Total frond area: **Growth rate E_rC_{50} = 13.9 µg s.a./L** Growth rate E_rC_{20} = 6.04 µg s.a./L Growth rate E_rC_{10} = 3.91 µg s.a./L NOE_rC=0.658 µg s.a./L 0-7 d Frond number: Yield: E_yC_{50} = 7.638 µg s.a./L Yield: E_yC_{20} = 2.95 µg s.a./L Yield: E_yC_{10} = 1.792 µg s.a./L NOE_yC = 0.658 µg s.a./L 0-7 d Total Frond Area: Yield E_yC_{50} = 6.824 µg s.a./L Yield E_yC_{20} = 2.531µg s.a./L EyC_{10} = 1.507 µg s.a./L NOE_yC = 0.658 µg s.a./L Although the renewal process is not finalised yet, no changes regarding the derived endpoints are expected. **The study was used in the risk assessment.**

Reference:	**KCP 10.2.3/01**
Title:	Lemna gibba G3 - Growth inhibition test with flufenacet (technical substance) under static conditions
Report:	Bruns, E.; 2013; EBFON004; M-451198-01-1
Authority registration No:	
Guideline(s):	EU Council Directive 91/414/EECOECD Guideline 221 - Lemna sp. Growth Inhibition Test - (March 23, 2006) US EPA OCSPP Guideline 850.4400
Deviations:	None
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process thus additional validation at the zonal level is deemed not necessary
Duplication (if vertebrate study)	

Objective

The aim of the study was to determine the influence of the test item on exponentially growing *Lemna gibba G3* expressed as NOEC, LOEC and ECx for growth rate of both response variables, frond number and total frond area of plants.

Material and methods

Flufenacet (tech.) analysed purity: 97.49 % w/w was tested, specified by origin batch no: NK61BX0367, certificate no.: MZ 00466, customer order no.: TOX 09547-00 and specification no.: 102000006978.

6 x 12 fronds of *Lemna gibba* G3 per test concentration were exposed in a chronic multigeneration test for 7 days under static exposure conditions to nominal concentrations of 0.658, 1.50, 3.40, 7.73, 17.6 and 39.9 µg a.s./L in comparison to a water control. The pH values ranged from 7.5 to 8.0 in the control and the incubation temperature ranged from 24.6 °C to 25.0 °C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 9031 lux.
Quantitative amounts of flufenacet were measured in all freshly prepared test levels on day 0 and additionally in all aged test levels on day 7 of the exposure period.

Results and discussions

Findings and observations:
The study met all validity criteria, requested by the mentioned guideline. The analytical determination of flufenacet revealed mean recoveries of 99% of nominal on day 0 and 94% of nominal on day 7. The analytical findings confirm the nominal concentrations. Therefore, the results of this study are given based on nominal concentrations of the test substance.

The static 7-day growth inhibition test provided the following tabulated effects:

Nominal test levels	Final frond number	Final total frond area of plants	% inhibition* of average growth rate of	
formulation [µg/L]	mean day 7	mean [mm²]	frond numbers	total frond area of plants
control	212.3	1726.0	–	–
0.658	220.7	1711.3	-1.4	-1.9
1.50	161.0	1284.7	9.8	6.6
3.40	172.7	1376.0	7.2	9.8
7.73	135.7	1037.0	15.7	20.7
17.6	36.0	280.0	62.3	67.7
39.9	23.7	198.0	76.3	80.2

Observed visual effect:
No morphological change in *Lemna gibba* was observed at any test concentration.

Results are based on nominal concentrations of the test item:

Endpoint (0-7 day)	Effect on frond no. [µg formulation/L]	Effect on total frond area of plant [µg formulation/L]
E_rC_{50} (CI 95%)	16.1 (10.4 – 25.8)	13.9 (9.71 – 20.0)
LOE_rC	1.50	1.50
NOE_rC	0.658	0.658

The LOErC determination is based on statistical data analysis.

Conclusion
The most sensitive response variable in this study was total frond area of plants resulting in a (0-7 day) E_rC_{50} of 13.9 µg a.s./L.
The NOE_rC was 0.658 µg a.s./L and was based on statistical data analysis of the total frond area of plants and frond numbers. All endpoints are based on nominal concentrations.

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Comments of zRMS:	The study was evaluated and agreed by the RMS in the course of the ongoing EU renewal process with the following endpoints (based on nominal concentration): Based on frond number 7d E_rC_{50} > 100 mg Flufenacet-oxalate/L

	NOE_rC = 50 mg Flufenacet-oxalate/L Based on frond area 7d E_rC_{50} > 100 mg Flufenacet-oxalate/L $NOE_rC \geq$ 100 mg Flufenacet-oxalate/L Although the renewal process is not finalised yet, no changes regarding the derived endpoints are expected. **The study was not used in the risk assessment.**

Reference:	**KCP 10.2.3/02**
Title:	Lemna gibba G3 Growth inhibition test with flufenacet-oxalate under static conditions
Report:	Bruns, E.; 2009; EBFOL138; M-359515-02-1
Authority registration No:	
Guideline(s):	OECD Guideline 221 (March 23, 2006);
Deviations:	none
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process thus additional validation at the zonal level is deemed not necessary
Duplication (if vertebrate study)	

Objective

The aim of the study was to determine the influence of the flufenacet-oxalate on exponentially growing *Lemna gibba* G3 expressed as NOEC, LOEC and EC_x for growth rate of the response variables, frond number and total frond area of plants.

Materials and methods

Test item: Flufenacet-oxalate: flufenacet-oxalate, analysed content of active substance: flufenacet-oxalate (BCS-AB16305): 95.3% w/w, specified by Batch code: BCS-AB16305-01-01, Tox No.: 08524-01.
3 x 12 fronds of *Lemna gibba* G3 per test concentration were exposed in a chronic multi-generation test for 7 days under static exposure conditions to the nominal concentrations of 1.56, 3.13, 6.25, 12.5, 25.0, 50.0 and 100 mg formulation/L in comparison to control. The pH values ranged from 7.5 to 8.7 and the incubation temperature ranged from 22.7 °C to 24.1 °C measured over the whole period of testing at a continuous illumination of 8090 lux (mean).
Quantitative amounts of flufenacet were measured in all freshly prepared test levels on day 0 and additionally in all aged test levels on day 7 of the exposure period.

Results and discussions

Test conditions met all validity criteria, given by the mentioned guideline.
The analytical findings of flufenacet-oxalate determined in all test levels on day 0 ranged between 100 and 106% (average 104%), on day 7 the analysed concentrations ranged between 103 and 132% (average 110%) of nominal concentrations.
As the toxicity has to be attributed to the tested formulation as a whole, all results submitted by this report are related to nominal test concentrations of the formulated product.

The static 7-day growth inhibition test provided the following tabulated effects:

Nominal test levels	Final frond number	Final total frond area of plants	% inhibition* of average growth rate of	
Flufenacet-oxalate [mg/L]	mean day 7	mean [mm2]	frond numbers	total frond area of plants

control	134	458	–	–
1.56	125	456	2.92	-4.94
3.13	130	462	1.15	-3.66
6.25	124	464	3.29	-3.35
12.5	131	497	0.88	-2.46
25.0	116	401	5.88	6.34
50.0	120	405	4.65	9.23
100	114	395	6.48	7.59

*negative values mean growth stimulation

Observed visual effects:

Test level (mg flufenacet-oxalate/L)	Observations
Control	no visual effects observed
0.156	no visual effects observed
3.13	no visual effects observed
6.25	no visual effects observed
12.5	no visual effects observed
25.0	no visual effects observed
50.0	some small fronds on day 7
100	some small fronds on day 7

Results are based on nominal concentrations of the flufenacet-oxalate:

End point (0-7 day)	Effect on frond no. [mg flufenacet-oxalate/L]	Effect on total frond area of plants [mg flufenacet-oxalate/L]
E_rC_{50} (CI 95%)	> 100 (n.d. – n.d.)	> 100 (n.d. – n.d.)
LOE_rC	100	> 100
NOE_rC	50.0	>= 100

The LOE_rC and NOE_rC determinations are based on statistical data analysis, n.d. = not determined due to mathematical reasons

Conclusion

The most sensitive response variable was total frond number of plants resulting in (0-7 day) E_rC_{50} of >100 mg flufenacet-oxalate/L and a lowest (0-7 day) NOE_rC of 50.0 mg flufenacet-oxalate/L. All end-points are based on nominal concentrations.

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Comments of zRMS:	The study was conducted in line with OECD 221 with no deviations. The mean measured concentrations of the active substance were not maintained within 80-120% of nominal; therefore, the endpoints are based on mean measured concentrations. All the validity criteria were met and overall the study is considered acceptable with the following endpoints relevant for the risk assessment (based on mean measured concentration): E_rC_{50} (growth) = 110 µg product/L NOE_rC = 4.6 µg product/L E_bC_{50} (biomass/dry weight) = 58 µg product/L NOE_bC = 4.6 µg product/L

Reference:	**KCP 10.2.3/03**
Title:	Toxicity of flufenacet SC 500 to the aquatic higher plant Lemna gibba in a 7-day static

	growth inhibition test
Report:	Baetscher, R.; 2001; 796342; M-055476-01-1
Authority registration No:	
Guideline(s):	OECD Guidelines for the testing of chemicals: Proposal for a new guideline 221: "*Lemna* sp. Growth Inhibition Test", (Draft October 2000) –
Deviations:	None –
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication (if vertebrate study)	

Materials and methods
Test item: Flufenacet SC 500; specification: Batch No. 04402/0161 (0096); Tox. No. 5554-00; active ingredient Flufenacet; content of active ingredient: 533.4 g/L.
Lemna gibba was exposed under static conditions for 7 days. The following nominal test item concentrations were tested: 0.51, 1.6, 5.1, 16, and 51, and 160 µg/L. The mean measured test item concentrations were in the range of 72 to 112% of the nominal values. Therefore, the calculations are based on mean measured concentrations: 0.37 µg/L (nominal 0.51 µg/L), 1.27 µg/L (nominal 1.60 µg/L), 4.6 µg/L (nominal 5.1 µg/L), 17 µg/L (nominal 16 µg/L), 55 µg/L (nominal 51 µg/L), and 180 µg/L (nominal 160 µg/L).
The test vessels were incubated in a temperature-controlled water bath in a random order at about 22 °C. They were continuously illuminated at a light intensity of about 8500 Lux (mean value), range: 8000 to 9000 Lux (minimum and maximum value of measurements before test start at nine places distributed over the experimental area at the surface of the test media). The test was started with three randomly selected colonies per vessel. Each colony had four fronds, resulting in twelve fronds per vessel. At the start of the test, the pH value in the test media ranged from pH 7.5 to 8.0. At the end
of the test, pH values were measured between 8.7 and 9.1.

Dates of work: March 21, 2001 - June 27, 2001

Results and discussions
Growth rate related values are preferred, because the validity criteria according to exponential growth are fulfilled.
At the three lower mean measured test concentrations of 0.37, 1.27, and 4.6 ug/l (nominal 0.51, 1.6, and 5.1 ug/l, respectively), the average growth of *Lemna gibba* on Day 7 was statistically not significantly reduced compared to the control (results of Dunnett-tests, one-sided, $\alpha = 0.05$). The growth parameters of average specific growth rate (r) after the test period of 7 days were statistically significantly reduced at the test concentration of 17 ug/l and above. The same result was obtained for the mean dry weight of the plants after 7 days.
After the 7 days test duration, shorter roots were observed at the plants growing in the test concentrations of 17, 55, and 180 ug/l. At the test concentrations of 55 and 180 ug/l, the fronds formed during the test period were much smaller than the fronds of the control plants. Additionally, the number of fronds per colony was statistically significantly smaller than in the control at the highest test concentration of 180 ug/l (results of Dunnett-tests, one-sided, $\alpha = 0.05$).
The doubling time ($Td = \ln 2 / r$) of *Lemna* growth in the control was calculated to be 2.2 days. Therefore, the growth of *Lemna gibba* was sufficiently high under the test conditions and the validity criterion ($Td < 2.5$ days) was fulfilled.

Effects on the growth rate after 7 days test duration:

Test item	**Flufenacet SC 500**
Test system	*Lemna gibba*

Exposure	7 day, static	
results based upon:	product	a.s. *
E_rC_{50} (0-72 h) [µg/L]	110	48.29
Lowest observed effect concentration (0-7 d LOE_rC) [µg/L]	17	7.46
No observed effect concentration (0-7 d NOE_rC) [µg/L]	4.6	2.02

* recalculated on the basis of a content of 43.9% w/w of active ingredient within the test compound (as given in the report)

Conclusion

Lemna gibba was exposed for 7 days under static conditions to six test item concentrations of Flufenacet SC 500. The 7d-E_rC_{50} was determined to be 110 µg product/L (corresponding to 48.29 µg a.s./L) based on mean measured test item concentrations.

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

Comments of zRMS:	The study was performed in line with OECD 213 and 214 with minor deviations. It was noted that in the contact test a single 5 µL droplet was chosen for application of the test item instead of 1 µL droplet since, according to the testing facility's experience, the higher volume ensures a better solubility of the test items and no adverse effects on the outcome of the study are expected. During the oral test the relative humidity was 40 – 46% and in the contact test 44 – 48% which is below the recommended minimum of 50%. Also the 24 h contact LD_{50} of the toxic standard dimethoate was 0.36 µg a.s./bee which is outside the guideline recommended range of 0.10 – 0.30 µg a.s./bee. It was explained as a biological variety in the sensitivity of the bees since the historical data shows that the LD_{50} of the bees normally ranges between 0.10 and 0.30 µg a.i. and the difference amounts to only 0.06 µg a.s. Because the test item LD_{50} is clearly above 200 µg a.s./bee, this deviation of the toxic standard LD_{50} is considered to have had had no influence on the scientific outcome and the results of the study. In zRMS opinion all the deviations listed above are considered to have no impact on the outcome of the study because all the validity criteria were met: • the average mortality for the total number of controls must be < 10 % at the end of the test (observed: oral 0 %, contact 2 %), • the LD_{50} of the toxic standard must be in the range of 0.10 – 0.35 µg a.s./bee in the oral test (observed 0.11 µg a.s./bee); • the LD_{50} of the toxic standard must be in the range of 0.10 – 0.30 µg a.s./bee in the contact test (observed 0.36 µg a.s./bee – deviation justified above); Overall, the study is considered acceptable with the following endpoints relevant for the risk assessment: 48h oral LD_{50} > 228.0 µg a.s./bee 48h contact LD_{50} > 200.0 µg a.s./bee

Reference:	**KCP 10.3.1.1/01**
Title:	Effects of Flufenacet SC 500 (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory (limit test)
Report:	Schmitzer, S.; 2001; 9971036; M-136977-01-1
Authority registration No:	
Guideline(s):	OECD 213: OECD Guideline for the Testing of Chemicals, Honeybees, Acute Oral Toxicity Test, (adopted 21st September 1998); OECD 214: OECD Guideline for the Testing of Chemicals, Honeybees, Acute Contact Toxicity Test, (adopted 21st September 1998); recent recommendations of the ICPBR group, held in Avignon, France, 1999 –
Deviations:	Minor (see the commenting box above) –
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication	

(if vertebrate study)	

Materials and methods
Flufenacet SC 500 (FOE 5043 500 SC), (specification: Article No.: 0005559022, Formulation No.: 04402/0167(0096); Tox-No.: 05684-00; content: Flufenacet: 519.2 g/L);
Under laboratory conditions, *Apis mellifera* (50 worker bees per treatment: 5 replicates per test item dosage, controls, and toxic standard dosages, 10 bees per replicate) were used for the oral and contact tests.
For the oral exposure, ca. 25 mg food (ca. 20 uL ready-to-use syrup) per bee was mixed with Flufenacet SC 500, toxic standard and tap water (test item solution and sugar were mixed together in a way that the final sugar solution was 50 %). This diet was offered in syringes which were weighed before and after introduction into the cages (duration of uptake did not exceed 2 hours). The measured dosage of the test item was 228.0 µg a.s./bee.
For topical application, one single 5 µL droplet of Flufenacet SC 500 (200.0 µg a.s. per bee) or the toxic standard, respectively in solvent (solvent = water + 1 % Adhäsit*) was placed on the dorsal bee thorax using a Burkard - Applicator. For the controls one 5 µL droplet of tap water with 1 % Adhäsit was used (a single 5 uL droplet was chosen in deviation to the guideline (here: 1 µL) since this higher volume ensures a better solubility of the test items.
Commercial ready-to-use syrup (Apiinvert; 30 % Saccharose, 31 % Glucose, 39 % Fructose) was provided (*ad libitum*) directly after treatments in syringes and food was not replaced during the experimental time of the experiments (48 h).
The temperature was 25°C and the relative humidity ranged between 40 to 48%. The tests were performed in darkness except during observation.
The toxic standard dimethoate (417.5 g/L analytical, 400 g/L nominal) was applied in the contact test at rates of 0.1, 0.2, 0.3 and 0.4 µg a.s./bee and in the oral test at rates of 0.04, 0.09, 0.17 and 0.34 µg a.s./bee.

Dates of experimental work: May 22, 2001 – May 31, 2001

Results and discussions
Under laboratory conditions *Apis mellifera* (50 worker bees per treatment) were exposed to a dose of 228.0 µg a.s. per bee for feeding (oral, value based on the actual intake of the test item) causing a mortality of 14 % after 48 hours and to a dose of 200.0 µg a.s. per bee for topical application (contact) causing a mortality of 16 % after 48 hours.
The oral LD_{50} of the reference item was 0.11 µg dimethoate per bee in the oral and 0.36 µg dimethoate per bee in the contact exposure after 24 hours.

Toxicity of Flufenacet SC 500 to Honey Bees, Laboratory Tests

Test item	Flufenacet SC 500	
Test object	*Apis mellifera*	
Exposure	oral (50% sugar solution)	contact (solution in water + 1 % wetting agent)
LD_{50} µg a.s./bee [48 h]	> 228.0	> 200.0

Observations:
In the oral test behavioural impairments like discoordinated movements of 3 bees were observed during the 24 hours check in the test item treatment group. No further behavioural abnormalities occurred after 48 hours.
In the contact test 4 bees were apathetic after 4 hours. After 24 hours one bee showed discoordinated movements and one bee was apathetic. No further behavioural abnormalities occurred until the end of the experiment.

Conclusions
The LD_{50} (contact) was determined to be > 200 µg a.s./bee and the LD_{50} (oral) was determined to be >228.0 µg a.s./bee.

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Comments of zRMS:	The study was performed in line with OECD 213 and 214 with a minor deviation. It was noted that in the contact test a single 5 µL droplet was chosen for application of the test item instead of 1 µL droplet since, according to the testing facility's experience, a higher volume ensured a more reliable dispersion of the test item and no adverse effects on the outcome of the study are expected. In zRMS opinion this deviation is considered to have no impact on the outcome of the study because all the validity criteria were met: • the average mortality for the total number of controls must be < 10 % at the end of the test (observed: oral 6 %, contact 2 %), • the LD_{50} of the toxic standard must be in the range of 0.10 – 0.35 µg a.s./bee in the oral test (observed 0.14 µg a.s./bee); • the LD_{50} of the toxic standard must be in the range of 0.10 – 0.30 µg a.s./bee in the contact test (observed 0.23 µg a.s./bee); Overall, the study is considered acceptable with the following endpoints relevant for the risk assessment: 48h oral LD_{50} > 224.0 µg a.s./bee 48h contact LD_{50} > 200.0 µg a.s./bee

Reference:	**KCP 10.3.1.1/02**
Title:	Flufenacet SC 508.8 G: Effects (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory
Report:	Sekine, T.; 2019; 145951035; M-671405-01-1
Authority registration No:	
Guideline(s):	Regulation (EC) No. 1107/2009 Directive 2003-01 (Canada/PMRA) US EPA OCSPP 850.3020, 850.supp. OECD 213 and 214 (1998)
Deviations:	Minor (see the commenting box above) ~~None~~
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication (if vertebrate study)	

Materials and methods

Flufenacet SC 508.8 G: flufenacet (FOE 5043): 42.8 % w/w, 517.7 g/L (analytical); Supplier Batch No.: EFKF003330; Sample Description: TOX20848-00; Specification No.: 102000007779; Density: 1.210 g/mL (20 °C).

As part of this 48-hour laboratory study, a total of 50 worker honey bees (*Apis mellifera* L.) (10 bees per replicate, 5 replicates per test unit) were exposed to a single dose of 200.0 µg a.s. per bee by topical application (contact limit test). The test item was applied as one 5 µL droplet of flufenacet SC 508.8 G, dissolved in tap water with 0.5 % Adhäsit*, placed on the dorsal bee thorax using a calibrated pipette (Multipette©, Eppendorf). The reference item was applied as one 5 µL droplet of dimethoate, dissolved in tap water with 0.5 % Adhäsit*. For the control, one 5 µL droplet of tap water containing 0.5 % Adhäsit* was used.

A 5 µL droplet was chosen in deviation to the guideline recommendation of a 1 µL droplet, since a higher volume ensured a more reliable dispersion of the test item; ibacon experience has proven that higher volumes are suitable and no adverse effects on the outcome of the study are to be expected.

A separate batch of 50 worker bees was exposed to a single target dose of 200.0 µg a.s. per bee by feeding (corresponding to actual consumption of 224.0 µg a.s. per bee by feeding (oral limit test, value based on the actual intake of the test item)). The treated food was offered in syringes, which were weighed before and after introduction into the cages (duration of uptake was one hour for the test item treatment). After a maximum of one hour, the uptake was complete and the syringes containing the treated food were removed, weighed and replaced by ones containing fresh, untreated food.
50 % w/v sucrose solution (500 g/L tap water) (provided as "household sugar") *ad libitum*; was given directly after treatment.
The temperature was between 24 and 25°C and the relative humidity ranged between 61 to 65%. The tests were performed in darkness except during observation.

Results and discussions

Toxicity to Honey Bees; laboratory tests

Test Item	Flufenacet SC 508.8 G	
Test Species	*Apis mellifera* L.	
Exposure	contact (solution in Adhäsit (0.5 %)/water)	oral (sucrose solution)
Dose rate µg a.s./bee	200.0	target: 200.0 consumed: 224.0
LD_{50} µg a.s./bee	> 200.0	> 224.0
LD_{20} µg a.s./bee	> 200.0	> 224.0
LD_{10} µg a.s./bee	> 200.0	> 224.0
NOED µg a.s./bee*	≥ 200.0	≥ 224.0

* The NOED was estimated using Fisher's Exact Binomial Test (pairwise comparison, one-sided greater, α = 0.05).

The contact and oral LD_{50} (24 h) values of the reference item (dimethoate) were calculated to be 0.23 and 0.14 µg a.s./bee, respectively.

Observations:
Contact Test:
At the end of the contact toxicity test (48 hours after application), 6.0 % mortality occurred at 200.0 µg a.s./bee. There was 2.0 % mortality in the control group (water + 0.5 % Adhäsit). No test item induced behavioural abnormalities occurred.

Oral Test:
In the oral toxicity test, the maximum nominal test level of flufenacet SC 508.8 G (*i.e.* 200 µg a.s./bee) corresponded to an actual intake of 224.0 µg a.s./bee. This dose level led to no mortality after 48 hours. In the control group (50 % w/v sucrose solution = 500 g sucrose/L tap water), 6.0 % mortality was observed. No test item induced behavioural abnormalities occurred.

Conclusion
The toxicity of Flufenacet SC 508.8 G was tested in both an acute contact and an acute oral toxicity test on honey bees.
The contact LD_{50}, LD_{20}, LD_{10} values (24 and 48 h) were all > 200.0 µg a.s./bee.
The contact NOED values (24 and 48 h) were both ≥ 200.0 µg a.s./bee.
The oral LD_{50}, LD_{20}, LD_{10} values (24 and 48 h) were all > 224.0 µg a.s./bee.
The oral NOED values (24 and 48 h) were both ≥ 224.0 µg a.s./bee.

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

See A 2.3.1.1

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

See A 2.3.1.1

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	The study was evaluated and agreed by the RMS in the course of the ongoing EU renewal process with the following endpoints (based on nominal concentration): LC_{50} > 120 mg a.s./kg (nominal) corresponding to LD_{50} > 4.42 µg a.s./bee/day NOEC = 120 mg a.s./kg (nominal) corresponding to NOED = 4.42 µg a.s./bee/day Although the renewal process is not finalised yet, no changes regarding the derived endpoints are expected. **The study was not used in the risk assessment.**

Reference:	**KCP 10.3.1.2/01**
Title:	Flufenacet (tech.) - Assessment of chronic effects to the honeybee, Apis mellifera L., in a 10 days continuous laboratory feeding limit test
Report:	Kling, A.; 2014; S13-00145; M-477339-01-2
Authority registration No:	
Guideline(s):	US EPA OCSPP Guideline 850.SUPP
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process thus additional validation at the zonal level is deemed not necessary
Duplication (if vertebrate study)	

Objective

The objective of this study was to determine the chronic effects of the test item flufenacet (tech.) on the honey bee, *Apis mellifera* L., in a 10 days continuous feeding test in the laboratory. The NOEC (no observed effect concentration) was determined at the end of the test period.

Materials and methods

Test item: Flufenacet (tech.) (TOX No: 10011-00; Origin Batch No.: NK61CK0650; Purity: 98.18 % w/w (analysed))

Test design: The chronic effects of the test item flufenacet (tech.) on the honey bee, *Apis mellifera* L., were assessed in a 10 days continuous feeding in the laboratory.

Over a period of 10 days, honey bees were exposed to 50% (w/v) aqueous sucrose application (feeding) solution, containing nominally 120 mg a.s./kg of the test item flufenacet (tech.) by continuous and ad libitum feeding. Because the test item was first dissolved in acetone and then diluted with aqueous sucrose solution, the final test item application (feeding) solution contained 3% acetone. The control group was exposed for the same period of time under identical exposure conditions to untreated 50% (w/v) aqueous sucrose application (feeding) solution, also containing 3% acetone. Mortality, sub-lethal effects and behavioural observations were assessed every day throughout the 10 days exposure period. Furthermore, the daily food uptake was determined.

Results and discussions

After 10 days of continuous exposure, mortality at the test item treatment level of 120 mg a.s./kg of flufenacet (tech.) was not statistically significantly different when compared to the control group.
The cumulative control mortality was 0.0%, as determined at the final assessment after 10 days. The

cumulative mortality at the treatment level of 120 mg a.s./kg flufenacet (tech.) was 3.0% at the final assessment.
At 120 mg a.s./kg flufenacet (tech.), no remarkable sub-lethal effects or behavioural abnormalities were observed throughout the entire observation period of 10 days.
After 10 days of continuous exposure, by considering the actual food consumption of the honey bees, the accumulated nominal intake of the test item flufenacet (tech.) at the treatment level of 120 mg a.s./kg was 44.2 µg a.s./bee, the corresponding average daily dose was therefore 4.4 µg a.s./bee.
The overall mean daily consumption of the application (feeding) solution (i.e. the average value over 10 days) in the test item treatment group was not statistically significantly different (lower) when compared to the untreated control group (36.8 mg/bee at 120 mg a.s./kg, compared to 38.4 mg/bee in the control group).
The mean daily consumption of the aqueous sucrose application (feeding) solution was not statistically significantly different (lower) between the control group and the test item treatment group throughout the entire testing period (day-by-day comparison), except for the first day and the 8th day of exposure.

Mean consumption of application solution, mean nominal intake of test item accumulated over all test days, average daily dose, cumulative mortality after ten days of continuous exposure (test end) as well as the LC_{50} and NOEC

Treatment Level	Control [1]	Flufenacet (tech.) at 120 mg a.s./kg (nominal) [2]
Cumulative mortality after ten days of continuous exposure [%]	0.0	3.0
Overall mean daily consumption of application (feeding) solution [mg/bee] [3]	38.4	36.8
Mean nominal intake accumulated over ten test days [µg a.s./bee/10d]	-	44.2
Average daily dose (nominal) throughout ten days of continuous exposure [µg a.s./bee/d]	-	4.4
LC_{50}	> 120 mg a.s./kg (nominal)	
NOEC [4]	120 mg a.s./kg (nominal)	

[1] Application (feeding) solution: 50% (w/v) aqueous sucrose solution containing 3% acetone
[2] Application (feeding) solution: 50% (w/v) aqueous sucrose solution containing 3% acetone and flufenacet (tech.)
[3] The mean values per replicate over the test period (non-rounded values) were used for the calculation of the overall mean daily consumption of application (feeding) solution per treatment
[4] Determined to be the NOEC based on mortality (not statistically significantly different compared to the control; Fisher's Exact Test, Bonferroni-Holms corrected, one-sided, $p \leq 0.05$)
a.s. = active substance

Conclusion
It can be concluded that the continuous *ad libitum* feeding of honey bees in the laboratory over a period of 10 consecutive days with the test item flufenacet (tech.) at the treatment level of 120 mg a.s./kg caused no adverse effect regarding mortality, sub-lethal effects and behaviour.
The overall mean daily consumption of application (feeding) solution (i.e. the average value over 10 days) in the test item treatment group was not statistically significantly lower compared to the untreated control group. Further, on every single day during the 10-day continuous exposure period the mean food consumption per bee was not statistically significantly different (lower) in the test item treatment group compared to the control group, except for the first day and the 8th day of exposure.
As the overall mean daily food uptake in the test item treatment group was not statistically significantly lower compared to the control group, it can be concluded that there was no repellent effect of the test item at the treatment level of 120 mg a.s./kg.
The NOEC for mortality was determined at the end of the test period to be 120 mg a.s./kg (nominal).
The LC_{50} after 10 days of continuous exposure was determined to be > 120 mg a.s./kg (nominal).

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Comments of zRMS:	The study was evaluated and agreed by the RMS in the course of the ongoing EU renewal process with the following endpoints: NOED = 75 µg a.s./larva ED_{10} = 2.8 µg a.s./larva Although the renewal process is not finalised yet, no changes regarding the derived endpoints are expected. **The study was not used in the risk assessment.**

Reference:	**KCP 10.3.1.3/01**
Title:	Flufenacet: Honey bee (Apis mellifera L.) larval toxicity test, repeated exposure
Report:	Rathjen, K. A.; 2018; 13798.6448; M-615473-01-1
Authority registration No:	
Guideline(s):	Regulation (EC) No. 1107/2009 Directive 2003-01 (Canada/PMRA) US EPA OCSPP 850.SUPP OECD Guidance Document No 239, Honey Bee (Apis mellifera) Larval Toxicity Test, Repeated Exposure
Deviations:	none
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process thus additional validation at the zonal level is deemed not necessary
Duplication (if vertebrate study)	

Objective

The objective of this study was to evaluate the effect of flufenacet on honey bee adult emergence from repeated feeding exposure

Materials and methods

Test item: Flufenacet technical (tech.) (batch ID.: NK61GX1776; CAS no.: 142459-58-3; Specification No.: 102000006978; analytical content: 98.4 % w/w; density: not reported)

Test species: honey bee larvae, *Apis mellifera* (≤ 24 hours old at initiation of acclimation), Source: a total of 3 queen right, healthy hives from Wood's Beekeeping Supply, Lincoln, Rhode Island.

Test design: This dose-response test was conducted over a period of 22 days, commencing with the grafting of first instar larvae and ending with the assessment of adult emergence. First instar larvae were transferred to 48-well plates for a two-day acclimation phase and then exposed to flufenacet during four days of the larval treatment phase (days 3, 4, 5, and 6). Samples of each treated diet as well as the negative control and solvent control were collected and analysed for flufenacet concentration during each day of the larval exposure phase. Replication consisted of 12 larvae obtained from each of three hives, for a total of 36 larvae per treatment group. Treatment groups included five different concentrations of technical grade flufenacet, as well as a solvent control (0.39% acetone), a negative control (untreated royal jelly diet), and a reference toxicant (dimethoate). The test was conducted in near total darkness. On day 8, the number of replicates with uneaten diet was recorded. Only larvae that had completely consumed their diet were transferred to pupal plates. Assessments of larval mortality occurred on days 4, 5, 6, 7, and 8. Pupal mortality was assessed on day 15 and adult emergence was evaluated on days 15 to 22.

Nominal test concentrations: 0 (solvent control), 1.5, 4.6, 13, 41, 120 mg a.s./mL
Nominal cumulative dose and diet concentrations: 0.93, 2.8, 8.3, 25, 75 µg a.s./larva (corresponding to 5.8, 18, 52, 160, 470 µg a.s./g diet)
Reference item: 9.2 mg dimethoate/mL (corresponding to 7.4 µg a.s./larva)

Test conditions: Temperature and relative humidity within a surrogate cell plate, placed in the incubator among the test plates, were monitored continuously using a HOBO data logger.

Temperature: 33 to 34 ºC (larval phase); 31 to 35 ºC (pupal phase)
Relative humidity: 83 – 98 % (larval phase); 65 to 86 ºC (pupal phase)
Photoperiod: 24 h darkness, except 30 minutes each day during observations and renewal of the diet

Statistics: Only the day 22 adult emergence endpoint was used for statistical analysis and for determining the NOED/NOEC, LOED/LOEC, and ED_x/EC_x effect levels. Larval (day 4 to 8) and pupal survival (day 15) was quantified but not used in determining effect levels.
All comparisons for determination of a NOED/LOED were made at ≥ 95% level of certainty ($p < 0.05$) and compared on a per treatment basis. CETIS Version 1.8 (Ives, 2013) was used to perform these calculations.
If ≥ 50% reduction in adult percent emergence was observed, then the appropriate statistical model (e.g., linear regression, non-linear regression, linear interpolation) within CETIS Version 1.8 (Ives, 2013) was used to determine the ED_{50} value and corresponding 95% confidence intervals. If no treatment level tested resulted in ≥ 50% reduction in the endpoint, the ED_{50} value was empirically estimated to be greater than the highest dose tested. Additionally, the determination of the ED_{10} and ED_{20} for adult emergence followed the same process described for the ED_{50}. Diet concentrations (µg a.s./g diet) are reported as EC_x values.

Dates of experimental work: July 12th 2017 - August 2nd 2017

Results and discussions
Analytical results:
Analysis of the stock solutions added to the diets:

Concentrations of flufenacet measured in the stock solutions added to the diets during the honey bee (*Apis mellifera* L.) larval toxicity test, repeat exposure.

Nominal stock concentration [mg a.s./mL]	Day 0 measured stock concentration [a] [mg a.s./mL]	Day 6 measured stock concentration [a] [mg a.s./mL]	% of nominal [a] (Day 0 / Day 6
Solvent Control	<0.25[b]	<0.25[b]	NA / NA
1.5	1.5	1.6	100 / 110
4.6	4.6	5.1	100 / 110
13	14	13	110 / 97
41	42	46	100 / 110
120	120	140	100 / 120

NA = Not Applicable
[a] Measured stock and percent of nominal concentrations were calculated using the actual analytical (unrounded) results and not the rounded (two significant figures) values presented in this table.
[b] Concentrations expressed as less than values were below the method detection limit (MDL). The MDL is dependent upon the lowest concentration calibration standard and the dilution factor of the controls.

Analysis of royal jelly diet:

Concentrations of flufenacet measured in the royal jelly diet during the honey bee (*Apis mellifera* L.) larval toxicity test, repeat exposure.

Nominal cumulative dose and nominal diet concentration	Measured diet concentration [µg a.s./g diet] [a]	Mean % of nominal [a]

(µg a.s./larva)	(µg a.s./g diet)	Day 3 [b,c]	Day 4 [c]	Day 5 [c]	Day 6 [c]	Mean (SD)	
Negative control	Negative control	< 0.84	< 0.84	< 0.84	< 0.84	NA (NA)	NA
Solvent control	Solvent control	< 0.84	< 0.84	< 0.84	< 0.84	NA (NA)	NA
0.93	5.8	6.1	6.1	6.3	6.0	6.1 (0.12)	110
2.8	18	18	19	20	16	18 (1.6)	100
8.3	52	51	49	52	48	50 (1.8	96
25	160	140	170	160	200	170 (23)	100
75	470	570	470	470	520	510 (50)	110
	QC #1 (3.00)	3.13 (104)	2.76 (92.2)	2.98 (99.3)	2.58 (85.9)		
	QC #2 (50.0)	46.2 (92.5)	47.9 (95.7)	49.1 (98.2)	45.9 (91.8)		
	QC #3 (500)	496 (99.2)	504 (101)	504 (101)	513 (103)		

NA = Not Applicable
SD = Standard Deviation
QC = Quality Control sample.
Percent recovery for each QC sample is presented in parentheses.
[a] Measured diet and percent of nominal concentrations were calculated using the actual analytical (unrounded) results and not the rounded (two significant figures) values presented in this table.
[b] Diet B was fed on day 3.
[c] Diet C was fed on days 4, 5, and 6.
[d] Concentrations expressed as less than values were below the method detection limit (MDL). The MDL is dependent upon the lowest concentration calibration standard and the dilution factor of the controls.

Since the mean measured diet concentration closely approximated the desired nominal diet concentrations (recoveries within 80.0 to 120%), the results of this study are reported based on nominal diet concentrations (µg a.s./g diet) and nominal cumulative dose rates (µg a.s./larva).

Validity criteria:
The study is considered valid since the control and reference item validity criteria were met.

Validity criteria	Required	Obtained
Larval mortality from days 3 to 8 in the negative control and solvent control, if present.	≤ 15% prior to pupation	Larval mortality in the negative control and solvent control was 0 and 3%, respectively.
Percent emergence in the negative control and solvent control, if present.	≥ 70% at day 22	Emergence in the negative control and solvent control was 97 and 92%, respectively.
Larval mortality in the reference toxicant treatment level (7.4 µg a.s. dimethoate/larva)	≥ 50% on day 8	Larval mortality in the 7.4 µg a.s. dimethoate/larva treatment was 72%.

Biological findings:

The effects of flufenacet on larval mortality and adult emergence of the honey bee, *Apis mellifera* l., from repeated exposure and corresponding endpoints [a]

Nominal test concentration [µg a.s./g diet] [e]	Nominal cumulative dose [µg a.s./larva] [e,f]	Larval Mortality on Day 8 [b,c]		Pupal Mortality on Day 15 [c]	Adult Emergence on Day 22 [c]
		[%]	Corrected [d] [%]	[%]	[%]
Negative control	Negative control	0	0	0	100
Solvent control	Solvent control	3	0	8	92
5.8	0.93	3	0	8	92
18	2.8	19	16	22	78

52	8.3	6	3	11	86
160	25	8	5	17	83
470	75	8	5	19	81
Reference Item	Reference Item	72	69	72	25

Endpoints for Day 22				
LOEC	NOEC	EC_{10} (95 % CL)	EC_{20} (95 % CL)	EC_{50} (95 % CL)
[µg Flufenacet/g diet][e]				
> 470	470	18[g]	> 470	> 470
LOED	NOED	ED_{10} (95 % CL)	ED_{20} (95 % CL)	ED_{50} (95 % CL)
[µg Flufenacet/larva][ef]				
> 75	75	2.8[g]	> 75	> 75

CL = Confidence Limit
[a] Additional information pertaining to U.S. EPA can be found in study report.
[b] All surviving larvae were observed to have complete food consumption.
[c] All acceptability criteria were met.
[d] Corrected using solvent control (e.g., corrected % mortality = treatment % mortality – solvent control % mortality)
[e] Based on the analyzed purity
[f] Based on the cumulative feeding volume from day 3 until day 6 of 140 µL diet/larva and a density of the diet of 1.1424 g/cm³.
[g] Compared to the solvent control

Conclusion

The 22-day percent emergence NOED and LOED values for flufenacet were determined to be 75 and > 75 µg a.s./larva when compared to the solvent control. The corresponding NOEC and LOEC values were determined to be 470 and > 470 µg a.s./g diet when compared to the solvent control. The study was deemed valid as all validity criteria were met.

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Comments of zRMS:	The study (first amended report) was evaluated by the RMS in the course of the ongoing EU renewal process and the results were considered as additional information only. The second amended report included only additional information on the test item since the certificate of analysis was not available at the time when the study plan was issued. Based on the study results it can be concluded that the consumption of the test item by honey bee colonies at a concentration of 1.5 g flufenacet a.s./L, corresponding to 2.89 mL Flufenacet SC 508.8 in 1 L 50 % (w/v) aqueous sucrose solution, had no adverse effects on the colony conditions and survival of honeybee life stages (eggs, young larvae and old larvae), developing in brood cells within the hives. No adverse effects on the survival of the exposed adult worker bees. Although the renewal process is not finalised yet, no changes regarding the conclusions of this study are expected.

Reference:	**KCP 10.3.1.3/02**
Title:	Second amended report - Flufenacet SC 508.8: A honeybee brood feeding study to evaluate the effects on brood development of the honeybee, Apis mellifera L. (Hymenoptera: Apidae)
Report:	Kimmel, S.; 2018; 20110057; M-456504-03-1
Authority registration No:	

Guideline(s):	EPPO Bulletin 22 (Oomen et al., 1992) US EPA OCSPP Guideline 850.SUPP
Deviations:	None
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process and considered as additional information only
Duplication (if vertebrate study)	

Objective

The purpose of the honeybee brood feeding study was to evaluate the effect of Flufenacet SC 508.8 on brood development and mortality of adult worker honeybees, *Apis mellifera* L. (Hymenoptera Apida). The colonies were freely flying with access to natural nectar and pollen sources, however, the study was conducted at a time without mass flowering plants/agricultural crops in the study region, so that the nectar flow of natural sources was low at the time of treatment administration.

Materials and methods

Test item:

Flufenacet SC 508.8 (active ingredient: flufenacet (BAY005NOR); Batch ID.: EFKF001049, Sample Description: TOX09446-00, Specification No.: 102000007779-02; Analytical content: 42.8% w/w; 519.2 g flufenacet/L; Density: 1.213 g/mL at 20 °C).

Test species:

Honey bees (*Apis mellifera* L.); honey bee colonies were maintained according to normal beekeeping practice, containing two magazines with 12 combs, each. The colonies were freely flying with access to natural nectar and pollen sources, however, the study was conducted at a time without mass flowering plants/agricultural crops in the study region, so that the nectar flow of natural sources was low at the time of treatment administration.

Endpoints:

- Bee mortality of adult worker bees, pupae and larvae before (DAT -3 to 0) and after treatment/feeding (DAT 1 to 21), in dead bee traps
- Flight activity shortly before (DAT 0) and on the day after treatment/feeding (DAT 1)
- Condition of the colonies at study initiation (DAT -2/0) and at study termination (DAT 21) (On DAT 0 the intended colony 1C was replaced by one of the back-up colonies (old larvae stage was missing). Since the colony was assessed and replaced before treatment/feeding (also the mortality was assessed during the pre- treatment/feeding period), this operation had no impact on the study result.)

Test concentrations:

Control: 1 L untreated commercial ready-to-use sugar syrup (Apiinvert; 30% sucrose, 31% glucose, 39% fructose) per colony.

Test Item: Colonies were fed with 1.5 g flufenacet a.s./L, corresponding to 2.89 mL Flufenacet SC 508.8 in 1 L 50% (w/v) aqueous sucrose solution. Each colony in the test item group was fed with 1 L test item fortified 50% (w/v) aqueous sucrose solution.

Reference Item: 1.6 g reference item (Insegar; 25% fenoxycarb) in 1 L commercial ready-to-use sugar syrup per colony, equivalent to a nominal active substance concentration of 0.4 g fenoxycarb a.s./L.

Results and discussions

Honeybee mortality

Date	Mortality [mean daily number of dead bees[1)] per replicate ± SD]		
	Control	Treatment	Reference item
Ø DAT -2 to 0	30.2	24.9	30.8
Ø DAT 1	92.3	84.7	126.3*
Ø DAT 1 to 21	49.5	53.2	104.4**
$Q_{M(0(at))}$	3.1	3.4	4.1
$Q_{M(mean)}$	1.6	2.1	3.4

DAT = days after treatment
SD = standard deviation
QM(0(at)) = Ø mortality on the day after treatment/feeding 1 ÷ Ø pre-application mortality (per treatment group)
QM(mean) = Ø post-treatment mortality ÷ Ø pre- treatment mortality (per treatment group)
1) including adult worker bees, freshly emerged bees, pupae and larvae
* statistically significantly different when compared to the control
** statistically significantly different when compared to the pre-phase (DAT -2 to 0)

Colony conditions

Date	Mean percentage [%] of comb covered by brood stages (egg, larvae, pupae)		
	Control	Treatment	Reference item
Ø DAT -2 to 0	22.2	16.7[n.s.]	22.7[n.s]
Ø DAT 1	25.3	26.7[n.s.]	23.3[n.s]

DAT = days after treatment/feeding [n.s.] not statistically significantly different when compared to the control

Detailed brood development of observed eggs

Date	Brood termination rate [%] [n.s.]		
	Control	Treatment	Reference item
BFD0/DAT0	0.0	0.0	0.0
BFD6/DAT6	25.1	9.1	63.3
BFD10/DAT10	27.8	9.3	64.9
BFD16/DAT17	32.0	10.7	67.6
BFD21/DAT21	32.0	34.2	67.6
Brood Index [n.s.]			
BFD0/DAT0	1.0	1.0	1.0
BFD6/DAT6	2.5	2.9	1.0
BFD10/DAT10	2.9	3.6	1.4
BFD17/DAT17	2.7	3.6	1.3
BFD21/DAT21	3.4	4.5	1.6
Compensation Index [n.s.]			
BFD0/DAT0	1.0	1.0	1.0
BFD6/DAT6	2.5	2.9	1.1
BFD10/DAT10	2.9	3.6	1.8
BFD17/DAT17	3.0	3.6	2.7
BFD21/DAT21	4.0	4.5	3.5

BFD = brood fixing day
DAT = days after treatment
ns not statistically significantly different when compared to the control

Detailed brood development of observed young larvae

Date	Brood termination rate [%] [n.s.]		
	Control	Treatment	Reference item
BFD0/DAT0	0.0	0.0	0.0
BFD6/DAT6	35.6	14.9	70.2

BFD10/DAT10	38.0	17.6	72.2
BFD17/DAT17	38.0	17.6	72.2
BFD21/DAT21	38.0	50.0	72.2
Brood Index n.s.			
BFD0/DAT0	2.0	2.0	2.0
BFD6/DAT6	2.6	3.4	1.2
BFD10/DAT10	2.5	3.3	1.1
BFD17/DAT17	3.1	4.1	1.4
BFD21/DAT21	3.1	4.1	1.3
Compensation Index n.s.			
BFD0/DAT0	2.0	2.0	2.0
BFD6/DAT6	2.6	3.4	1.3
BFD10/DAT10	2.6	3.3	1.6
BFD17/DAT17	3.8	4.2	2.6
BFD21/DAT21	4.1	4.3	3.0

BFD = brood fixing day
DAT = days after treatment
ns not statistically significantly different when compared to the control

Detailed brood development of old larvae

Date	Brood termination rate [%] n.s.		
	Control	Treatment	Reference item
BFD0/DAT0	0.0	0.0	0.0
BFD6/DAT6	10.2	3.8	8.3
BFD10/DAT10	10.4	5.2	61.9*
BFD17/DAT17	10.4	5.2	61.9*
BFD21/DAT21	10.4	5.2	61.9
Brood Index n.s.			
BFD0/DAT0	3.0	3.0	3.0
BFD6/DAT6	3.6	3.5	3.7
BFD10/DAT10	3.6	3.8	1.5*
BFD17/DAT17	4.5	4.7	1.9*
BFD21/DAT21	4.4	4.7	1.8*
Compensation Index n.s.			
BFD0/DAT0	3.0	3.0	3.0
BFD6/DAT6	3.6	3.8	3.7
BFD10/DAT10	3.6	3.8	1.5*
BFD17/DAT17	4.7	4.8	3.1*
BFD21/DAT21	4.8	4.9	3.8*

BFD = brood fixing day
DAT = days after treatment
n.s. not statistically significantly different when compared to the control
* statistically significantly different when compared to the control

Conclusion

The consumption of the test item by honey bee colonies at a concentration of 1.5 g flufenacet a.s./L, corresponding to 2.89 mL Flufenacet SC 508.8 in 1 L 50% (w/v) aqueous sucrose solution, had no adverse effects on the colony conditions and survival of honeybee life stages (eggs, young larvae and old larvae), developing in brood cells within the hives. Also, the test item had no adverse effects on the survival of the exposed adult worker bees. Overall, it can be concluded according to the results of this study that Flufenacet SC 508.8 does neither adversely affect honey bee colonies nor bee brood development.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

No additional studies are submitted.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

Comments of zRMS:	The study was evaluated by the RMS in the course of the ongoing EU renewal process and the results were considered as additional information only. NOEC = 240 g a.s./ha Although the renewal process is not finalised yet, no changes regarding the conclusions of this study are expected. **The study was used in the risk assessment.**

Reference:	**KCP 10.3.1.5/01**
Title:	Flufenacet SC 508.8 G: Effects on honey bee brood (Apis mellifera L.) under semi-field conditions - Tunnel test
Report:	Taenzler, V.; 2016; 87441033; M-553011-01-1
Authority registration No:	
Guideline(s):	OECD No. 75 (2007) and OEPP/EPPO No. 170 (4)(2010)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process and considered as additional information only
Duplication (if vertebrate study)	

Materials and methods

Test item: Flufenacet SC 508.8 (Flufenacet (FOE 5043) content: 508.8 g/L, (analysed: 513.6 g/L); 42.5 % w/w; Supplier Batch ID.: EFIB001770; Sample Description: TOX10538-00; Specification No.: 102000007779; density: 1.208 g/mL (20 °C).

Test Species: Honey bees (*Apis mellifera carnica* L.); small bee colonies, maintained according to normal beekeeping practice, containing 11 combs with honey, pollen and brood. The preliminary brood check indicated healthy colonies with all brood stages present and a sufficient supply with nectar and pollen. The mean strength of the colonies per treatment group, one day before the application ranged between 6593 and 7133 adult bees per colony.

Test Design: The test was conducted under forced/confined exposure conditions (tunnel), in order to assess potential effects of Flufenacet SC 508.8 G to honey bee colonies including brood development under semi-field conditions. Tunnels (25 m length × 5.0 m width × 2.5 m height) were set up on a *ca.* 80 m² plot of *Phacelia tanacetifolia* (2 × 40 m²). Small bee colonies were introduced to the tunnels 4 days before the application. One honey bee colony was used per tunnel.

The test item, water and a reference item were applied on the whole plot of plants in two operations, with foraging bees present. The trial was carried out using four tunnels (*i.e.* replicates) for the test item treatment, the control and the reference item treatment (Insegar, 250 g/kg fenoxycarb), respectively. The confined exposure phase of the honey bees inside the treated crop was 7 days following the test item application. In the evening of day 7 (7 days of confined exposure), all bee colonies (*i.e.* the colonies from the test item, the water and the reference item group, respectively) were relocated from their respective tunnels and placed in an area with no main flowering, bee attractive crops.

After foliar (spray) application of the water (control), test item and the reference item, ontogenesis of a

defined number of honey bee eggs was observed for each group and colony. Mortality of adult bees and pupae/larvae as well as foraging activity of the adult bees was also assessed. The condition of the colonies was assessed in regular intervals until the end of the trial.
Ontogenesis of the bees from egg to adult workers was observed for a period of 22 days (*i.e.* one complete honey bee brood cycle). This was done one day before the application by taking out one or more brood combs and taking a digital picture of the brood combs. After saving the file on a computer, 200 eggs per colony were marked at this first brood area fixing day BFD0 (BFD = Brood Area Fixing Day). For each subsequent brood assessment (BFDn), again, the respective combs were taken out of the hive and another digital photo was taken in order to investigate the progress of the brood development until day 21 following the application (BFD22 following BFD0).

Test Parameters:

- Mortality of adult bees and pupae: 3 days before to 27 days after application (= end of the trial);
- Behavioural abnormalities: 3 days before to 27 days after application (= end of the trial);
- Foraging activity of the bees: 3 days before to 7 days after application;
- Condition of the colonies (food stores, brood status and colony strength): 1 day before and 5, 9, 16, 21 and 27 days after application;
- Bee brood development (eggs): 1 day before (= BFD0) and 5 (= BFD 6), 9 (= BFD 10), 16 (= BFD 17), 21 (= BFD 22) days after the application.

Application Rates:

- Control: 400 L tap water/ha
- Test Item: 240 g flufenacet a.s./ha; 467.3 mL (564.5 g) product in 400 L tap water/ha (corresponding to 1.411 g product/L)
- Reference Item: 300 g fenoxycarb a.s. (1200 g product)/ha in 400 L spray solution/ha (corresponding to nominally 3.00 g product/L)

All applied during full flowering of the crop when honey bees were actively foraging on the Phacelia-crop.

Test Conditions:
Natural field conditions. On the application day, the mean temperature was 15.9°C. However, there was a high honeybee foraging activity on the crop within the tunnels at the time of each spray application. Mean temperature during the whole experiment was between 12.0 and 30.0°C.
First precipitation (5 mm) occurred on day 1 (*ca.* 25 hours following the application of control tunnels, *ca.* 24 hours following the application of the test item tunnels and *ca.* 23 hours following the last application of the reference item tunnels). Thereafter, rain occurred on days 3 (3.0 mm), 4 (0.5 mm), 5 (24.0 mm), 6 (12.0 mm), 7 (3.0 mm), 10 (4.0 mm), 18 (3.0 mm), 19 (4.0 mm), 21 (3.0 mm), 22 (7.0 mm), 23 (0.5 mm), 26 (4.0 mm), and 27 (11.0 mm).

Dates of experimental work: June 14th to July 14th, 2015

Results and discussions
Pre-application phase (day -3 to day 0 before application):
Mortality of the pre-application phase in the control, test item and reference item group was 59.4, 41.4 and 59.9 dead bees/colony/day, respectively. This was not statistically significantly different compared to the water control (Student t-test, pairwise comparison, two-sided, $\alpha = 0.05$).

Exposure phase in the tunnels (day 0 after application to day 7):
There was no sign of an acute effect on the mortality of the bees following the test item treatment. The average control, test item and reference item group mortality of adult bees during the exposition phase (day 0 to day 7 following the application) was 53.5, 53.9 and 57.8 dead bees/colony/day, respectively. This was not statistically significantly different compared to the water control (Student t-test, pairwise

comparison, one-sided greater, α = 0.05).
Phase outside the tunnels (day 8 after application to day 27):
An overall comparison of the mean number of dead bees found in the traps after the application from day 8 to day 27 did also not show a statistical significant difference between the control and the test item treatment group (Student t-test, pairwise comparison, one-sided greater, α = 0.05).
A mean of 8.2 and 7.4 dead bees per day was found for the period from day 8 to day 27 after treatment in the control and test item group, respectively. Neither did the overall evaluation of the post-application period from day 0 to day 27 show a statistical significant difference between the control and the test item treatment (Student t-test, pairwise comparison, α = 0.05, one-sided greater). There was no impact of the reference item on the adult bee mortality.

Mortality of pupae
Pre-application phase (day -3 to day 0 before application):
Mortality of the pupae in the control, test item and reference item groups was 0.1, 0.1 and 0.4 dead pupae/colony/day, respectively. There was no statistically significant difference between the treatment groups (Welch t-test, pairwise comparison to the control, two-sided, α = 0.05).

Exposure phase in the tunnels (day 0 after application to day 7):
Mean pupae mortality during exposure phase in the control and test item groups was also very low (0.1 and 0.2 dead pupae/day/colony, respectively). Accordingly, this was not statistically significantly different to the control group (Welch t-test, pairwise comparison one-sided greater, α = 0.05). Mean pupae mortality in the reference item group was 0.7 dead pupae/day/colony. This was statistically significantly different when compared to the control group (Welch t-test, pairwise comparison one-sided greater, α = 0.05).

Phase outside the tunnels (day 8 after application to day 27):
Mean pupae mortality from day 8 to day 27 was 0.2 dead pupae/colony/day in the test item group and 0.1 dead pupae/colony/day in the control group. This difference was not statistically significant when compared to the control group (Welch t-test, pairwise comparison to the control, one-sided greater, α = 0.05). Pupae mortality in the reference item group was increased and statistically significantly different to the control group. The reference item induced pupae mortality was 36.8 dead pupae/colony/day from day 8 to day 27 and 26.5 dead pupae/colony/day from day 0 to day 27 after the day of application. In both cases, this was statistically significantly different to the control group (Welch t-test, pairwise comparison one-sided greater, α = 0.05).

Foraging Activity
Pre-application phase (day -3 to day 0 before application):
The mean foraging activities in the intended test item and reference item groups were comparable to the control group, resulting in overall daily mean values of 10.1, 12.3 and 10.8 bees/m²/day in the control, test item and reference item groups, respectively. No statistically significant differences were found between the control, the test and reference item treatment groups at the overall daily mean comparison of this period (Student t-test, pairwise comparison two-sided, α = 0.05).

Exposure phase in the tunnels (day 0 after application to day 7):
Overall, mean foraging activities from day 1 to day 7 in the test item and reference item group were comparable to the control values on these days. The overall daily mean foraging activity from day 0 to day 7 in the test item and reference item group was 7.0 and 7.2 bees/m²/day, respectively compared to 7.8 bees/m²/day the control group. This was not statistically significantly different (Student t-test, pairwise comparison one-sided smaller, α = 0.05).

Behavioural abnormalities
No test item related behavioural abnormalities occurred at any time during the whole assessment period (up to day 27). No behavioural abnormalities were observed in the control group.

Condition of the Colonies

At the beginning of the trial, all queens and all brood stages (eggs, larvae and closed brood), as well as a sufficient amount of nectar and pollen storage was found in all colonies as an indication of healthy colonies.
All queens and/or a sufficient presence of eggs were found in the test item treated colonies during all brood checks indicating that the queens were alive and healthy.
After application, no indication of a test item related effect on the condition of the colonies was observed. All test item treated colonies remained vital with increasing bee numbers and healthy brood. There was no indication of any hazard of the test item on the condition of the bee colonies.

Colony Strength
The mean number of honey bees per colony in all treatment groups was very similar one day before application and did not differ statistically (mean of 6593 to 7133 per colony). There was a strong increase of colony strength in the control and test item group over the course of the study with a maximum of 143% in the control group on day +21 and 172% in the test item group. At the end of the trial on day +27 following the application the increase in the test item group was higher (156%) compared to the data of the control group (131%). The mean number of honey bees per colony in the reference item group increased also over the course of the study and resulted in a mean colony strength of 122% on day +27 compared to the beginning of observation.

No statistically significant difference in the colony strength between the test item treated colonies and the control colonies occurred at any assessment date. The subsequent development of the colony strength among the colonies in the control and test item treatment groups followed more or less the same pattern. Overall, no adverse effects of the test item on colony strength and population development were observed throughout the study.
Considering the initial mean number of bees per treatment group before the application as 100 %, the following relative mean numbers of bees were determined:

Treatment Group	Day -1	Day +6	Day +9	Day +16	Day +21	Day +27
Control	100%	127%	119%	135%	143%	131%
Test Item	100%	127%	133%	166%	172%	156%
Reference Item	100%	114%	124%	128%	131%	122%

Development of Bee Brood
Brood Termination Rate:
Following the assessment of single cells from the egg stage to the successfully hatched worker bee, the mean termination rate at BFD (Brood Fixing Day) 22 in both, the control and test item group, was identical with 18.6%. Accordingly, this was not statistically significantly different compared to the control group (Student t-test, pairwise comparison, one-sided greater).
Treatment with the reference item Insegar (a.s.: fenoxycarb) caused a decrease of brood development of the marked eggs, resulting in a termination rate of 55.0 %. This decrease was statistically significantly different compared to the control group.

Brood Compensation Index:

The Brood Compensation Index is an indication for recovery and shows the development of the brood at each assessment. A continuous brood development was observed in the test item group as well as in the control group. The Brood Compensation Indices following the labelling of the egg stage up to day 21 after application (BFD+22) were either identical or slightly lower on one occasion in the test item group compared to the control. There was no statistically significantly difference of the test item group compared to the values estimated for the control group (Student t-test, pair-wise comparison, one-sided smaller, $\alpha = 0.05$). At the end of the assessment period the Brood Compensation Index of the test item group was comparable to the control group (4.5 *vs* 4.4) and no statistical difference was detected. The higher termination rate of the marked cells after treatment with the reference item Insegar (a.s.: fenoxycarb) is also reflected by the statistically significantly lower Brood Compensation Indices in the reference item group when compared to the control (Student t-test, pair-wise comparison, one-sided smaller, $\alpha = 0.05$).

Treatment Group	**BFD +6**	**BFD +10**	**BFD +17**	**BFD +22**
Control	2.9	3.4	3.4	4.5
Test Item	2.9 (n.s.)	3.4 (n.s.)	3.4 (n.s.)	4.4 (n.s.)
Reference Item	1.9 (*)	2.4 (n.s.)	2.5 (*)	3.3 (*)

n.s. = not statistically significant to the control, * = statistically significant to the control, Student t-test, α=0.05, pairwise; one-sided smaller.

Brood Index:

The Brood Index as an additional indicator for the bee brood development facilitates a comparison between the different treatments. Following the labelling of the egg stage, the Brood Indices of the test item group were identical with those for the control group. Therefore, no statistically significantly difference compared to the control group was detected (Student t-test, pair-wise comparison, one-sided smaller, $\alpha = 0.05$). The higher termination rate of the marked cells after treatment with the reference item Insegar (a.s.: fenoxycarb) is also reflected by the statistically significantly lower Brood Indices in the reference item group when compared to the control (Student t-test, pair-wise comparison, one-sided smaller, $\alpha = 0.05$).

Treatment Group	**BFD +6**	**BFD +10**	**BFD +17**	**BFD +22**
Control	2.9	3.3	3.3	4.1
Test Item	2.9 (n.s.)	3.3 (n.s.)	3.3 (n.s.)	4.1 (n.s.)
Reference Item	1.9 (*)	2.2 (n.s.)	1.8 (*)	2.3 (*)

n.s. = not statistically significant to the control, * = statistically significant to the control, Student t-test, α=0.05, pairwise; one-sided smaller.

Accordingly, no adverse effects of the test item on brood development were observed throughout the study, following the labelling of the egg stage up to day 21 after application (BFD+22).

Effects of Flufenacet SC 508.8 G on honey bee brood under semi-field conditions (Tunnel Test)

Parameter	Treatment group[1]		
	Control	Test Item	Reference Item Insegar [0.3 kg a.i./ha]
Mean mortality of worker bees / colony / day [%] during			
pre-application phase [2]	59.4 ± 32.6	41.4 ± 21.3 (n.s.)	59.9 ± 22.6 (n.s.)
exposure phase in the tunnels [2]	53.5 ± 28.0	53.9 ± 22.8 (n.s.)	57.8 ± 30.2 (n.s.)
phase outside the tunnels [3]	8.2 ± 6.3	7.4 ± 6.1 (n.s.)	8.3 ± 7.1 (n.s.)
overall after application	21.1 ± 25.8	20.7 ± 24.9 (n.s.)	22.4 ± 28.1 (n.s.)
Mean mortality of larvae and pupae [n] during			
pre-application phase [4]	0.1 ± 0.1	0.1 ± 0.1 (n.s.)	0.4 ± 0.3 (n.s.)
exposure phase in the tunnels [4]	0.1 ± 0.1	0.2 ± 0.3 (n.s.)	0.7 ± 0.5 (*)
phase outside the tunnels [5]	0.1 ± 0.2	0.2 ± 0.4 (n.s.)	36.8 ± 59.9 (*)
overall after application	0.1 ± 0.2	0.2 ± 0.4 (n.s.)	26.5 ± 52.9 (*)
Mean foraging activity / m² / colony / day [n] during			
pre-application phase	10.1 ± 2.6	12.3 ± 4.3 (n.s.)	10.8 ± 2.6 (n.s.)
exposure phase in the tunnels	7.8 ± 5.2	7.0 ± 5.1 (n.s.)	7.2 ± 4.3 (n.s.)
Mean brood termination rate [%] [6]	18.6	18.6 (n.s.)	55.0 (*)

1) each with four tunnels (replicate)
2) mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels
3) mean number of dead honey bees per day and colony found in dead bee traps, only
4) mean number of dead pupae/larvae per day and colony found in dead bee traps and on gauze strips in the tunnels
5) mean number of dead pupae/larvae per day and colony found in dead bee traps, only
6) at BFD 22

Statistic: Student t-test, α=0.05,Welch t-test pairwise; before application: two-sided; after application: one-sided greater (mortality, termination rate), one-sided smaller (foraging activity, colony strength).
n.s. = not statistically significant compared to the control; * = statistically significant compared to the control

Conclusion

To assess the potential effects of Flufenacet SC 508.8 G on honey bee colonies including brood development, 467.3 mL product in 400 L tap water/ha (corresponding to 1.411 g flufenacet a.s./ha), tap water for the control and a reference item were applied to a full-flowering and highly bee-attractive crop (i.e. *Phacelia tanacetifolia*) under semi-field (tunnel) conditions during bee-flight.

No adverse effects on mortality of worker bees or pupae were observed. Foraging activity, behaviour, nectar- and pollen storage as well as queen survival was not affected.

No effects on colony development, colony strength or bee brood were observed.

Based on the results of this study, it can be concluded that Flufenacet SC 508.8 G does not adversely affect honey bees and honey bee brood when applied at a rate of 467.3 mL product in 400 L tap water/ha (corresponding to 240 g flufenacet a.s./ha), during honey bees actively foraging on a bee-attractive, flowering crop.

The observed, characteristic brood effects of the reference item Insegar (a.s.: fenoxycarb) in terms of typicality, time of occurrence and extent, showed that the prevailing test conditions allowed for a profound detection of effects on immature honey bee life stages.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

No additional studies are submitted.

A 2.3.2 KCP 10.3.2. Effects on non-target arthropods other than bees

A 2.3.2.1 KCP 10.3.2.1. Standard laboratory testing for non-target arthropods

Comments of zRMS:	The study was conducted in line with the respective guideline with a minor deviation. It was noted that for the test item treatment groups there were 4 replicates with 20 protonymphs each while the guideline recommends 5 replicates with 20 protonymphs. The minimum number of replicates required by the guideline is three with 20 protonymphs, thus the total number of individuals used in the present study was still higher than the minimum. Therefore, this deviation is considered to have no impact on the outcome of the study since all the validity criteria were met: • the mean mortality in the control did not exceed 20 % (observed 14 %), • the cumulative number of eggs per female in the control (from day 7 to day 14) was ≥ 4 eggs/female (observed 6.5), • the cumulative mean mortality in the toxic reference item group was between 50 and 100 % (observed 54 %). Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment: LR_{50} = 9.6 g a.s./ha

Reference:	**KCP 10.3.2.1/01**
Title:	A laboratory dose-response study to evaluate the effects of Flufenacet SC 500 on survival reproduction of the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae)
Report:	Loose, E. D.; 2003; B110TPL; M-075227-01-1
Authority registration No:	
Guideline(s):	Blümel et al. 2000 –
Deviations:	Minor (see the commenting box above) –
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication (if vertebrate study)	

Materials and methods

Test item: Flufenacet SC 500 (active ingredient FOE 5043 (=Flufenacet), content: 511.89 g/L, TOX no.: 06061-00, Art. no.: 0005559022, Batch no.: 04402/0167(0096)).

The test compound was applied to glass and inert PTFE-mortality-units (‘coffin cells’) and glass reproduction units at five nominal rates, viz. 2.0, 4.9, 11.8, 28.8 and 70.0 g a.s./ha, using an application volume of 200 L/ha (calculations based on the measured content of active ingredient). The control was treated with deionised water. Dimethoate at a rate of 106 mg a.s./ha (0.027% of the highest recommended field rate) was used as toxic reference. Deionised water was used as solvent for all solutions.

Typhlodromus pyri (1-day old protonymphs) was exposed in groups of 20 per unit to dry residues within 1.5 hours after application. There were 5 units for the water control, 4 units for each Flufenacet SC 500 treatment and 3 units for the toxic reference.

Mortality was assessed after a 7-day exposure period. The toxic reference treatment was stopped after mortality assessments.
All surviving individuals of the deionised water control group and the Flufenacet SC 500 rates equivalent to 2.0 and 4.9 g a.s./ha were transferred to treated (on day 0) open glass arenas, because corrected mortality in these rates was ≤50%. Reproduction for these treatments was determined during 7-days in total (3 consecutive assessments at 2-3 day intervals).
During the test the temperature was between 24.9 and 25.1°C, the relative humidity was between 64.5 and 73.2 %, and the light intensity during the 16 h photoperiod was between 700 and 1130 Lux.

Results and discussions
Low control mortality and high reproductive performance in the control treatment indicated that the test animals were in good condition. Mortality in the toxic reference treatment showed that the test animals were sufficiently sensitive and that potential adverse effects of exposure to the test item residues could be detected with the set-up used in this experiment.

After 7 days of exposure to Flufenacet SC 500 at rates equivalent to 11.8, 28.8 and 70.0 g a.s./ha, survival of *Typhlodromus pyri* was statistically significantly reduced compared to the water control. Exposure to rates equivalent to 2.0 and 4.9 g a.s./ha had no significant effect on survival.
The LR_{50} was calculated as 9.6 g a.s./ha.
Reproduction of *T. pyri* on glass plates treated with Flufenacet SC 500 at rates equivalent to 2.0 and 4.9 g a.s./ha had no significant effect on reproduction.

A summary of the findings is given in the table.

Test substance	Flufenacet SC 500			
Test species	*Typhlodromus pyri*			
Exposure	7 days on glass and inert PTFE mortality units (Coffin cells) + 7 days on glass reproduction units (total period: 14 days)			
Nominal application volume	200 L/ha			
	Mortality after 7 days		Reproduction (eggs/female/7 days)	
Deionised water control	14 %		6.5	
Application rates of Flufenacet SC 500 [g a.s./ha)]	Corrected mortality after 7 days		Reproduction in eggs/female/7 days (reduction relative to control in %)	
2.0	7 %	P=0.308	5.5 (14 %)	P=0.778
4.9	-4 %	P=0.642	3.8 (41 %)	P=0.356
11.8	75 %	P<0.001*	Not assessed	
28.8	96 %	P<0.001*	Not assessed	
70.0	100 %	P<0.001*	Not assessed	
Toxic reference	54 %	P<0.001*	Not assessed	
LR_{50}	9.6 g a.s./ha (95 % Confidence limits were 7.1 and 13.1 g a.s./ha)			

* Statistically significantly different from deionised water control. Statistical analysis: mortality data with Fisher's Exact Test and reproduction data with ANOVA/Fisher's LSD tests.

Conclusion
The LR_{50} was calculated as 9.6 g a.s./ha with 95% confidence limits of 7.1 and 13.1 g a.s./ha.

A 2.3.2.2 KCP 10.3.2.2. Extended laboratory testing, aged residue studies with non-target arthropods

Comments of zRMS:	The study was conducted in line with the respective guideline with a minor deviation to the guideline and the study protocol. It was noted that during the test the relative humidity fell down to 54 % which was lower than the recommended minimum of 60 %. Also, the study protocol indicated that, during the fecundity assessments, the pots of aphid-infested plants would be maintained under a light intensity of 4000-8000 lux. The intensity actually recorded was 3000-7300 lux and in error adjustments were not made to correct the lighting levels. However, these deviations are considered to have no impact on the outcome of the study since all the validity criteria were met. Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment: LR_{50} > 1.2 L product/ha (corresponding to 600 g a.s./ha)

Reference:	**KCP 10.3.2.2/01**
Title:	An extended laboratory test to determine the effects of FOE 5043 500 SC on the parasitic wasp, Aphidius rhopalosiphi
Report:	Vinall, S.; 2001; BAY-01-12; M-137160-02-1
Authority registration No:	
Guideline(s):	ESCORT (Barrett et al., 1994) Guidance document on regulatory testing procedures for pesticides with non-target arthropods –
Deviations:	Minor (see the commenting box above) –
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication (if vertebrate study)	

Materials and methods

Test item: FOE 5043 500 SC (Article No. 0005559022; Formulation No. 04402/0161(0096); TOX No. 05554-00; content = 533.4 g/L);

The test item was diluted in deionised water (400 L/ha) and applied to pots of seedling barley at rates equivalent to 1.2, 0.775 and 0.5 L product/ha (nominally 600, 387.5 and 250 g a.s./ha, respectively). A control treatment of deionised water (400 L/ha) and a toxic reference treatment of BASF Perfekthion (nominally 400 g/L dimethoate, applied at a rate equivalent to 60 mL product/400 L water/ha) were also included in the experiment.

Once dry, the treated plants were enclosed within cylindrical, ventilated collars. Five female wasps were confined over each pot, with six replicates (30 wasps) prepared for each treatment. The behaviour of the wasps was assessed during the first 2½ h, to determine whether there was any apparent repellence from the treated plants, and wasp survival was assessed over a period of 48 h. After that, surviving female wasps (n = 15 per treatment) were removed and their fecundity was assessed by confining them individually over untreated aphid-infested barley plants for a further 24 h. The wasps were then removed, and the plants left for a further 11 days before the numbers of aphid mummies that developed was assessed. During the mortality assessment the pots were stored in a controlled environment room maintained at 19-22°C and 54-86% relative humidity. The arenas were maintained under a 16 h photoperiod of 2000-3000 lux. During the fecundity assessment the pots of seedlings and parasitoids were placed in

a controlled environment room maintained at 19-23°C, with a 16 h photoperiod of 3000-7300 lux.

Dates of experimental work: between 4 April 2001 and 18 April 2001.

Results and discussions

Test item	FOE 5043 500 SC		
Test species	*Aphidius rhopalosiphi*		
Exposure	Barley plants		
Treatment	Mortality at 48 h (%)	Mean number mummies per female	
Control	0	13.9	
Application rate (nominal)	Corrected mortality at 48 h (%)	Mean number mummies per female	Reproductive performance relative to control (%)
600 g a.s./ha	10	23.3	168
387.5 g a.s./ha	0	23.2	167
250 g a.s./ha	0	24.7	178
Toxic reference item	100	-	-
Observations	No adverse effects of the individual treatments on wasp behaviour were observed.		

For the test to be considered valid, the protocol indicated that control mortality after 48 h should not exceed 17% (5 wasps from 30) and mortality within the toxic reference treatment should not exceed 25% within the initial 2 h, but should be 50-100% at 48 h. The protocol also indicated that, for the fecundity assessments, the mean number of mummies in the control treatment should be > 5.0 per female and there should not be more than two zero values in the control treatment. All of these criteria were met.

Conclusion
Under these extended laboratory test conditions, FOE 5043 500 SC was harmless to the parasitic wasp, *A. rhopalosiphi*, when applied at rates equivalent to 1.2, 0.775 or 0.5 L product/ha (nominally 600, 387.5 and 250 g a.s./ha, respectively). That is, it did not result in > 25% corrected mortality or result in a significant reduction in the fecundity of the test insects.

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Comments of zRMS:	The study was conducted in line with the respective guideline with minor deviations. It was noted that during the mortality phase of the test the relative humidity fell down to 58 % which was slightly lower than the recommended minimum of 60 %. Also, for the test item treatment groups there were 6 replicates with 10 protonymphs each while the guideline recommends 5 replicates with 20 protonymphs. The minimum number of replicates required by the guideline is three with 20 protonymphs, thus the total number of individuals used in the present study was equivalent to that requirement. However, these deviations are considered to have no impact on the outcome of the study since all the validity criteria were met: • the mean mortality in the control did not exceed 20 % (observed 9 %), • the cumulative number of eggs per female in the control (from day 7 to day 14) was ≥ 4 eggs/female (observed 6.93), • the cumulative mean mortality in the toxic reference item group was between 50 and 100 % (observed 76 %). Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment: LR_{50} = 51.5 g a.s./ha

Reference:	**KCP 10.3.2.2/02**
Title:	An extended laboratory dose-response study to evaluate the effects of flufenacet SC 500 on survival and reproduction of the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on zea mays leaves
Report:	Wientjes, J. C.; 2001; B076TPE; M-074126-01-1
Authority registration No:	
Guideline(s):	Bakker et al. (1992), Blümel et al. 2000 –
Deviations:	Minor (see the commenting box above) –
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication (if vertebrate study)	

Materials and methods

The herbicide (active ingredient Flufenacet, content: 533.4 g/L, TOX no.: 05554-00, Art. No.: 0005559022, Formulation no. 04402/0161(0096)) was applied to the upper side of detached *Zea Mays* leaves at five nominal rates, viz. 10.0, 21.8, 47.4, 103.3 and 225.0 g a.s./ha, at a spray application volume of approximately 200 L/ha. After drying of the residues, leaves were installed in Munger cells (inert glass and Plexi glass™ material). The control was treated with deionised water. Dimethoate at a rate of 1920 mg as/ha (0.48 % of the highest recommended field rate) was used as toxic reference.
Typhlodromus pyri Scheuten (1-day old protonymphs) was confined to the test item residues in Munger cells in 6 groups (replicates) of 10 individuals per treatment, except in the deionised water control where 10 groups of 10 animals were used. Mortality was assessed after a 7-day exposure period. All surviving individuals of the deionised water control group and the test item rates equivalent to 10.0, 21.8, and 47.4 g a.s./ha were transferred to untreated open glass arenas on the day of the mortality assessment. Reproduction for these treatments was determined during 7 days in total (3 consecutive assessments at 2-3 day intervals). During the test the temperature was between 24.6 and 25.2°C, the relative humidity was between 58 and 71.4 %, and under the 16 h photoperiod of 100-2000 Lux.

Dates of work: 16 May 2001 – 30 May 2001

Results and discussions

Test substance	Flufenacet SC 500			
Test species	*Typhlodromus pyri*			
Exposure	Detached *Zea Mays* leaves (Munger cell)			
Nominal application volume	200 L/ha			
	Mortality after 7 days		Reproduction (eggs/female/7 days)	
Deionised water control	9 %		6.93	
Application rates of Flufenacet SC 500	Corrected mortality after 7-days		Reproduction relative to the control after 7-days	
10.0 g as/ha	- 2 %	P=0.763	132 %	P=0.027*
21.8 g as/ha	5 %	P=0.422	122 %	P=0.088
47.4 g as/ha	56 %	P<0.001*	121 %	P=0.211
103.3 g as/ha	85 %	P<0.001*	Not assessed	
225.0 g as/ha	93 %	P<0.001*	Not assessed	
Toxic reference	76 %	-	Not assessed	

LR_{50}	51.5 g as/ha (95 % Confidence limits were 36.1 and 73.5 g as/ha)

* Statistically significantly different from deionised water control. Statistical analysis: mortality data with Fisher's Exact Test and reproduction data with ANOVA/Fisher's LSD tests.

Conclusion

The LR_{50} of the test item was calculated as 51.5 g a.s./ha with 95% confidence limits of 36.1 and 73.5 g a.s./ha.

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Reference:	**KCP 10.3.2.2/03**
Title:	Dose response toxicity (LR50) of flufenacet & terbuthylazin SC 200 + 333 to the predatory mite Typhlodromus pyri (Scheuten) under Extended laboratory conditions
Report:	Roehlig, U.; 2005; 05-10-48-086; M-255645-01-1
Authority registration No:	
Guideline(s):	IOBC (Blümel et al. 2000), modified
Deviations:	modified for the extended laboratory test (exposure on natural substrate) in such a way that maize leaves were used instead of glass plates
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study)	

Materials and methods

The test item Flufenacet & Terbuthylazine SC 533 (AE F133402 09 SC47 A103, analysed purity: 30.3% w/w Terbuthylazine (AE C503787), 17.4% w/w Flufenacet (AE F133402), specification: Development No.: 0365923, Batch No.: EFIM000344, TOX No.: 07152-00, density: 1.163 g/cm^3) was tested under extended laboratory conditions after exposure of protonymphs of the predatory mite *Typhlodromus pyri* (SCHEUTEN) to spray residues with rates of 160 – 333 – 693 – 1442 and 3000 mL product/ha in 200 L deionised water/ha applied on maize leaf discs. The control was treated with deionised water (200 L/ha). Dimethoate EC 400 (15 mL product/ha in 200 L/ha of water) was used as a toxic reference treatment.

Protonymphs of *T. pyri* were exposed in 5 replicates of 20 mites (per treatment group) to the spray residues of the test item, reference item and control, respectively. During the assessments the predatory mites were fed with pollen (*Pinus nigra* and *Betula pendula*). The number of surviving, dead and escaped predatory mites and the number of eggs laid per viable female per evaluation period as well as behavioural impacts were recorded over a period of 14 days. From these data the endpoints mortality and effect on reproduction were calculated.
The dose-response relationship for mortality (LR_{50}) was determined.

All validity criteria according to BLÜMEL *et al.* (2000) for conducting the laboratory test with *Typhlodromus pyri* and adapted to the extended laboratory test were met.

Deviations:

deviations from the guideline:
modified for the extended laboratory test (exposure on natural substrate) in such a way that maize leaves were used instead of glass plates
deviations from the study plan:
agreed with the sponsor, a reproduction test was performed in the 693 mL product/ha test item treatment group, although the corrected mortality was higher than 50 %.

Results and discussions

Summary of the toxicity of Flufenacet & Terbuthylazine SC 533 to *Typhlodromus pyri*

Test item	Flufenacet & Terbuthylazine SC 533			
Test object	*Typhlodromus pyri* (SCHEUTEN)			
Exposure	dried spray deposits on maize leaf discs			
Treatment	Mortality after 7 days [%]	Reproduction		
		Mean number of eggs/female	Relative to control [%]	Reduction relative to control [%]
Control	4	9.64	-	
Application rate [mL product/ha]	corrected mortality [%]			
160	2.1	8.84	91.7	8.3
333	6.3	8.79	91.2	8.8
693	57.3*	11.32	117.4	0 (+ 17.4)
1442	89.6*	n.a.	n.a.	n.a.
3000	97.9*	n.a.	n.a.	n.a.
LR_{50}/ER_{50} [CL 95 %]	**619 mL product/ha** [lower CL: 554 mL product/ha upper CL: 690 mL product/ha]	-	-	-
Reference item Dimethoate EC 400 15 mL product/ha	100	-	-	-

* statistically significant at $p \leq 0.05$
n.a. not assessed, because > 50 % corrected mortality
CL: confidence limit

Observations:
The results of the control group indicated that the test organisms were in a good condition (mortality: 4 %, reproduction: 9.64 eggs/female).
The results of the toxic standard group indicated that the test system was sensitive to harmful substances (corrected mortality: 100 %).

Statistical analysis (FISHER'S Exact Binomial Test, 1-sided, $p \leq 0.05$) revealed a significant difference concerning the mortality after 7 days between the control and the 693, 1442 and 3000 mL product/ha test item treatment groups.

There was no statistically significant effect of the test item on reproduction at the tested rates (STUDENT-t-test for homogeneous variances with BONFERRONI adjustment, 1-sided, $p \leq 0.05$) compared to the control group.

Conclusion
The LR_{50} (median lethal rate) of Flufenacet & Terbuthylazine SC 533 to *Typhlodromus pyri* was calculated to be 619 mL product/ha, with 95 % confidence limits ranging from 554 mL to 690 mL product/ha.

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Reference:	**KCP 10.3.2.2/04**
Title:	Dose-response toxicity (LR50) of Flufenacet & Terbuthylazine SC 200 + 333 to the parasitic wasp Aphidius rhopalosiphi (DESTEFANI-PEREZ) under extended laboratory conditions
Report:	Roehlig, U.; 2005; 051048085; M-258796-01-1
Authority registration No:	

Guideline(s):	IOBC (MEAD-BRIGGS et al. 2000), IOBC proposal (MEAD-BRIGGS & LONGLEY 1997)
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study)	

Materials and methods

The test item Flufenacet & Terbuthylazine SC 533 (AE F133402 09 SC47 A103, analysed purity: 30.3% w/w Terbuthylazine (AE C503787), 17.4% w/w Flufenacet (AE F133402), specification: Development No.: 0365923, Batch No.: EFIM000344, TOX No.: 07152-00, density: 1.163 g/cm^3) was tested under extended laboratory conditions after residual contact exposure of adults of the parasitic wasp *Aphidius rhopalosiphi* (DESTEFANI-PEREZ) to spray residues on potted barley plants. The test item was applied at rates of 187.5 – 375 – 750 – 1500 and 3000 mL product/ha in 200 L water/ha. The control was treated with deionised water (200 L/ha) in the same way as the test item treatment. Dimethoate EC 400 (10 mL product/ha in 200 L/ha of water) was used as a toxic reference group.

Adults of *Aphidius rhopalosiphi* were exposed in 4 replicates of 7 female wasps (per treatment group) to the residues of the test item, reference item (only 1 replicate) and control, respectively. During the mortality test, the wasps were fed with aqueous fructose solution (25% w/v). Aphids (*Rhopalosiphum padi*) were used as host organisms. The number of surviving wasps, behaviour and position and the number of parasitized aphids (mummies) were recorded over a period of 14 days. From these data the endpoints mortality and fecundity were calculated.

All validity criteria according to MEAD BRIGGS *et al.* (2000) for conducting the laboratory test with *Aphidius rhopalosiphi* and adapted to the extended laboratory test were met.

Results and discussions

Summary of the toxicity of Flufenacet & Terbuthylazine SC 533 to *Aphidius rhopalosiphi*

Test item	Flufenacet & Terbuthylazine SC 533			
Test object	*Aphidius rhopalosiphi* (DESTEFANI-PEREZ)			
Exposure	Dried spray deposits on potted barley plants			
Treatment	Mortality after 48 hours [%]	Reproduction		
		Mean number of mummies/female	Relative to control [%]	Reduction relative to control [%]
Control	0	13.4	–	
Application rate [mL product/ha]	corrected mortality [%]			
187.5	0	12.5	93.3	6.7
375	0	13.3	99.3	0.7
750	0	13.6	101.5	0 (+1.5)
1500	3.6	12.5	93.3	6.7
3000	35.7*	11.5	85.8	14.2
LR_{50}	**> 3000 mL product/ha**			
Reference item Dimethoate EC 400 10 mL product/ha	100	–	–	–

* statistically significant at $p \leq 0.05$

Observations:

The results of the control group indicated that the test organisms were in a good condition (mortality: 0%, reproduction: 13.4 mummies per female).

The results of the toxic standard group indicated that the test system was sensitive to harmful substances (corrected mortality: 100%).

Statistical analysis (FISHER'S Exact Binomial Test with BONFERRONI Correction, 1-sided, $p \leq 0.05$) revealed a significant difference concerning the mortality after 48 hours between the control and the 3000 mL product/ha test item treatment group.

No or only low effects on mortality were observed in all test item treatment groups. Therefore, a calculation of the LR_{50} (median lethal rate) was not possible. The LR_{50} is empirically estimated to exceed the highest tested application rate, i.e. 3000 mL product/ha.

The behaviour assessments showed statistically significant differences (DUNNETT t-test, WILLIAMS t-test, $p \leq 0.05$) only in the 375 and 3000 mL product/ha test item treatment groups 30 minutes after exposure and no statistically significant differences in all test item treatment groups 2 hours after exposure compared to the control group.

There was no statistically significant effect (STUDENT t-test for homogeneous variances with BONFERRONI adjustment, 2-sided, $p \leq 0.05$) of Flufenacet & Terbuthylazine SC 533 on reproduction (mean number of mummies/female) at all test item treatment groups compared to the control group.

Conclusion
The LR_{50} (median lethal rate) of Flufenacet & Terbuthylazine SC 533 to *Aphidius rhopalosiphi* was estimated to be > 3000 mL product/ha, the highest application rate tested.

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Reference:	**KCP 10.3.2.2/05**
Title:	Effects of flufenacet + terbuthylazine SC 533 (200 + 333 g/L) on the lacewing Chrysoperla carnea, extended laboratory study – Dose response test
Report:	Moll, M.; 2013; 76541047; M-444858-01-1
Authority registration No:	
Guideline(s):	Vogt et al. 2000; this guideline was modified for exposure of Chrysoperla carnea on natural substrate.
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study)	

Objective:
The purpose of this study was to produce a concentration-response curve for mortality effects. From these the LR50 value was estimated.
Chrysoperla carnea is recommended as standard species for non-target arthropod regulatory testing for plant protection products (Candolfi *et al.* 2001).
The effect of Flufenacet + Terbuthylazine SC 533 (200 + 333 g/L) on the larvae of the lacewing *Chrysoperla carnea* was determined in the laboratory by contacting substance treated leaf surfaces (exposure period) compared to a water treated control and a reference item. Additionally, an assessment for sublethal effects on reproduction of the survivors (reproduction) was made

Materials and methods

Flufenacet + Terbuthylazine SC 533 (200 + 333 g/L): Sample Description: TOX09803-00, Batch ID: EV56003609, content of a.s.: 16.5% w/w (192.2 g/L) flufenacet (FOE 5043) and 29.3% w/w (341.3 g/L) terbuthylazine (AE C503787); density: 1.165 g/mL .

Under extended laboratory conditions 2 – 3 day old larvae of the lacewing *Chrysoperla carnea* were exposed to dried spray deposits of 250, 445, 791, 1406 and 2500 mL product/ha (diluted in 200 L deionised water/ha) on treated vine leaves (40 replicates, each containing 1 larva per treatment group). Deionised water was used as a control treatment and dimethoate (Perfekthion: 140 mL product/ha diluted in 200 L deionised water/ha) as a reference treatment. Exposure time lasted until pupae were transferred to the reproduction units for development of adults. Mortality checks were carried out regularly until eclosion of adult lacewings (up to 20 days after test start). In addition, for the control and the test item treatment groups where the corrected mortality was < 50%, the reproduction performance, *i.e.* egg deposition and larval hatching rate, was determined (2 checks/week, 24 hours period each check).

The experiment was performed in a controlled environment room at a temperature range of 24 – 25 °C and a relative humidity range of 60 – 86%. The light / dark cycle was 16:8 h. The light intensity range was 1010 - 1830 Lux.

Results and discussions

Flufenacet + Terbuthylazine SC 533 (200 + 333 g/L)					
		Mortality [%]		Reproduction	
Treatment	mL product/ha	Mortality[2] [%]	Mortality corr.[3] [%]	Eggs per female and day	Fertility [hatching rate in %]
Control	0	0.0	-	30.9	84.3
Test item	250	2.5 n.s.	2.5	37.8	89.3
Test item	445	0.0 n.s.	0.0	23.9	86.8
Test item	791	2.5 n.s.	2.5	41.1	88.6
Test item	1406	0.0 n.s.	0.0	41.8	90.8
Test item	2500	0.0 n.s.	0.0	42.7	89.6
Reference Item	140	97.5*	97.5	-	-
LR_{50}: > 2500 mL product/ha					

1) Application rate in 200 L deionised water/ha

2) Pre-imaginal mortality after exposure to spray residues on leaf surfaces (Fisher's Exact Test, α = 0.05: n.s. = not significant, * = significant)

3) Corrected pre-imaginal mortality according to Abbott and improvements by Schneider-Orelli

Observations:

The results can be considered as valid, as all validity criteria of the test were met. Mortality in the water control was 0% (≤ 20% required), corrected mortality of the reference item was 97.5% (> 50% required). The mean number of eggs per female and day for the control during the test period was 30.9 (≥ 15 required) and hatching rate (= fertility) of the eggs was 84.3% (≥ 70 required).

Conclusion

In this extended laboratory study, the effects of Flufenacet + Terbuthylazine SC 533 (200 + 333 g/L) residues to larvae of the lacewing *Chrysoperla carnea* were determined at 250, 445, 791, 1406 and 2500 mL product/ha. The application was done onto vine leaves (*Vitis vinifera*).

The corrected mortality for all test item rates was below 3%.

The LR50 is estimated to be greater than 2500 mL product/ha in 200 L water/ha.

The reproductive capacity of *C. carnea* was tested at all test item rates. Reproduction was > 15 eggs per female per day and the mean hatching rate was > 70% at all tested test item rates. This indicates that there was no negative effect of the test item on reproductive performance of *C. carnea* up to and including 2500 mL product/ha.

The figures obtained fulfil the validity criteria of the laboratory method for the exposure on glass plates.

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Reference:	**KCP 10.3.2.2/06**
Title:	Effects of flufenacet + terbuthylazine SC 533 (200 + 333 g/L) on the reproduction of rove beetles Aleochara bilineata – Extended laboratory study – Dose response test
Report:	Schmitzer, S.; 2013; 76542071; M-449144-01-1
Authority registration No:	
Guideline(s):	Grimm et al. 2000
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study)	

Objective

The aim of this study was to estimate the reproduction efficiency of *Aleochara bilineata* under the impact of residues of Flufenacet + Terbuthylazine SC 533 (200 + 333 g/L) on a worst case natural soil (LUFA 2.1) in an extended laboratory experiment, compared to water treated control and a reference item group.

Each treatment group included 4 replicates with 10 female and 10 male beetles, respectively. The study was carried out under extended laboratory conditions.

The larvae hatched from the eggs (laid in the soil by the female beetles) parasitized the fly pupae. To assess the reproductive efficiency the number of beetles emerging from the successfully parasitized fly pupae were counted.

Materials and methods

Flufenacet + Terbuthylazine SC 533 (200 + 333 g/L): Batch ID: EV56003609, Sample Description: TOX09803-00, Material No.: 06029530, Specification No.: 102000014364–02, content of a.s.: 16.5% w/w (192.2 g/L) flufenacet (FOE 5043) and 29.3% w/w (341.3 g/L) terbuthylazine (AE C503787); density: 1.165 g/mL (20 °C).

3 to 6 days old staphylinid beetles (*Aleochara bilineata*) were used for the test.

The test item at 5 concentrations, control and reference item were sprayed via laboratory spray applicator on the soil surface at a water amount of 400 L water/ha. Test rates of Flufenacet + Terbuthylazine SC 533 (200 + 333 g/L) were: 250, 445, 791, 1406 and 2500 mL product/ha in 400 L water/ha. Exposure of the beetles was reached via treated natural soil LUFA 2.1. The results were compared to a deionised water treated control and a reference item group (Perfekthion EC [400 g/L dimethoate], at a rate of 4.4 L/ha in 400 L deionised water/ha). The beetles were introduced into the test units immediately after treatment. Each replicate contained 10 female and 10 male beetles and 4 replicates per treatment. The beetles were exposed to control, test and reference items for 28 days. On day 7, 14, and 21 approx. 500 pupae of *Delia antiqua* were buried into the soil of each replicate to be parasitized by the larvae of the beetles. On day 28 the adults were separated from the soil and the soil with the pupae was allowed to dry for seven days. On day 35 the pupae were washed out of the natural soil and transferred into an emergence container.

The emergence of the F1 generation of beetles was observed from day 37 – 79 and the effect on reproduction of *Aleochara bilineata* was assessed.

The experiment was performed in a controlled environment room at a temperature range of 18.0 – 22.0 °C and a relative humidity range of 60 – 88%. The light / dark cycle was 16:8 h with a light intensity range of 490 – 1190 Lux.

Results and discussions

In the control group the average number of hatched beetles of the F1-generation per replicate was 968

(> 400 required). The reduction of reproductive capacity of the reference item group relative to control was 99.8% (≥ 50% required). Therefore, the results of this study can be considered as valid.

Test item		Flufenacet + Terbuthylazine SC 533 (200 + 333 g/L)	
Test organism		*Aleochara bilineata*	
Exposure on		Dried spray deposits on sandy soil (LUFA 2.1)	
		Reproductive capacity	
Treatment	Rate[1] [mL prod./ha]	Reproduction efficiency [mean number of emerged beetles±Standard deviation]	Effect on reproduction[2] [%]
Control	-	968 ± 69	-
Test item	250	880 ± 21 (n.s.)	9.1
Test item	445	925 ± 63 (n.s.)	4.4
Test item	791	950 ± 37 (n.s.)	1.9
Test item	1406	873 ± 83 (n.s.)	9.7
Test item	2500	831 ± 86 (n.s.)	14.1
Reference item	4400	2 ± 1 (*)	99.8

[1] Application rate in 400 L water/ha
[2] Effect on reproduction according to the following formula: (1-Rt/Rc)*100 % calculated on the exact raw data (positive values represent a decreased reproduction compared to the control)
* = statistically significantly difference compared to the control; n.s. = not statistically significantly difference compared to the control; Test Item: Dunnett's multiple t-test; Reference Item: Student pairwise t-test, one-sided smaller, α = 0.05

Conclusion
In this extended laboratory study, the effects of Flufenacet + Terbuthylazine SC 533 (200 + 333 g/L) on the reproduction capacity of the rove beetle *Aleochara bilineata* at rates of 250, 445, 791, 1406 and 2500 mL product/ha in 400 L water/ha was determined.
The reduction of reproduction capacity of the rove beetle *Aleochara bilineata* exposed to Flufenacet + Terbuthylazine SC 533 (200 + 333 g/L) at all test item rates was below 15%.

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Comments of zRMS:	The study was conducted in line with the respective guideline with a minor deviation. It was noted for the test item treatment groups there were 10 replicates with 10 protonymphs each while the guideline recommends 5 replicates with 20 protonymphs. However, the total number of individuals used in the study was equivalent to the required number. Therefore, this deviation is considered to have no impact on the outcome of the study since all the validity criteria were met. All the validity criteria were met and the study is considered acceptable. LR_{50} was not determined in the study. Therefore, the results of the study will be used as supportive information.

Reference:	**KCP 10.3.2.2/07**
Title:	Extended laboratory study to evaluate the effects of Flufenacet SC 500 on the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on corn plants -aged residue
Report:	Loose, E. D.; 2002; B108TPE; M-053185-01-1
Authority registration No:	
Guideline(s):	Blümel et al. 2000 –
Deviations:	Minor (see the commenting box above) –
GLP/GEP:	yes

Acceptability:	Acceptable as supportive information
Duplication (if vertebrate study)	

Materials and methods
Test item: Flufenacet SC 500 (active ingredient FOE 5043 (=Flufenacet), content: 511.89 g/L, TOX no.: 06061-00, Art. no.: 0005559022, Batch no.: 04402/0167(0096)).
The test compound was applied once at a rate of 1.2 L product/ha, which is equivalent to 614 g a.s./ha referring to the analysed content of active ingredient, using an application volume of 300 L/ha on potted corn plants. After drying of the residues and 7, 14 and 21 days after the last application leaves were installed in Munger cells (inert glass and Plexi glass™ material). The deionised water control, and a toxic field reference, dimethoate applied at the highest recommended field rate (1L product/ha), used to facilitate validation of the application method, were applied in the same way as the test item treatment. A toxic laboratory standard, dimethoate applied at 4.8 mL product/ha using an application rate of 200 L/ha, was applied to leaf cuts of corn each time a bioassay was initiated to validate the bioassay sensitivity.
Typhlodromus pyri Scheuten (1-day old protonymphs) was confined to the test substance residues in Munger cells, in 10 groups (replicates) of 10 individuals per treatment. Mortality was assessed after a 7-day exposure period. If corrected mortality in the test item was ≤50%, all surviving individuals of the deionised water control group and the test item group were transferred to untreated open glass arenas on the day of the mortality assessment. Reproduction for these treatments was determined during 7 days in total (3 consecutive assessments at 2-3 day intervals). Nominal settings in the walk-in climate room during mortality phase and a climate cabinet during reproduction phase, were 25 ± 2°C, 60 - 90% RH, 16 h light at 100 - 2000 lux - 8h dark. There were four exposure phase bioassays and two reproduction phase bioassays carried out.

Dates of work (biological part): 8 May 2002 – 12 June 2002

Results and discussions
Overall control mortality and reproduction in the control treatment indicated that test animals were in good condition. The toxic laboratory standard showed that test animals were sufficiently sensitive and that potential adverse effects of exposure to test item residues could be detected with the set-up used in this experiment. The toxic field reference showed that the application method used was valid.
Flufenacet SC 500, applied to *Zea mays* at a nominal rate of 1.2 L product/ha, has an adverse effect on survival of the predacious mite *Typhlodromus pyri* when exposed to the residues immediately after application and 7 days later. No effects on mortality or reproduction were found when exposed to the residue 14 and 21 days after application.

A summary of findings is given in the following tables.

Summary of findings: mortality of the 4 bioassays after 7 days of exposure

Bioassay initiated after:	Mortality mean	Mortality standard deviation	Mortality Abbott's corrected	P-value*	escape rate	juveniles** on day 7	no. of units
Bioassay initiated on the day of application							
Deionised water control	22%	10%	-	-	13%	3%	9
Toxic field reference	100%	0%	**100%**	P<0.001	29%	-	10
Toxic laboratory standard	67%	33%	**58%**	P<0.001	36%	3%	10
Flufenacet 500 SC							
1.2 l product/ha	89%	10%	**86%**	P<0.001	30%	9%	10
Bioassay initiated 7 days after application							
Deionised water control	19%	20%	-	-	14%	1%	10
Toxic laboratory standard	80%	20%	**75%**	P<0.001	49%	44%	9
Flufenacet 500 SC							
1.2 l product/ha	62%	31%	**54%**	P<0.001	24%	0%	8
Bioassay initiated 14 days after application							
Deionised water control	19%	19%	-	-	11%	4%	7
Toxic laboratory standard	92%	12%	**90%**	P<0.001	40%	0%	10
Flufenacet 500 SC							
1.2 l product/ha	25%	12%	**8%**	P=0.432	19%	2%	8
Bioassay initiated 21 days after application							
Deionised water control	20%	13%	-	-	20%	0%	6
Toxic laboratory standard	100%	0%	**100%**	P<0.001	33%	-	10
Flufenacet 500 SC							
1.2 l product/ha	21%	21%	**0%**	P>0.999	16%	2%	7

*statistically different from water control performance Statistical analysis: Fisher's Exact Test
** (from surviving individuals)

Summary of findings: reproduction

Validity criteria

Table 3.1 Mean number of eggs per female per day (over 2- or 3 day observation periods)

Bioassay:	daily egg rates 1st period	2nd period	3rd period	total	reproduction relative to the control	P-value
Bioassay initiated 14 days after application						
Deionised water control	0.54	1.03	1.31	6.80	-	-
Flufenacet 500 SC						
1.2 l product/ha	0.46	1.19	1.29	7.08	**104%**	P=0.563[1]
Bioassay initiated 21 days after application						
Deionised water control	0.51	1.09	1.27	6.83	-	-
Flufenacet 500 SC						
1.2 l product/ha	0.42	1.00	1.34	6.52	**96%**	P=0.633[2]

Statistical analysis: [1]Mann-Whitney U test; [2]ANOVA

Control mortality and mortality caused by the toxic laboratory standard were in agreement with the validity criteria. However, there was one exception; control mortality in the first assay was 22%, 2% over the threshold. However, the results of the subsequent assays make the first assay redundant, the test as a whole is considered valid. See table below for details.

	Criterion	Finding	Validity
Mortality deionised water control bioassay 1	≤ 20%	22%	valid*
Mortality deionised water control bioassay 2	≤ 20%	19%	valid
Mortality deionised water control bioassay 3	≤ 20%	19%	valid
Mortality deionised water control bioassay 4	≤ 20%	20%	valid
Corrected mortality toxic field reference bioassay 1	50 – 100%	100%	valid
Corrected mortality toxic laboratory standard bioassay 1	50 – 100%	58%	valid
Corrected mortality toxic laboratory standard bioassay 2	50 – 100%	78%	valid
Corrected mortality toxic laboratory standard bioassay 3	50 – 100%	90%	valid
Corrected mortality toxic laboratory standard bioassay 4	50 – 100%	100%	valid
Mean reproduction deionised water control bioassay 3	≥4 / 7 days	6.80 / 7 days	valid
Mean reproduction deionised water control bioassay 4	≥4 / 7 days	6.83 / 7 days	valid

*In Protocol deviation 7 (see Appendix I) is described why deviation of the validity criterion does not affect the integrity of the study.

Conclusion
Overall control mortality and reproduction in the control treatment indicated that test animals were in good condition. The toxic laboratory standard showed that test animals were sufficiently sensitive and that potential adverse effects of exposure to test item residues could be detected with the set-up used in this experiment. The toxic field reference showed that the application method used was valid.

Flufenacet SC 500, applied to *Zea mays* at a nominal rate of 1.2 l product/ha (which is equivalent to 614 g a.s./ha) with an application volume of 300 l/ha, has an adverse effect on survival of the predacious mite *Typhlodromus pyri* when exposed to the residue immediately after and 7 days after application. No effects on mortality or reproduction were found when exposed to the residue 14 and 21 days after application.

Comments of zRMS:	The study was conducted in line with the respective guideline with no deviation. All the validity criteria were met and the study is considered acceptable. Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment: LR_{50} > 600 g a.s./ha

Reference:	**KCP 10.3.2.2/08**
Title:	Toxicity to the green lacewing Chrysoperla carnea STEPH. (Neuroptera: Chrysopidae) using an extended laboratory test on bean; flufenacet SC 508.8 (508.8 g/L)
Report:	Roehlig, U.; 2022; 22 48 NCE 0002; M-814876-01-1
Authority registration No:	
Guideline(s):	US EPA OCSPP 850.SUPP VOGT ET AL. (2000) (with exception) CANDOLFI ET AL. (2001)
Deviations:	None
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication (if vertebrate study):	

Materials and methods
The test item Flufenacet SC 508.8 G (508.8 g/L) [analysed active substance: flufenacet 511.8 g/L, 42.4 % w/w, specification no.: 102000007779; supplier batch no.: 2020-010174; study ID of characterisation study: TOX21819-00.

Flufenacet SC 508.8 G was tested under extended laboratory conditions after contact exposure of larvae of the green lacewing *Chrysoperla carnea* to dried spray residues. Flufenacet SC 508.8 G was applied with rates of 60 – 107 – 190 – 337 – 600 g a.s./ha (equivalent to 117.2 – 209.1 – 371.2 – 658.5 – 1172.3 mL product/ha, based on the analysed active ingredient) in 200 L deionised water/ha on bean leaves (*Phaseolus vulgaris*) using a calibrated laboratory track sprayer (mean measured application rate: 202 L/ha). The control was treated with deionised water (200 L/ha). Dimethoate EC 400 (40 mL product/ha, nominally equivalent to 16 g a.s./ha, in 200 L deionised water/ha) was used as a reference item.
Larvae of *Chrysoperla carnea* (2-3 days old at study start, therefore only larvae hatched from eggs that were laid within 24 hours were used in the test) were exposed in 40 replicates per treatment group and one larva per replicate to the residues of the test item, reference item and control treatments, respectively. During the assessments the larvae were fed with UV-sterilized eggs of *Sitotroga cerealella*. The number of dead larvae, pupae and hatched adults were recorded over a period of 20 days. From these data the endpoint mortality was calculated.

Effects on reproduction were investigated for the control and all test item rates. The reproduction assessment of the surviving hatched adults started one week after the first eggs could be observed. Artificial diet was used as food for the adults. The number of eggs laid, and larvae hatched as well as the number of living females were counted twice a week. From these data the reproductive capacity (average number of eggs per female per day and the hatching rate) was calculated.

Climatic test conditions: Temperature: 23-25°C, relative humidity: 71-81%, light-dark-cycle: 16 hours light, 8 hours dark, 1120 lux.

Statisticals: ToxRat Professional 3.3.0 (Ratte, 2018), Chi2 2 × 2 Table Test with ($\alpha = 0.05$) with Bonferroni Correction ($\alpha = 0.05$) for mortality

Dates of work (biological part): 10 March 2022 – 12 April 2022

Results and discussions:

Summary of findings: mortality and reproduction

Test item	Flufenacet SC 508.8 (508.8 g/L)			
Test organism	*Chrysoperla carnea* STEPH.			
Exposure	Dried spray deposits on detached bean leaves			
Treatment	Mortality	Corrected Mortality[2]	Reproduction	
			Fecundity	Fertility
	[%]	[%]	Average number of eggs/female/day (number)	Hatching rate [%]
Control	5.0	-	19.0	74.1
Product application rate[1] [g a.s./ha]				
60	5.0 (n.s.)	0	19.7	74.4
107	2.5 (n.s.)	-2.6	19.1	74.1
190	2.5 (n.s.)	-2.6	19.2	74.2
337	5.0 (n.s.)	0	19.5	74.1
600	2.5 (n.s.)	-2.6	19.0	74.3
Reference item dimethoate EC 400 40 mL product/ha	65.0	63.2	n.d.	n.d.

[1] Application rate in 200 L water/ha
[2] Corrected mortality according to Abbott (1925)
n.s. = not statistically different compared to the control, n.d. = not determined

The LR_{50} was estimated to be > 600 g a.s./ha.

In an extended laboratory study with Flufenacet SC 508.8 G (508.8 g/L) no corrected mortality was found at rates up to 600 g a.s./ha. No statistically significant effects on mortality were determined at all test item treatment rates of up to and including 600 g a.s./ha, compared to the control by using the Chi2 2 × 2 Table Test with BONFERRONI Correction ($\alpha = 0.05$). There were no adverse effects of the test item on the reproductive performance at all tested rates up to and including 600 g a.s./ha. The reproductive output was above the lower limit given as validity criterion regarding the average number of fertile eggs per viable female per day ≥ 15 and above the validity criterion for the mean hatching rate of ≥ 70 % in the control group according to the historical database of the ring testing group (VOGT ET AL. 2000). The results of the control group indicated that the test organisms were in a good condition (mortality: 5.0 %, reproduction: 19.0 eggs per viable female per day, hatching rate: 74.1 %). The results of the reference item group indicated that the test system was sensitive to harmful substances (corrected mortality: 63.2 %). Concerning mortality and the mean number of eggs/female/day and the hatching rate in the control group as well as the susceptibility of the test organisms to the reference item, the study is proved to be valid.

Validity of the study:

Validity criteria of the study according to VOGT ET AL. (2000)

Validity criteria	Recommended by the guideline	Obtained in this study
Average number of fertile eggs per viable female per day in the control	≥ 15	19.0
Mean hatching rate in the control (%)	≥ 70	74.1

Conclusion

The LR_{50} was estimated to be > 600 g a.s./ha. The NOER (no observed effect rate) for mortality was ≥ 600 g a.s./ha. The reproductive performance was not affected up to and including the test item rate of 600 g a.s./ha. All validity criteria according to VOGT ET AL. (2000) for conducting the laboratory test with *Chrysoperla carnea* were met.

Comments of zRMS:	The study was conducted in line with the respective guideline with no deviation. All the validity criteria were met and the study is considered acceptable. Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment: The ER_{50} > 600 g a.s./ha.

Reference:	**KCP 10.3.2.2/09**
Title:	Toxicity to the rove beetle Aleochara bilineata GYLL. (Coleoptera: Staphylinidae) using an extended laboratory test onto sandy soil; flufenacet SC 508.8 (508.8 g/L)
Report:	Röhlig, U.; 2022; 22 48 NKE 0002; M-816749-01-1
Authority registration No:	
Guideline(s):	US EPA OCSPP 850.SUPP GRIMM ET AL. (2000) CANDOLFI ET AL. (2001)
Deviations:	None
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication (if vertebrate study):	

Material and methods

Flufenacet SC 508.8 G (508.8 g/L) [analysed active substance: flufenacet 511.8 g/L, 42.4 % w/w, specification no.: 102000007779; supplier batch no.: 2020-010174; study ID of characterisation study: TOX21819-00] was tested under extended laboratory conditions after contact exposure of adults of the rove beetle *Aleochara bilineata* GYLL. to dried spray residues.

Flufenacet SC 508.8 was applied with rates of 60 – 107 – 190 – 337 – 600 g a.s./ha (equivalent to 117.2 – 209.1 – 371.2 – 658.5 – 1172.3 mL product/ha, based on the analysed active ingredient) in 400 L deionised water/ha on onto sandy soil (LUFA 2.1) using a calibrated laboratory track sprayer (mean measured application rate: 402 L/ha). The control was treated with deionised water (400 L/ha). Dimethoate EC 400 (1.5 L product/ha, nominally equivalent to 600 g a.s./ha, in 400 L deionised water/ha) was used as a reference item.

Adults of *Aleochara bilineata* GYLL. (1-7 days old at study start) were exposed in 4 replicates per treatment group and 20 beetles per replicate onto spray residues of Flufenacet SC 508.8, reference item and control, respectively. During the assessments, the beetles were fed with deep frozen larvae of *Chironomus* spp. To each replicate approximately 500 onion fly pupae *Delia antiqua* were added as host organism on day 7, 14 and 21 after application. 28 days after application the adult beetles were removed from the soil and the soil left to dry. At day 35 after application the fly pupae were removed from the substrate and placed in hatching units. The number of hatched beetles of the F_1 generation was recorded over a period of 31 days. From these data the endpoint reproductive capacity was calculated.

Climatic test conditions: Temperature: 19-22°C, relative humidity: 65-74%, light-dark-cycle: 16 hours light, 8 hours dark, 1920 lux.

Statisticals: ToxRat Professional 3.3.0 (RATTE, 2018), WILLIAMS Multiple Sequential t-test ($\alpha = 0.05$) for reproductive capacity.

Dates of work (biological part): 15th March 2022 – 20th May 2022

Results and discussion

Test item	Flufenacet SC 508.8 G (508.8 g/L)			
Test organism	*Aleochara bilineata* GYLL			
Exposure	Dried spray deposits onto sandy soil (LUFA 2.1)			
Treatment Application rate[1]	Reproductive capacity			
Control	482	48.2 ± 0.9	1926	-
Product 60 g.a.s/ha	486 (n.s.)	48.6 ± 0.81	1942	-0.8
Product 107 g.a.s/ha	484 (n.s.)	48.4 ± 2.29	1934	-0.4
Product 190 g.a.s/ha	462*	46.2 ± 1.35	1849	4.0
Product 337 g.a.s/ha	460*	46.0 ± 0.97	1838	4.6
Product 600 g.a.s/ha	437*	43.7 ± 0.34	1746	9.3
Reference item dimethoate EC 400 1.5 L product/ha[1]	19	1.9 ± 1.5	75	96.1

[1] Application rate in 400 L water/ha
[2] Effect on reproduction according to the following formula: (1-Pt/Pc) * 100% (based on the absolute number of beetles emerged) calculated on the exact raw data (negative values represent an increase and positive values indicates a decrease on reproduction compared to the control)
s.d. = standard deviation, n.s. = not significantly different compared to the control: Williams-t-Test ($\alpha = 0.05$)
* = significantly different compared to the control: ($\alpha = 0.05$)

The ER_{50} was estimated to be > 600 g a.s./ha.

In an extended laboratory study with Flufenacet SC 508.8 G (508.8 g/L) the effect on reproductive capacity was lower than or equal to 9.3 % at rates up to and including 600 g a.s./ha. No statistically significant effect on reproductive capacity was determined at test item treatment rates up to and including 107 g a.s./ha compared to the control by using the WILLIAMS-t-Test ($\alpha = 0.05$). The results of the control group indicated that the test organisms were in a good condition (average number of hatched beetles per replicate of the F1 generation: 482). The results of the reference item group indicated that the test system was sensitive to harmful substances (reduction of the reproductive capacity relative to the control: 96.1%). Concerning average number of hatched beetles per replicate of the F_1 generation in

the control group as well as the susceptibility of the test organisms to the reference item, the study is proved to be valid.

Validity of the study:

Validity criteria of the study according to GRIMM ET AL. (2000)

Validity criteria	Recommended by the guideline	Obtained in this study
Average number of hatched beetles per replicate of the F1-generation in the control	> 400	482
Parasitisation rate of 1500 introduced fly pupae per replicate (%)	> 26.7	32.1
Reduction of the reproductive capacity in the reference item treatment relative to control (%)	≥ 50	96.1

Conclusion

The ER_{50} was estimated to be > 600 g a.s./ha. The NOER (no observed effect rate) for reproductive capacity was 107 g a.s./ha. All validity criteria according to GRIMM ET AL. (2000) for conducting the extended laboratory test with *Aleochara bilineata* were met.

A 2.3.2.3 KCP 10.3.2.3. Semi-field studies with non-target arthropods

No additional studies are submitted.

A 2.3.2.4 KCP 10.3.2.4. Field studies with non-target arthropods

No additional studies are submitted.

A 2.3.2.5 KCP 10.3.2.5. Other routes of exposure for non-target arthropods

No additional studies are submitted.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:	The study was evaluated by the RMS during first approval of flufenacet at EU level. **The study was not used in the risk assessment.**

Reference:	**KCP 10.4.1.1/01**
Title:	Influence of FOE 5043 WG 60 on the reproduction of earthworms (Eisenia fetida)
Report:	Kratz, M. A.; 1997 ~~2011~~; HBF/RG 251; M-004878-02-1
Authority registration No:	
Guideline(s):	ISO/DIS 11268-2 (1995): Part 2 ; ISO/DIS 11268-2 (1995)
Deviations:	None
GLP/GEP:	yes
Acceptability:	

Duplication (if vertebrate study)	

Objective

The chronic earthworm study (Heimbach 1997, M-004878-01-1, peer-reviewed) was amended in 2011 (Kratz, M-004878-02-1) for two reasons:

1st Reason for the Amendment: New statistical calculation with the obtained data.

2nd Reason for the Amendment: Change of study director

Results and discussions (as presented in amended version)

Mortality:

No mortality of adult earthworms was observed after 28 days of exposure at any test concentration of the test item in this study.

Effects on growth:

Changes in body weight values of the surviving test organisms of the treatment groups during the test period were compared to the values of the control group. The normal distribution of the data was tested by Kolmogorov-Smirnov test. The normality hypothesis was accepted. The homogeneity of variances of the data was checked by Cochran's test. The homogeneity hypothesis was rejected. Therefore, the data were transformed (y' = ln(y)). The homogeneity of variances of these transformed data was given. The data were statistically evaluated by means of a Williams multiple sequential t-test, two-sided, $\alpha = 0.05$. The data for 2 and 5 kg test item/ha was statistically significant different to the control. The statistical software package ToxRatPro Version 2.09® was used for the calculation.

Therefore:

NOEC related to growth: 1 kg test item/ha

LOEC related to growth: 2 kg test item/ha

Effects on reproduction:

The reproduction of the surviving test organisms per test vessel at the end of the study was compared to the control values. The normal distribution of the data was tested by Kolmogorov-Smirnov test. The normality hypothesis was accepted. The homogeneity of variances of the data was checked by Cochran's test. The homogeneity hypothesis was accepted. The homogeneity hypothesis was accepted.

The data were statistically evaluated by means of a Williams multiple sequential t-test, one-sided smaller,

$\alpha = 0.05$. The statistical software package ToxRatPro Version 2.09® was used for the calculation. No statistically significant different values for the number of juveniles per test vessel relative to the control were observed at all test concentrations.

Therefore, based on statistical significance:

NOEC related to reproduction: ≥ 5 kg test item/ha

LOEC related to reproduction: > 5 kg test item/ha

Conclusion

Overall, based on the biological and statistical significance of the effects observed on growth or reproduction, it is concluded, that the NOEC for this study is 1 kg test item/ha and the overall LOEC is determined to be 2 kg test item/ha.

[Comment: The revised NOEC was re-calculated into 1.2 mg a.s./kg dws based on 605 g flufenacet/10000 m², size of test boxes = 198 cm² and 500 g dry weight substrate per test box.]

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Comments of zRMS:	The study was evaluated and agreed by the RMS in the course of the ongoing EU renewal process with the following endpoints: $NOEC_{growth}$ = 138 mg test item/kg dws $LOEC_{growth}$ = 236 mg test item/kg dws $NOEC_{reproduction}$ = 48 mg test item/kg dws $LOEC_{reproduction}$ = 82 mg test item/kg dws Overall $NOEC_{reproduction}$ = 48 mg test item/kg dws Although the renewal process is not finalised yet, no changes regarding the derived endpoints are expected. **The study was used in the risk assessment.**

Reference:	**KCP 10.4.1.1/02**
Title:	Flufenacet SC 500: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 % peat
Report:	Leicher, T.; 2007; LRT-RG-R-35/07; M-294431-01-1
Authority registration No:	
Guideline(s):	ISO 11268-2: 1998 (E) and OECD 222: April 13, 2004
Deviations:	Study was expanded with a 2. Run (three further concentrations to determine the LOEC)
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process thus additional validation at the zonal level is deemed not necessary
Duplication (if vertebrate study)	

Objective

The purpose of this study was to assess the effect of Flufenacet SC 500 on survival, growth, and reproduction on the earthworm *Eisenia fetida* during an exposure into an artificial soil with 5 different test concentrations (1. Run) and additional 3 different test concentrations (2. Run). The method of application and the test species are recommended by the international test guidelines (ISO 11268-2: 1998 (E) and OECD 222: April 13, 2004).

Materials and methods

Test item: Flufenacet SC 500; specification: Specification no.: 102000007779; Batch no.: EFKF000175; Tox. no.: 07958-00; content of a.s. (analysed): Flufenacet 499.9 g/L (41.7% w/w); density: 1.199 g/mL. Principles of the testing procedure: Adult *Eisenia fetida* (6-7 months old, 8 x 10 animals for the control group and 4 x 10 animals per test concentration of the treatment group) were exposed in an artificial soil to the test concentrations of 6 – 10 – 17 – 29 and 48 mg test item/kg dry weight artificial soil (1. Run); and 82 – 138 and 236 mg test item/kg dry weight artificial soil (2. Run). The test item was mixed into the soil. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined.

The validity criteria of the test according to the guideline were fulfilled (mortality of the adults, mean change in growth of the adult earthworms during the exposure period of four weeks, mean rate of reproduction of juveniles and the coefficient of variance of reproduction in the control).

Dates of experimental work: May 11, 2007 to July 12, 2007 (1. Run)
July 20, 2007 to September 21, 2007 (2. Run)

Results and discussions

(1. Run): Effects on mortality and changes in body weight of the adults after an exposure period of 28 days and the number of offspring per test vessel after 56 days. (Values in this table are rounded values)

Test object	***Eisenia fetida***					
Test item	**Control**	**Flufenacet SC 500**				
Test concentration (mg test item/kg DS*)	—	6	10	17	29	48
Mortality of adult earthworms [%] after 28 days	0	0	0	0	0	0
Mean change of body weight of the adults from day 0 to day 28 [%]	+ 72.4	+ 69.7	+ 70.3	+ 75.7	+ 75.5	+ 71.3
Standard Deviation	± 14.1	± 7.7	± 9.0	± 9.2	± 15.0	± 7.8
Statistical comparison to the control **	—	n.s.	n.s.	n.s.	n.s.	n.s.
Mean number of offspring per test vessel after 56 days	218.1	223.5	190.3	196.8	177.5	210.5
Standard Deviation	± 32.5	± 28.2	± 31.1	± 35.1	± 25. 7	± 28.7
Statistical comparison to the control ***	—	n.s.	n.s.	n.s.	n.s.	n.s.

* DS = Dry weight artificial soil
** Result of a Dunnett´s Multiple t-test, two-sided, α = 0.05
*** Result of a Dunnett´s Multiple t-test Multiple Sequential t-test, one-sided smaller, α = 0.05
n.s.: mean value not statistically significant different compared to the control ($p \geq 0.05$)
s.: mean value statistically significant different compared to the control ($p < 0.05$)

(2. Run): Effects on mortality and changes in body weight of the adults after an exposure period of 28 days and the number of offspring per test vessel after 56 days. (Values in this table are rounded values)

Test object	***Eisenia fetida***			
Test item	**Control**	**Flufenacet SC 500**		
Test concentration (mg test item/kg DS*)	—	82	138	236
Mortality of adult earthworms [%] after 28 days	0	0	0	5
Mean change of body weight of the adults from day 0 to day 28 [%]	+ 80.8	+ 71.0	+ 71.2	+ 31.4
Standard Deviation	± 9.7	± 4.2	± 7.4	± 5.2
Statistical comparison to the control **	—	n.s.	n.s.	s.
Mean number of offspring per test vessel after 56 days	230.6	140.8	77.5	5.3
Standard Deviation	± 40.7	± 36.3	± 9.8	± 3.0
Statistical comparison to the control ***	—	s.	s.	s.

* DS = Dry weight artificial soil
** Result of a Williams´s Multiple t-test, two-sided, α = 0.05
*** Result of a Williams´s Multiple Sequential t-test, one-sided smaller, α = 0.05
n.s.: mean value not statistically significant different compared to the control ($p \geq 0.05$)
s.: mean value statistically significant different compared to the control ($p < 0.05$)

Observations

No mortality of adult earthworms was observed after 28 days of exposure in the control group and the test concentrations of 6, 10, 17, 29 and 48 mg test item/kg dry weight artificial soil (1. Run) and no mortality was observed at 82 and 138 mg test item/kg dry weight artificial soil (2. Run).
A mortality of 5 % was determined at the test concentration of 236 mg test item/kg dry weight artificial soil (2. Run). This mortality is not considered as treatment related, but rather a sporadic event.

No statistically significant different values for the growth relative to control were observed at the test concentrations 6, 10, 17, 29 and 48 mg test item/kg dry weight artificial soil (1. Run) and no statistically significant different values for the growth was observed at 82 and 138 mg test item/kg dry weight artificial soil (2. Run).

~~For the test concentration 236 mg test item/kg dry weight artificial soil (2. Run), a statistically significant decrease in bodyweight relatively to the control was observed.~~

~~No statistically significant different values for the number of juveniles per test vessel relatively to the control were observed at the test concentrations of 6, 10, 17, 29 and 48 mg test item/kg dry weight artificial soil (1. Run).~~
~~Statistically significant different values for the number of juveniles per test vessel relatively to the control were observed at the test concentrations of 82, 138 and 236 mg test item/kg dry weight artificial soil (2. Run).~~

~~**Conclusion**~~
~~Therefore:~~
~~NOEC related to growth: 138 mg test item/kg dry weight artificial soil~~
~~LOEC related to growth: 236 mg test item/kg dry weight artificial soil~~

~~NOEC related to reproduction: 48 mg test item/kg dry weight artificial soil~~
~~LOEC related to reproduction: 82 mg test item/kg dry weight artificial soil~~

~~The overall NOEC is determined to be 48 mg test item/kg dry weight artificial soil. Thus, the overall LOEC is determined to be 82 mg test item/kg dry weight artificial soil.~~

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

Comments of zRMS:	The study was evaluated and agreed by the RMS in the course of the ongoing EU renewal process with the following endpoints: NOAER = 1.2 L Flufenacet 500 SC/ha corresponding to 600 g flufenacet/ha and 0.438 mg a.s./kg soil dw, measured value at 10 cm depth, corresponding to 0.876 mg flufenacet/kg dw at 5 cm depth However, the most sensitive species to flufenacet - *Octolasion lacteum*, identified as such in another field study for representative formulation was not tested. Therefore, the NOAER value of 0.876 mg flufenacet/kg dws (measured value at 5 cm depth) is not to be used in the risk assesment. Although the renewal process is not finalised yet, no changes regarding the derived endpoints are expected. **The study was not used in the risk assessment. The additional information only.**

Reference:	**KCP 10.4.1.2/01**
Title:	Flufenacet SC 500: effect on the earthworm fauna of a grassland area within one year
Report:	Leicher, T.; 2008; LRT/RG-F-4/08; M-307211-01-1
Authority registration No:	
Guideline(s):	BBA (Federal Biological Research Centre for Agriculture and Forstry, Germany): Guidelines for the Testing of Plant Protection Products within Registration, Part VI, 2 - 3 (January 1994): Effects of Plant Protection Products on Earthworms in the Field ISO (International Standard Organisation): Guideline CD 11268-3 (E), Soil Quality - Effects of pollutants on Earthworms, Part 3: Guidance on the determination of effects in field situations (1999)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process thus additional validation at the zonal level is deemed not necessary

Duplication (if vertebrate study)	

Material and methods

The effects of Flufenacet SC 500 (content of Flufenacet. (analysed): 499.9 g/L, Batch No.: EFKF000175, TOX No.: 07958-00) on earthworm populations under field conditions were studied. To ensure an abundant earthworm population, an area was selected which was used as grassland for several years, located in Monheim (Germany). The soil was characterized as loamy sand. On April 19, 2007 a presampling of earthworms was conducted to ensure a sufficient number of earthworms being present at the test plot. Four selected plots within this area were treated with 1.2 l Flufenacet SC 500/ha on May 22, 2007. Four untreated plots served as negative controls, as positive control 4 plots were treated with Carbendazim (8 kg/ha). Within three days after application 14.5 mm of precipitation was measured. All plots were screened for alive and dead earthworms on the soil surface within three days after the applications. For chemical verification of the exposure soil samples from the control and from the treated plots were taken on May 22, 2007 after the applications and analysed for the presence of Flufenacet. On treated plots Flufenacet was detected on average in a concentration of 0.438 mg/kg dry weight soil, assuming a soil depth of 10 cm and a soil density of 1.5 g/cm³. This is equivalent to 110% of the nominal application rate of 1.2 l Flufenacet SC500/ha resulting in a nominal concentration of 0.399 Flufenacet mg/kg dry weight soil.

The earthworm numbers and biomass were determined nine weeks (July 25, 2007), five months (October 30, 2007) and eleven months (April 22, 2008) after application by sampling earthworms using formalin method. At each sampling time 16 samples per treatment (4 plots, 4 samples per plot) were collected.

Results and discussions

Findings and observations:

Earthworm number and diversity in pre-sampling and in the control plots:

The abundance of earthworms at the study site was determined 5 weeks before the application of the test substance (April 19, 2007) by pre-sampling using the formalin method. The mean total abundance of earthworms determined was 196 worms/m^2. The five species *Lumbricus terrestris*, *Lumbricus rubellus*, *Lumbricus castaneus*, *Aporrectodea caliginosa*, were found. Nine weeks after the application the mean number of earthworms in the control plots, sampled with the formalin method, was determined to be 113 earthworms/m^2, five months after the application 164 earthworms/m^2 and eleven months after the application 306 earthworms/m^2., respectively

Six different earthworm species were identified in the test area at different abundances: *Lumbricus terrestris*, *Lumbricus rubellus*, *Lumbricus castaneus*, *Aporrectodea caliginosa*, *Allolobophora chlorotica* and *Aporrectodea terrestris longa*.

These data indicate that the earthworm population of the selected test area can be assumed to be quite high (BAUCHHENSS 1982, EDWARDS & LOFTY 1977, KENNEL & NIKLAS 1980).

Adult and juvenile earthworms, changes in numbers and biomass:

Data for category "**adult and juvenile**" and for the species classes "total", "total anecic", "total endogeic" and "total epigeic" earthworms. The values are replicate means (n = 4) and standard deviations per 0.25 m². Values between parentheses are relative differences to the control in %:

Treatment group	9 weeks after the application		5 months after the application		11 months after the application	
	Numbers (n) / replicate					
	Total earthworms					
Control	28.31 ± 3.46		40.88 ± 2.99		76.50 ± 14.86	
Flufenacet	20.75 ± 3.69	(-27%) *	39.81 ± 8.61	(-3%)	76.19 ± 5.54	(0%)
Carbendazim	13.88 ± 2.92	(-51%) *	40.88 ± 8.61	(0%)	54.00 ± 5.07	(-29%)*
	Total of anecic earthworms					
Control	10.06 ± 1.55		25.25 ± 2.35		17.06 ± 3.13	
Flufenacet	9.63 ± 1.16	(-4%)	24.56 ± 3.64	(-3%)	19.75 ± 1.34	(+16%)
Carbendazim	3.38 ± 1.05	(-66%) *	20.06 ± 2.49	(-21%) *	15.63 ± 4.09	(-8%)
	Total of endogeic earthworms					
Control	8.81 ± 3.99		5.44 ± 2.81		53.13 ± 13.68	
Flufenacet	5.13 ± 2.72	(-42%)	6.81 ± 4.52	(+25%)	48.88 ± 7.11	(-8%)
Carbendazim	2.81 ± 1.71	(-68%) *	9.69 ± 2.38	(+78%)	26.69 ± 4.93	(-50%)*
	Total of epigeic earthworms					
Control	9.44 ± 1.48		10.19 ± 3.45		6.31 ± 2.15	
Flufenacet	6.00 ± 1.15	(-36%) *	8.44 ± 1.13	(-17%)	7.56 ± 2.68	(+20%)
Carbendazim	7.69 ± 3.15	(-19%)	11.13 ± 7.74	(+9%)	11.69 ± 3.78	(+85%)
	Biomass (g) / replicate					
	Total earthworms					
Control	18.21 ± 3.31		36.46 ± 9.78		44.79 ± 5.64	
Flufenacet	15.83 ± 4.86	(-13%)	36.45 ± 4.32	(0%)	47.64 ± 2.47	(+6%)
Carbendazim	5.74 ± 1.25	(-68%) *	28.34 ± 6.23	(-22%)	32.84 ± 2.67	(-27%)*
	Total of anecic earthworms					
Control	16.42 ± 3.08		33.34 ± 9.81		24.01 ± 4.22	
Flufenacet	15.13 ± 4.75	(-8%)	32.54 ± 2.54	(-2%)	28.00 ± 3.47	(+17%)
Carbendazim	4.39 ± 1.34	(-73%) *	18.96 ± 4.74	(-43%)	16.11 ± 4.44	(-33%)
	Total of endogeic earthworms					
Control	1.12 ± 0.54		2.09 ± 0.98		20.23 ± 4.36	
Flufenacet	0.40 ± 0.23	(-64%) *	2.86 ± 1.48	(+37%)	18.86 ± 2.96	(-7%)
Carbendazim	0.70 ± 0.53	(-38%)	7.11 ± 2.03	(+241%) *	15.19 ± 1.63	(-25%)
	Total of epigeic earthworms					
Control	0.67 ± 0.26		1.04 ± 0.31		0.55 ± 0.24	
Flufenacet	0.29 ± 0.26	(-56%) *	1.06 ± 0.50	(+2%)	0.78 ± 0.12	(+41%)
Carbendazim	0.66 ± 0.28	(-2%)	2.27 ± 1.54	(+119%) *	1.54 ± 0.27	(+180%)*

* indicates a statistically significant difference between treatment and control (Wilcoxon, Mann and Withney U-Test, p = 0.05)

An application of 1.2 l product/ha Flufenacet SC 500 has no statistically significant effect on the parameters "numbers" and "biomass" of all tested categories earthworms five and 11 months after the application, indicating no effect of Flufenacet on the earthworm community. However, nine weeks after application for the category "total earthworms" a statistically significant reduction in number of -27% and a statistically insignificant reduction of the biomass of -13 % were observed. The group of anecic earthworms was not affected on Flufenacet treated plots nine weeks after application (Numbers -4 %; biomass -8%). The ecological groups of endogeic (Number -42%; biomass -64 %) and epigeic (Number -36 %; biomass -56%) earthworms were reduced on Flufenacet treated plots nine weeks after application. A possible explanation for this observation is the influence of Flufenacet acting as herbicide on the vegetation of the treated plots. Although all plots were treated with Glyphos before start of the test, untreated plots showed a regrowing of weeds. Especially in the dry summer period this has a strong influence on the water regime of the soil thereby affecting the habitat of the endo- and epigeic earthworms. Therefore, this variation is not considered to be a compound related effect but rather a secondary effect of the herbicide Flufenacet on the earthworm community.

Adult earthworms; changes in numbers and biomass:
Data for category "**adult**" and for the species classes "total", "total anecic", "total endogeic" and "total epigeic" earthworms. The values are replicate means (n = 4) and standard deviations per 0.25 m². Values between parentheses are relative differences to the control in %:

Treatment group	9 weeks after the application	5 months after the application	11 months after the application
	Numbers (n) / replicate		

Treatment group	9 weeks after the application		5 months after the application		11 months after the application	
	Total earthworms					
Control	5.25 ± 1.46		14.88 ± 3.11		20.94 ± 6.62	
Flufenacet	4.56 ± 1.61	(-13%)	14.81 ± 1.36	(0%)	21.63 ± 2.90	(+3%)
Carbendazim	2.00 ± 0.61	(-62%) *	19.25 ± 6.00	(+29%)	20.13 ± 2.22	(-4%)
	Total of anecic earthworms					
Control	4.94 ± 1.03		10.44 ± 3.07		7.38 ± 2.39	
Flufenacet	4.56 ± 1.61	(-8%)	10.31 ± 0.90	(-1%)	8.63 ± 1.11	(+17%)
Carbendazim	1.44 ± 0.69	(-71%) *	5.00 ± 1.06	(-52%) *	3.63 ± 1.74	(-51%) *
	Total of endogeic earthworms					
Control	0.13 ± 0.16		1.88 ± 1.70		12.38 ± 5.04	
Flufenacet	0 ± 0	(-100%)	2.44 ± 1.18	(+30%)	10.56 ± 2.13	(-15%)
Carbendazim	0.31 ± 0.38	(+150%)	7.38 ± 2.66	(+293%)*	11.94 ± 1.82	(-4%)
	Total of epigeic earthworms					
Control	0.19 ± 0.24		2.56 ± 1.74		1.19 ± 0.69	
Flufenacet	0 ± 0	(-100%)	2.06 ± 0.97	(-20%)	2.44 ± 0.92	(+105%)
Carbendazim	0.25 ± 0.20	(+33%)	6.88 ± 6.47	(+168%)	4.56 ± 1.60	(+284%) *
	Biomass (g) / replicate					
	Total earthworms					
Control	11.20 ± 2.28		25.63 ± 9.26		24.50 ± 4.72	
Flufenacet	10.10 ± 3.96	(-10%)	25.40 ± 3.63	(-1%)	26.19 ± 3.71	(+7%)
Carbendazim	3.11 ± 1.08	(-72%) *	18.48 ± 3.99	(-28%)	18.02 ± 2.86	(-26%)
	Total of anecic earthworms					
Control	11.05 ± 2.06		24.29 ± 9.07		16.51 ± 4.05	
Flufenacet	10.10 ± 3.96	(-9%)	23.44 ± 3.28	(-3%)	19.42 ± 2.94	(+18%)
Carbendazim	2.83 ± 1.20	(-74%) *	10.77 ± 3.30	(-56%) *	7.93 ± 4.17	(-52%)*
	Total of endogeic earthworms					
Control	0.08 ± 0.16		0.82 ± 0.62		7.78 ± 3.38	
Flufenacet	0 ± 0	(-100%)	1.43 ± 0.61	(+74%)	6.35 ± 1.33	(-18%)
Carbendazim	0.19 ± 0.24	(+136%)	5.83 ± 2.07	(+610%) *	9.05 ± 1.68	(+16%)
	Total of epigeic earthworms					
Control	0.07 ± 0.12		0.53 ± 0.32		0.21 ± 0.18	
Flufenacet	0 ± 0	(-100%)	0.54 ± 0.37	(+2%)	0.42 ± 0.04	(+103%)
Carbendazim	0.09 ± 0.11	(+19%)	1.89 ± 1.49	(+259%) *	1.04 ± 0.16	(+401%) *

*) indicates a statistically significant difference between treatment and control (Wilcoxon, Mann and Withney U-Test, p= 0.05)

An application of 1.2 L product/ha Flufenacet SC 500 has no statistically significant effect on the parameters "numbers" and "biomass" of the categories "total", "total anecic", "total endogeic" and "total epigeic" adult earthworms compared to control plots five and 11 months after the application.

Nine weeks after application also no statistically significant differences between Flufenacet and control plots were found. However, the number of earthworms identified in the categories epigeic and endogeic were less than 0.31 earthworm/m². This abundance is too low to perform an appropriate statistical analysis of the data. In addition, this data also indicates that the analysis for the 9 week sampling should not be overestimated.

Juvenile worms; changes in numbers and biomass:
Data for category "**juvenile**" and for the species classes "total", "total anecic", "total endogeic" and "total epigeic" earthworms. The values are replicate means (n = 4) and standard deviations per 0.25 m². Values between parentheses are relative differences to the control in %:

Treatment group	9 weeks after the application		5 months after the application		11 months after the application	
	Numbers (n) / replicate					
	Total earthworms					
Control	23.06 ± 2.92		26.00 ± 2.39		55.56 ± 9.64	
Flufenacet	16.19 ± 3.36	(-30%) *	25.00 ± 7.43	(-4%)	54.56 ± 7.63	(-2%)
Carbendazim	11.88 ± 2.66	(-49%) *	21.63 ± 3.00	(-17%)	33.88 ± 4.09	(-39%)*
	Total of anecic earthworms					
Control	5.13 ± 0.60		14.81 ± 1.31		9.69 ± 1.14	
Flufenacet	5.06 ± 0.63	(-1%)	14.25 ± 3.52	(-4%)	11.13 ± 1.05	(+15%)

Treatment group	9 weeks after the application		5 months after the application		11 months after the application	
Carbendazim	1.94 ± 0.47	(-62%) *	15.06 ± 1.60	(+2%)	12.00 ± 3.33	(+24%)
	Total of endogeic earthworms					
Control	8.69 ± 4.05		3.56 ± 1.39		40.75 ± 9.43	
Flufenacet	5.13 ± 2.72	(-41%)	4.38 ± 3.62	(+23%)	38.31 ± 7.80	(-6%)
Carbendazim	2.50 ± 1.34	(-71%) *	2.31 ± 1.71	(-35%)	14.75 ± 3.38	(-64%)*
	Total of epigeic earthworms					
Control	9.25 ±1.34		7.63 ± 1.76		5.13 ± 2.05	
Flufenacet	6.00 ±1.15	(-35%) *	6.38 ± 0.72	(-16%)	5.13 ± 2.11	(0%)
Carbendazim	7.44 ± 3.11	(-20%)	4.25 ± 1.66	(-44%)*	7.13 ± 2.24	(+39%)
	Biomass (g) / replicate					
	Total earthworms					
Control	7.01 ±1.07		10.83 ± 1.15		20.30 ± 2.16	
Flufenacet	5.73 ±1.40	(-18%)	11.05 ± 1.99	(+2%)	21.44 ± 2.07	(+6%)
Carbendazim	2.63 ±0.31	(-62%) *	9.86 ± 2.41	(-9%)	14.82 ± 1.54	(-27%)*
	Total of anecic earthworms					
Control	5.38 ±1.20		9.05 ± 1.31		7.50 ± 1.16	
Flufenacet	5.03 ±1.20	(-6%)	9.10 ± 1.69	(+1%)	8.58 ± 1.40	(+14%)
Carbendazim	1.56 ±0.18	(-71%) *	8.19 ± 1.68	(-9%)	8.18 ± 1.16	(+9%)
	Total of endogeic earthworms					
Control	1.04 ±0.61		1.27 ± 0.56		12.45 ± 1.29	
Flufenacet	0.40 ±0.23	(-61%)	1.43 ± 1.00	(+13%)	12.51 ± 3.24	(0%)
Carbendazim	0.50 ±0.30	(-55%)	1.35 ± 0.97	(+6%)	6.24 ± 1.05	(-50%)*
	Total of epigeic earthworms					
Control	0.60 ±0.16		0.51 ± 0.09		0.34 ± 0.18	
Flufenacet	0.29 ±0.07	(-51%) *	0.52 ± 0.20	(+1%)	0.36 ± 0.09	(+4%)
Carbendazim	0.57 ±0.23	(-5%)	0.38 ± 0.13	(-26%)	0.50 ± 0.15	(+46%)

*) indicates a statistically significant difference between treatment and control (Wilcoxon, Mann and Withney U-Test, p= 0.05)

An application of 1.2 L product/ha Flufenacet SC 500 has no statistically significant effect on the parameters "numbers" and "biomass" of the categories "total", "total anecic", "total endogeic" and "total epigeic" juvenile earthworms five and 11 months after the application.
Nine weeks after application also no statistically significant differences in number and biomass between Flufenacet and control plots for the categories "total anecic" and "total endogeic" were found. For the category "total" the number of earthworms was reduced by 30 % and for the group of "total epigeic" earthworms the biomass was reduced by 51 %.
A possible explanation for this observation is the influence of Flufenacet acting as herbicide on the vegetation of the treated plots. Although all plots were treated with Glyphos before start of the test, untreated plots showed a regrowing of weeds. Especially in the dry summer period this has a strong influence on the water regime of the soil thereby affecting the habitat of the endo- and epigeic earthworms. Therefore, this variation is not considered to be a compound related effect but rather a secondary effect of the herbicide Flufenacet on the earthworm community.

Conclusion
The present earthworm field study shows, that Flufenacet SC 500 applied at a rate of 1.2 l product/ha on grassland has no adverse effect on the population of earthworms 11 months after the application date (Table 1). Compared to the control plots, plots treated with Flufenacet SC 500 showed changes of the relative abundance of adult & juvenile earthworms relative to control of 0% (number) and +6% (biomass) 11 months after application.
5 months after application plots treated with Flufenacet SC500 showed a reduction in the total number of juvenile and adult earthworms by -3 % and no change in the biomass compared to control plots.
Nine weeks after application of Flufenacet SC500 a relative reduction of adult & juvenile earthworms of -27 % (number) and -13 % (biomass) was observed.

Changes in numbers and biomass for juvenile & adult earthworms, summary
The values are replicate means (n = 4) and standard deviations per 0.25 m². Values between parentheses are relative differences to the control in %:

Treatment group	9 weeks after the application		5 months after the application		11 months after the application	
	Relative number of juvenile & adult earthworms in the study plots (from replicate means)					
	Total earthworms					
Control	28.31 ± 3.46		40.88 ± 2.99		76.50 ± 14.86	
Flufenacet	20.75 ± 3.69	(-27%) *	39.81 ± 8.61	(-3%)	76.19 ± 5.54	(0%)
Carbendazim	13.88 ± 2.92	(-51%) *	40.88 ± 8.61	(0%)	54.00 ± 5.07	(-29%) *
	Relative changes of biomass of juvenile & adult earthworms in the study plots (from replicate means)					
Control	18.21 ± 3.31		36.46 ± 9.78		44.79 ± 5.64	
Flufenacet	15.83 ± 4.86	(-13%)	36.45 ± 4.32	(0%)	47.64 ± 2.47	(+6%)
Carbendazim	5.74 ± 1.25	(-68%) *	28.34 ± 6.23	(-22%)	32.84 ± 2.67	(-27%) *

*) Significant difference from control according to the U-test, two sided at the significance level alpha = 0.05 (U-test from Wilcoxon, Mann and Whitney after SACHS 1978).

Overall, no effect according to the criteria defined by the EPPO standards (2003) of more than 30 % difference between control and Flufenacet SC 500 treated plots was observed at nine weeks, 5 months or 11 months after application of Flufenacet SC500.
In addition, there were no negative findings within three days directly after the application.
Considering the variability of earthworm abundances in natural soils, this study indicates that earthworm populations were not adversely affected by the application of Flufenacet SC 500 of 1.2 l product/ha.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Reference:	**KCP 10.4.2.1/01**
Title:	Diflufenican + flufenacet SC 600 (200+400) G: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil.
Report:	Frommholz, U.; 2011; FRM-Coll-125/11; M-415903-01-1
Authority registration No:	
Guideline(s):	OECD 232 adopted, September 07, 2009: OECD Guidelines for Testing Chemicals – Collembolan Reproduction Test in Soil
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study)	

Objective
The purpose of this study was to assess the effect of Diflufenican + Flufenacet SC 600 (200+400) on survival and reproduction of the collembolan species *Folsomia candida* during an exposure of 28 days in an artificial soil comparing control and treatment.

Materials and methods
Diflufenican + Flufenacet SC 600 (200+400) G (analytical findings: 16.4 % w/w diflufenican (AE F088657) equivalent to 203.8 g/L; 32.7 % w/w flufenacet (FOE 5043) equivalent to 407.5 g/L; density: 1.246 g/mL (20°C), batch ID: EV56002670, sample description: FAR 01538-00, specification no.: 102000007948-03, material no.: 05700094.

Toxic standard: Boric acid.
Control: same application as test item but with deionised water only.
Ten collembolans (9-12 days old) per replicate (8 replicates for the control group and 4 replicates per treatment group) were exposed to control (water treated), 100, 178, 316, 562 and 1000 mg test item/kg artificial soil dry weight at 18 – 22°C, 400 – 800 Lux, 16h light : 8h dark, 5 % peat in the artificial soil. During the test they were fed with granulated dry yeast.
Mortality and reproduction were determined after 28 days.

Results and discussions

The results can be considered as valid, as all validity criteria of the test were met. Mortality in the control was ≤ 20% (5.0% in this study), reproduction of the control was ≥ 100 juveniles per control vessel (1539.3 juveniles in this study) and the coefficient of variation of reproduction in the control was ≤ 30% (7.6% in this study).

Test item **Test object** **Exposure**	**Diflufenican + Flufenacet SC 600 (200+400)** ***Folsomia candida*** **Artificial Soil**		
mg test item/kg soil dry weight nominal concentration	**Adult mortality (%)**	**Mean number of juveniles±SD**	**Reproduction (% of control)**
Control	5.0	1539.3 ± 117.0	-
100	7.5	1566.0 ± 110.1	101.7 n.s.
178	7.5	1490.0 ± 123.3	96.8 n.s.
316	30.0	1228.0 ± 160.7	79.8 *
562	27.5	335.3 ± 87.6	21.8 *
1000	42.5	155.0 ± 59.3	10.1 *
NOEC (mg test item/kg soil dry weight) LOEC (mg test item/kg soil dry weight)			178 316

* Statistically significant (William's – t test one-sided smaller, $\alpha = 0.05$)
n.s. = statistically not significant (William's – t test one-sided smaller, $\alpha = 0.05$)

Observations:

Concerning the number of juveniles, statistical analysis revealed statistically significant difference between control and the treatment groups from 316 up to 1000 mg test item/kg artificial soil dry weight. Therefore, the No-Observed-Effect-Concentration (NOEC) for reproduction is 178 mg test item/kg artificial soil dry weight. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 316 mg test item/kg artificial soil dry weight.

Conclusion

$NOEC_{reproduction}$: 178 mg test item/kg artificial soil dry weight.
$LOEC_{reproduction}$: 316 mg test item/kg artificial soil dry weight.

Comments of zRMS:	The study was conducted in line with the respective guideline with no deviation. All the validity criteria were met and the study is considered acceptable. Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment: $NOEC_{reproduction}$ = 18 mg product/kg dws $EC_{10\text{-}reproduction}$ = 28 mg product/kg dws

Reference:	**KCP 10.4.2.1/02**
Title:	Flufenacet SC 508.8 g/L: Influence on mortality and reproduction of the collembolan species Folsomia candida tested in artificial soil
Report:	Richter, A.; 2022; E 314 05757-2; M-818073-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 OECD Guideline 232 US EPA OCSPP Not Applicable
Deviations:	None pH from the soil charge was in other studies
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication (if vertebrate study):	

Objective
The purpose of this study was to assess the effect of Flufenacet SC 508.8 G g/L on survival and reproduction of the collembolan species *Folsomia candida* during an exposure of 28 days in an artificial soil comparing control and treatment.

Materials and methods
Supplier Batch No.: 2020-010174, Study ID of Characterization Study: TOX21819-00, Spec. No.: 102000007779, Sample ID: M21000121001, (analytical findings: 42.4% w/w (Flufenacet) equivalent to 511.8 g/L; density: 1.208 g/mL).

10 collembolans (9-12 days old) per replicate (8 replicates for the control group and 4 replicates for each treatment group) were exposed to control and treatment. Concentrations of 18, 32, 56, 100, 178, 316, 562 and 1000 mg product/kg dry weight artificial soil were mixed into the artificial soil. During the study, they were fed with granulated dry yeast. A temperature of 20±2 °C and a light regime of 400 – 800 lux, 16 h light : 8 h darkness during the conduct of the study was applied. The artificial soil was prepared according to the guideline with the following constituents (percentage distribution on dry weight basis): 75% fine quartz sand, 5% Sphagnum peat, air dried and finely ground, 20% Kaolin clay. Mortality and reproduction were determined after 28 days.

Dates of work (biological part): 4th May 2022 – 9th June 2022

Results and discussions:

Test item	Flufenacet SC 508 g/L				
Test object	*Folsomia candida*				
Exposure	Artificial soil				
	Adult mortality (%)	Significance (*)	Mean number of juveniles per test vessel ± standard deviation	Reproduction (% of control)	Significance (**)
Control	15.0	N/A	479.3 ± 97.1	N/A	N/A
18	10.0	-	501.8 ± 47.5	104.7	-
32	12.5	-	408.8 ± 33.0	85.3	+
56	20.0	-	388.3 ± 77.4	81.0	+
100	5.0	-	371.8 ± 41.6	77.6	+
178	37.5	+	267.5 ± 38.1	55.8	+
316	15.0	-	202.8 ± 43.4	42.3	+
562	30.0	-	131.0 ± 16.9	27.3	+
1000	37.5	+	49.0 ± 19.7	10.2	+
				Mortality	Reproduction
NOEC (product/kg dry weight artificial soil)				100	18
LOEC (product/kg dry weight artificial soil)				178	32
				Mortality	Reproduction
LC/EC_{10} (product/kg dry weight artificial soil) [1)]				n.d.	28
95% confidence limits				(n.d. – n.d.)	(18 - 46)
LC/EC_{20} (product/kg dry weight artificial soil) [1)]				n.d.	68
95% confidence limits				(n.d. – n.d.)	(49 – 94)

The calculations were performed with unrounded values
Results are expressed as mg test item/kg dry weight artificial soil.
(*) = Chi^2 2 × 2 Table Test with Bonferroni Correction, one sided greater, α = 0.05, "+" = significant, "-" = not significant)
(**) = (William's test one-sided smaller, α = 0.05; "+" = significant, "-" = not significant)
[1)] Reproduction = Weibull analysis
Mortality = n.d. = could not be determined (see observations)
N/A = not applicable

Observations:

Mortality:

In the control group 15% of the adult *Folsomia candida* died which is below the allowed maximum of ≤ 20% mortality. Concerning the mortality of the adult test organisms statistical analysis (Chi^2 2 × 2 Table Test with Bonferroni Correction, one-sided-greater, α = 0.05) revealed no significant difference between control and any treatment group up to and including 100 mg product/kg dry weight artificial soil. Therefore, the No-Observed-Effect-Concentration (NOEC) for mortality is 100 mg product/kg dry weight artificial soil. The Lowest-Observed-Effect-Concentration (LOEC) for mortality is 178 mg product/kg dry weight artificial soil. Due to the lack of a concentration-response relationship no reliable LCx-calculation was possible. Therefore, no LC_{10}/LC_{20}-value can be reported.

Reproduction:

Concerning the number of juveniles statistical analysis (William's t-test, one-sided smaller, α = 0.05) revealed no significant difference between control and any treatment group up to and including 18 mg product/kg dry weight artificial soil. Therefore, the No-Observed-Effect-Concentration (NOEC) for reproduction is 18 mg test item/kg dry weight artificial soil. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 32 mg product/kg dry weight artificial soil. The EC_{10} and EC_{20} values for reproduction were calculated to be 28 mg product/kg soil dry weight (95% confidence limits: 18 – 46) and 68 mg test item/kg soil dry weight (95% confidence limits: 49 – 94), respectively (Weibull analysis).

Validity of the study:

Validity criteria for the untreated control of the study according OECD Guideline 232 (2016)

Validity criteria	Recommended by the guideline	Obtained in this study
Mean adult mortality	≤ 20%	15.0%
Number of juveniles per replicate (with 10 collembolans introduced)	≥ 100	479.3
Coefficient of variation calculated for the number of juveniles per replicate	less than 30%	20.3%

Toxic Reference test:

The most recent non-GLP-test (Coll-Ref-40/22, April 2022) with the reference item Boric acid was performed at test concentrations 44, 67, 100, 150 and 225 mg Boric acid/kg dry weight artificial soil. The NOECreproduction was calculated to be 67 mg Boric acid/kg dry weight artificial soil and accordingly the LOECreproduction is 100 mg Boric acid/kg dry weight artificial soil according Williams t-test, $\alpha = 0.05$, one-sided smaller.
Boric acid showed an EC_{50} of 165 mg test item/kg dry weight artificial soil (95% confidence limits from 158 mg to 173 mg Boric acid/kg dry weight artificial soil) for reproduction according Logit analysis using linear maximum likelihood regression.
The result is in the recommended range of the guideline (about 100 mg Boric acid/kg artificial soil dry weight).

Conclusions:

$NOEC_{mortality}$: 100 mg product/kg dry weight artificial soil
$LOEC_{mortality}$: 178 mg product/kg dry weight artificial soil

$NOEC_{reproduction}$: 18 mg product/kg dry weight artificial soil
$LOEC_{reproduction}$: 32 mg product/kg dry weight artificial soil

$EC_{10\text{-}reproduction}$: 28 mg product/kg dry weight artificial soil
$EC_{20\text{-}reprodcution}$: 68 mg product/kg dry weight artificial soil

Comments of zRMS:	The study was conducted in line with the respective guideline with no deviation. All the validity criteria were met and the study is considered acceptable. Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment: $NOEC_{reproduction}$:= 316 mg product/kg dws $EC_{10\text{-}reproduction}$ = 441 mg product/kg dws

Reference:	**KCP 10.4.2.1/03**
Title:	Flufenacet SC 508.8 g/L: Influence on mortality and reproduction of the soil mite species Hypoaspis aculeifer tested in artificial soil
Report:	Richter, A.; 2022; E 428 05758-9; M-818456-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 OECD Guideline 232 US EPA OCSPP Not Applicable
Deviations:	None pH from the soil charge was in other studies
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication (if vertebrate study):	

Objective
The purpose of this study was to assess the effect of Flufenacet SC 508.8 G g/L on mortality and reproduction of the soil mite species *Hypoaspis aculeifer* tested during an exposure of 14 days in artificial soil by comparing control and treatment.

Materials and methods
Test item: Flufenacet SC 508.8 G g/L, Supplier Batch ID: 2020-010174; Sample identification code: TOX21819-00; specification no.: 102000007779; Sample ID: M21000121001; Lot No.: 2020-010174-01; (analytical findings: 42.4% w/w flufenacet (BCS-AB27364) equivalent to 511.8 g/L; density: 1.208 g/mL).
Ten adult, fertilized female *Hypoaspis aculeifer* per replicate (8 replicates for the control group and 4 replicates for each treatment group) were exposed to control and treatments. Concentrations of 18, 32, 56, 100, 178, 316, 562 and 1000 mg product/kg dry weight artificial soil were mixed into the artificial soil. During the test, the *Hypoaspis aculeifer* were fed with nematodes bred on watered oat flakes. During the study a temperature of 20±2 °C and a light regime of 400 – 800 Lux, 16 h light : 8 h dark were applied. The artificial soil was prepared according to the guideline with the following constituents (percentage distribution on dry weight basis): 75% fine quartz sand, 5% Sphagnum peat, air dried and finely ground, 20% Kaolin clay.
After a period of 14 days, the surviving adults and the living juveniles were extracted by applying a temperature gradient using a MacFadyen-apparatus. Extracted mites were collected in a fixing solution (20% ethylene glycol, 80% deionised water, 2 g detergent/L fixing solution). All *Hypoaspis aculeifer* were counted under a binocular.

Dates of work (biological part): 3rd May 2022 – 1st June 2022

Results and discussions:

Test item	Flufenacet SC 508 g/L				
Test object	*Hypoaspis aculeifer*				
Exposure	Artificial soil				
	Adult mortality (%)	Significance (*)	Mean number of juveniles per test vessel ± standard deviation	Reproduction (% of control)	Significance (**)
Control	2.5	N/A	376.1 ± 10.5	N/A	N/A
18	0.0	-	391.5 ± 9.7	104.1	-
32	2.5	-	374.5 ± 11.1	99.6	-
56	5.0	-	360.0 ± 23.6	95.7	-
100	2.5	-	360.8 ± 18.2	95.9	-
178	0.0	-	362.5 ± 33.6	96.4	-
316	0.0	-	372.0 ± 25.9	98.9	-
562	7.5	-	297.3 ± 11.1	79.0	+
1000	27.5	+	132.5 ± 37.8	35.2	+
				Mortality	Reproduction
NOEC (product/kg dry weight artificial soil)				562	316
LOEC (product/kg dry weight artificial soil)				1000	562

	Reproduction
EC_{10} (product/kg dry weight artificial soil) [1)]	441
95% confidence limits	(364 - 501)
EC_{20} (product/kg dry weight artificial soil) [1)]	549
95% confidence limits	(479-602)

Calculations were done with un-rounded values.
(*) = Step-down Cochran-Armitage Test Procedure, one-sided greater, α = 0.05, "-": non-significant; "+": significant
(**) = Williams Multiple Seqential t-test, one sided smaller; α = 0.05; "-": non-significant; "+": significant
[1)] = Probit analysis, N/A = not applicable

Observations:

Mortality:

In the control group 2.5% of the adult *Hypoaspis aculeifer* died which is below the allowed maximum of ≤ 20% mortality.
Concerning the mortality of the female adult test organisms statistical analysis (Step-down Cochran-Armitage Test Procedure, one-sided greater, α = 0.05) revealed no significant difference between control group and any treatment group up to and including 562 mg product/kg dry weight artificial soil. Statistically significant differences in mortality compared to the control group were observed at 1000 mg product/kg dry weight artificial soil.
Therefore, the No-Observed-Effect-Concentration (NOEC) for mortality is 562 mg product/kg dry weight artificial soil. The Lowest-Observed-Effect-Concentration (LOEC) for mortality is 1000 mg product/kg dry weight artificial soil.

Reproduction:

Concerning the number of juveniles statistical analysis (Williams Multiple Sequential t-test, one-sided smaller, α = 0.05) revealed no significant difference between control group and any treatment group up to and including 316 mg product/kg dry weight artificial soil. Statistically significant differences in number of juveniles compared to the control group were observed at 562 and 1000 mg product/kg dry weight artificial soil.
Therefore, the No-Observed-Effect-Concentration (NOEC) for reproduction is 316 mg prodcut/kg dry weight artificial soil. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 562 mg product/kg dry weight artificial soil.
The EC_{10} and EC_{20} values for reproduction were calculated to be 441 mg (95% confidence limits: 364–501) and 549 mg (95% confidence limits: 479–602) product/kg soil dry weight, respectively (Probit analysis).

Validity of the study:

Validity criteria for the untreated control of the study according OECD Guideline 226 (2016)

Validity criteria	Recommended by the guideline	Obtained in this study
Mean adult female mortality %	≤ 20	2.5
Number of juveniles per replicate (with 10 collembolans introduced)	≥ 50	376
Coefficient of variation calculated for the number of juveniles per replicate	< 30	2.8

Reference test:
The corresponding non-GLP-test (HR-Ref-32/21, December 06, 2021) with the reference item dimethoate was performed at test concentrations of 1.0, 1.8, 3.2, 5.6 and 10.0 mg dimethoate/kg dry weight artificial soil.
Dimethoate a.s. showed a LC_{50} of 3.8 mg a.s./kg for mortality of the adult mites according Weibull analysis using maximum likelihood regression (confidence limits from 2.5 mg a.s./kg to 5.7 mg a.s./kg). The reproduction of the soil mites was not significantly reduced in comparison to the control up to and including 3.2 mg a.s./kg dry weight artificial soil. Therefore, the NOEC is calculated to be 3.2 mg a.s./kg dry weight artificial soil and accordingly the LOEC is 5.6 mg a.s./kg dry weight artificial soil. Since variances of the data were homogenous, Williams Multiple Sequential t-test Procedure $\alpha = 0.05$, one-sided smaller was used.

Dimethoate a.s. showed an EC_{50} of 6.9 mg a.s./kg dry weight artificial soil (95% confidence limits from 6.7 mg a.s./kg to 7.0 mg a.s./kg) for reproduction according Logit analysis using maximum likelihood regression. This is in the recommended range of the guideline, indicating that an EC_{50} based on the number of juveniles of 3.0 – 7.0 mg a.s./kg dry weight artificial soil shows that the test organisms are sufficiently sensitive.

Conclusions:

$NOEC_{mortality}$: 562 mg product/kg dry weight artificial soil
$LOEC_{mortality}$: 1000 mg product/kg dry weight artificial soil

$NOEC_{reproduction}$: 316 mg product/kg dry weight artificial soil
$LOEC_{reproduction}$: 562 mg product/kg dry weight artificial soil

$EC_{10\text{-}reproduction}$: 441 mg product/kg dry weight artificial soil
$EC_{20\text{-}reprodcution}$: 549 mg product/kg dry weight artificial soil

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

No additional studies are submitted.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Reference:	**KCP 10.5/01**
Title:	Diflufenican + flufenacet SC 600 (200+400) G: determination of effects on nitrogen transformation in soil
Report:	Frommholz, U.; 2009; FRM_N_121/09; M_357934_01_1
Authority registration No:	
Guideline(s):	OECD 216; adopted January 21, 2000, OECD Guideline for the Testing of Chemicals, Soil Microorganisms: Nitrogen Transformation Test.
Deviations:	minor deviations
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study)	

Objectives

The objective of the test was to determine the influence of 0.8 µL and 4.0 µL of Diflufenican + Flufenacet SC 600 (200+400) G/kg dry weight soil on nitrogen transformation in an agricultural soil.

Materials and Methods

Test item: Diflufenican + Flufenacet SC 600 (200+400) G; analytical as contents: Diflufenican, 191.4 g/L, Flufenacet, 394.5 g/L; specification No.: 102000007948, batch No.: EV56001418, TOX-No.: FAR 01403-00; density: 1.229 g/mL.

A loamy sand soil (according to DIN 'mittel lehmiger Sand') was exposed for 28 d to 0.8 µL and 4.0 µL test item/kg dry weight soil, which is equivalent to 0.983 mg test item/kg dws and 4.916 mg test item/kg dws, respectively. Application rates were equivalent to 0.6 L and 3.0 L test item/ha. Lucerne-grass-green meal was added to the soil (5 g/kg dry weight soil) to stimulate nitrogen transformation.

Results and discussions

The coefficient of variation in the control at the end of the study was 10 %. Therefore, the validity criteria for the study, which requires a coefficient of variation ≤ 15 % in the control, was fulfilled.

Effects on non-target soil microorganisms

Time interval (days)	**Application rates**				
	Diflufenican + Flufenacet SC 600 (200+400) G				
	Control	**0.8 µL/kg dry weight soil**		**4.0 µL/kg dry weight soil**	
	Nitrate-N[1)]	**Nitrate-N[1)]**	**% difference to control**	**Nitrate-N[1)]**	**% difference to control**
0-7	1.86±0.11	1.93±0.04	4 n.s.	1.80±0.09	3 n.s.
7-14	1.16±0.30	1.13±0.07	2 n.s.	1.03±0.15	11 n.s.
14-28	1.83±0.13	1.79±0.08	3 n.s.	1.68±0.01	8 n.s.

[1)] Rate: Nitrate-N in mg/kg dry weight soil/time interval/day, mean of 3 replicates and standard deviation
n.s. = no statistically significant difference to the control (Student-t Test, two-sided, α = 0.05)

Observations:

During the 28-day test, 0.983 mg Diflufenican + Flufenacet SC 600 (200+400) G/kg dry weight soil and the 5-fold dose (4.916 mg test item/kg dws) had no unacceptable influence on nitrogen transformation in a loamy sand soil supplemented with Lucerne-grass-green meal. In none of the time intervals analysed during the 28-day exposure the difference in the daily nitrate-N rates between control soil samples and treated soil samples exceeds the trigger value of 25 %.

~~**Conclusion**~~
~~If used as recommended, Diflufenican + Flufenacet SC 600 (200+400) G should not have an impact on nitrogen transformation in soils.~~

Comments of zRMS:	The study was conducted in line with the respective guideline with no deviation. All the validity criteria were met and the study is considered acceptable. Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment: Flufenacet SC 508.8 G (508.8 g/L) caused no adverse effects (difference to control < 25% on the soil nitrogen transformation (expressed as NO_3-N-production) at the end of the 28-day incubation period up to 12.5 mg/kg soil dry weight.

Reference:	**KCP 10.5/02**
Title:	Flufenacet SC 508.8 (508.8 g/L): Effects on the activity of soil microflora (nitrogen transformation test)
Report:	Schulz, L.; 2022; 22 48 SMN 0016; M-821638-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No 1107/2009 (2009) OECD 216 US EPA OCSPP Not Applicable
Deviations:	None
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication (if vertebrate study):	

Objectives:
The objective of the test was to determine the influence of 2.5 and 12.5 mg of Flufenacet SC 508.8 G g/L/kg dry weight soil on nitrogen transformation in an agricultural soil.

Materials and Methods:
Flufenacet SC 508.8 G (508.8 g/L), [Short name: Flufenacet SC 508.8 G (508.8 g/L)], BCS-code: BCS-AB27364, Supplier batch No.: 2020-010174, Study ID of characterization study: TOX21819-00, Specification No.: 102000007779, analytical findings: 42.4 % w/w (511.8 g/L) flufenacet (FOE 5043), Density: 1.208 g/mL, water solubility: dispersible.

A loamy sand soil (DIN 4220) was exposed for 28 days to 2.5 mg product/kg soil dry weight and 12.5 mg product/kg soil dry weight. The nitrogen transformation was determined in soil enriched with lucerne meal (concentration in soil 0.5%). NH_4-nitrogen, NO_3- and NO_2-nitrogen were determined by an autoanalyzer at different sampling intervals (0, 7, 14 and 28 days after treatment).

The coefficients of variation in the control (NO_3-N) were maximum 10.1 % and thus fulfilled the demanded range (≤ 15 %).

Results and discussions:
The coefficient of variation in the control at the end of the study was 10.1 %. Therefore, the validity criteria for the study, which requires a coefficient of variation ≤ 15 % in the control, was fulfilled.

Effects on non-target soil microorganisms

Time interval (days)	Control			2.5 mg product/kg soil dry weight				12.5 mg product/kg soil dry weight			
	Nitrate-N [1)]			Nitrate-N [1)]			% difference to control	Nitrate-N [1)]			% difference to control
0-7	2.16	±	0.85	3.08	±	0.37	+42.6 [n.s.]	2.98	±	0.31	+38.2 [n.s.]
7-14	1.65	±	0.53	1.65	±	0.16	+0.3 [n.s.]	2.48	±	0.17	+50.3 [n.s.]
14-28	1.97	±	0.16	1.78	±	0.20	-9.3 [n.s.]	1.90	±	0.23	-3.5 [n.s.]

The calculations were performed with unrounded values

[1)] Rate: Nitrate-N in mg/kg soil dry weight/time interval/day, mean of 3 replicates and standard deviation

[n.s.] = No statistically significant difference to the control (Student-t-test for homogeneous variances, 2-sided, $\alpha = 0.05$)

Observations:

The test item Flufenacet SC 508.8 G (508.8 g/L) caused temporary stimulation of the daily nitrate rate at the tested concentration of 2.5 mg/kg soil dry weight at time interval 0-7 days after application.
However, no adverse effects Flufenacet SC 508.8 G (508.8 g/L) on nitrogen transformation in soil could be observed at a test concentration of 2.5 mg/kg dry soil, 28 days after application (time interval 14-28 days after application).
A difference from control of -9.3 % (test concentration 2.5 mg/kg dry soil) was measured 28 days after application (time interval 14-28 days after application).

The test item Flufenacet SC 508.8 G (508.8 g/L) caused temporary stimulations of the daily nitrate rate at the tested concentration of 12.5 mg/kg soil dry weight up to time interval 7-14 days after application. However, no adverse effects of Flufenacet SC 508.8 G (508.8 g/L) on nitrogen transformation in soil could be observed at the tested concentration of 12.5 mg/kg dry at the end of the test, 28 days after application (time interval 7-14 days).
A difference from the control of -3.5 % (test concentration 12.5 mg/kg dry soil) was measured at the end of the 28-day incubation period (time interval 14-28).

Conclusion:

Flufenacet SC 508.8 G (508.8 g/L) caused no adverse effects (difference to control < 25 %, OECD 216) on the soil nitrogen transformation (expressed as NO_3-N-production) at the end of the 28-day incubation period. The study was performed in a field soil at concentrations up to 12.5 mg/kg soil dry weight.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

No additional studies are submitted.

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	The study was considered acceptable. The study was evaluated and agreed by the RMS in the course of the ongoing EU renewal process with the following endpoints: EC_{50} = 11.5 g a.s./ha, Lolium perenne EC_{50} = 10.5 g a.s./ha, Sorgum biclor EC_{50} = 53.3 g s.a./ha, Allium cepa EC_{50} = 80.9 g s.a./ha, Avena sativa EC_{50} = 477.9 g s.a./ha, Zea mays EC_{50} > 101 g a.s./ha Cucumis sativa EC_{50} = 282.7 g a.s./ha, Brassica rapa EC_{50} = 275.4 g a.s./ha, Beta vulgaris EC_{50} > 93.6 g a.s./ha, Lycopersicon esc. EC_{50} > 600 g a.s./ha, Glycine max The most sensitive plant species: Sorgum biclor with EC_{50} = 10.5 g a.s./ha, based on shoot fresh weight The study was used in the risk assessment.

Reference:	**KCP 10.6.2/01**
Title:	Flufenacet SC 500: seedling emergence and seedling growth test on terrestrial non-target plants
Report:	Friedrich, S.; 2005; 041048104; M-248250-01-1
Authority registration No:	
Guideline(s):	OECD 208 A (2000, draft): seedling emergence and seedling growth test US EPA OCSPP 850.4225
Deviations:	none
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process thus additional validation at the zonal level is deemed not necessary
Duplication (if vertebrate study)	

~~**Objective**~~

~~The purpose of this specific study was to evaluate the phytotoxic effect of Flufenacet SC 500 on the seedling emergence and seedling growth of non-target terrestrial plant species following a pre-emergence application of the product onto the soil surface. The plant species used in this study are representative of a wide range of plant families and were chosen because they are readily cultivated test organisms and widely used in research.~~

~~**Material and methods**~~

~~Test item: Flufenacet SC 500, containing 42.3 % w/w flufenacet (FOE 5043), Article No.: 05559022,~~

Development No.: 0209689, Batch No.: EFKF000175, TOX No.: 06900-00; control: water treated.

In ten experiments, each with a duration of 21 days after 50 % seedling emergence, the toxicity of the test item Flufenacet SC 500 to 4 monocotyledonae and 6 dicotyledonae plant species: (*Zea mays*, *Avena sativa*, *Allium cepa*, *Lolium perenne*, *Sorghum bicolor*, *Brassica rapa*, *Beta vulgaris*, *Cucumis sativa*, *Lycopersicon esculentum*, *Glycine max)* was examined in comparison with control treatments under greenhouse conditions. For the different plant species were 2 (*Zea mays*, *Cucumis sativa*, *Lycopersicon esculentum*, *Glycine max*), 4 (*Sorghum bicolor*, *Brassica rapa*, *Beta vulgaris*) or 5 (*Avena sativa*, *Allium cepa*, *Lolium perenne*,) plants per pot grown and there were 16, 8 or 7 replicates/pots (resulting in 32-35 plants per treatment), respectively.

In the experiments, the test item Flufenacet SC 500 was applied to the test plants at nominal application rates of 18.75, 37.5, 75, 150, 300, 600 g a.s./ha (*Zea mays*, *Avena sativa*, *Brassica rapa*, *Beta vulgaris*, *Cucumis sativa*, *Lycopersicon esculentum*, *Glycine max*), 4.7, 9.4, 18.75, 37.5, 75, 150 g a.s./ha (*Allium cepa*, *Lolium perenne*) and 2.4, 4.7, 9.4, 18.75, 37.5, 75 g a.s./ha (*Sorghum bicolor*), respectively, in 400 L/ha of water. The test item was sprayed onto the soil surface after sowing. Plants were grown and maintained under glasshouse conditions at a temperature of 11 to 31° C with a 16 h photoperiod. The relative humidity was in a range between 35 and 82 %. Natural daylight supplemented by artificial lighting. However, the light intensity was not recorded. Seedling emergence, survival (mortality) after emergence, shoot fresh weight, phytotoxicity and growth inhibition of the plants were recorded and treated plants were evaluated against untreated controls for inhibitory effects. Statistical analysis of data was performed to obtain NOER/LOER values and ER_{50}, where possible, using the software ToxRat Professional 2.07 (RATTE 2002). NOER/LOER and ER_{50} were determined for seedling emergence, survival after emergence and shoot fresh weight at the final assessment on day 21 after 50 % seedling emergence.

Dates of work: November 05, 2004 – December 23, 2004

Results
This study can be considered valid as the validity criteria of at least 70% emergence and at least 90% survival of the emerged seedlings throughout the study period for the untreated controls was achieved for all species tested. The control seedlings of each species did not exhibit visible visual injuries (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) and control plants exhibited normal variation in growth and morphology for that particular species.

Analytical results:
The highest dosed test solutions at the start of the test were analysed for Flufenacet and resulted in recoveries between 87.6% and 103.9% of nominal.

The NOER, LOER and ER_{50} for emergence and survival and shoot fresh weight expressed as g a.s./ha are summarized for each of the plant species for the final assessment (21 days post emergence of 50% of the control seedlings) and can be found in the following tables.

Growth stage of the treated plants according to BBCH scale (min – max BBCH) was determined for the last assessment day and is compared to the growth stage of the control plants. Results are displayed in the following tables.

The severity and occurrence of phytotoxic injury and growth inhibition was estimated in percent. Observations made at the final assessment (21 days post emergence of 50% of the control seedlings) are shown in the following tables.

on day 21 after 50 % emergence	Flufenacet SC 500 [g a.s./ha in 400 L/ha]		
Plant species	Seedling emergence	Survival after emergence	Shoot fresh weight

	~~ER_{50}~~	~~ER_{50}~~	~~ER_{50}~~	~~NOER~~	~~LOER~~
~~*Zea mays*~~	~~> 600~~	~~> 600~~	~~477.9~~	~~75~~	~~150~~
~~*Avena sativa*~~	~~472.3~~	~~418.0~~	~~80.9~~	~~37.5~~	~~75~~
~~*Allium cepa*~~	~~> 150~~	~~> 150~~	~~53.3~~	~~18.75~~	~~37.5~~
~~*Lolium perenne*~~	~~47.2~~	~~18.0~~	~~11.5~~	~~4.7~~	~~9.4~~
~~*Sorghum bicolor*~~	~~34.7~~	~~36.6~~	~~10.5~~	~~4.7~~	~~9.4~~
~~*Brassica rapa*~~	~~> 600~~	~~> 600~~	~~282.7~~	~~75~~	~~150~~
~~*Beta vulgaris*~~	~~> 600~~	~~> 600~~	~~275.4~~	~~75~~	~~150~~
~~*Cucumis sativa*~~	~~> 600~~	~~> 600~~	~~101.1~~	~~18.75~~	~~37.5~~
~~*Lycopersicon esculentum*~~	~~> 600~~	~~365.1~~	~~93.6~~	~~18.75~~	~~37.5~~
~~*Glycine max*~~	~~> 600~~	~~> 600~~	~~> 600~~	~~150~~	~~300~~

on day 21 after 50 % emergence	*Plant species*						
Flufenacet SC 500 (g a.i./ha)	***Zea mays***	***Avena sativa***	***Brassica rapa***	***Beta vulgaris***	***Cucumis sativa***	***Lycopers. escul.***	***Glycine max***
	Necrosis (%)						
Control	0	0	0	0	0	0	0
18.75	0	0	0	0	0	0	0
37.5	0	0	0	0	0	2	0
75	0	5	0	0	0	4	0
150	0	5	0	0	2	3	0
300	0	2	5	3	4	9	0
600	2	2	2	3	4	9	0
	Chlorosis (%)						
Control	0	0	0	0	0	0	0
18.75	0	0	0	0	0	0	0
37.5	0	0	0	0	0	0	0
75	0	0	0	0	2	0	0
150	0	0	0	0	5	9	0
300	0	0	2	2	4	6	0
600	2	0	2	5	2	0	0
	Growth inhibition (%)						
Control	0	0	0	0	0	0	0
18.75	0	0	0	0	0	0	0
37.5	0	11	0	0	7	17	0
75	0	46	6	5	31	27	0
150	13	81	34	26	64	63	0
300	30	91	51	51	82	84	12*
600	52	98	76	80	91	91	27*
	Deformation (%)						
Control	0	0	0	0	0	0	0
18.75	0	0	0	0	0	0	0
37.5	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0
150	0	0	3	2	0	0	0
300	0	0	5	5	0	0	0
600	0	0	11	5	0	0	0
	BBCH growth stage						
Control	13	15	16	12-13	12-13	12	14
18.75	13	15	16	12-13	12-13	12	14
37.5	13	15	16	12-13	12-13	12	14
75	13	14-15	14-15	12-13	12-13	12	14
150	13	13	14-15	12	12	11-12	14
300	12-13	10-11	13-14	12	10-11	10	14
600	12	10	11-12	10-12	10 -	n.d.	13-14

n.d.: not determinable
* plants weakened in the habit

21 days after application	Plant species			Plant species
Flufenacet SC 500 (g a.i./ha)	*Allium cepa*	*Lolium perenne*	Flufenacet SC 500 (g a.i./ha)	*Sorghum bicolor*
	Necrosis (%)			
Control	0	0	Control	0
4.7	0	0	2.4	0
9.4	0	0	4.7	0
18.75	0	0	9.4	0
37.5	0	3	18.75	0
75	5	4	37.5	0
150	8	4	75	2
	Chlorosis (%)			
Control	0	0	Control	0
4.7	0	0	2.4	0
9.4	0	0	4.7	0
18.75	0	0	9.4	0
37.5	2	2	18.75	0
75	5	4	37.5	0
150	10	2	75	0
	Growth inhibition (%)			
Control	0	0	Control	0
4.7	0	0	2.4	0
9.4	0	10	4.7	0
18.75	12	54	9.4	5
37.5	20	77	18.75	10
75	30	85	37.5	40
150	40	92	75	70
	Deformation (%)			
Control	0	0	Control	0
4.7	0	0	2.4	0
9.4	0	0	4.7	0
18.75	0	0	9.4	0
37.5	0	0	18.75	0
75	0	0	37.5	0
150	0	0	75	0
	BBCH growth stage			
Control	15	23	Control	21
4.7	15	23	2.4	21
9.4	15	23	4.7	21
18.75	15	22-23	9.4	15
37.5	14-15	21	18.75	15
75	13-14	12-13	37.5	14
150	12	12	75	13

~~**Conclusion**~~

~~In a seedling emergence and growth study, Flufenacet SC 500 was tested under greenhouse conditions for effects on the survival, growth and shoot dry weight of ten non-target terrestrial plant species, following a post-emergence application of the test item onto the foliage of plants at the 2 leaf stage. The most sensitive species was found to be *Sorghum bicolor* with the lowest ER_{50} of 10.5 g a.s./ha based on shoot fresh weight, 34.7 g a.s./ha based on seedling emergence and 36.6 g a.s./ha based on survival.~~

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Comments of zRMS:	The study was considered acceptable. The study was evaluated and agreed by the RMS in the course of the ongoing EU renewal process with the following endpoints: EC_{50} = 17 g a.s./ha, Lolium perenne EC_{50} = 43 g a.s./ha, Sorgum biclor EC_{50} = 132 g s.a./ha, Allium cepa EC_{50} = 196 g s.a./ha, Avena sativa EC_{50} > 600 g a.s./ha, Zea mays EC_{50} = 102 g s.a./ha, Cucuma sativa EC_{50} = 167 g a.s./ha, Brassica rapa EC_{50} = 525 g a.s./ha, Beta vulgaris EC_{50} > 600 g a.s./ha, Lycopersicon EC_{50} = 168 g a.s./ha, Glycine max The most sensitive plant species: Lolium perenne with EC_{50} = 17 g a.s./ha, based on shoot fresh weight Although the renewal process is not finalised yet, no changes regarding the derived endpoints are expected.

Reference:	**KCP 10.6.2/02**
Title:	Flufenacet SC 500: vegetative vigour test on non-target terrestrial plants
Report:	Friedrich, S.; 2005; 041048105; M-248251-01-1
Authority registration No:	
Guideline(s):	OECD 208 B (Draft 2000) US EPA OCSPP 850.4250
Deviations:	--
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process thus additional validation at the zonal level is deemed not necessary
Duplication (if vertebrate study)	

~~**Objective**~~

~~The objective of this study was to evaluate the potential effects of Flufenacet SC 500 on the vegetative vigour of ten species of non-target terrestrial plants, following a post-emergence application of the product onto the foliage and above-ground portions of plants. The plant species used in this study are representative of a wide range of plant families and were chosen because they are readily cultivated test organisms and widely used in research.~~

~~**Material and methods**~~

~~Test item: Flufenacet SC 500, containing 42.3 % w/w flufenacet (FOE 5043), Article No.: 05559022, Development No.: 0209689, Batch No.: EFKF000175, TOX No.: 06900-00; control: water treated.~~

~~In ten experiments, each with a duration of 21 days, the toxicity of the test item Flufenacet SC 500 to 4 monocotyledonae and 6 dicotyledonae plant species: plant species (*Zea mays*, *Avena sativa*, *Allium cepa*, *Lolium perenne*, *Sorghum bicolor*, *Brassica rapa*, *Beta vulgaris*, *Cucumis sativa*, *Lycopersicon esculentum*, *Glycine max*) was examined in comparison with control treatments under greenhouse conditions. For the different plant species were 2 (*Zea mays*, *Cucumis sativa*, *Lycopersicon esculentum*, *Glycine max*), 4 (*Sorghum bicolor*, *Brassica rapa*, *Beta vulgaris*) or 5 (*Avena sativa*, *Allium cepa*, *Lolium*~~

perenne,) plants per pot grown and there were 16, 8 or 7 replicates/pots (resulting in 32-35 plants per treatment), respectively.

In the experiments, the test item Flufenacet SC 500 was applied to the test plants at nominal application rates of 18.75, 37.5, 75, 150, 300, 600 g a.s./ha (*Zea mays*, *Avena sativa*, *Brassica rapa*, *Beta vulgaris*, *Cucumis sativa*, *Lycopersicon esculentum*, *Glycine max*), 4.7, 9.4, 18.75, 37.5, 75, 150 g a.s./ha (*Allium cepa*, *Lolium perenne*) and 2.4, 4.7, 9.4, 18.75, 37.5, 75 g a.s./ha (*Sorghum bicolor*), respectively, in 400 L/ha of water. Plants in the 2 leaf stage were used (i.e. approximately 3 to 5 weeks after the plants had emerged from the soil). The test item was sprayed onto the plant foliage. Plants were grown and maintained under glasshouse conditions at a temperature of 11 to 31° C with a 16 h photoperiod. The relative humidity was in a range between 35 and 82 %. Natural daylight supplemented by artificial lighting. However, the light intensity was not recorded. Survival, shoot fresh weight, phytotoxicity and growth inhibition of the plants were recorded, and treated plants were evaluated against untreated controls for inhibitory effects. Statistical analysis of data was performed to obtain NOER/LOER values and ER_{50}, where possible, using the software ToxRat Professional 2.07 (Ratte 2002). NOER/LOER and ER_{50} were determined for survival and shoot fresh weight at the final assessment on day 21 after application.

Dates of work: November 05, 2004 – December 23, 2004

Results

All validity criteria were met but the germination rate of the seeds used in this study was not reported. However, as routine germination tests were carried out on the seeds to ensure their viability, the germination rate can be considered to be in the acceptable range. The survival of the emerged seedlings throughout the study period for the untreated controls was 90% for all species tested. The control seedlings of each species did not exhibit visible visual injuries (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) and control plants exhibited normal variation in growth and morphology for that particular species.

Analytical results:
The highest dosed test solutions at the start of the test were analysed for Flufenacet and resulted in recoveries between 87.6% and 99.9% of nominal.

The NOER, LOER and ER_{50} for survival and shoot fresh weight expressed as g a.s./ha are summarized for each of the plant species for the final assessment (21 days post emergence of 50% of the control seedlings) and can be found in the following tables.

Growth stage of the treated plants according to BBCH scale (min – max BBCH) was determined for the last assessment day and is compared to the growth stage of the control plants. Results are displayed in the following tables.

The severity and occurrence of phytotoxic injury and growth inhibition was estimated in percent. Observations made at the final assessment (21 days post emergence of 50% of the control seedlings) are shown in the following tables.

21 days after application	**Flufenacet SC 500 {g a.s./ha in 400 L/ha}**			
Plant species	**Survival ER_{50}**	**Shoot fresh weight**		
		ER_{50}	**NOER**	**LOER**
Zea mays	> 600	> 600	300	600
Avena sativa	> 600	196	37.5	75
Allium cepa	> 150	132	9.4	18.75
Lolium perenne	> 150	17	4.7	9.4
Sorghum bicolor	> 75	43	9.4	18.75
Brassica rapa	> 600	167	37.5	75
Beta vulgaris	> 600	525	150	300

Cucumis sativa	> 600	102	< 18.75	18.75
Lycopersicon esculentum	> 600	> 600	18.75	37.5
Glycine max	> 600	168	18.75	37.5

21 days after application	Plant species						
Flufenacet SC 500 (g a.i./ha)	***Zea mays***	***Avena sativa***	***Brassica rapa***	***Beta vulgaris***	***Cucumis sativa***	***Lycopers. esculent.***	***Glycine max***
	Necrosis (%)						
Control	0	0	0	0	0	0	0
18.75	0	0	0	0	3	0	2
37.5	0	0	3	0	7	2	5
75	0	0	6	0	10	4	7
150	0	0	11	2	11	6	17
300	0	0	14	5	12	8	22
600	0	0	20	6	14	12	20
	Chlorosis (%)						
Control	0	0	0	0	0	0	0
18.75	0	0	0	0	2	0	2
37.5	0	0	0	0	5	0	5
75	0	0	2	0	6	2	8
150	0	0	5	2	9	5	10
300	0	0	5	5	7	10	8
600	0	0	6	9	6	8	5
	Growth inhibition (%)						
Control	0	0	0	0	0	0	0
18.75	0	0	0	0	10	0	0
37.5	0	2	6	0	14	10	11
75	0	16	13	2	35	18	20
150	0	35	31	11	47	24	38
300	5	64	55	25	56	28	44
600	11	77	69	54	62	33	53
	Deformation (%)						
Control	0	0	0	0	0	0	0
18.75	0	0	0	0	0	0	0
37.5	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0
150	0	0	2	0	0	0	0
300	0	0	5	0	0	0	0
600	0	0	2	0	0	0	0
	BBCH growth stage						
Control	15	21	19	15-16	61	55	21
18.75	15	21	19	15-16	61	55	21
37.5	15	21	19	15-16	61	55	21
75	15	21	18	15-16	60	54	14
150	15	21	14	15-16	60	51	13
300	15	13-14	13	14-15	55	15-16	12-13
600	14-15	13	12	12-14	12	13-14	12

21 days after application	*Plant species*			*Plant species*
Flufenacet SC 500 (g a.i./ha)	***Allium cepa***	***Lolium perenne***	**Flufenacet SC 500** (g a.i./ha)	***Sorghum bicolor***
	Necrosis (%)			
Control	0	0	Control	0
4.7	0	0	2.4	0
9.4	0	0	4.7	0
18.75	0	0	9.4	0
37.5	0	3	18.75	0
75	5	4	37.5	0
150	8	4	75	2
	Chlorosis (%)			
Control	0	0	Control	0
4.7	0	0	2.4	0
9.4	0	0	4.7	0
18.75	0	0	9.4	0
37.5	2	2	18.75	0
75	5	4	37.5	0
150	10	2	75	0
	Growth inhibition (%)			
Control	0	0	Control	0
4.7	0	0	2.4	0
9.4	0	10	4.7	0
18.75	12	54	9.4	5
37.5	20	77	18.75	10
75	30	85	37.5	40
150	40	92	75	70
	Deformation (%)			
Control	0	0	Control	0
4.7	0	0	2.4	0
9.4	0	0	4.7	0
18.75	0	0	9.4	0
37.5	0	0	18.75	0
75	0	0	37.5	0
150	0	0	75	0
	BBCH growth stage			
Control	15	23	Control	21
4.7	15	23	2.4	21
9.4	15	23	4.7	21
18.75	15	22-23	9.4	15
37.5	14-15	21	18.75	15
75	13-14	12-13	37.5	14
150	12	12	75	13

~~**Conclusion**~~

~~In a vegetative vigour study, Flufenacet SC 500 was tested under greenhouse conditions for effects on the seedling emergence, survival, growth and shoot dry weight of ten non-target terrestrial plant species, following a pre-emergence application of the test item to the soil surface. The most sensitive species was found to be *Lolium perenne* with the lowest ER_{50} of 17 g a.s./ha based on biomass (shoot fresh weight) and >150 g a.s./ha based on survival. The second most sensitive species was *Sorghum bicolor with* an ER_{50} of >75 g a.s./ha and >75 g a.s./ha, based on shoot dry weight and survival, respectively.~~

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

No additional studies are submitted.

A 2.6.4 KCP 10.6.4. Semi-field and field tests on non-target plants

No additional studies are submitted.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

No additional studies are submitted.

A 2.8 KCP 10.8 Monitoring data

No additional studies are submitted.