REGISTRATION REPORT

Part A

Risk Management

Product code: 102000007779

Product name(s): Flufenacet SC 508.8 G

(Active substance(s)): Flufenacet 508.8 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT: Poland

(Authorization)

Applicant: Bayer SAS

Submission date: 30 June 2021

MS Finalisation date: March 2023 (initial National Assessment)
June 2023 (final Core Assessment)

Version history

When	What
June 2021	Original Bayer Crop Science Division submission
March 2023	Initial zRMS assessment In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and the product label are highlighted in grey, while not agreed use pattern ~~is struck through and shaded~~.
June 2023	Final report (National Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This document describes the acceptable use conditions required for the registration of the product Flufenacet SC 508.8 G (508.8 g/L) in the Central Zone – Poland acts as zonal Rapporteur Member State (zRMS).
Other concerned Member States (cMS) – Ireland, Slovakia, Belgium.

This product has been developed by Bayer S.A.S. Crop Science Division to protect cereals – winter wheat, winter barley, winter triticale, rye, durum wheat and spelt against weeds – black twitch (ALOMY), annual bluegrass (POAAN), loose silky bent (APESV), Lolium sp. (LOLSS), broad-leaved plants (BBBBB), dicotyledonous grain weed plants (TTTDS). This new product contains 508.8 g/L of flufenacet.

FFA SC 508.8 G is an aqueous suspension concentrate containing 508.8 g/L flufenacet approved in accordance with Commission Directive 2003/84/EC.

The risk assessment conclusions are based on the information, data and assessments provided in the draft Registration Report, Part B Sections 1-10 and Part C.

It also includes assessment of data and information relating to Flufenacet SC 508.8 (508.8 g/L) where data have not been considered in the EU review. Otherwise assessments for the safe use of Flufenacet SC 508.8 (508.8 g/L) have been made using endpoints agreed in the EU review of flufenacet.

This document describes the specific conditions of use and labelling required in Poland for the authorisation of FFA SC 508.8 G.

1.2 Letters of Access

Bayer CropScience is the notifier for the active substance Flufenacet and therefore is the company owning and submitting a complete set of data, resulting in the approval of the active substance Flufenacet according to Regulation Nº 1107/2009.

1.3 Justification for submission of tests and studies

The tests and studies on vertebrate animals submitted within this dossier are necessary to complete the data package as required in the Commission Regulation (EU) No 284/2013 setting out the data requirements for Plant Protection Products. Existing data was not available from another source.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as mentioned in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	Flufenacet SC 508.8 (508.8 g/L) FFA SC 508.8 G Specification No.: 102000007779	
Product name in MS	CADOU	
Authorisation number	-	
Function	Herbicide	
Applicant	Bayer SAS, France	
Active substance(s) (incl. content)	508.8 g/L flufenacet	
Formulation type	Aqueous suspension concentrate [Code: e.g. SC]	
Packaging	Type: Materials: Capacity: Opening and type of closure: Compliance **Outer packaging** Type:	Bottle/Canister:from HDPE or coextruded HDPE, COEX/EVOH Coextruded high density polyethylene (HDPE) with an internal barrier layer made of ethylene vinyl alcohol copolymer (EVOH) or COEX/PA Coextruded high density polyethylene (HDPE) with an internal barrier layer made of polyamide (PA) 1 L, 3 L, 5L, 10 L, 15 L Screw cap 50 mm Cobra, 63 mm Glostar (with HF seal or internal wad) - to fit container neck as defined in ECPA One Trip Container Guidelines. The packaging complies with CropLife International recommendations for one way agrochemical packaging design criteria for liquids and solids [Guidelines for the safe formulation and packaging of crop protection products (Guideline 6)]. The product may or may not be packed in an outer corrugated fibreboard case like: 12 x 1 litre bottle; 4 x 5 litres bottles
Coformulants of concern for national authorisations	None	
Restrictions related to identity	None	
Mandatory tank mixtures	None	
Recommended tank mixtures	None	

2.2 Conclusion

The evaluation of the application for the product FFA SC 508.8 G (Cadou) resulted in the decision to grant the authorization.

2.3 Substances of concern for national monitoring

No national monitoring data required for flufenacet.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute oral toxicity: Category 4 Specific target organ toxicity - repeated exposure: Category 2 Acute aquatic toxicity: Category 1 Chronic aquatic toxicity: Category 1

The following labelling information is derived from the classification and is to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms	 **GHS07**  **GHS08**  **GHS09**
Signal word:	Warning
Hazard statement(s):	**H302** Harmful if swallowed **H373** May cause damage to organs (Nervous system) through prolonged or repeated exposure if swallowed. **H410** Very toxic to aquatic life with long lasting effects. EUH208 Contains Flufenacet, 1,2-benzisothiazolin-3-one, 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one. May produce an allergic reaction EUH401 To avoid risks to man and the environment, comply with the instructions for use.
Precautionary statement(s):	P260 Do not breathe gas/ mist/ vapours/ spray. P280 Wear protective gloves~~/ protective clothing/ eye protection/ face protection~~. P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor/ physician. P391 Collect spillage. P501 Dispose of contents/container in accordance with local regulation.
Additional labelling phrases:	-

Special rule for labelling of plant protection product (PPP):	
Further labelling statements under Regulation (EC) No 1272/2008:	
Hazardous components which must be listed on the label	Flufenacet

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None	

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
	Gloves during mixing/loading and when handling contaminated surfaces
Worker protection:	
	None
Integrated pest management (IPM)/sustainable use:	
	None
Environmental protection	
SP1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
Other specific restrictions	
SPe3	Cereals 1 x 0.24 l/ha To protect aquatic organisms respect an vegetated filter strip of 10 m to surface water bodies.
SPe3	Cereals 1 x 0.48 l/ha To protect aquatic organisms respect an vegetated filter strip of 20 m to surface water bodies

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
	None

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
	None	
Environmental protection:		Relevant for use no.
SPe3	Cereals 1 x 0.24 l/ha To protect aquatic organisms respect an vegetated filter strip of 10 m to surface water bodies.	31,32,35,36,39,40,91,92,95,96131,132
SPe3	1 x 0.48 l/ha To protect aquatic organisms respect an vegetated filter strip of 20 m to surface water bodies	29,30,33,34,37,38,89,90,93,94,129,130

2.6 Intended uses (only NATIONAL GAP)

GAP rev.1, date: 2023-March

PPP (product name/code):	FFA SC 508.8 G / 102000007779	Formulation type:	SC [a, b]
Active substance 1:	Flufenacet (FFA)	Conc. of as 1:	508.8 g/L [c]
Active substance 2:	-	Conc. of as 2:	- [c]
Active substance….:	-	Conc. of as ….:	- [c]
Safener:	no	Conc. of safener:	not relevant [c]
Synergist:	no	Conc. of synergist:	not relevant [c]
Applicant:	Bayer CropScience	Professional use:	☒
Zone(s):	central [d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15								
Use-No. [e]	**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 [f]	**Overall conclusions**							
					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			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																						
29	POL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, ~~LOLSS~~ LOLMU, ~~BBBBB, TTTDS~~ MATIN, PAPRH, VERPE	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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
30	POL	Wheat, winter (TRZAW)	F	~~ALOMY~~, POAAN, APESV, ~~LOLSS~~	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		A	A	A	A	A	R Aquatics,	A	A

				LOLMU, ~~BBBBB, TTTDS~~														A Remaining species		
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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
33	POL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, ~~LOLSS~~ LOLMU, ~~BBBBB, TTTDS~~ MATIN, PAPRH, VERPE	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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
34	POL	Triticale, winter (TTLWI)	F	~~ALOMY~~, POAAN, APESV, ~~LOLSS~~ LOLMU, ~~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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
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		A	A	A	A	A	R Aquatics, A Remaining species	A	A

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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
37	POL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, ~~LOLSS~~ LOLMU, ~~BBBBB, TTTDS~~ MATIN, PAPRH, VERPE	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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
38	POL	Barley, winter (HORVW)	F	~~ALOMY,~~ POAAN, APESV, ~~LOLSS~~ LOLMU, ~~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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
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		A	A	A	A	A	R Aquatics, A Remaining species	A	A

89	POL	Rye (SECCW)	F	ALOMY, POAAN, APESV, ~~LOLSS~~ LOLMU, ~~BBBBB, TTTDS~~ MATIN, PAPRH, VERPE	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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
90	POL	Rye (SECCW)	F	~~ALOMY,~~ POAAN, APESV, ~~LOLSS~~ LOLMU, ~~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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
93	POL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, ~~LOLSS~~ LOLMU,	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		A	A	A	A	A	R Aquatics,	A	A

				~~BBBBB,~~ ~~TTTDS,~~ MATIN, PAPRH, VERPE														A Remaining species		
94	POL	Durum wheat (TRZDW)	F	~~ALOMY,~~ POAAN, APESV, ~~LOLSS~~ LOLMU, ~~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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
129	POL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, ~~LOLSS~~ LOLMU, ~~BBBBB,~~ ~~TTTDS~~ MATIN, PAPRH, VERPE	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		A	A	A	A	A	R Aquatics, NTP A Remaining species	A	A
130	POL	Spelt (TRZSP)	F	~~ALOMY,~~ POAAN, APESV, ~~LOLSS~~	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		A	A	A	A	A	R Aquatics,	A	A

				LOLMU, ~~BBBBB, TTTDS~~														A Remaining species		
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		A	A	A	A	A	R Aquatics, A Remaining species	A	A
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		A	A	A	A	A	R Aquatics, A Remaining species	A	A

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when 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
15 Overall conclusions - explanation for the column 15 is below *

* Explanation for column 15 “Overall conclusions”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a beige opaque liquid, with no odour. It is not explosive, has no oxidising properties. The product has no flash point up to 95°C. It has an auto-ignition temperature of 417 C. In aqueous solution, it has a pH value around 5.9 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed.
The 2 years storage stability is still on going and will be submitted upon finalization.

3.2 Efficacy (Part B, Section 3)

Please refer to 3.3.

3.3 Efficacy data

For FFA SC508.8 no specific preliminary range finding tests are presented here since this product contains one active substance. The active substance flufenacet has been used for approximately 20 years and the herbicidal effects are well known.
Data shows that FFA SC508.8 applied at 0.24 L/ha at BBCH 00-09 is an effective product for the control of APESV and POAAN.
Data shows that FFA SC508.8 applied at 0.48 L/ha at BBCH 00-09 is an effective product for the control of the grasses ALOMY, APESV, LOLMU, POAAN and the broad-leaved weeds MATIN, PAPRH and VERPE.
Data shows that FFA SC508.8 applied at 0.24 L/ha at BBCH 10-13 is an effective product for the control of APESV and POAAN.
Data shows that FFA SC508.8 applied at 0.48 L/ha at BBCH 10-13 is an effective product for the control of APESV, LOLMU and POAAN.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Acceptability of the Resistance Risk
An acceptable practical risk of selecting resistant biotypes is suggested when the product is used following the rotation of herbicide mode of action and crop rotation in the cropping system. Moreover, the inherent risk of flufenacet is considered to be low.

Resistance Management Strategy and Use Pattern
To avoid the selection of resistance it is recommended to perform one application of Flufenacet SC 508.8 at the recommended dose(s) in winter cereals per season according to the phenological stage of the weeds to control.

Communication and Implementation of the Management Strategy
The anti-resistance strategy for the product Flufenacet SC 508.8 is communicated to the advisory and at farmer's level essentially on the product label. In addition, leaflets and brochures that describe the product properties in a detailed manner contain the essential anti-resistance strategy points

3.3.2 Adverse effects on treated crops

It is concluded that application of FFA SC 508.8 G applied at 0.24 L/ha (USE001 and USE003) in winter cereals as tested in a range of climatic and soil conditions, will not cause any unacceptable adverse effects, when applied according to the recommendations for use at crop BBCH 00-09 or BBCH 10-13.

It is concluded that application of FFA SC 508.8 G applied at 0.48 L/ha (USE 002 and USE004) in winter soft wheat, winter barley, rye, triticale, spelt and durum wheat, as tested in a range of climatic and soil conditions can cause some transient phytotoxicity symptoms i.a. volume reduction, stunting, thinning, either in pre- and post-emergence application.

3.3.3 Observations on other undesirable or unintended side-effects

Considering the aforementioned studies, the test product FFA SC 508.8 G does not pose any risk for adjacent crops. No risk mitigation measurements must be considered.

Detailed studies on the potential adverse effects to beneficial organisms are submitted and summarised in the core dossier Part B, Section 9 (Ecotoxicology).

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical method AM036120MF1

The analytical method AM036120MF1 was validated with success for the determination of flufenacet in the test item Flufenacet SC 508.8 (508.8 g/L) according to the requirements laid down by SANCO/3030/99 rev.5, all criteria were met.

3.4.2 Analytical methods for residues

An overview on the acceptable methods for analysis of residues of flufenacet for the generation of pre-authorization data is given in the core dossier, Part B, Section 5.
Sufficiently sensitive and selective analytical methods are available and validated for all analytes included in the residue definition for plant and animal commodities, soil, drinking and surface water, body fluids and air.

The Applicant submitted a number of methods for analysis of residues of flufenacet for the generation of pre-authorization data and methods for post-authorization control and monitoring purposes.
Many analytical methods for the determination of flufenacet in different matrices were submitted in the ongoing AIR dossier for renewal of flufenacet and was evaluated by RMS-Poland in the frame of the re-approval (RAR for Flufenacet; Vol. 3 – B.5, April 2022). Therefore, the studies are not evaluated in this dossier.
The details of the evaluation of additional studies are referred in Appendix 2 of Part B5.

3.5 Mammalian toxicology (Part B, Section 6)

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended. No specific PPE is necessary.
For more detailed information please refer to the core dossier.

3.5.1 Acute toxicity

Full summaries of the acute toxicity studies on the product have been provided in the Core assessment. Studies are acceptable. FFA SC 508.8 G has a low toxicity in respect to acute dermal and inhalation toxicity and is neither a skin or an eye irritant nor a skin sensitizer. It is classified with regard to acute oral toxicity and must be labelled with H302: harmful if swallowed.

3.5.2 Operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mentioned personal

protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

3.5.3 Worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

3.5.4 Bystander and resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for flufenacet will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

3.6 Residues and consumer exposure (Part B, Section 7)

3.6.1 Residues

The data available are considered sufficient for risk assessment.
For flufenacet, the GAP evaluated in the EU peer review involved pre-/early post-emergence application at 240 g a.s./ha on small grain cereals (wheat, rye, barley) in the northern climatic zone. All these studies (17 trials) involving application rates at 240 g a.s./ha (actual 220-254 g a.s./ha) are considered adequate to support the use of FFA SC 508.8 in the northern climatic region by means of a risk envelope. The data set was generated using a WG formulation, however, WG and SC formulations are known to produce comparable residues (SANCO 7525/VI/95 rev 10.2; 23 September 2016). Therefore, both formulation types can be used interchangeably to support either of the products.
In addition, with the present dossier 6 supplementary residue trials are reported on mixture products involving also SC formulations containing flufenacet and diflufenican.
The residue trials have been performed according to the critical GAP in the northern climatic zone and were also considered in the EFSA Reasoned Opinion (Article 12 review; EFSA Journal 2012;10(4):2689). In all 6 trials the residues in wheat and barley grain and straw were below the LOQ of 0.05 and 0.1 mg/kg, respectively, and thus confirm that the residue situation is covered by the established EU MRLs (Regulation (EC) No. 1127/2014).
An exceedance of the current MRL of 0.1 mg/kg for wheat and barley and 0.05 mg/kg for rye for flufenacet as laid down in Reg. (EU) 1127/2014 is not expected.

The effects of processing on the nature of flufenacet residues have been investigated. As residues of flufenacet do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing on the magnitude of residues in processed products from wheat or barley.

In the Monograph (France 1997), Report of ECCO 73 (1999) and in the EFSA Reasoned Opinion (EFSA 2012) further investigation of residue levels of flufenacet in succeeding crops was not considered necessary. However, 4 field rotational crops were performed which confirmed a ‘no residue situation’ in winter cereals when grown following a spring crop (e.g. potatoes) and both crops received the maximum registered rates.

In the EU peer review (Report of ECCO 73, 1999) and the EFSA Reasoned Opinion (EFSA 2012) it was concluded that on the basis of the dietary burden calculation and the animal metabolism studies residue levels in livestock commodities are expected to remain below the LOQ of the enforcement method and thus no livestock feeding studies are needed. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary. The dietary burdens calculated using the dietary burden calculation spreadsheet (animal model 2017) does not change the outcome of the evaluation.

The chronic and the short-term intakes of flufenacet residues are unlikely to present a public health concern.

According to available data, no specific mitigation measures should apply.

3.6.2 Consumer exposure

The IEDI estimates for the various diets were found at 35% of ADI at maximum (NL toddler). For this diet, milk (cattle) was the highest contributor to the residue intake, representing 12% of ADI.
The highest IESTI of flufenacet was 7% for children (consumption of milk, cattle) and 3% of ARfD for adults (consumption of poultry muscle) based on the MRL (LOQ of the analytical method). For the uses under consideration the IESTI was highest for wheat (4% ARfD, based on children diet).

The proposed uses of flufenacet in the formulation FFA SC 508.8 G do not represent unacceptable acute and chronic risks for the consumer.

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The soil exposure was estimated for the intended use pattern of FFA SC 508.8 G in line with FOCUS methodology. Obtained PEC_{SOIL} values were used in the risk assessment for soil organisms.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The groundwater modelling was performed for the intended use pattern of FFA SC 508.8 G in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models.

On the basis of the obtained results flufenacet is not expected to migrate to groundwater at concentrations exceeding 0.1 µg/L when FFA SC 508.8 G is used according to the intended use pattern.

PEC_{GW} for toxicologically non-relevant metabolite sulfonic acid were >0.75 µg/L (with maximum PEC_{GW} of 8.8 µg/L calculated using PEARL in Jokioinen scenario following pre-emergence application at 244.2 g a.s./ha. at pre-emergence application). Based on the outcome of evaluation presented in the Core Assessment, Part B, Section 10, acceptable risk to the consumer may be, however, concluded for this compound for this maximum concentration, covering all remaining scenarios and uses where PEC_{GW} is >0.75 µg/L.

PEC_{GW} for toxicologically non-relevant metabolite flufenacet oxalate were above 0.1 µg/L in most of scenarios but below 0.75 µg/L, which is the relevant threshold for toxicologically not relevant compound, such as FOE oxalate. The only exception is scenario Porto in which maximum PEC_{GW} of 0.832 µg/L was obtained using PELMO for the pre-emergence application of the higher rate (244.2 g a.s./ha). Based on the outcome of evaluation presented in the Core Assessment, Part B, Section 10, acceptable risk to the consumer may be, however, concluded for PEC_{GW} exceeding threshold of 0.75 µg/L in this single scenario.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The surface water modelling was performed for the intended use pattern of FFA SC 508.8 G in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models. The surface water exposure to the formulated product was calculated using Spray Drift Calculator. Obtained $PEC_{SW}/_{SED}$ values were used in the risk assessment for aquatic organisms.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

Although the vapour pressure is above the trigger of 10^{-5} Pa and EU agreed data indicate potential volatilisation from soil surfaces (up to 29% within 1 day), due to the rapid degradation in the atmosphere (DT_{50} of 4.7 hours) flufenacet is not expected to be subject of short- or long-range transport.
Unacceptable contamination of the atmosphere following application of FFA SC 508.8 G to winter cereals is not expected.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

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.

3.8.2 Effects on aquatic species

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 for scenarios relevant for Poland should be applied to surface water bodies.
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 for scenarios relevant for Poland should be applied to surface water bodies.

3.8.3 Effects on bees

The hazard quotients for both contact and oral exposure are below the trigger of concern (QH $\leq$ 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. To fullfield criteria of EU Reg 284/2009 the applicant should submit the chronic studies for adult and laarve bees for formulation.

3.8.4 Effects on other arthropod species other than bees

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.

3.8.5 Effects on soil organisms

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.

3.8.6 Effects on non-target terrestrial plants

Based on the probabilistic risk assessment agreed by zRMS for Poland 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.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No further information is available or considered to be necessary.

3.9 Relevance of metabolites (Part B, Section 10)

The metabolites FOE oxalate (M01) and FOE sulfonic acid (M02) are predicted to occur in groundwater at concentrations at or above 0.1 µg/L (see dRR Part B, Section 8 (Environmental fate and behaviour) chapter 8.8.2.2). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.

FOE oxalate (M01)
The relevance of the groundwater metabolite FOE oxalate (M01) has already been assessed and the assessment agreed at EU level (see Addendum to DAR (Monograph), January 2003), but the relevance assessment is not applicable for the GAP and groundwater scenarios considered in this dRR (*i.e.* the conclusions made at the EU-level are not valid with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Therefore, the assessment and conclusions are presented here.
FOE oxalate is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in the corresponding sections.

FOE sulfonic acid (M02)
The relevance of the groundwater metabolite FOE sulfonic acid (M02) has already been assessed and the assessment agreed at EU level (see Addendum to DAR (Monograph), January 2003), but the relevance assessment is not applicable for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions made at the EU-level are not valid with regard to the PECgw calculated for the GAP and groundwater scenarios considered in this dRR). Therefore, the assessment and conclusions are presented here. FOE sulfonic acid is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given the corresponding sections

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Reference:	**KCP 3.1/01**
Title:	Registration report - Comparative assessment - FFA 508.8 SC - Country: Poland - Central zone - Zonal rapporteur member state: Poland - National comparative assessment
Report:	Anon.; 2021; M-767305-01-1
Authority registration No:	
Guideline(s):	--
Deviations:	--
GLP/GEP:	not applicable
Acceptability:	
Duplication (if vertebrate study):	

FFA SC 508.8 G contains flufenacet which is approved as a candidate for substitution according to criteria in Annex II (point 4) and in Annex III (point 7) of Regulation (EC) 1107/2009.

FFA SC 508.8 G is intended to be used as herbicide to protect winter wheat, winter barley, winter triticale, rye, durum wheat and spelt against grasses and dicotyledonous weeds. According to the national regulation (from 18 September 2019), durum and spelt wheat belong to the minor crops. Currently the limited number of herbicides is authorized for wheat durum and spelt protection in Poland.

On the polish marketed there is still observed lack of the product, which can be used as a compound for tank mixture. An approval of FFA SC 508.8 G gives farmers opportunity to look after new solutions for

autumn application. FFA SC 508.8 G can be successfully used in tank mixture and brings better efficacy against grasses and dicots in autumn application

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

None.

Appendix 1 Copy of the product authorization

None.

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, toksykologii i istotności toksykologicznej metabolitów, pozostałości, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym podświetleniem tekstu (fragmenty dodane) lub ~~przekreśleniem i jasno szarą czcionką~~ (fragmenty usunięte).

Zakres zmian jest następujący:

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008r. nie jest wymagane.
2. Okres ważności: 2 letnie badania stabilności są w toku. Możliwe jest wydanie zgody warunkowo, na podstawie zaakceptowanych wyników 14-dniowego badania przyspieszonego starzenia w temperaturze 54^{o}C środka przechowywanego w opakowaniach wykonanych z HDPE. Zgodnie z zapisami aktualnie obowiązującej wytycznej Ministerstwa Rolnictwa i Rozwoju Wsi w sprawie zasad zatwierdzania opakowań środków ochrony roślin z dnia 18/10/2021 możliwa jest ekstrapolacja wyników badań stabilności z opakowań wykonanych w HDPE na HDPE/EVOH i HDPE/PA. W związku z powyższym, wszystkie opakowania wymienione, w punktach 2.1 dokumentu A i 4.1 Sekcji 1 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania.
4. Brak uwag do zapisu nazwy grupy chemicznej, do której przyporządkowano substancję czynną. Dodano zawartość substancji czynnej (zawartość substancji czynnej wyrażoną w procentach obliczono w oparciu o gęstość środka ochrony roślin 1,2 g/ml zgodnie z danymi zawartymi w punkcie 1.2.1 dokumentu C).
5. Zgodnie z informacjami zawartymi w punktach IIIA 2.9.1 i IIIA 2.9.2 Sekcji 1,2,4 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania.

Sekcja skuteczność:

1. Na podstawie danych przedłożonych przez wnioskodawcę w zakresie sekcji skuteczność, możliwa jest rejestracja środka Cadou przeznaczonego do zwalczania chwastów jednoliściennych oraz niektórych dwuliściennych w zbożach ozimych w dawkach 0,24 l/ha i 0,48 l/ha, przed- i powschodowo, 1 raz w sezonie wegetacyjnym, zgodnie z informacjami zawartymi w tabeli GAP.
2. Substancja czynna flufenacet, zawarta w środku Cadou, to znana substancja czynna zarejestrowana obecnie w Polsce w pszenicy ozimej, jęczmieniu ozimym, pszenżycie ozimym oraz życie ozimym. Nowym zastosowaniem jest rejestracja w zakresie ochrony pszenicy durum i orkisz, które są uprawami małoobszarowymi w Polsce.
3. Z uwagi na brak badań skuteczności dla pszenżyta, żyta, pszenicy durum i orkisz oraz ograniczoną liczbę badań dla jęczmienia ozimego, zastosowano ekstrapolację z pszenicy ozimej. Wnioskodawca przedstawił pakiet badań selektywności dla każdego z gatunków uprawnych. W przypadku pszenżyta ozimego oraz żyta ozimego przedłożono wyłącznie badania prowadzone w latach 2003-2004. Zgodnie z ustaleniami harmonizacyjnymi należy dążyć do wyeliminowania przypadków, gdy obecna rejestracja opiera się na wynikach badań sprzed 10 i więcej lat. Mając na uwadze wytyczne, jak również fakt że substancja czynna flufenacet jest już zarejestrowana w pszenżycie i życie ozimym, podjęto decyzję o akceptacji obu zastosowań w tabeli GAP. Niemniej jednak, w komentarzu w raporcie B3 podkreślono, że dla celów przyszłościowego odnowienia środka Cadou, należy przedłożyć bardziej aktualne badania selektywności.
4. Ponadto, w przedłożonych badaniach selektywności środek Cadou testowano wyłącznie w dawkach 0,48 l/ha (1N) oraz 0,96 l/ha (2N), co pokrywa wymagany pakiet dla wyższej z wnioskowanych dawek. Niemniej jednak, dawka 0,48 l/ha jest również podwojoną dawką dla 0,24 l/ha, co częściowo także spełnia wymagania dla niższej z wnioskowanych dawek. Zgodnie z wytyczną EPPO PP 1/135(4), w przypadku herbicydów wymagane jest przedłożenie badań selektywności w dawce pojedynczej i podwojonej (1N i 2N). Mając na uwadze fakt, że substancja czynna flufenacet jest już zarejestrowana w Polsce w pszenicy, jęczmieniu pszenżycie i życie, jak również ze względu na brak wyraźnych objawów fitotoksyczności w badaniach skuteczności po aplikacji środka Cadou w dawce 0,24 l/ha, zarówno przed- jak i powschodowo, zaakceptowano powyższe zastosowania.
5. W przypadku pszenicy durum i orkisz, które są nowymi zastosowaniami dla substancji flufenacet, także zaakceptowano niepełne pakiety badań selektywności, w których brak było wyraźnych objawów

fitotoksyczności po aplikacji dawki 0,48 l/ha. Niemniej jednak możliwa jest rejestracja tych zastosowań w trybie art. 51, ponieważ są to uprawy małoobszarowe.
6. W części „DZIAŁANIE NA CHWASTY" wykreślono wyczyńca polnego z zastosowania powschodowego dla dawki 0,48 l/ha. Przedłożono tylko 3 badania w pszenicy ozimej i 1 badanie w jęczmieniu ozimym dla tego chwastu, podczas gdy jest on ważny dla pszenicy i jęczmienia, dlatego wymagane jest przedłożenie min. 4 badań skuteczności dla jednego ze zbóż.
7. W części „ŚRODKI OSTROŻNOŚCI" dodano zapis o możliwości wystąpienia przemijających objawów fitotoksyczności po zastosowaniu dawki 0,48 l/ha.
8. W części „POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY" dodano zapis do instrukcji usuwania resztek cieczy.

Sekcja metody analityczne:
1. Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:
1. W części dotyczącej klasyfikacji zagrożeń zmodyfikowno zwrot P280 zgodnie z CLP
2. W części dotyczącej środków ostrożności dla osób stosujących środek, pracowników oraz osób postronnych zapis zmodyfikowano zgodnie z wymaganiami harmonizacyjnymi dot. oceny toksykologicznej wer. 2021

Sekcja pozostałości:
1. Zapisy dotyczące okresu karencji oraz następstwa roślin zostały zaakcpetowane.

Sekcja los i zachowanie:
1. Brak uwag

Sekcja ekotoksykologia:
1. Zmieniono zarządzanie ryzykiem (tj: szerokość zadarnionej strefy buforowej) dla organizmów wodych.

Posiadacz zezwolenia:
Bayer SAS, 16, rue Jean-Marie Leclair, CS 90106, 69266 Lyon Cedex 09, Republika Francuska, tel.: + 33 4 72 85 21 82

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:
Bayer Sp. z o.o., Al. Jerozolimskie 158, 02-326 Warszawa, tel.: 22 572 35 00, fax: 22 572 36 03,

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:
…….

CADOU

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:
flufenacet (związek z grupy oksyacetamidów) – 508,8 g/l (42,4%)

Zezwolenie MRiRW nr R- z dnia

Uwaga

H302	Działa szkodliwie po połknięciu.
H373	Może powodować uszkodzenie narządów (układ nerwowy) poprzez długotrwałe lub narażenie powtarzane drogą pokarmową.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH 208	Zawiera flufenacet, masę poreakcyjną 5-chloro-2-metylo-2H-izotiazol-3-onu i 2-metylo-2H-izotiazol-3-onu (3:1). Może powodować wystąpienie reakcji alergicznej.
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P260	Nie wdychać gazu, mgły, par, rozpylonej cieczy.
P280	Stosować rękawice ochronne, odzież ochronną, ochronę oczu i ochronę twarzy.
P308+P311	W przypadku narażenia lub styczności: Skontaktować się z OŚRODKIEM ZATRUĆ lub z lekarzem.
P391	Zebrać wyciek.
P501	Zawartość i pojemnik usuwać zgodnie z lokalnymi przepisami.

OPIS DZIAŁANIA

Cadou 508,8 SC jest herbicydem selektywnym o działaniu układowym, stosowany doglebowo lub nalistnie, koncentrat w formie stężonej zawiesiny do rozcieńczania wodą (SC).

Zgodnie z klasyfikacją HRAC substancja czynna flufenacet zaliczana jest do grupy 15 (dawnej grupy K3).

DZIAŁANIE NA CHWASTY

Flufenacet jest substancją aktywną o działaniu układowym, zaliczaną do inhibitorów syntezy kwasów tłuszczowych o długich łańcuchach. Pobierany jest głównie przez korzenie i hypokotyl kiełkujących chwastów.
Najlepszy efekt chwastobójczy uzyskuje się stosując środek we wczesnych fazach rozwojowych chwastów, to jest w czasie kiełkowania lub krótko po ich wschodach, w fazie siewek.
Środek stosować na dobrze uprawioną (bez grud) glebę.

Dawka 0,24 l/ha – zastosowanie przed- oraz powschodowe

Chwasty wrażliwe:	miotła zbożowa, wiechlina roczna

Dawka 0,48 l/ha – zastosowanie przedwschodowe

Chwasty wrażliwe:	miotła zbożowa, wiechlina roczna, wyczyniec polny, życica wielokwiatowa
Chwasty średnio odporne:	maruna bezwonna, mak polny, przetacznik perski

Dawka 0,48 l/ha – zastosowanie powschodowe

Chwasty wrażliwe:	miotła zbożowa, wiechlina roczna, wyczyniec polny, życica wielokwiatowa

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Pszenica ozima, jęczmień ozimy, pszenżyto ozime, żyto, pszenica durum, pszenica orkisz
Maksymalna dawka dla jednorazowego zastosowania: 0,48 l/ha
Zalecana dawka dla jednorazowego zastosowania: 0,24-0,48 l/ha

Termin stosowania środka: Środek stosować przedwschodowo (BBCH 00-09) lub po wschodach zbóż - do fazy trzech liści (BBCH 10-13).

Zalecana ilość wody: 100-400 l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):
nie wymagany

1. Strategia zarządzania odpornością
   - postępować zgodnie z zaleceniami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce w terminie zapewniającym najlepsze zwalczania chwastów,
   - środek należy stosować we wczesnych fazach rozwojowych chwastów, tak wcześnie jak to możliwe
   - dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
   - używać różnych metod kontroli zachwaszczenia w tym rotację upraw, itp.,
   - stosować rotacje herbicydów o różnym mechanizmie działania,
   - stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów,
   - stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
   - poinformować posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
   - w celu uzyskania szczegółowych informacji skontaktować się z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.
2. Niekorzystne warunki klimatyczne, które mogą wystąpić po wykonaniu zabiegu, mogą powodować osłabienie rośliny uprawnej, które przemija i nie wpływa ujemnie na plon i jego parametry.
3. Stosowanie dawki 0,48 l/ha może powodować wystąpienie przemijających objawów fitotoksyczności (m.in. przerzedzenia, zahamowanie wzrostu lub zmniejszenie objętości), które nie mają wpływu na jakość i ilość plonu roślin uprawnych.
4. Środka nie stosować:
   - na rośliny mokre, osłabione lub uszkodzone przez choroby, szkodniki czy przymrozki,
   - przed spodziewanym silnym przymrozkiem,
   - w okresie dużych wahań temperatur występujących między dniem, a nocą.
5. Podczas stosowania środka nie dopuścić do:
   - znoszenia cieczy użytkowej na sąsiadujące plantacje roślin uprawnych,
   - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

NASTĘPSTWO ROŚLIN

Środek rozkłada się w ciągu okresu wegetacji nie stwarzając zagrożenia dla roślin następczych. W przypadku konieczności wcześniejszego zlikwidowania plantacji w wyniku uszkodzenia roślin przez mrozy, szkodniki lub choroby, po upływie minimum 4 miesięcy od zastosowania preparatu, wiosną po wykonaniu głębokiej orki można uprawiać pszenicę jarą, kukurydzę, rzepak jary, len zwyczajny oraz fasolę.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem), a następnie dodać adiuwant.

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.
W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy, ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:
– jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
– unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
– unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Ze względu na bardzo dużą wrażliwość niektórych roślin uprawnych nawet na znikome ilości środka, bardzo ważne jest dokładne wymycie opryskiwacza po zabiegu, zwłaszcza przed użyciem w innych roślinach niż zalecane. Dwukrotne płukanie oraz dokładne oczyszczenie wszystkich filtrów zapewnia usunięcie lub zredukowanie pozostałości substancji czynnych do poziomu bezpiecznego dla następnych upraw.

W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną do środka myjącego.

Niewystarczające wymycie aparatury po zabiegu i pozostawienie resztek środka w opryskiwaczu może być przyczyną silnych uszkodzeń roślin uprawnych wrażliwych na ten środek.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

~~Stosować rękawice ochronne, ochronę oczu lub twarzy i odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu.~~

Stosować rękawice ochronne i odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych w następujących uprawach: pszenica ozima, jęczmień ozimy, pszenżyto ozime, żyto, pszenica durum, pszenica orkisz w dawce 1 x 0.24 L/ha

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20 m od zbiorników i cieków wodnych wnastępujacych uprawach: pszenica ozima, jęczmień ozimy, pszenżyto ozime, żyto, pszenica durum, pszenica orkisz w dawce 1 x 0.48 L/ha

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0 ^{o}C-30^{o}C, z dala od źródeł ciepła

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.
Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.
Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.
W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.
W przypadku kontaktu ze skórą: Umyć dużą ilością wody z mydłem.
W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać
W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Appendix 3 Letter of Access

No letters of access to protected data from third companies are needed for evaluation of the formulation.

Appendix 4 Lists of data considered for national authorization

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	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 / 01 **... also filed:** **2.4.1 / 01** **2.4.2 / 01** **2.5.1 / 01** **2.5.2 / 01** **2.6.1 / 01** **2.7.1 / 01** **2.7.3 / 01** **2.7.4 / 01** **2.8.3.1 / 01** **2.8.3.2 / 01** **2.8.5.1.1 / 01** **2.8.5.1.2 / 01** **KCP 2.8.2 / 01** **KCP 2.8.7 / 01**	Hoppe, M.	2021	Storage stability at elevated temperature and cold stability of flufenacet SC 508.8 (508.8 g/L) - Packaging material: HDPE - Final report (14 days) Report No.: FM0415(PKF01)G01, Edition Number: M-770211-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Data never submitted to POL	Bayer
2.2.1 / 01 **... also filed:** **2.2.2 / 01** **2.3.1 / 01** **2.3.3 / 01**	Heinz, U.	2021	Safety-relevant data of flufenacet SC 508.8 (508.8 g/L) Report No.: 2021/00068, Edition Number: M-767061-01-1 Bayer AG, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Yes	Data never submitted to POL	Bayer
KCP Section 12 / 01	Anon.	2021	Flufenacet SC 508.8 (508.8 g/L) Report No.: M-761606-01-1 Bayer AG, Leverkusen, Germany GLP/GEP: n.a. unpublished	No	-public data-	KCP Section 12 / 01	Anon.
KCP Section 12 / 02	Anon.	2019	Flufenacet TC Report No.: M-359892-05-1 Bayer AG, Leverkusen, Germany GLP/GEP: n.a. unpublished	No	-public data-	KCP Section 12 / 02	Anon.

Data Point	Author(s)	Year	**Title** **Company Report No.** **Source** **GLP or GEP status** **published or not**	**Vertebrate study Y/N**	**Data protect. claimed Y/N**	**Justification if data protection is claimed**	**Owner**
KCP 4.2 / 01	Friessleben, R.	2008	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 - 2008 Report No.: M-357166-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: n.a. unpublished	No	Bayer	KCP 4.2 / 01	Friessleben, R.
KCP 3.1 / 01	Anon.	2021	Registration report - Comparative assessment - FFA 508.8 SC - Country: Poland - Central zone - Zonal rapporteur member state: Poland - National comparative assessment Report No.: M-767305-01-1 Zonal Rapporteur Member State: Poland GLP/GEP: n.a. unpublished	No	No		Bayer
KCP 5.1.1 / 01	Hoffmann, D.	2020	Determination of flufenacet in formulations - HPLC-UV, external standard Report No.: M-688742-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No		Bayer
KCP 5.1.1 / 02	Hoffmann, D.; Garcia Sanchez, M. T.	2020	Validation of analytical method AM036120MF1 - Determination of flufenacet in the formulation flufenacet SC 508.8 (508.8 g/L) Report No.: FM0415(MVF00)G01, Edition Number: M-758632-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Data never submitted to POL	Bayer
KCP 5.1.2.5 / 01 **... also filed: KCA 6.3.1.1 / 01**	Seym, M.	1996	Determination of residues of FOE 5043 & Diflufenican 60 WG in/on winter barley, winter rye and winter wheat following early post-emergence spray application in Germany Report No.: RA-2010/94, Edition Number: M-004451-01-2 Bayer AG, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The method was not evaluated in RR of Part B Section 2 (Analytical Method) for Baccara Trio	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2.5 / 02 **... also filed: KCA 6.3.1.1 / 02**	Hoffmann, M.	2002	Determination of residues of FOE 5043 in/on wheat and barley following spray application of FOE 5043 & Diflufenican (600 SC) to winter wheat and winter barley in the field in Northern and Southern France, Germany and Spain Report No.: RA-2144/00, Edition Number: M-058156-01-1 Bayer AG, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The method was not evaluated in RR of Part B Section 2 (Analytical Method) for Baccara Trio	Bayer
KCP 5.1.2.5 / 03	Rzepka, S.	2006	Supplement E004 of Method 00346 for the determination of residues of FOE 5043, FOE 5043 Oxalate, FOE 5043 Sulfonic Acid, and FOE 5043 Thioglycolate Sulfoxide in rice (grain) Report No.: 00346/E004, Edition Number: M-277805-01-1 Method Report No.: BAY-0610V Eurofins Analytik GmbH, Hamburg, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The method 00346 and its supplement E004 was evaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.5, April 2022).	Bayer
KCP 5.1.2.5 / 04 **... also filed: KCA 6.6.2 / 01**	Melrose, I.; Erler, S.	2008	Determination of the residues of FOE 5043 in/on the rotational crops cereals after spraying of Artist (41.5 WG) and Liberator (500 SC) in the field in the United Kingdom, Germany and Northern France Report No.: RA-2020/06, Edition Number: M-306269-01-1 Bayer CropScience S.A., Lyon, France GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The method was not evaluated in RR of Part B Section 2 (Analytical Method) for Baccara Trio	Bayer
KCP 5.1.2.6 / 01	Brumhard, B.	2009	Analytical method 01080 for the determination of residues of flufenacet (FOE 5043) in soil using LC-MS/MS Report No.: 01080, Edition Number: M-357296-01-1 Method Report No.: MR-07/352 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Data never submitted to POL	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2.6 / 02 **... also filed: 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	Yes	Data never submitted to POL	Bayer
KCP 5.1.2.6 / 03	Krebber, R.; Leppelt, L.	2009	Method 01169 for the determination of flufenacet-oxalate in test water by HPLC-MS/MS Report No.: 01169, Edition Number: M-357278-01-1 Method Report No.: MR-09/120 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	The method was evaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.5, April 2022).	Bayer
KCP 5.1.2.6 / 06 **... also filed: 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	Yes	Data never submitted to POL	Bayer
KCP 5.1.2.6 / 07 **... also filed: 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	Yes	Data never submitted to POL	Bayer
KCP 5.1.2.6 / 08	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-477339-01-1 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 This method was not evaluated in RR of Part B Section 2 (Analytical Method) for Baccara Trio	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2.6 / 09 **... also filed:** **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	Yes	Data never submitted to POL The studyevaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.9, 2018).	Bayer
KCP 5.1.2.6 / 10 **... also filed:** **KCP 10.6.2 / 01** **KCP 6.5.2 / 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	Yes	Data never submitted to POL The studyevaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.9, 2018).	Bayer
KCP 5.1.2.6 / 11 **... also filed:** **KCP 10.6.2 / 02** **KCP 6.5.2 / 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	Yes	Data never submitted to POL The studyevaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.9, 2018).	Bayer
KCP 5.2.1 / 01	Class, Th.; Merdian, H.	2010	Validation of BCS analytical method no. 01179 for the determination of residues of flufenacet in/on plant materials by HPLC-MS/MS Report No.: 01179, Edition Number: M-362716-01-1 Method Report No.: B 1778 G PTRL Europe GmbH, Ulm, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The method 01179 was evaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.5, April 2022).	Bayer
KCP 5.2.1 / 02	Stuke, S.	2018	Amendment no. 02 to final report: Analytical method 01100 for the determination of residues of flufenacet (FOE5043) and its metabolites in/on plant material Report No.: 01100, Edition Number: M-362575-03-1 Method Report No.: MR-08/060 Bayer AG, Crop Science Division, Monheim, Germany **... amended: 2018-09-20** GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 Amendment no.02 was not evaluated	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2.1 / 03 **... also filed:** **KCA 6.1 / 01**	Stuke, S.	2018	Amendment no. 01 to final report: Modification M001 of the residue analytical method 01100 for the determination of residues of flufenacet (FOE5043) and its metabolites in/on cereals (straw, grain, and green material) at a LOQ of 0.01 mg/kg for grain and green material and at a LOQ of 0.05 mg/kg for straw by HPLC-MS/MS Report No.: 01100/M001, Edition Number: M-433720-02-1 Method Report No.: MR-11/011 Bayer AG, Crop Science Division, Monheim, Germany **... amended: 2018-09-20** GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 Amendment no.01 was not evaluated	Bayer
KCP 5.2.1 / 04	Meyer, M.	2011	Independent laboratory validation of the Bayer CropScience methods 01100 and 01179 for the determination of residues of Flufenacet (FOE5043) in/on plant materials Report No.: P612107502, Edition Number: M-405654-01-1 Method Report No.: IF-10/01717126 SGS Institut Fresenius GmbH, Taunusstein, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The ILV was evaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.5, April 2022).	Bayer
KCP 5.2.1 / 05	Stuke, S.; Weile, M.	2011	Position paper: Subject: Flufenacet: Answer to CRD questions related to the authorization of the product Liberator SC 500 (flufenacet + diflufenican 400 g/L + 100 g/L) - Comparison of flufenacet residue analytical method nos. 00346 vs. 01179 Report No.: M-416013-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: n.a. unpublished	No	No	The position paper has been presented in RAR for Flufenacet (Vol. 3, B-5, RMS-PL, April 2022).	Bayer
KCP 5.2.1 / 06 **... also filed:** **KCA 6.2.1 / 01**	Krolski, M. E.; Bosnak, L. L.	1997	The metabolism of [Fluorophenyl-UL-14C] FOE 5043 in wheat after postemergent foliar spray application Report No.: 107399, Edition Number: M-002275-01-1 Bayer Corporation, Stilwell, KS, USA GLP/GEP: Yes unpublished	No	Yes	Data never submitted to POL The study was evaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.5, April 2022).	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2.2 / 01	xxx	2013	Validation of the Bayer methods 00418 (M-019605-01-1) and 00418/M001 (M-019614-01-1) for the determination of residues of flufenacet (FOE 5043) and its metabolites in animal tissues and animal products Report No.: S12-00052, Edition Number: M-461242-01-1 xxx GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The method 00418 and 00418/M001 was evaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.5, April 2022).	Bayer
KCP 5.2.3 / 01	Kaussmann, M.	2016	Analytical method 01486 for the determination of various pesticides and selected pesticide metabolites in plasma by HPLC-MS/MS Report No.: 01486, Edition Number: M-556577-01-1 Method Report No.: P683166504 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Data never submitted to POL The method 01486 was evaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.5, April 2022).	Bayer
KCP 5.2.4 / 01	Brumhard, B.	2005	Modification M001 of method 00359 for the determination of the herbicide FOE 5043 and its metabolite FOE 5043-alcohol, FOE 5043-oxalate and FOE 5043-sulfonic acid in soil using HPLC-MS/MS Report No.: 00359/M001, Edition Number: M-248543-01-1 Method Report No.: MR-028/05 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The method was evaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.5, April 2022).	Bayer
KCP 5.2.5 / 01	Krebber, R.; Braune, M.	2013	Analytical method 01387 for the determination of various pesticides in drinking and surface water by HPLC-MS/MS Report No.: MR-13/085, Edition Number: M-466732-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The method was evaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.5, April 2022).	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2.5 / 02	Stanislowski, T.	2013	Independent laboratory validation of BCS analytical methods 01333 and 01387 for determination of various pesticides in surface water by Di-HPLC-MS/MS Report No.: P3117 G, Edition Number: M-470714-02-1 PTRL Europe GmbH, Ulm, Germany **... amended: 2013-12-13** GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The ILV was evaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.5, April 2022).	Bayer
KCP 5.2.6 / 01	Hellpointner, E.	2000	Confirmatory method for the determination of FOE 5043 in air (confirmed method: 00410) Report No.: 00410C, Edition Number: M-048783-01-1 Method Report No.: MR-469/00 Bayer AG, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The method was evaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.5, April 2022).	Bayer
KCP Section 6 / 01	Feuerhahn, I.; Nielsen, T.; Bartlett, M.	2021	Biological assessment dossier - Efficacy data and information - Detailed summary - FFA SC 508.8 - Flufenacet, 508.8 g/L - Central zone - Zonal rapporteur member state: Poland - Core assessment (authorization) Report No.: M-767892-01-1 Bayer S.A.S., Crop Science Division, Lyon, France GLP/GEP: n.a. unpublished	No	No		Bayer
KCP 6.2 / 01 **... also filed: KCP 6.4.1 / 01**	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Minimum effective dose and efficacy trials on grass and broadleaved weeds on winter cereals - USE001 and USE002 Report No.: M-761917-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Yes	Data never submitted to POL	Bayer
KCP 6.2 / 02 **... also filed: KCP 6.4.1 / 03**	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Minimum effective dose and efficacy trials on grass weeds on winter cereals - USE003 and USE004 Report No.: M-761933-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Yes	Data never submitted to POL	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2 / 03	Anon.	2016	Methodological instruction no. 2/2014 on submission of the number of biological effectiveness experiments for an applicant for authorisation, extension of an authorisation, change or amendment to an authorisation, or re-assessment of a plant protection products authorisation Report No.: M-630120-01-1 Central Controlling and Testing Institute in Agriculture, Bratislava, Slovakia GLP/GEP: n.a. unpublished	No	No		-public data-
KCP 6.3 / 01	Collavo, A.; Kaiser, J.	2020	Statement - Information on the occurrence or possible occurrence of the development of resistance of the plant protection product - Flufenacet (508.8 g/L) for use in cereals (for submission in Europe) Report No.: M-759325-01-1 Bayer AG GLP/GEP: n.a. unpublished	No	No		Bayer
KCP 6.4.1 / 02 **... also filed:** **KCP 6.4.2 / 01** **KCP 6.4.3 / 01**	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Selectivity trials on winter cereals - USE001 and USE002 Report No.: M-761947-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Yes	Data never submitted to POL	Bayer
KCP 6.4.1 / 04 **... also filed:** **KCP 6.4.2 / 02** **KCP 6.4.3 / 02**	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Selectivity trials on winter cereals - USE003 and USE004 Report No.: M-761954-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Yes	Data never submitted to POL	Bayer
KCP 6.5.1 / 01	Slater, A. E.	2003	Soil mix crop screening tests - Cadou WG Report No.: MO-04-011245, Edition Number: M-092929-01-1 Bayer CropScience GmbH, Frankfurt am Main, Germany GLP/GEP: No unpublished	No	No		Bayer
KCP 6.5.3 / 01	Friessleben, R.	2008	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 - 2008 Report No.: M-357166-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: n.a. unpublished	No	No		Bayer

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KCP 7.1.1 / 01	xxx	1998	FOE 5043 500 SC 04402/0096 (Fluthiamid (prop.)) - Study for acute oral toxicity in rats Report No.: 27271, Edition Number: M-005460-01-1 xxx GLP/GEP: Yes unpublished	Yes	Yes	Data never submitted to POL	Bayer
KCP 7.1.2 / 01	xxx	1998	FOE 5043 500 SC 04402/0096 (c.n.: Fluthiamid (prop.)) - Study for acute dermal toxicity in rats Report No.: 27416, Edition Number: M-004746-01-1 xxx GLP/GEP: Yes unpublished	Yes	Yes	Data never submitted to POL	Bayer
KCP 7.1.3 / 01	xxx	1999	FOE 5043 500 SC 04402/0096 (c.n.: Fluthiamid (proposed)) - Study on acute inhalation toxicity in rats according to OECD no. 403 Report No.: 28609, Edition Number: M-009812-01-1 xxx GLP/GEP: Yes unpublished	Yes	Yes	Data never submitted to POL	Bayer
KCP 7.1.4 / 01	xxx	2001	Acute skin irritation test (patch test) of FOE 5043 500 SC 04402/0096 in rabbits - first revision of report no. R7215 Report No.: R7993, Edition Number: M-004806-02-1 xxx **... amended: 2001-05-28** GLP/GEP: Yes unpublished	Yes	Yes	Data never submitted to POL	Bayer
KCP 7.1.5 / 01	xxx	2001	Acute eye irritation study of FOE 5043 500 SC 04402/0096 by instillation into the conjunctival sac of rabbits - first revision of report no. R7216 Report No.: R7994, Edition Number: M-004807-02-1 xxx **... amended: 2001-05-28** GLP/GEP: Yes unpublished	Yes	Yes	Data never submitted to POL	Bayer
KCP 7.1.6 / 01	xxx	2005	Flufenacet SC 500 (Project: Flufenacet (FOE 5043)) - Local lymph node assay in mice (LLNA/IMDS) Report No.: AT02459, Edition Number: M-258556-01-1 xxx GLP/GEP: Yes unpublished	Yes	Yes	Data never submitted to POL	Bayer

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KCP 7.3 / 01	Maas, W.	2020	The in vitro percutaneous absorption of radiolabelled flufenacet in a concentrate formulation (flufenacet SC 508.8) and two in-use dilutions through human split-thickness skin Report No.: 20215140, Edition Number: M-676520-01-1 Charles River Laboratories Den Bosch BV, DD 's-Hertogenbosch, The Netherlands GLP/GEP: Yes unpublished	No	Yes	Data never submitted to POL	Bayer
KCP 9.1.3 / 01	Reinken, G.; Porschewski, R.	2017	Flufenacet (FFA) core PECsoil EUR - Modelling core info document for soil risk assessment in Europe Report No.: EnSa-16-0744, Edition Number: M-577701-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No		Bayer
KCP 9.1.3 / 02	Reinken, G.; Serode, R.	2020	Flufenacet (FFA) and metabolites: PECsoil EUR - Use in winter cereals in Europe Report No.: EnSa-20-0760, Edition Number: M-765638-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No		Bayer
KCP 9.2.4.1 / 01	Reinken, G.; Tamazashvili, A.	2017	Flufenacet (FFA) core PECgw FRA - Modelling core info document for groundwater risk assessment in France Report No.: EnSa-17-0044, Edition Number: M-579316-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No		Bayer
KCP 9.2.4.1 / 02	Reinken, G.; Serode, R.	2020	Flufenacet (FFA) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 1a) - Use in winter cereals in Europe Report No.: EnSa-20-0761, Edition Number: M-765637-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No		Bayer
KCP 9.2.5 / 01	Reinken, G.; Porschewski, R.	2017	Flufenacet (FFA) core PECsw EUR - Modelling core info document for surface water risk assessment in Europe Report No.: EnSa-16-0743, Edition Number: M-577700-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No		Bayer

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KCP 9.2.5 / 02	Reinken, G.; Serode, R.	2020	Flufenacet (FFA) and metabolites: PECsw,sed FOCUS EUR - Use in winter cereals in Europe Report No.: EnSa-20-0749, Edition Number: M-765640-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No		Bayer
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	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	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	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The studyevaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.9, 2018).	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	Yes	Data never submitted to POL	Bayer
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	Yes	Data never submitted to POL	Bayer

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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	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The studyevaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.9, 2018).	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	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The studyevaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.9, 2018).	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	Yes	Data never submitted to POL	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	Yes	Data never submitted to POL	Bayer

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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	Yes	Data never submitted to POL	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	Yes	Data never submitted to POL The studyevaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.9, 2018).	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	Yes	Data never submitted to POL	Bayer
KCP Section 12 / 01	Anon.	2021	Flufenacet SC 508.8 (508.8 g/L) Report No.: M-761606-01-1 Bayer AG, Leverkusen, Germany GLP/GEP: n.a. unpublished	No	No		-public data-
KCP Section 12 / 02	Anon.	2019	Flufenacet TC Report No.: M-359892-05-1 Bayer AG, Leverkusen, Germany GLP/GEP: n.a. unpublished	No	No		-public data-
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		Bayer

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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		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		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		Bayer

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KCA Section 3 / 01	Hills, M.	2009	Evaluation of the pre-emergence biological activity of FOE 5043-Oxalate (code: BCS-AB16305) a metabolite of flufenacet Report No.: PP09022, Edition Number: M-353844-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: No unpublished	No	No		Bayer
KCA Section 3 / 02	Dahmen, P.	2004	Screening and efficacy data for WAK6222 (metabolite of FOE5043) Report No.: PF-F-HB_WAK6222_01, Edition Number: M-089475-01-1 Bayer AG, Leverkusen, Germany GLP/GEP: No unpublished	No	No		Bayer
KCA 5.8.1 / 01	Herbold, B.	2009	FOE 5043-Oxalate (Project: FOE 5043 (Flufenacet/AE F133402)) - Salmonella/microsome test - Plate incorporation and preincubation method Report No.: AT05640, Edition Number: M-358953-01-1 Bayer HealthCare AG, Wuppertal, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019	Bayer
KCA 5.8.1 / 02	Wollny, H. E.	2010	FOE 5043-Oxalate - Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) Report No.: 1277301, Edition Number: M-361724-01-1 Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019	Bayer
KCA 5.8.1 / 03	xxx	2009	FOE 5043-oxalate (Project: Flufenacet (FOE 5043)) - In vitro chromosome aberration test with Chinese hamster V79 cells Report No.: AT05598, Edition Number: M-358043-01-1 xxx GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019	Bayer
KCA 5.8.1 / 04	xxx	2009	FOE 5043-Sulfonic acid Na-salt - Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) Report No.: 1277302, Edition Number: M-361158-01-1 xxx GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.1 / 05	xxx	2010	FOE 5043-sulfonic acid Na-salt (Project: Flufenacet (FOE 5043)) - In vitro chromosome aberration test with Chinese hamster V79 cells Report No.: AT05870, Edition Number: M-366380-01-1 xxx GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019	Bayer
KCA 5.8.1 / 06	xxx	2010	FOE 5043-sulfonic acid Na-salt - Project: Flufenacet (FOE 5043) - Micronucleus-test on the male mouse Report No.: AT05913, Edition Number: M-368627-01-1 xxx GLP/GEP: Yes unpublished	Yes	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019	Bayer
KCA 5.8.1 / 07	xxx	2017	[phenyl-UL-14C]Flufenacet, [thiadiazole-5-14C]Flufenacet and [phenyl-UL-14C]BCS-AZ23374: Distribution of radioactivity in the bone marrow of mice by quantitative whole-body autoradiography Report No.: EnSa-16-1016, Edition Number: M-580054-01-1 xxx GLP/GEP: Yes unpublished	Yes	Yes	Data never submitted to POL	Bayer
KCA 5.8.1 / 08	xxx	2010	FOE 5043-sulfonic acid Na-salt (Project: Flufenacet (FOE 5043)) - Unscheduled DNA synthesis test with male rat liver cells in vivo Report No.: AT06167, Edition Number: M-397810-01-1 xxx GLP/GEP: Yes unpublished	Yes	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019	Bayer
KCA 6.1 / 01 **... also filed: KCP 5.2.1 / 03**	Stuke, S.	2018	Amendment no. 01 to final report: Modification M001 of the residue analytical method 01100 for the determination of residues of flufenacet (FOE5043) and its metabolites in/on cereals (straw, grain, and green material) at a LOQ of 0.01 mg/kg for grain and green material and at a LOQ of 0.05 mg/kg for straw by HPLC-MS/MS Report No.: 01100/M001, Edition Number: M-433720-02-1 Method Report No.: MR-11/011 Bayer AG, Crop Science Division, Monheim, Germany **... amended: 2018-09-20** GLP/GEP: Yes unpublished	No	Yes	Data never submitted to POL The study has already been evaluated in the Draft Renewal Assessment Report by RMS Poland (DRAR, 2018).	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.1 / 01 **... also filed:** **KCP 5.2.1 / 06**	Krolski, M. E.; Bosnak, L. L.	1997	The metabolism of [Fluorophenyl-UL-14C] FOE 5043 in wheat after postemergent foliar spray application Report No.: 107399, Edition Number: M-002275-01-1 Bayer Corporation, Stilwell, KS, USA GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The study has already been evaluated in the Draft Renewal Assessment Report by RMS Poland (DRAR, 2018).	Bayer
KCA 6.3.1.1 / 01 **... also filed:** **KCP 5.1.2.5 / 01**	Seym, M.	1996	Determination of residues of FOE 5043 & Diflufenican 60 WG in/on winter barley, winter rye and winter wheat following early post-emergence spray application in Germany Report No.: RA-2010/94, Edition Number: M-004451-01-2 Bayer AG, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The study has already been evaluated in the Draft Renewal Assessment Report by RMS Poland (DRAR, 2018).	Bayer
KCA 6.3.1.1 / 02 **... also filed:** **KCP 5.1.2.5 / 02**	Hoffmann, M.	2002	Determination of residues of FOE 5043 in/on wheat and barley following spray application of FOE 5043 & Diflufenican (600 SC) to winter wheat and winter barley in the field in Northern and Southern France, Germany and Spain Report No.: RA-2144/00, Edition Number: M-058156-01-1 Bayer AG, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The study has already been evaluated in the Draft Renewal Assessment Report by RMS Poland (DRAR, 2018).	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.6.2 / 01 **... also filed:** **KCP 5.1.2.5 / 04**	Melrose, I.; Erler, S.	2008	Determination of the residues of FOE 5043 in/on the rotational crops cereals after spraying of Artist (41.5 WG) and Liberator (500 SC) in the field in the United Kingdom, Germany and Northern France Report No.: RA-2020/06, Edition Number: M-306269-01-1 Bayer CropScience S.A., Lyon, France GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019 The study has already been evaluated in the Draft Renewal Assessment Report by RMS Poland (DRAR, 2018).	Bayer
KCA 7.1.2.1.1 / 01	Schaefer, H.	1998	Calculation of DT-50 values of two metabolites of FOE 5043 in soil under aerobic conditions Report No.: MR-037/98, Edition Number: M-004479-02-1 Bayer AG, Leverkusen, Germany **... amended: 1998-01-15** GLP/GEP: No unpublished	No	No		Bayer
KCA 7.1.3.1.2 / 02	Blumhorst, M. R.; Yen, P. Y.; Marlow, V. A.	1994	Soil adsorption/desorption of FOE 5043 degradates: FOE Sulfonic Acid, FOE Methyl Sulfoxide, FOE Oxalate, FOE Alcohol, and Thiadone Report No.: MR106598, Edition Number: M-002185-01-1 EPL Bio-Analytical Service, Inc., Harristown, IL, USA GLP/GEP: Yes unpublished	No	Yes	Data protection started with: product DFF+FFA+MRB SC 516 Baccara Trio Reg nr R-171/2019	Bayer

Report number: M-761917-01-1

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HD18GBRA10FDM1	United Kingdom	2018	ETO SC 500 PoC/ Efficacy against ALOMY and dicots. Autumn pre and post-emergence applications in TRZAW FieldArm Ltd GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HD19GBRL16FDM1	United Kingdom	2019	ETO SC 500 PoC/ Efficacy against ALOMY and dicots in TRZAW Autumn pre and post-emergence applications in cereals FieldArm Ltd GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HD19GBRL16FDM2	United Kingdom	2019	ETO SC 500 PoC/ Efficacy against ALOMY and dicots in TRZAW Autumn pre and post-emergence applications in cereals FieldArm Ltd GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HD19GBRL16FDM3	United Kingdom	2019	ETO SC 500 PoC/ Efficacy against ALOMY and dicots in TRZAW Autumn pre and post-emergence applications in cereals FieldArm Ltd GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR18AUT002KN04	Austria	2018	FFA SC 508,8 / MED and Efficacy against Grasses and dicots. pre-emergence applications in cereals (autumn) and early post em GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR18AUT002KN06	Austria	2018	FFA SC 508,8 / MED and Efficacy against Grasses and dicots. pre-emergence applications in cereals (autumn) and early post em GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR18BELWBA1001	Belgium	2018	FFA SC 508,8 / MED and Efficacy against Grasses and dicots. pre-emergence applications in cereals (autumn) GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR18CZE454KD01	Czech Republic	2018	FFA SC 508,8 / MED and Efficacy against Grasses and dicots. pre-emergence applications in cereals (autumn) Ing. Jitka Mareckova GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19CZE454IAT1	Czech Republic	2019	FFA SC 508.8 / Efficacy and MED against grasses and dicots pre-emergence applications InTec Agro Trials, s.r.o. GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU511AT01	Germany	2019	Efficacy against ALOMY and dicots in pre-emergence appl. autumn in wwheat GEP-registration trial - confidential Agrartest GmbH GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU511P210	Germany	2019	Efficacy against ALOMY and dicots in pre-emergence appl. autumn in wwheat GEP-registration trial - confidential BioChem agrar, Niederlassung Agroplan GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU511P801	Germany	2019	Efficacy against ALOMY and dicots in pre-emergence appl. autumn in wwheat GEP-registration trial - confidential Martin -Feldversuchswesen GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU511SBH1	Germany	2019	Efficacy against ALOMY and dicots in pre-emergence appl. autumn in wwheat GEP-registration trial - confidential GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU511XJE1	Germany	2019	Efficacy against ALOMY and dicots in pre-emergence appl. autumn in wwheat GEP-registration trial - confidential GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19GBRL13JW01	United Kingdom	2019	FFA SC508.8/DFF+FFA SC500 Efficacy and MED against POAAN + dicots - cereals pre-emergence applications (TRZAW) GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19GBRL13RB01	United Kingdom	2019	FFA SC508.8/DFF+FFA SC500 Efficacy and MED against POAAN + dicots - cereals pre-emergence applications (TRZAW) GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19GBRL13RW01	United Kingdom	2019	FFA SC508.8/DFF+FFA SC500 Efficacy and MED against POAAN + dicots - cereals pre-emergence applications (TRZAW) GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20BELWCA1001	Belgium	2020	FFA SC 508.8/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20BELWCA1002	Belgium	2020	FFA SC 508.8/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20CZE454IAT1	Czech Republic	2020	FFA SC 508.8/ Efficacy and MED against grasses in winter cereals Pre-emergence application InTec Agro Trials, s.r.o. GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20CZE454TU01	Czech Republic	2020	FFA SC 508.8/ Efficacy and MED against grasses in winter cereals Pre-emergence application ZKUSEBNI STANICE Trutnov s.r.o. GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20CZE455IAT1	Czech Republic	2020	FFA SC 508.8/ Efficacy and MED against grasses in winter cereals Pre-emergence application InTec Agro Trials, s.r.o. GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC64BOU1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC64CHA1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC64CHA2	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC64GRA1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC64MAF1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC64MN01	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC64RAD1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC64RAD2	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC64SAI1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC64SAI2	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC66BOU1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against dicots in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC66RAD1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against dicots in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20GBRL10SW01	United Kingdom	2020	FFA SC508.8/DFF+FFA SC500 Efficacy and MED against POAAN + dicots - cereals pre-emergence applications (TRZAW) GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC09ASP1	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC09AT01	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC09AZ02	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC09JJ11	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC09LK09	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC09LK10	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC09SZWK	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20SVK105RS20	Slovakia	2020	FFA SC 508.8; ACL+FFA SC 500 / Efficacy and MED in winter cereals Pre-emergence application Gemerprodukt Valice OVD GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20SVK106106A	Slovakia	2020	FFA SC 508.8; ACL+FFA SC 500 / Efficacy and MED in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20SVK108RS20	Slovakia	2020	FFA SC 508.8; ACL+FFA SC 500 / Efficacy and MED in winter cereals Early post-emergence application Gemerprodukt Valice OVD GEP Unpublished	Yes	Bayer CropScience Division

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Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HD18GBRA10FDM1	United Kingdom	2018	ETO SC 500 PoC/ Efficacy against ALOMY and dicots. Autumn pre and post-emergence applications in TRZAW FieldArm Ltd GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HD18GBRA10FDM2	United Kingdom	2018	ETO SC 500 PoC/ Efficacy against ALOMY and dicots. Autumn pre and post-emergence applications in TRZAW FieldArm Ltd GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HD18GBRA10FDM3	United Kingdom	2018	ETO SC 500 PoC/ Efficacy against ALOMY and dicots. Autumn pre and post-emergence applications in TRZAW FieldArm Ltd GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HD19GBRL16FDM2	United Kingdom	2019	ETO SC 500 PoC/ Efficacy against ALOMY and dicots in TRZAW Autumn pre and post-emergence applications in cereals FieldArm Ltd GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HD19GBRL16FDM3	United Kingdom	2019	ETO SC 500 PoC/ Efficacy against ALOMY and dicots in TRZAW Autumn pre and post-emergence applications in cereals FieldArm Ltd GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR18AUT002KN04	Austria	2018	FFA SC 508,8 / MED and Efficacy against Grasses and dicots. pre-emergence applications in cereals (autumn) and early post em GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR18AUT002KN06	Austria	2018	FFA SC 508,8 / MED and Efficacy against Grasses and dicots. pre-emergence applications in cereals (autumn) and early post em GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR18BELWWB1001	Belgium	2018	FFA SC 508,8 / MED and Efficacy against Grasses and dicots. Early post-em applications in cereals (autumn) GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR18CZE455KD01	Czech Republic	2018	FFA SC 508,8 / MED and Efficacy against Grasses and dicots. Early post-em applications in cereals (autumn) Ing. Jitka Mareckova GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19AUT207RK15	Austria	2019	ACL+DFF+FFA SC 600/ FFA SC 508.8 / Efficacy and MED on grasses and dicots in cereals, epost-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19CZE455IAT1	Czech Republic	2019	FFA SC 508.8 / Efficacy and MED on grasses and dicots in cereals epost-emergence applications InTec Agro Trials, s.r.o. GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU557NHA1	Germany	2019	Efficacy against APESV and dicots in post-emergence appl. autumn in wwheat GEP-registration trial - confidential GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU557P801	Germany	2019	Efficacy against APESV and dicots in post-emergence appl. autumn in wwheat GEP-registration trial - confidential Firma Martin -Feldversuchswesen GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU557P901	Germany	2019	Efficacy against APESV and dicots in post-emergence appl. autumn in wwheat GEP-registration trial - confidential GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU557SGE1	Germany	2019	Efficacy against APESV and dicots in post-emergence appl. autumn in wwheat GEP-registration trial - confidential GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU557SMS1	Germany	2019	Efficacy against APESV and dicots in post-emergence appl. autumn in wwheat GEP-registration trial - confidential GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU558NSK1	Germany	2019	Efficacy against POAAN and dicots in post-emergence appl. autumn in wwheat GEP-registration trial - confidential GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU558P406	Germany	2019	Efficacy against POAAN and dicots in post-emergence appl. autumn in wwheat GEP-registration trial - confidential Hetterich Fieldwork GbR GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU558P526	Germany	2019	Efficacy against POAAN and dicots in post-emergence appl. autumn in wwheat GEP-registration trial - confidential Eurofins Agroscience Services GmbH GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU558P801	Germany	2019	Efficacy against POAAN and dicots in post-emergence appl. autumn in wwheat GEP-registration trial - confidential Firma Martin -Feldversuchswesen GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19DEU558SMS1	Germany	2019	Efficacy against POAAN and dicots in post-emergence appl. autumn in wwheat GEP-registration trial - confidential GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19GBRL14JW01	United Kingdom	2019	FFA SC508.8 and DFF+FFA SC500 / Efficacy and MED on POAAN + dicots - cereals epost-emergence applications (TRZAW) GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19GBRL14RP01	United Kingdom	2019	FFA SC508.8 and DFF+FFA SC500 / Efficacy and MED on POAAN + dicots - cereals epost-emergence applications (TRZAW) GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR19GBRL14RW01	United Kingdom	2019	FFA SC508.8 and DFF+FFA SC500 / Efficacy and MED on POAAN + dicots - cereals epost-emergence applications (TRZAW) GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20BELWCB1001	Belgium	2020	FFA SC 508.8/ Efficacy and MED against grasses and dicots in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20BELWCB1002	Belgium	2020	FFA SC 508.8/ Efficacy and MED against grasses and dicots in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20CZE456IAT1	Czech Republic	2020	FFA SC 508.8/ Efficacy and MED against grasses and dicots in winter cereals Early post-emergence application InTec Agro Trials, s.r.o. GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20CZE456TU01	Czech Republic	2020	FFA SC 508.8/ Efficacy and MED against grasses and dicots in winter cereals Early post-emergence application ZKUSEBNI STANICE Trutnov s.r.o. GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20CZE457IAT1	Czech Republic	2020	FFA SC 508.8/ Efficacy and MED against grasses and dicots in winter cereals Early post-emergence application InTec Agro Trials, s.r.o. GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC65BOU1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC65CHA1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division

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3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC65CHA2	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC65GRA1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC65MAF1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC65MN01	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC65RAD1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC65RAD2	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC65RIC1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC65SAI1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC65SAI2	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against grasses in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC67BOU1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against dicots in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20FRAC67RAD1	France	2020	ACL+FFA SC500 & FFA SC508/ Efficacy and MED against dicots in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20GBRL11SW01	United Kingdom	2020	FFA SC508.8 and DFF+FFA SC500 / Efficacy and MED on POAAN + dicots - cereals epost-emergence applications (TRZAW) GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC10ASP1	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses and dicots in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC10AT02	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses and dicots in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC10JJ12	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses and dicots in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC10LK11	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses and dicots in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC10LK12	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses and dicots in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20POLC10S2WK	Poland	2020	FFA SC 508.8/ Efficacy and MED against grasses and dicots in winter cereals Early post-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20SVK107107A	Slovakia	2020	FFA SC 508.8; ACL+FFA SC 500 / Efficacy and MED in winter cereals Early post-emergence application - GEP Unpublished	Yes	Bayer CropScience Division
3.2.2, 3.2.3, 3.4	KCP 6.2, KCP 6.4	HR20SVK108RS20	Slovakia	2020	FFA SC 508.8; ACL+FFA SC 500 / Efficacy and MED in winter cereals Early post-emergence application Gemerprodukt Valice OVD GEP Unpublished	Yes	Bayer CropScience Division

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Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.4	KCP 6.4	HD03DEU5401KE1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU5401SW1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU5405CZ1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU540AJU1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU540BAH1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU6401KE1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU6401SP1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.4	KCP 6.4	HD03DEU6409CZ1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU640BAH1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU7401KE1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU7401RU1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU7401SP1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU7451RU1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintertriticale im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU7451SP1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintertriticale im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.4	KCP 6.4	HD03DEU745BAH1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintertriticale im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD03DEU745XJE1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintertriticale im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU540NAH1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU540NJU1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU540NKE1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU540SRU1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU540WES1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.4	KCP 6.4	HD04DEU6401SW1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU640NBA1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU640NCZ1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU640NSK1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU640SRU1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU740NAH1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche ! GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU740NBO1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.4	KCP 6.4	HD04DEU740NDR1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU740NSK1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU740SFR2	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU745NDR1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in W.-Triticale im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU745NDR2	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in W.-Triticale im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU745NME1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in W.-Triticale im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.4	KCP 6.4	HD04DEU745WSE1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in W.-Triticale im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD04DEU745XJE1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in W.-Triticale im VA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD15DEU542P430	Germany	2015	Selectivity/yield in pre emergence autumn application in winter durum weed free dose/double dose GEP-registration trial - confidential Hetterich Fieldwork GbR GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD15DEU542P801	Germany	2015	Selectivity/yield in pre emergence autumn application in winter durum weed free dose/double dose GEP-registration trial - confidential Firma Martin- Feldversuchswesen GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD15DEU543P427	Germany	2015	Selectivity/yield in pre emergence autumn application in winter spelt weed free dose/double dose GEP-registration trial - confidential Hetterich Fieldwork GbR GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HD15DEU543P801	Germany	2015	Selectivity/yield in pre emergence autumn application in winter spelt weed free dose/double dose GEP-registration trial - confidential Firma Martin -Feldversuchswesen GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.4	KCP 6.4	HR19DEU541P216	Germany	2019	Selectivity/yield in pre emergence autumn application in w.durum wheat weed free dose/double dose GEP-registration trial - confidential BioChem agrar GmbH; VS Ebrach GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR19DEU541P411	Germany	2019	Selectivity/yield in pre emergence autumn application in w.durum wheat weed free dose/double dose GEP-registration trial - confidential Hetterich Fieldwork GbR GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR19DEU541P801	Germany	2019	Selectivity/yield in pre emergence autumn application in w.durum wheat weed free dose/double dose GEP-registration trial - confidential Thomas Martin Feldversuchswesen GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR19DEU541WHB1	Germany	2019	Selectivity/yield in pre emergence autumn application in w.durum wheat weed free dose/double dose GEP-registration trial - confidential GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR19DEU542P213	Germany	2019	Selectivity/yield in pre emergence autumn application in w.spelt wheat weed free dose/double dose GEP-registration trial - confidential BioChem agrar GmbH; VS Ebrach GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR19DEU542P413	Germany	2019	Selectivity/yield in pre emergence autumn application in w.spelt wheat weed free dose/double dose GEP-registration trial - confidential Hetterich Fieldwork GbR GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.4	KCP 6.4	HR19DEU542P527	Germany	2019	Selectivity/yield in pre emergence autumn application in w.spelt wheat weed free dose/double dose GEP-registration trial - confidential Eurofins Agroscience Services GmbH GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR19DEU542P801	Germany	2019	Selectivity/yield in pre emergence autumn application in w.spelt wheat weed free dose/double dose GEP-registration trial - confidential Martin -Feldversuchswesen GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20BELWCC1001	Belgium	2020	FFA SC508.8/ Crop safety in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20BELWCC1002	Belgium	2020	FFA SC508.8/ Crop safety in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20CZE554UOS1	Czech Republic	2020	FFA SC508.8/ Crop safety in winter cereals Pre-emergence application INF Agro, s.r.o. GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20CZE554ZUS1	Czech Republic	2020	FFA SC508.8/ Crop safety in winter cereals Pre-emergence application OSEVA PRO Ltd., Grassland Research Station GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20CZE555DOS1	Czech Republic	2020	FFA SC508.8/ Crop safety in winter cereals Pre-emergence application Zemservis zkusebni stanice Domainek s.r.o. GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.4	KCP 6.4	HR20FRAC53BEN1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (TRZAW) Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20FRAC53CHA1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (TRZAW) Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20FRAC53RAD1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (TRZAW) Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20FRAC53TAR1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (TRZAW) Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20FRAC55ALL1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (HORVW) Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20FRAC55ARN1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (HORVW) Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20FRAC55BOU1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (HORVW) Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20FRAC55CHM1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (HORVW) Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20POLC1105RK	Poland	2020	FFA SC508.8/ Crop safety in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division

Dossier Point(s)	KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
3.4	KCP 6.4	HR20POLC11ASL1	Poland	2020	FFA SC508.8/ Crop safety in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20POLC11ASS1	Poland	2020	FFA SC508.8/ Crop safety in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20POLC11HR14	Poland	2020	FFA SC508.8/ Crop safety in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20POLC11JJ06	Poland	2020	FFA SC508.8/ Crop safety in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20POLC11JJ19	Poland	2020	FFA SC508.8/ Crop safety in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division
3.4	KCP 6.4	HR20POLC11PRWK	Poland	2020	FFA SC508.8/ Crop safety in winter cereals Pre-emergence application GEP Unpublished	Yes	Bayer CropScience Division

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KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
KCP 6.4	HD03DEU5401KE1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU5401SW1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU5405CZ1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU540BAH1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU6401KE1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU6401SP1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division

KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
KCP 6.4	HD03DEU6409CZ1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU640BAH1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU640WSE1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU7401KE1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU7401RU1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU7401SP1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU740XSL1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im Herbst. Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division

KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
KCP 6.4	HD03DEU7451RU1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintertriticale im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU7451SP1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintertriticale im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU745BAH1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintertriticale im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD03DEU745XJE1	Germany	2003	Selektivität und Ertragswirkung von Herbiziden in Wintertriticale im Herbst Dosis und Doppeldosis (unkrautfrei) mit Nachbau, Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU541NAH1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU541NJU1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU541NKE1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division

KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
KCP 6.4	HD04DEU541SRU1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU541WES1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterweizen im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU6401SW1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU640NBA1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU640NCZ1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU640NSK1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU640SRU1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Wintergerste im Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU741NAH1	Germany	2004	Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU741NBO1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im NA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division

KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
KCP 6.4	HD04DEU741NDR1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im NA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche. GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU741NSK1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im NA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU741SFR1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in Winterroggen im NA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU746NAH1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in W.-Triticale im NA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU746NDR1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in W.-Triticale im NA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche. BCSD# GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU746NDR2	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in W.-Triticale im NA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche. BCSD GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU746NME1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in W.-Triticale im NA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU746WSE1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in W.-Triticale im NA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division

KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
KCP 6.4	HD04DEU746XJE1	Germany	2004	Selektivität und Ertragswirkung von Herbiziden in W.-Triticale im NA Herbst Dosis und Doppeldosis (unkrautfrei), Registrierungsversuche GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU750WSE1	Germany	2004	Selektivität von Herbiziden in Wintergetreide-Sorten im Herbst Dosis und Doppeldosis (unkrautfrei), Sortenversuche für Registrierung GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD04DEU750XJE1	Germany	2004	Selektivität von Herbiziden in Wintergetreide-Sorten im Herbst Dosis und Doppeldosis (unkrautfrei), Sortenversuche für Registrierung GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD15DEU545P801	Germany	2015	Selectivity/yield in early post emergence autumn application in winter durum weed free dose/double dose GEP-registration trial - confidential Firma Martin- Feldversuchswesen GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD15DEU546P428	Germany	2015	Selectivity/yield in early post emergence autumn application in winter spelt weed free dose/double dose GEP-registration trial - confidential Hetterich Fieldwork GbR GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD15DEU549P801	Germany	2015	Selectivity/yield in late post emergence autumn application in winter durum weed free dose/double dose GEP-registration trial - confidential Firma Martin- Feldversuchswesen GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HD15DEU550P429	Germany	2015	Selectivity/yield in late post emergence autumn application in winter spelt weed free dose/double dose GEP-registration trial - confidential Hetterich Fieldwork GbR GEP Unpublished	Yes	Bayer CropScience Division

KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
KCP 6.4	HR19DEU545P214	Germany	2019	Selectivity/yield in post emergence autumn application in w.durum wheat weed free dose/double dose GEP-registration trial - confidential BioChem agrar GmbH; VS Ebrach GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR19DEU545P801	Germany	2019	Selectivity/yield in post emergence autumn application in w.durum wheat weed free dose/double dose GEP-registration trial - confidential Firma Martin -Feldversuchswesen GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR19DEU545WHB1	Germany	2019	Selectivity/yield in post emergence autumn application in w.durum wheat weed free dose/double dose GEP-registration trial - confidential GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR19DEU546P215	Germany	2019	Selectivity/yield in post emergence autumn application in w. spelt wheat weed free dose/double dose GEP-registration trial - confidential BioChem agrar GmbH; VS Ebrach GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR19DEU546P414	Germany	2019	Selectivity/yield in post emergence autumn application in w. spelt wheat weed free dose/double dose GEP-registration trial - confidential Hetterich Fieldwork GbR GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR19DEU546P528	Germany	2019	Selectivity/yield in post emergence autumn application in w. spelt wheat weed free dose/double dose GEP-registration trial - confidential Eurofins Agroscience Services GmbH GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR19DEU546P801	Germany	2019	Selectivity/yield in post emergence autumn application in w. spelt wheat weed free dose/double dose GEP-registration trial - confidential Firma Martin -Feldversuchswesen GEP Unpublished	Yes	Bayer CropScience Division

KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
KCP 6.4	HR20BELWCD1001	Belgium	2020	FFA SC 508.8/ Crop safety in winter cereals. Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20BELWCD1002	Belgium	2020	FFA SC 508.8/ Crop safety in winter cereals. Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20CZE556UOS1	Czech Republic	2020	FFA SC 508.8/ Crop safety in winter cereals. Early post emergence application INF Agro, s.r.o. GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20CZE556ZUS1	Czech Republic	2020	FFA SC 508.8/ Crop safety in winter cereals. Early post emergence application OSEVA PRO Ltd., Grassland Research Station GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20CZE557DOS1	Czech Republic	2020	FFA SC 508.8/ Crop safety in winter cereals. Early post emergence application Zemservis zkusebni stanice Domainek s.r.o. GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20FRAC54BEN1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (TRZAW) Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20FRAC54CHA1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (TRZAW) Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division

KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
KCP 6.4	HR20FRAC54RAD1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (TRZAW) Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20FRAC56ARN1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (HORVW) Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20FRAC56BOU1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (HORVW) Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20FRAC56CHM1	France	2020	ACL+FFA SC 500 & FFA SC508.8 / Crop safety in winter cereals (HORVW) Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20POLC1216RK	Poland	2020	FFA SC 508.8/ Crop safety in winter cereals. Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20POLC12ASL1	Poland	2020	FFA SC 508.8/ Crop safety in winter cereals. Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20POLC12ASS1	Poland	2020	FFA SC 508.8/ Crop safety in winter cereals. Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20POLC12HR22	Poland	2020	FFA SC 508.8/ Crop safety in winter cereals. Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20POLC12JJ07	Poland	2020	FFA SC 508.8/ Crop safety in winter cereals. Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division

KCP Point(s)	Trial ID	Country	Year	Title Source (where different from company) GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed (Yes/No)	Owner
KCP 6.4	HR20POLC12JJ24	Poland	2020	FFA SC 508.8/ Crop safety in winter cereals. Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division
KCP 6.4	HR20POLC12PRWK	Poland	2020	FFA SC 508.8/ Crop safety in winter cereals. Early post emergence application GEP Unpublished	Yes	Bayer CropScience Division

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

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

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 9.2.4.1 / 03	Reinken, G.; Serode, R.	2021	Flufenacet (FFA) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 2) - Use in winter cereals in Europe Report No.: EnSa-21-0150, Edition Number: M-765725-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCA 7.1.2.1.2 / 01 ... also filed: KCA 7.1.3.1.2 / 01	Hellpointner, E.	2003	Time-dependent sorption of FOE5043-sulfonic acid in soil Report No.: MEF-229/03, Edition Number: M-111445-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 7.1.2.2.1 / 01	Hammel, K.	2008	Kinetic evaluation of the dissipation of flufenacet and its metabolite flufenacet - sulfonic acid in soil based on field studies	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
			Report No.: MEF-08/266, Edition Number: M-306683-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished		
KCA 7.1.3.1.2 / 01 ... also filed: KCA 7.1.2.1.2 / 01	Hellpointner, E.	2003	Time-dependent sorption of FOE5043-sulfonic acid in soil Report No.: MEF-229/03, Edition Number: M-111445-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.1 / 01	Bruns, E.	2013	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 Data never submitted to POL The studyevaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.9, 2018).
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
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	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
			Bayer AG, Leverkusen, Germany **... amended: 2011-09-06** GLP/GEP: Yes unpublished		
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
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	Yes Data never submitted to POL The studyevaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.9, 2018).
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 Data never submitted to POL The studyevaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.9, 2018).
KCP 5.1.2.6 / 04 **... also filed:** **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 The studyevaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.9, 2018).
KCP 5.1.2.6 / 05	Bruns, E.	2009	Lemna gibba G3 Growth inhibition test with flufenacet-oxalate under static conditions	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
... also filed: **KCP 10.2.3 / 02**			Report No.: EBFOL138, Edition Number: M-359515-02-1 Bayer CropScience AG, Monheim, Germany **... amended: 2009-12-08** GLP/GEP: Yes unpublished		The studyevaluated by RMS-Poland in RAR for Flufenacet (Vol. 3 – B.9, 2018).

List of data relied on and 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
-	-	-	-	-	-