FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: CHR/H/FDF 574 SC

Product name(s): Cezaro 574 SC/ Huron 574 SC

Chemical active substance(s):

Florasulam, 12 g/kg
Diflufenican, 250 g/kg
Flufenacet, 312 g/kg

Central Zone

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

MS Finalisation date: 21/11/2022

Version history

When	What
November 2021	Submission to the Polish Ministry of Agriculture and Rural Development
March 2022	Submission to the evaluation
September 2022	Updated version of dRR
September 2022	zRMS finalised evaluation
November 2022	Final version prepared by zRMS after Commenting period

Table of Contents

9 Ecotoxicology (KCP 10)

Review Comments:

This application was submitted by Innvigo Sp. z o.o. for approval of the formulation CHR/H/FDF 574 SC/ Cezaro 574 SC, Huron 574 SC: florasulam, 12 g/kg; diflufenican, 250 g/kg and flufenacet, 312 g/kg

for use as a herbicide in winter cereals.

This dRR report Part B reviews only ecotoxicological data (Annex III) and additional information that has not previously been considered within the EU review process.

The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations, and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency.

In the following document, data for active substances - diflufenican and flufenacet - was described during its inclusion on Annex 1 process in respectively 2009 and 2004 . Were reference to active substance data in the current risk assessment has been made, it was based on the data which protection for expired 10 years from date of inclusion of active substances on Annex I.
Data matching studies for florasulam have been evaluated by Poland. As a result of the assessment all reports were accepted and considered as equivalent to protected studies. Therefore, to support the authorization of CHR/H/FDF 574 SC INNVIGO is allowed to refer to EU approved reports

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

PPP product name:		Formulation type:	
product code:	CHR/H/FDF		
Active substance 1:	flufenacet	Conc. of as 1:	
Active substance 2:	diflufenican	Conc. of as 2:	
Active substance 3:	florasulam	Conc. of as 3:	
Safener:	-	Conc. of safener:	
Synergist:	-	Conc. of synergist:	
Applicant:	PUH Chemirol Sp. z o.o.	Professional use:	
Zone(s):	Central (d)	Non professional use:	
Verified by MS:	Yes ~~no~~		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15	16	17	18	19	20	21
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)	**zRMS Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants

Zonal uses (field or outdoor uses, certain types of protected crops)																		
1	PL	Winter wheat (TRZAW), Winter triticale (TTLWI), Winter barley (HORVW), Winter rye (SECCW)	F	dicotyle-donous weeds	Spray, medium sprayer	autumn BBCH 11-25	a)1 b)1	n/a	a) 0.4 l/ha b) 0.4 l/ha	a) 0.2296 kg a.s./ha (0.1248 FLU + 0.1 D + 0.0048 FLO) b) 0.2296 kg a.s./ha (0.1248 FLU + 0.1 D + 0.0048 FLO)	200-400	n/a						
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																		
2																		
3																		
Minor uses according to Article 51 (zonal uses)																		
4																		
5																		
Minor uses according to Article 51 (interzonal uses)																		
6																		
7																		

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at 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
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval

(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench

(m) Remarks may include: Extent of use/economic importance/restrictions

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 "Conclusion"

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

Remarks table:

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

Review Comments:

Critical GAP presented in the Table 9.1-1 of this document is revised with consideration of the outcome of the evaluation performed in area of ecotoxicology.

9.1.1 Overall conclusions

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

The risk assessment for birds and mammals was carried out according to the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

CHR/H/FDF 574 SC pose no unacceptable risk to birds and mammals used according to the label.

There were also no negative effects regarding to drinking water exposure and of secondary poisoning (diflufenican, flufenacet). There is no influence to evaluated organism regarding to dangerous to food poisoning. Furthermore, for mixture toxicity acceptable risk could be demonstrated.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

CHR/H/FDF 574 SC pose no unacceptable risk to aquatic organisms according to the label with appropriate buffer zones.

Concerned Member States must decide on the applicability of indicated risk mitigation measures at the product authorization.

9.1.1.3 Effects on bees (KCP 10.3.1)

The evaluation of the risk for bees has been performed in line with SANCO/10329/2002 rev 2 final.

CHR/H/FDF 574 SC pose no unacceptable risk to bees according to the label

Concerned Member States must decide on the consideration of data requirements of the EFSA Bee guidance (2013) on national level.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

CHR/H/FDF 574 SC pose no unacceptable risk to NTA according to the label

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

CHR/H/FDF 574 SC pose no unacceptable risk to non-target soil meso- and macrofauna and microbial activity according to the label.

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

CHR/H/FDF 574 SC pose no unacceptable risk to non-target terrestrial plants according to the label with appropriate buffer zone and drift reducing techniques.

Concerned Member States must decide on the applicability of indicated risk mitigation measures at the product authorization.

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

Not relevant

9.1.2 Grouping of intended uses for risk assessment

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

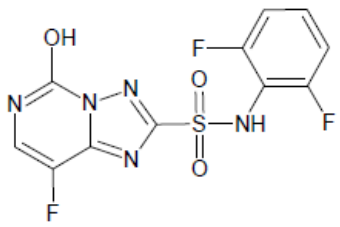
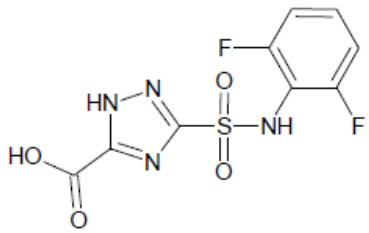
Table 9.1-2: Critical use pattern of CHR/H/FDF 574 SC grouped according to criterion

Grouping according to crop, application rate, number of application, timing criterion			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
1	Winter Cereals BBCH 11-25 483.08 ~~489.08~~ g [product]/ha	crop, application rate, number of applications, timing,	crop, application rate, number of applications, timing,

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of CHR/H/FDF 574 SC is indicated in the table.

Table 9.1-3: Metabolites of florasulam potentially relevant for exposure assessment

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
5-OH florasulam	345.26		Soil (lab): max 71.6 % at 3-7 d (n= 5) Maximum detected in aquatic environment: 99.0%	Yes
DFP-ASTCA	304.20		Soil (Lab): max 17.8 % at 14-59 d (n= 5) Maximum detected in aquatic environment: 8.9%	Yes

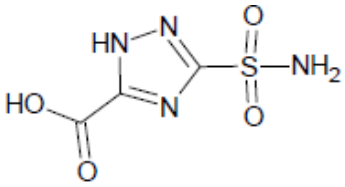
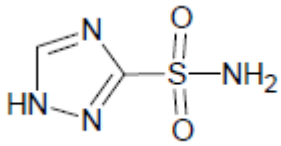
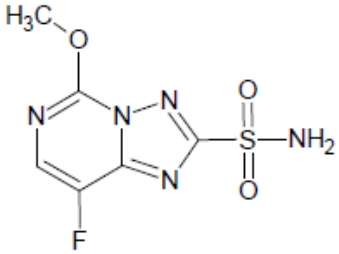
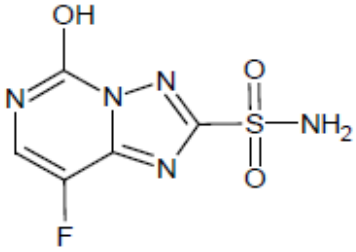
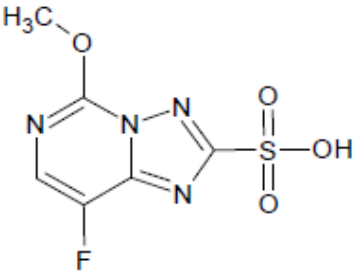
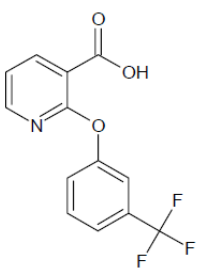
Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
ASTCA	192.13		Soil (Lab): max 40.0 % (n= 4) at 59-100 d Maximum detected in aquatic environment: 53.8%	Yes
TSA	148.14		Soil (Lab): max 15.9 % (n= 4) at 14 - 100 d Maximum detected in aquatic environment: 0.0001	Yes
ASTP	247.20		Maximum detected in aquatic environment: 21.9%	Yes
5-OH ASTP	233.18		Maximum detected in aquatic environment: 28.9%	Yes
TPSA	248.17		Maximum detected in aquatic environment: 58.3%	Yes

Table 9.1-4: Metabolites of diflufenican potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
AE B107137	283		Soil: 16.8% Water: 32.6% Sed: 13.3%	Yes

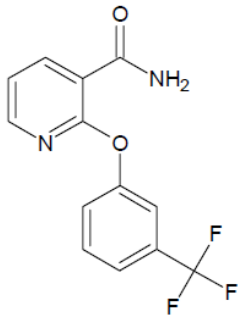
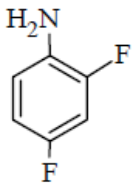
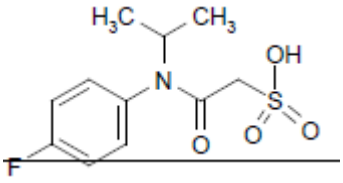
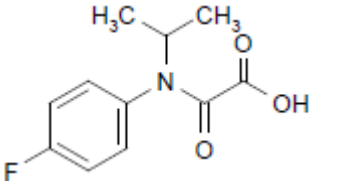
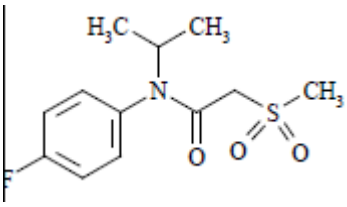
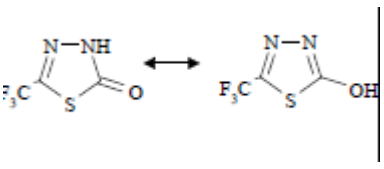
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
AE 0542291	282		Soil: 26.3% Water: 6.1% Sed: 1.0%	Yes
AE C522392	129.11		Soil: 26.3% Water: 6.1% Sed: 1.0%	Yes

Table 9.1-5: Metabolites of flufenacet potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
FOE sulfonic acid	275.3g/mol		Soil (lab): max 26.3% AR	Yes
FOE oxalate	225.2g/mol		Soil (Lab): max 15.6 % AR	Yes
FOE methyl-sulfone	273.3g/mol		Water/sediment max. 8 % in water, 3.4 % in sediment on day 157	Yes
FOE-thiadone	170.1g/mol		Maximum occurrence observed in sediment/ water studies: 82 % in water (55 d)	Yes

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with florasulam, diflufenican, flufenacet and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents. Effects on birds of CHR/H/FDF 574 SC were not evaluated as part of the EU assessment of florasulam, diflufenican and Flufenacet.
However, the provision of further data on the CHR/H/FDF 574 SC is not considered essential, because studies from Annex I inclusion can be used in Annex I inclusion.
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

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

Species	Substance	Exposure System	Results	Reference
Japanese quails Coturnix coturnix japonica	Florasulam	Oral 1 d Acute	LD50= 1046 mg a.s./kg bw per day	EFSA Journal 2015; 13(1):3984
Mallard duck (Anas platyrhynchos)	Florasulam	Dietary Reproductive toxicity	Endpoint use in long-term risk assessment is LD50 for florasulam of 1046 mg/kg bw divided by 10. The resulting value is lower than the NOEC from reproductive study for florasulam of 1500 mg/kg diet multiplied by a factor 0.1.	EFSA Journal 2015; 13(1):3984
Bobwhite quail	Diflufenican	Oral 1 d Acute	LD50 >2150 mg a.s./kg bw	EFSA Scientific Repor EFSA Scientific Report (2007) 122, 1-84
Bobhwite quail	Diflufenican	Dietary Reproductive toxicity	NOAEL= 91.84 mg a.s./kg bw per day	EFSA Scientific Repor EFSA Scientific Report (2007) 122, 1-84
Bobwhite quail	Flufenacet	Oral Acute	LD50 = 1608 mg a.s./kg bw	7469/VI/98-Final 3 July 2003
Mallard duck	Flufenacet	Dietary Short-term	LC50 > > 4970 ppm	7469/VI/98-Final 3 July 2003
Japanese quail	Flufenacet	Dietary Reproductive toxicity	NOEC (mallard duck) = 88 ppm, equivalent to 9.87 mg/kg bw/day	7469/VI/98-Final 3 July 2003

Review Comments:

In addition to the EU agreed values the Applicant propose to perform reproductive risk assessment with conservative endpoint LD_{50}/10 of 104.6 mg/kg bw. Since in the long-term risk assessment for florasulam LD_{50}/10 was considered as being lower than the experimentally derived NOEL value zRMS agree with this approach.

9.2.2 Risk assessment for spray applications

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

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

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

Table 9.2-2: Screening ~~First-tier~~ assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/H/FDF 574 SC in cereals winter for the florasulam

Intended use		**Cereals**			
Active substance/product		Florasulam			
Application rate (g/ha)		1 x 4.8			
Acute toxicity (mg/kg bw)		1046			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1.0	0.76	1372.3
Reprod. toxicity (mg/kg bw/d)		104.6			
TER criterion		5			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small omnivorous bird	64.8	0.53	0.16	634.5

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

Table 9.2-3: Screening ~~First-tier~~ assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/H/FDF 574 SC in cereals winter for the diflufenican

Intended use		**Cereals**			
Active substance/product		Diflufenican			
Application rate (g/ha)		1 x 100			
Acute toxicity (mg/kg bw)		2150 ~~2250~~			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1.0	15.88	135.4
Reprod. toxicity (mg/kg bw/d)		91.8			
TER criterion		5			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small omnivorous bird	64.8	0.53	3.43	26.7

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

Table 9.2-4: Screening and First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/H/FDF 574 SC in cereals winter for the flufenacet

Intended use	**Cereals**				
Active substance/product	Flufenacet				
Application rate (g/ha)	1 x 124.8				
Acute toxicity (mg/kg bw)	1608				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1.0	19.83	81.1
Reprod. toxicity (mg/kg bw/d)	9.87 ~~9.9~~				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small omnivorous bird	64.8	0.53	4.29	2.3
First Tier					
Cereals BBCH 10 - 29	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	0.53	0.72	13.7
~~Cereals BBCH 10 - 29~~	~~Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods~~	~~10.9~~			~~13.7~~
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose" Grass + cereals 100% cereal shoots	16.2	0.53	1.07	9.2

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

Combined risk assessment for CHR/H/FDF 574 SC mixture

At the screening assessment following formula was used:

All TER values > Trigger x n (n = number active substances in the mixture - 3)

TER_A Florasulam	**TER_A Diflufenican**	**TER_A Flufenacet**	**Trigger value**
1372.3	135.4	81.1	30
TER_{LT} Florasulam	**TER_{LT} Diflufenican**	**TER_{Lt} Flufenacet**	**Trigger value**
634.5	26.7	2.3	15

634.5	26.7	9.2	

At the screening step acute risk assessment for mixture is acceptable. For long-term exposure further consideration is needed.

As proposed there, the calculations follow the concentration addition model.

The combined TER_{LT} value is calculated according to the following formula:

$$TER_{LT\ combi} = trigger/((trigger/TER_{LT\ substance\ 1})+(trigger/TER_{LT\ substance\ 2}) +(trigger/TERLT\ substance\ 3))$$

An acceptable risk is expected when $TER_{LT\ combi} > trigger$.

Crop	**TER_{LT}**			**5/TER**	**5/TER**	**5/TER**	Sum	**$TER_{LTcombi}$**	**Trigger**
	florasulam	Diflufenican	Flufenacet						
Cereals	634.5	26.7	2.3[1]	0.007	0.19	2.17	2.37	2.1	5
	634.5	26.7	9.2 [2]	0.007	0.19	0.54	0.74	6.75	

[1]TER form screening step
[2]TER from First Tier

Provided long-term risk assessment for the mixture indicated acceptable risk. No further refinement is needed.

~~For the risk refinment:~~

~~A TER_{mix} was calculated with the following formula:~~

$$TER(mix) = \left(\sum_i \frac{1}{TER(a.s._i)} \right)^{-1}$$

where:

$TER_{(a.s.i)}$= calculated TER for the active substance *i*

~~TER_A Florasulam~~	~~TER_A Diflufenican~~	~~TER_A Flufenacet~~	~~$TER_{mix\ birds\ acute}$~~	~~Trigger value~~
~~1372.3~~	~~135.4~~	~~81.1~~	~~100.66~~	~~10~~
~~TER_{LT} Florasulam~~	~~TER_{LT} Diflufenican~~	~~TER_{Lt} Flufenacet~~	~~$TER_{mix\ birds\ acute}$~~	~~Trigger value~~
~~634.5~~	~~26.7~~	~~2.3~~	~~3.96~~	~~5~~
~~634.5~~	~~26.7~~	~~9.2~~	~~13.25~~	

Conclusion
The calculated TERmix and TER for individual active substance value is higher than the trigger value of 10 for acute risk assessment and higher than the trigger value of 5 for chronic risk assessment , indicating CHR/H/FDF 574 SC does not posses unacceptable acute and long-term risk for mammals.
No further risk refinement is needed.

9.2.2.2 Higher-tier risk assessment

Not required.

9.2.2.3 Drinking water exposure

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

Leaf scenario

Since CHR/H/FDF 574 SC is not a product for spray applications / not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

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

With a K(f)oc of 16, Florasulam belongs to the group of less/more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use winter/spring cereals:

Effective application rate (g/ha)	=	4.8		
Acute toxicity (mg/kg bw)	=	1046	quotient =	0.0046
Reprod. toxicity (mg/kg bw/d)	=	104.6	quotient =	0.046

With a K(f)oc of 3417, diflufenican belongs to the group of less/more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use winter/spring cereals:

Effective application rate (g/ha)	=	100		
Acute toxicity (mg/kg bw)	=	2150	quotient =	0.0465
Reprod. toxicity (mg/kg bw/d)	=	91.84	quotient =	1.089

With a K(f)oc of 349, Flufenacet belongs to the group of less/more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use winter/spring cereals:

Effective application rate (g/ha)	=	124.8		
Acute toxicity (mg/kg bw)	=	1608	quotient =	0.078
Reprod. toxicity (mg/kg bw/d)	=	9.87	quotient =	12.64

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Florasulam is below 3 and thus no exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

The log P_{ow} of Diflufenican amounts to 4.2 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use on winter cereals.

Table 9.2-5: Assessment of the risk for earthworm-eating birds due to exposure to Diflufenican via bioaccumulation in earthworms (secondary poisoning) for the intended use in winter cereals

Parameter	Diflufenican	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.1318	Escape ver 2.
log P_{ow} / P_{ow}	4.2	EFSA Scientific Report (2007) 122, 1-84
Koc	3417	EFSA Scientific Report (2007) 122, 1-84
foc	Organic carbon content of soil (0.02 taken as a default value)	Default
BCF_{worm}	2.8	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.3609	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.3875	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	91.8	EFSA Scientific Report (2007) 122, 1-84
TER_{lt}	236.9	Above trigger 5

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of Diflufenican in water.

Table 9.2-6: Assessment of the risk for fish-eating birds due to exposure to diflufenican via bioaccumulation in fish (secondary poisoning) for the intended use in winter cereals

Parameter	Flufenacet	comments
PEC_{sw} (initial) (mg/L)	0.00479	Focus STEP 2
BCF_{fish}	1596	EFSA Scientific Report (2007) 122, 1-84
BMF	Not relevant	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	7.65	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	1.22	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	91.8	EFSA Scientific Report (2007) 122, 1-84
TER_{lt}	75	Trigger 5

The log P_{ow} of Flufenacet amounts to 3.2 and thus exceeds the trigger value of 3. A risk assessment for

effects due to secondary poisoning is required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use on winter cereals.

Table 9.2-7: Assessment of the risk for earthworm-eating birds due to exposure to Flufenacetvia bioaccumulation in earthworms (secondary poisoning) for the intended use in winter cereals

Parameter	Flufenacet	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.1459	Escape ver 2.
log P_{ow} / P_{ow}	3.2/1585	7469/VI/98-Final 3 July 2003
Koc	349	7469/VI/98-Final 3 July 2003
foc	Organic carbon content of soil (0.02 taken as a default value)	Default
BCF_{worm}	2.85	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.4158	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.4366	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	9.87	7469/VI/98-Final 3 July 2003
TER_{lt}	22.6	Above trigger 5

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of Flufenacet in water.

Table 9.2-8: Assessment of the risk for fish-eating birds due to exposure to flufenacet via bioaccumulation in fish (secondary poisoning) for the intended use in winter cereals

Parameter	Flufenacet	comments
PEC_{sw} (initial) (mg/L)	0.01284	Focus STEP 2
BCF_{fish}	71.4	7469/VI/98-Final 3 July 2003
BMF	Not relevant	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.9168	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.146	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	9.87	7469/VI/98-Final 3 July 2003
TER_{lt}	67.7	Trigger 5

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.2.4 Overall conclusions

In conclusion, the acute, short term risk and long term to birds from the proposed uses of florasulam, diflufenican, flufenacet was found acceptable. CHR/H/FDF 574 SC ~~750 WG~~ pose no unacceptable risk to birds with according to the label.

Review comments:

The acute and long-term risk assessment for birds performed by the Applicant is agreed by the zRMS. It was performed in line with recommendations of the EFSA (2009) with assumption of EU agreed end-points. No formulation study was required.

TER_A and TER_{LT} in the acute and long-term risk assessment indicated acceptable risk assessment for all active substances at screening (florasulam, diflufenican) and first-tier step (flufenacet).

Provided acute and long-term risk assessment for the mixture indicated acceptable risk.
CHR/H/FDF 574 SC presents no unacceptable risk to birds resulting from exposure via drinking water. Presented secondary poisoning for diflufenican, flufenacet presents no unacceptable risk to birds.

Overall, acceptable acute and reproductive risk to birds may be concluded for application of CHR/H/FDF 574 SC in compliance with proposed GAP.

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

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with florasulam, diflufenican, flufenacet and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Section 6 (Mammalian Toxicology) of this report (new studies).

However, the provision of further data on the formulation CHR/H/FDF 574 SC is not considered essential, because the selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

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

Species	Substance	Exposure System	Results	Reference
Mouse	Florasulam	Acute	LD50>5000 mg a.s./kg bw	EFSA Journal 2015; 13(1):3984
Rat	Florasulam	Long term	NOEL>100 mg a.s./kg bw/d	EFSA Journal 2015; 13(1):3984

Species	Substance	Exposure System	Results	Reference
Rat	Diflufenican	Acute	LD50 rat oral >5000 mg a.s./kg bw	EFSA Scientific Repor EFSA Scientific Report (2007) 122, 1-84
Rat	Diflufenican	Long-term	NOAEL = 35.5 mg a.s./kg bw per day	EFSA Scientific Repor EFSA Scientific Report (2007) 122, 1-84
Rat	Flufenacet	Acute	LD_{50} = 589 mg/kg bw	7469/VI/98-Final 3 July 2003
Rat	Flufenacet	Long-term*	NOAEL = 500 ppm (37.4 mg/kg bw/d) – 2 generation rat	7469/VI/98-Final 3 July 2003 *According to the Toxicology section of the EU review report (2003) as there is no mammalian reproductive endpoint listed in the Ecotoxicoloy section

9.3.2 Risk assessment for spray applications

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

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

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

Table 9.3-2: Screening ~~First-tier~~ assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/H/FDF 574 SC in winter cereals for florasulam

Intended use	cereals				
Active substance/product	Florasulam				
Application rate (g/ha)	1 × 4.8				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1.0	0.57	8797.9
Reprod. toxicity (mg/kg bw/d)	100				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small herbivorous mammal	48.3	0.53	0.12	813.83

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

Table 9.3-3: Screening ~~First-tier~~ assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/H/FDF 574 SC in winter cereals for diflufenican

Intended use	cereals				
Active substance/product	Diflufenican				
Application rate (g/ha)	1 × 100				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1.0	11.84	422.3
Reprod. toxicity (mg/kg bw/d)	35.5				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small herbivorous mammal	48.3	0.53	2.56	13.87

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

Table 9.3-4: Screening ~~First-tier~~ assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/H/FDF 574 SC in winter cereals for flufenacet

Intended use	cereals				
Active substance/product	Flufenacet				
Application rate (g/ha)	1 × 124.8				
Acute toxicity (mg/kg bw)	589				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1.0	14.78	39.9
Reprod. toxicity (mg/kg bw/d)	37.4				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small herbivorous mammal	48.3	0.53	3.19	11.71

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

At the screening assessment following formula was used:

All TER values > Trigger x n (n = number active substances in the mixture - 3)

TER_A Florasulam	**TER_A Diflufenican**	**TER_A Flufenacet**	**Trigger value**

8797.9	422.3	39.9	30
TER_{LT} Florasulam	**TER_{LT} Diflufenican**	**TER_{Lt} Flufenacet**	**Trigger value**
813.83	13.87	11.71	15

At the screening step acute risk assessment for mixture is acceptable. For long-term exposure further consideration is needed.

As proposed there, the calculations follow the concentration addition model.

The combined TER_{LT} value is calculated according to the following formula:

$$TER_{LT\ combi} = trigger/((trigger/TER_{LT\ substance\ 1})+(trigger/TER_{LT\ substance\ 2}) +(trigger/TERLT\ substance\ 3))$$

An acceptable risk is expected when $TER_{LT\ combi} > trigger$.

Crop	TER_{LT}			5/TER	5/TER	5/TER	Sum	$TER_{LTcombi}$	Trigger
	florasulam	Diflufenican	Flufenacet						
Cereals	813.83	13.87	11.71	0.006	0.36	0.43	0.8	6.25	5

[1]TER form screening step
[2]TER from First Tier

Provided long-term risk assessment for the mixture indicated acceptable risk. No further refinement is needed.

~~**Combined risk assessment for CHR/H/FDF 574 SC mixture**~~

~~A TER_{mix} was calculated with the following formula:~~

$$TER(mix) = \left(\sum_i \frac{1}{TER(a.s._i)} \right)^{-1}$$

where:

$TER_{(a.s.i)}$= calculated TER for the active substance *i*

~~TER_A Florasulam~~	~~TER_A Diflufenican~~	~~TER_A Flufenacet~~	~~$TER_{mix\ mammals\ acute}$~~	~~Trigger value~~
~~8797.9~~	~~422.3~~	~~39.9~~		~~10~~
~~TER_{LT} Florasulam~~	~~TER_{LT} Diflufenican~~	~~TER_{Lt} Flufenacet~~	~~$TER_{mix\ mammals\ acute}$~~	~~Trigger value~~
~~813.83~~	~~13.87~~	~~11.71~~		~~5~~

Conclusion

The calculated TERmix and TER for individual active substance value is higher than the trigger value of 10 for acute risk assessment and higher than the trigger value of 5 for chronic risk assessment , indicating CHR/H/FDF 574 SC does not posses unacceptable acute and long-term risk for mammals. No further risk refinement is needed.

9.3.2.2 Higher-tier risk assessment

Not required.

9.3.2.3 Drinking water exposure

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

Puddle scenario

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

With a K(f)oc of 16, Florasulam belongs to the group of less/more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use winter/spring cereals:

Effective application rate (g/ha)	=	4.8		
Acute toxicity (mg/kg bw)	=	5000	quotient =	0.00096
Reprod. toxicity (mg/kg bw/d)	=	100	quotient =	0.048

With a K(f)oc of 3417, diflufenican belongs to the group of less/more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use winter/spring cereals:

Effective application rate (g/ha)	=	100		
Acute toxicity (mg/kg bw)	=	5000	quotient =	0.02
Reprod. toxicity (mg/kg bw/d)	=	35.5	quotient =	2.67

With a K(f)oc of 349, Flufenacet belongs to the group of less/more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use winter/spring cereals:

Effective application rate (g/ha)	=	124.8		
Acute toxicity (mg/kg bw)	=	589	quotient =	0.21
Reprod. toxicity (mg/kg bw/d)	=	37.4	quotient =	3.34

9.3.2.4 Effects of secondary poisoning

The log Pow of florasulam is below 3 and thusdo not exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required required..

The log Pow of Diflufenican amounts to 4.2 and thus exceeds the trigger value of 3. A risk as-sessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data.
To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.3-5: Assessment of the risk for earthworm-eating mammals due to exposure to Flufenacet via bioaccumulation in earthworms (secondary poisoning) for the intended use in winter wheat.

Parameter	Diflufenican	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.1318	Escape ver 2 calculations
log P_{ow} / P_{ow}	4.2	7469/VI/98-Final 3 July 2003
Koc	3417	7469/VI/98-Final 3 July 2003
foc	0.02	Default
BCF_{worm}	2.80	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.369	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.47	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	35.5	7469/VI/98-Final 3 July 2003
TER_{lt}	75.53	Trigger value 5

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of Flufenacet in water.

Table 9.3-6: Assessment of the risk for fish-eating mammals due to exposure to Flufenacet via bioaccumulation in fish (secondary poisoning) for the intended use in winter cereals

Parameter	Diflufenican	comments
PEC_{sw} (initial) (mg/L)	0.00479	Focus STEP 2
BCF_{fish}	1596	7469/VI/98-Final 3 July 2003
PEC_{fish}	7.65	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	1.08	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	35.5	7469/VI/98-Final 3 July 2003
TER_{lt}	32.87	Trigger value 5

The log Pow of Flufenacet amounts to 3.2 and thus exceeds the trigger value of 3. A risk as-sessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data.
To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.3-7: Assessment of the risk for earthworm-eating mammals due to exposure to Flufenacet via bioaccumulation in earthworms (secondary poisoning) for the intended use in winter wheat.

Parameter	Flufenacet	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.1459	Escape ver 2 calculations

Parameter	Flufenacet	comments
log P_{ow} / P_{ow}	3.2/1585	7469/VI/98-Final 3 July 2003
Koc	349	7469/VI/98-Final 3 July 2003
foc	0.02	Default
BCF_{worm}	2.85	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.4158	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.5322	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	9.87	7469/VI/98-Final 3 July 2003
TER_{lt}	18.55	Trigger value 5

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of Flufenacet in water.

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

Parameter	Flufenacet	comments
PEC_{sw} (initial) (mg/L)	0.01284	Focus STEP 2
BCF_{fish}	71.4	7469/VI/98-Final 3 July 2003
PEC_{fish}	0.9168	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.13	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	37.4	7469/VI/98-Final 3 July 2003
TER_{lt}	287,69	Trigger value 5

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.3.4 Overall conclusions

In conclusion, the acute~~, short term risk~~ and long term to mammals from the proposed uses of florasulam, diflufenican, flufenacet was found acceptable. CHR/H/FDF 574 SC ~~750 WG~~ pose no unacceptable risk to mammals with according to the label

Review comments:

The acute and long-term risk assessment for mammals performed by the Applicant is agreed by the

zRMS. It was performed in line with recommendations of the EFSA (2009) with assumption of EU agreed endpoints. No formulation study was required.

TER_A and TER_{LT} in the acute and long-term risk assessment indicated acceptable risk assessment for all active substances already at screening step.

Provided risk assessment for the mixture indicated acceptable risk.
CHR/H/FDF 574 SC presents no unacceptable risk to mammals resulting from exposure via drinking water. Presented secondary poisoning for diflufenican, flufenacet presents no unacceptable risk to mammals.
Overall, acceptable acute and reproductive risk to mammals may be concluded for application of CHR/H/FDF 574 SC in compliance with proposed GAP.

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

N/A

Review comments:

This issue is not assessed at the product level.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with florasulam, diflufenican, flufenacet and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of CHR/H/FDF 574 SC were not evaluated as part of the EU assessment of florasulam, diflufenican, flufenacet. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results mg/L	Reference
Oncorhynchus mykiss, Lepomis macrochirus	Florasulam	Acute static	96-h LC_{50} >100 nom	EFSA Journal 2015; 13(1):3984
Pimephales promelas	Florasulam	Chronic flow through (juveniles)	33-d NOEC ELS 2.9 mm	EFSA Journal 2015; 13(1):3984
Daphnia magna	Florasulam	Acute static	48-h EC50 >292 m	EFSA Journal 2015; 13(1):3984
Daphnia magna	Florasulam	Chronic semi-static	21-d NOEC= 23.4 nom	EFSA Journal 2015; 13(1):3984

Species	Substance	Exposure System	Results mg/L	Reference
Chironomus riparius	Florasulam	Chronic semi-static	28 day NOEC= 10 nom	EFSA Journal 2015; 13(1):3984
Pseudokirchneriella subcapitata	Florasulam	Static	72-h ErC50= 0.00894 mm	EFSA Journal 2015; 13(1):3984
Lemna gibba	Florasulam	Semi-static	14-day EC50= 0.00118 im	EFSA Journal 2015; 13(1):3984
Oncorhynchus mykiss	5-OH-florasulam	Acute static	96-h LC50 >91 nom	EFSA Journal 2015; 13(1):3984
Daphnia magna	5-OH-florasulam	Acute static	48-h EC50 >96.7 mm	EFSA Journal 2015; 13(1):3984
Pseudokirchneriella subcapitata	5-OH-florasulam	Static	72-h EbC50=21.32 mm 72-h ErC50= 21.57 mm	EFSA Journal 2015; 13(1):3984
Lemna gibba	5-OH-florasulam	Semi-static	7-d EC50=0.0378 mm	EFSA Journal 2015; 13(1):3984
Daphnia magna	DFP-ASTCA	Acute static	48-h EC50 >0.030 nom	EFSA Journal 2015; 13(1):3984
Pseudokirchneriella subcapitata	DFP-ASTCA	Static	72-h EyC50=96 nom	EFSA Journal 2015; 13(1):3984
Lemna gibba	DFP-ASTCA	Semi-static	7-d EyC50 & ErC50 >100 nom	EFSA Journal 2015; 13(1):3984
Daphnia magna	ASTCA	Acute static	48-h EC50 >0.030 nom	EFSA Journal 2015; 13(1):3984
Pseudokirchneriella subcapitata	ASTCA	Static	72-h & 96-h EC50, EbC50 & ErC50>9.2 mm	EFSA Journal 2015; 13(1):3984
Lemna gibba	ASTCA	Semi-static	7-d & 14-d EC50 >10.2 nom	EFSA Journal 2015; 13(1):3984
Daphnia magna	TSA	Acute static	48-h EC50 >0.030 nom	EFSA Journal 2015; 13(1):3984
Pseudokirchneriella subcapitata	TSA	Static	72 h EC50, EyC50& ErC50>94 mm	EFSA Journal 2015; 13(1):3984
Lemna gibba	TSA	Semi-static	7-d EyC50 & ErC50 >100 nom	EFSA Journal 2015; 13(1):3984
Pseudokirchneriella subcapitata	5-OH-ASTP	Static	72-h & 96-h EC50, EyC50 & ErC50>100 nom	EFSA Journal 2015; 13(1):3984
Lemna gibba	5-OH-ASTP	Semi-static	7-d EyC50 & ErC50 >100 nom	EFSA Journal 2015; 13(1):3984
Pseudokirchneriella subcapitata	ASTP	Static	72-h & 96-h EC50, EyC50 & ErC50>100 nom	EFSA Journal 2015; 13(1):3984
Lemna gibba	ASTP	Semi-static	7-d EyC50 (frond no.)=88 mm	EFSA Journal 2015; 13(1):3984

Species	Substance	Exposure System	Results mg/L	Reference
Higher-tier studies (micro- or mesocosm studies)				
No further tests submitted				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-2: **Endpoints and effect values relevant for the risk assessment for aquatic organisms – Diflufenican and relevant metabolites**

Species	Substance	Exposure System	Results	Reference
Ciprinus carpio	Diflufenican	96 h, s	LC50 > 0.0985* mg/L m	EFSA Scientific Report (2007) 122, 1-84
O. mykiss	AE B107137	96 h, s	LC50 > 17.3* mg/L, m	EFSA Scientific Report (2007) 122, 1-84
Pimephales promelas **(a)**	Diflufenican	35 d	NOEC = 0.015 mg/L	EFSA Scientific Report (2007) 122, 1-84
D. magna	Diflufenican	48 h, s	EC50 > 0.24* mg/L, m	EFSA Scientific Report (2007) 122, 1-84
D. magna	AE B107137	48 h, s	EC50 > 20.4* mg/L, m	EFSA Scientific Report (2007) 122, 1-84
D. magna	AE 0542291	48 h, s	EC50 > 10 mg/L nom	EFSA Scientific Report (2007) 122, 1-84
D. magna	Diflufenican	21 d	NOEC = 0.052 mg/L	EFSA Scientific Report (2007) 122, 1-84
Chironomus riparius (spiked water)	Diflufenican	28 d,s	NOEC = 0.10 mg/L, nom	EFSA Scientific Report (2007) 122, 1-84
C. riparius (spiked sediment)	Diflufenican	28 d, s	NOEC = 2.0 mg/kg sed nom	EFSA Scientific Report (2007) 122, 1-84
C. riparius (spiked sediment)	AE C522392	28 d, s	NOEC = 1.0 mg/kg sed nom	EFSA Scientific Report (2007) 122, 1-84
S. subspicatus (Without sediment)	Diflufenican	72 h, s	EbC50 = 0.00025 mg/L E_rC_{50} = 0.00045 mg/L NOEC = 0.0009 mg/L**(a)** m	EFSA Scientific Report (2007) 122, 1-84
S. subspicatus	Diflufenican	72 h, s	EbC50 = 0.0024	EFSA Scientific

Species	Substance	Exposure System	Results	Reference
(With sediment)			mg/L E_rC_{50} = 0.0047 mg/L NOEC = 0.00076 mg/L nom	Report (2007) 122, 1-84
S. subspicatus (Without sediment)	Diflufenican	72 h, s	EbC50 = 0.00046 mg/L E_rC_{50} = 0.00122 mg/L Maximum concentration from which recovery possible = 0.0042 mg/L NOEC = 0.00015 mg/L m	EFSA Scientific Report (2007) 122, 1-84
S. subspicatus (Without sediment)	AE B107137	72 h, s	EbC50 > 20.4* mg/L E_rC_{50} > 20.4* mg/L m	EFSA Scientific Report (2007) 122, 1-84
S. subspicatus (Without sediment)	AE 0542291	72 h, s	EbC50 = 36.0 mg/L E_rC_{50} = 66.0 mg/L	EFSA Scientific Report (2007) 122, 1-84
Pseudokirchneriella sub-capitata	AE 592370	72 h, s	E_bC_{50} > 39.0 mg/L(a) E_rC_{50} > 58.0 mg/L(a)	EFSA Scientific Report (2007) 122, 1-84
P. subcapitata	AE C522392	72 h, s	EbC50 = 3.4 mg/L E_rC_{50} = 16.0 mg/L m	EFSA Scientific Report (2007) 122, 1-84
L. gibba	Diflufenican	14 d, ss	EbC50 = 0.056 mg/L EC_{50} frond density = 0.039 mg/L m	EFSA Scientific Report (2007) 122, 1-84
Higher-tier studies (micro- or mesocosm studies)				
Higher tier data are available, but insufficient information is currently available to derive an endpoint.				

Table 9.5-3: **Endpoints and effect values relevant for the risk assessment for aquatic organisms – Flufenacet**

Species	Substance	Exposure System	Results	Reference
Lepomis macrochirus	Flufenacet	96 h	LC_{50} = 2.13 mg a.s./L	SANCO 7469/VI/98-Final 3 July 2003
Oncorhynchus mykiss	flufenacet-sulfonic acid	96 h	LC_{50} = 86.7 mg/ L	SANCO 7469/VI/98-Final 3 July 2003
Oncorhynchus mykiss	FOE thiadone	96 h	LC_{50} = 9.1 mg/L mm	SANCO 7469/VI/98-Final 3 July 2003
Oncorhynchus mykiss	Flufenacet	97 days	LC_{50} > 0.2 mg a.s./L mm	SANCO 7469/VI/98-Final 3 July 2003

Species	Substance	Exposure System	Results	Reference
Daphnia magna	Flufenacet	48 h	EC_{50} = 30.9 mg/L	SANCO 7469/VI/98-Final 3 July 2003
Daphnia magna	flufenacet-sulfonic acid	48 h	EC_{50} = 87.3 mg/L	SANCO 7469/VI/98-Final 3 July 2003
Daphnia magna	FOE thiadone	48 h	EC_{50}= 31.7 mg/L	SANCO 7469/VI/98-Final 3 July 2003
Daphnia magna	Flufenacet	21 d	NOEC=3.26 mg a.s./L	SANCO 7469/VI/98-Final 3 July 2003
Selenastrum capricornutum	Flufenacet	72 h	EbC50 = 0.00204 mg/l	SANCO 7469/VI/98-Final 3 July 2003
Scenedesmus subspicatus	flufenacet-sulfonic acid	120 h	ErC50 > 86.7 mg/L	SANCO 7469/VI/98-Final 3 July 2003
Selenastrum capricornutum	FOE thiadone	72 h	EbC50 = 4.1 mg/L	SANCO 7469/VI/98-Final 3 July 2003
Selenastrum capricornutum	flufenacet-methylsulfide	72 h (static)	ErC50 = 83.8 mg/L	SANCO 7469/VI/98-Final 3 July 2003
Lemna gibba	Flufenacet	14 d	EC50 = 0.00243 mg /l	SANCO 7469/VI/98-Final 3 July 2003
Lemna gibba	flufenacet-sulfonic acid	14 d	EC50 > 86.7 mg/L	SANCO 7469/VI/98-Final 3 July 2003

Higher-tier studies (micro- or mesocosm studies) SANCO 7469/VI/98-Final 3 July 2003

NOEC = 0.012 mg a.s./l (WG 60, macrophyte, duckweed and periphyton)

The fate and biological effects of Flufenacet WG 60 in aquatic microcosms.

Reference: Foekema E.M. and Jak R.G., 1999, TNO-MEP – R 99/423
Test guideline: OECD (1996), SETAC (1991)
GLP compliance: yes

An indoor microcosm test was performed to investigate the effect of a concentration series of FOE 5043 WG 60 (flufenacet: 61.5 %) on an aquatic biocoenosis.

Each microcosm consisted of a polyethylene container with a diameter of approximately 100 cm and a height of 80 cm. Fourteen of these containers were used in this study. In order to simulate a natural mixing regime, the water column was gently aerated throughout the study period. The microcosms contained a 10 cm deep layer of sediment, covered by a 50 cm deep water column.

Four weeks before application of the test substance, the microcosms were filled with natural sediment and water. Some days later submerged macrophytes were introduced. Duckweed and periphyton substrate were introduced two weeks before application.

The test substance was applied just under the water surface as a stock solution in water. The concentration series was: 0.75, 1.5, 3, 6, 12 and 24 microg as/l. All tests concentrations were duplicated, with the exception of the highest one, which was not replicated. Untreated reference systems were triplicated. The test period was 84 d.
Analysis of flufenacet in the water column of the microcosms 4 h after application confirmed nominal concentrations. The concentrations declined thereafter with a DT50 for the active ingredient of 18.8 d.

Overall, in the current microcosm experiment with the herbicide flufenacet significant treatment related effects could not be observed at any treatment level, although some slight differences in community metabolism (O2 and pH) were noted in the highest treatment level (24 microg as/l) as was a slightly reduced growth of some macrophytes and periphyton. All other measured parameters were unaffected. All the observations at the highest treatment

Species	Substance	Exposure System	Results	Reference
level were slight and transient only, with a recovery before the end of the study. The fact that treatment related effects were only observed at the highest concentration as well as the observed recovery of even the most sensitive endpoints (community metabolism) is in accordance with the short half-life of flufenacet in the water column.				

Table 9.5-4: Endpoints and effect values relevant for the risk assessment for aquatic organisms – CHR/H/FDF 574 SC

Species	Substance	Exposure System	Results	Reference
Daphnia magna	CHR/H/FDF 574 SC	48 h, s	EC_{50} > 100 mg/L $_{nom}$	E. Nierzędska, Study code: W-65-20
Pseudokirchneriella subcapitata	CHR/H/FDF 574 SC	72 h, static	ErC50= 0.75 µg test item/L NOEC = 0.1 µg test item/L	E. Nierzędska, Study code: W-68-20
Anabaena flos-aquae	CHR/H/FDF 574 SC	72 h, static	ErC_{50}=0.79 mg test item/L (measured concentration) EyC50=0.29 mg test item/L (measured concentration) ~~ErC50= 1.18 mg test item/L~~ ~~EyC50 = 0.43 mg test item/L~~	E. Nierzędska, Study code: W-66-20
Lemna Gibba	CHR/H/FDF 574 SC	7d, ss	ErC50 (7-day) Growth rate (frond number)= 0.134[mg test item/L] E_yC_{50} (7-day) Yield (frond number)= 0.040 [mg test item/L]	E. Nierzędska, Study code: W-67-20
Higher-tier studies (micro- or mesocosm studies)				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

zRMS comments:

New studies submitted by the Applicant on the effects on aquatic organisms of CHR/H/FDF 574 SC/ Cezaro 574 SC, Huron 574 SC has been evaluated and accepted by the zRMS. New data submitted with this Application are listed in Appendix 1 and summarised in Appendix 2.

In the study study for Anabaena flos-aquae concentration of florasulam was not stable under test conditions between renewals and drop below 80% of the nominal concentration. For this reason, the endpoints values would be based on the geometric mean concentrations.
Following endpoints are relevant for risk assessment purposes:
The concentration causing a 50% inhibition of the growth rate of *Anabaena flos-aquae:*

ErC50/72 h= 0.79 mg formulation/L measured (taking to consideration % of florasulam, which was at least stable substance)
EyC50/72 h= 0.29 mg formulation/L measured measured (taking to consideration % of florasulam, which was at least stable substance)

9.5.1.1 Justification for new endpoints

No new data for active substances is presented with this application.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).
The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

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

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Florasulam for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/H/FDF 574 SC in winter cereals

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***P.Subcapitata***	***Chironomus riparius***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EbC_{50}	NOEC	EC_{50}
(µg/L)		100000	2900	292000	23400	8.94	10000	1.18
AF		100	10	100	10	10	10	10
RAC (µg/L)		1000	290	2920	2340	0.894	1000	0.118
Exposure	**PEC $_{gl-max}$(µg/L)**							
Step 1								
	1.62	0.00162	0.00559	0.00055	0.00069	1.81208	0.00162	13.7288
Step 2								
	0.17	0.00017	0.00059	0.00006	0.00007	0.19016	0.00017	1.4407
Step 3								
D3/ditch	0.03020	0.00003	0.00010	0.00001	0.00001	0.03378	0.00003	0.2559
D4/pond	0.001099	0.00000	0.00000	0.00000	0.00000	0.00123	0.00000	0.0093
D4/stream	0.02620	0.0000262	0.00009	0.000009	0.000011	0.02931	0.000026	0.2220
D5/pond	0.001099	0.0000011	0.00000	0.000000	0.000000	0.00123	0.000001	0.0093
D5/stream	0.02826	0.0000283	0.00010	0.000010	0.000012	0.03161	0.000028	0.2395
R1/pond	0.001865	0.0000019	0.00001	0.000001	0.000001	0.00209	0.000002	0.0158
R1/stream	0.09043	0.0000904	0.00031	0.000031	0.000039	0.10115	0.000090	0.7664

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants
R3/stream	0.02820	0.0000282	0.00010	0.000010	0.000012	0.03154	0.000028	0.2390
R4/stream	0.02667	0.0000267	0.00009	0.000009	0.000011	0.02983	0.000027	0.2260

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

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite 5-OH Florasulam of Florasulam for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/H/FDF 574 SC in cereals winter.

5-OH Florasulam									
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Americamysis bahia***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	-	-	EbC50	-	EC_{50}
(µg/L)		91000	-	96700	-		21320		37.8
AF		100	-	100	-	-	10	-	10
RAC (µg/L)		910	-	967	-	-	2132	-	3.78
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
PEC/RAC	2.62	0.00288	-	0.00271	-	-	0.00123	-	0.6931

* Since EbC_{50} *Pseudokirchn. subcapitata* is lower than ErC_{50} (21570 µg/L) for this species, the enpoint is accepted for RA purposes as a worst-case

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite DFP-ASTCA of Florasulam for each organism group based on FOCUS Steps 1-2 calculations for the use of CHR/H/FDF 574 SC in cereals winter.

DFP-ASTCA									
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Americamysis bahia***	***Daphnia magna***	***Pseudokirchneriella***	***Chironomus riparius***	***Lemna Gibba***
Endpoint (µg/L)		LC_{50} -	-	EC_{50} 30	- -	-	EbC50 96000	-	EC50 100000
AF		-	-	100	-	-	10	-	10
RAC (µg/L)		-	-	0.3	-	-	9600	-	10000
Exposure	**PEC gl-max (µg/L)**								
Step 1									
PEC/RAC	0.33	-	-	**1.10000**	-	-	0.00003	-	0.0000
Step 2									
PEC/RAC	0.1	-	-	0.33333	-	-	0.00001	-	0.0000

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite ASTCA of Florasulam for each organism group based on FOCUS Steps 1-2 calculations for the use of CHR/H/FDF 574 SC in cereals winter.

ASTCA									
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Americamysis bahia***	***Daphnia magna***	***Pseudokirchneriella***	***Chironomus riparius***	***Lemna Gibba***
Endpoint (µg/L)		-	-	EC_{50} 30	- -	-	EbC50 9200	-	EC50 10200

ASTCA									
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Aquatic plants**
AF		-	-	100	-	-	10	-	10
RAC (µg/L)		-	-	0.3	-	-	920	-	1020
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
PEC/RAC	0.72	-	-	2.40000	-	-	0.00078	-	0.0007
Step 2									
PEC/RAC	0.19	-	-	0.63333	-	-	0.00021	-	0.0002

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite TSA of Florasulam for each organism group based on FOCUS Steps 1,2 calculations for the use of CHR/H/FDF 574 SC in cereals winter.

TSA									
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Americamysis bahia***	***Daphnia magna***	***Pseudokirchneriella***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		-		EC_{50}	-	-	EbC50	-	EyC50/ ErC50
(µg/L)			-	30	-		94000		100000
AF		-	-	100	-	-	10	-	10
RAC (µg/L)		-	-	0.3	-	-	9400	-	10000
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
PEC/RAC	0.1	-	-	0.33333	-	-	0.00001	-	0.0000

Table 9.5-10: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite 5-OH-ASTP of Florasulam for each organism group based on FOCUS Steps 1 calculations for the use of CHR/H/FDF 574 SC in cereals winter.**

5-OH-ASTP									
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Americamysis bahia***	***Daphnia magna***	***Pseudokirchneriella***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		-	-	-	-	-	EC50	-	EyC50/ ErC50
(µg/L)			-	-	-		100000		100000
AF		-	-	-	-	-	10	-	10
RAC (µg/L)		-	-	-	-	-	10000	-	10000
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
PEC/RAC	0.28	-	-	-	-	-	0.00003	-	0.0000

Table 9.5-11: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite ASTP of Florasulam for each organism group based on FOCUS Steps 1 calculations for the use of CHR/H/FDF 574 SC in cereals winter.**

ASTP									
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Americamysis bahia***	***Daphnia magna***	***Pseudokirchneriella***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		-	-	-	-	-	EC50	-	EC50
(µg/L)			-	-	-		100000		88000

ASTP									
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Aquatic plants**
AF		-	-	-	-	-	10	-	10
RAC (µg/L)		-	-	-	-	-	10000	-	8800
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
PEC/RAC	0.22	-	-	-	-	-	0.00002	-	0.0000

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite TPSA of Florasulam for each organism group based on FOCUS Steps 1 calculations for the use of CHR/H/FDF 574 SC in cereals winter.

TPSA									
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Americamysis bahia***	***Daphnia magna***	***Pseudokirchneriella***	***Chironomus riparius***	***Lemna Gibba***
Endpoint (µg/L)		- -	- -	- -	- -	-	EC50 >100000	-	EC50 >100000
AF		-	-	-	-	-	10	-	10
RAC (µg/L)		-	-	-	-	-	10000	-	10000
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
PEC/RAC	0.63	-	-	-	-	-	0.00006	-	0.0001

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Diflufenican for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/FDF 574 SC in cereals winter

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		*Cipri-nus carpio*	*Pimephales promelas*	***Daphnia magna***	***Daphnia magna***	***Selenastrum***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EbC50	NOEC	EC50
(µg/L)		98.5	15	240	5.2	4.2	2000	39
AF		100	10	100	10	10	10	10
RAC (µg/L)		0.985	1.5	2.4	5.2	0.42	200	3.9
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1								
	10.05	10.20305	6.70000	4.18750	1.93269	23.92857	0.05025	2.5769
Step 2								
	4.79	4.86294	3.19333	1.99583	0.92115	11.40476	0.02395	1.2282
Step 3								
D3/ditch	0.6299	0.63949	0.41993	0.26246	0.12113	1.49976	0.00315	0.1615
D4/pond	0.04667	0.04738	0.03111	0.01945	0.00898	0.11112	0.00023	0.0120
D4/stream	0.5464	0.5547208	0.36427	0.227667	0.105077	1.30095	0.002732	0.1401
D5/pond	0.02189	0.0222234	0.01459	0.009121	0.004210	0.05212	0.000109	0.0056
D5/stream	0.5896	0.5985787	0.39307	0.245667	0.113385	1.40381	0.002948	0.1512
R1/pond	0.06265	0.0636041	0.04177	0.026104	0.012048	0.14917	0.000313	0.0161
R1/stream	0.4154	0.4217259	0.27693	0.173083	0.079885	0.98905	0.002077	0.1065
R3/stream	0.5829	0.5917766	0.38860	0.242875	0.112096	1.38786	0.002915	0.1495

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed	Aquatic plants
R4/stream	0.5912	0.6002030	0.39413	0.246333	0.113692	1.40762	0.002956	0.1516
Step 4	10 meters vegetative buffer zone and 10 meters no-spray buffer zone							
D3/ditch	0.09049	0.09187	0.06033	0.03770	0.01740	0.21545	0.00045	0.0232
D4/pond	0.04452	0.04520	0.02968	0.01855	0.00856	0.10600	0.00022	0.0114
D4/stream	0.1656	0.1681218	0.11040	0.069000	0.031846	0.39429	0.000828	0.0425
D5/pond	0.01363	0.0138376	0.00909	0.005679	0.002621	0.03245	0.000068	0.0035
D5/stream	0.1140	0.1157360	0.07600	0.047500	0.021923	0.27143	0.000570	0.0292
R1/pond	0.02718	0.0275939	0.01812	0.011325	0.005227	0.06471	0.000136	0.0070
R1/stream	0.1749	0.1775635	0.11660	0.072875	0.033635	0.41643	0.000875	0.0448
R3/stream	0.1949	0.1978680	0.12993	0.081208	0.037481	0.46405	0.000975	0.0500
R4/stream	0.2667	0.2707614	0.17780	0.111125	0.051288	0.63500	0.001334	0.0684

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

Table 9.5-14: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-AE B10737 of Diflufenican for each organism based on FOCUS Steps 1, 2 calculations for the use of CHR/H/FDF 574 SC in cereals winter**

Group		Fish acute	Invertebrate acute	Algae
Test species		*Oncorhynchus mykiss*	*Daphnia magna*	*Scenedesmus sub-spicatus*
Endpoint		LC_{50}	EC50	EC_{50}
(µg/L)		17300	20400	20400
AF		100	100	10
RAC (µg/L)		173	204	2040
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			

Group		Fish acute	Invertebrate acute	Algae
Step 1				
	12.59	0.07277	0.06172	0.00617

Table 9.5-15: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite AE 0542291 of Diflufenican for each organism based on FOCUS Steps 1, 2 calculations for the use of CHR/H/FDF 574 SC in cereals winter**

Group		Invertebrate acute	Algae
Test species		*Daphnia magna*	*Scenedesmus sub-spicatus*
Endpoint		EC_{50}	EC_{50}
(µg/L)		10000	66000
AF		100	10
RAC (µg/L)		100	6600
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**		
Step 1			
	5.34	0.05340	0.00081

-

Table 9.5-16: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Flufenacet for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/FDF 574 SC 500 SC in winter cereals**

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Selenastrum capricornutum***	***Lemna Gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EbC50	EC50
(µg/L)		2130	200	30900	3260	2.04	2.43
AF		100	10	100	10	10	10
RAC (µg/L)		21.3	20	309	326	0.204	0.243

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**						
Step 1							
	29.54	1.38685	1.47700	0.09560	0.09061	144.80392	121.56379
Step 2							
	12.84	0.60282	0.64200	0.04155	0.03939	62.94118	52.83951
Step 3							
D3/ditch	0.7881	0.03700	0.03941	0.00255	0.00242	3.86324	3.24321
D4/pond	0.02724	0.00128	0.00136	0.00009	0.00008	0.13353	0.11210
D4/stream	0.6839	0.0321080	0.03420	0.002213	0.002098	3.35245	2.814403
D5/pond	0.3578	0.0167981	0.01789	0.001158	0.001098	1.75392	1.472428
D5/stream	0.7378	0.0346385	0.03689	0.002388	0.002263	3.61667	3.036214
R1/pond	0.08545	0.0040117	0.00427	0.000277	0.000262	0.41887	0.351646
R1/stream	2.046	0.0960563	0.10230	0.006621	0.006276	10.02941	8.419753
R3/stream	2.602	0.1221596	0.13010	0.008421	0.007982	12.75490	10.707819
R4/stream	2.429	0.1140376	0.12145	0.007861	0.007451	11.90686	9.995885

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

For the intended uses not, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for Selenastrum capricornutum as characterised by an EC_{50} for species of 2.04 □g/L and form Lemna 2.43□g/L in connection with an assessment factor of 10) in FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on risk mitigation in FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

Table 9.5-17: **Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Flufenacet based on FOCUS Step 4 calculations and toxicity data for most sensitive species. with mitigation of spray drift and run-off for the use of CHR/H/FDF 574 SC 500 SC in winter cereals**

Intended use		Winter cereals
Active substance		Flufencet
Application rate (g/ha)		1 × 124.8
Nozzle reduction	**No-spray buffer (m)**	10
	Vegetated filter strip (m)	10
None	D3/ditch	0.1134
None	D4/pond	0.01696
None	D4/stream	0.1325
None	D5/pond	0.3550
None	D5/stream	0.4940
None	R1/pond	0.03775
None	R1/stream	0.9162
None	R3/stream	1.173
None	R4/stream	1.096
RAC (µg/L) Selenastrum capricornutum 0.204		**PEC/RAC ratio**
None	D3/ditch	0.55588
None	D4/pond	0.08314
None	D4/stream	0.64951

Intended use		Winter cereals
Active substance		Flufencet
Application rate (g/ha)		1 × 124.8
Nozzle reduction	**No-spray buffer (m)**	10
	Vegetated filter strip (m)	10
None	D5/pond	1.74020
None	D5/stream	2.42157
None	R1/pond	0.18505
None	R1/stream	4.49118
None	R3/stream	5.75000
None	R4/stream	5.37255
RAC (µg/L) Lemna Gibba 0.243		**PEC/RAC ratio**
None	D3/ditch	0.46667
None	D4/pond	0.06979
None	D4/stream	0.545267
None	D5/pond	1.460905
None	D5/stream	2.032922
None	R1/pond	0.155350
None	R1/stream	3.770370
None	R3/stream	4.827160
None	R4/stream	4.510288

For the intended uses not, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for Selenastrum capricornutum as characterised by an EC_{50} for species of 2.04 □g/L and form Lemna 2.43□g/L in connection with an assessment factor of 10) in FOCUS Step4 with 10 m buffer zone scenarios. Therefore, higher tier study is necessary. Such study was performed on Annex I inclusion and was used in risk refinement and presented below.

Risk Refinement:

An indoor microcosm test was performed to investigate the effect of a concentration series of FOE 5043 WG 60 (flufenacet: 61.5 %) on an aquatic biocoenosis.

Each microcosm consisted of a polyethylene container with a diameter of approximately 100 cm and a height of 80 cm. Fourteen of these containers were used in this study. In order to simulate a natural mixing regime, the water column was gently aerated throughout the study period. The microcosms contained a 10 cm deep layer of sediment, covered by a 50 cm deep water column.

Four weeks before application of the test substance, the microcosms were filled with natural sediment and water. Some days later submerged macrophytes were introduced. Duck-weed and periphyton substrate were introduced two weeks before application.

The test substance was applied just under the water surface as a stock solution in water. The concentration series was: 0.75, 1.5, 3, 6, 12 and 24 microg as/l. All tests concentrations were duplicated, with the exception of the highest one, which was not replicated. Untreated reference systems were triplicated. The test period was 84 d.

Analysis of flufenacet in the water column of the microcosms 4 h after application confirmed nominal concentrations. The concentrations declined thereafter with a DT_{50} for the active ingredient of 18.8 d.

Overall, in the current microcosm experiment with the herbicide flufenacet significant treatment related effects could not be observed at any treatment level, although some slight differences in community metabolism (O2 and pH) were noted in the highest treatment level (24 microg as/l) as was a slightly reduced growth of some macrophytes and periphyton. All other measured parameters were unaffected. All the observations at the highest treatment level were slight and transient only, with a recovery before the end of the study. The fact that treatment related effects were only observed at the highest concentration as well as the observed recovery of even the most sensitive endpoints (community metabolism) is in accordance with the short half-life of flufenacet in the water column.

Agreed NOEC = 0.012 mg a.s./l

Table 9.5-18: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Flufenacet based on FOCUS Step 4 calculations and toxicity data for microcosm study. with mitigation of spray drift and run-off for the use of CHR/H/FDF 574 SC 500 SC in winter cereals

Intended use **Active substance** **Application rate (g/ha)** **RAC 1.2 µg/L (AF=10 and NOEC microcosm=12 µg/L)**		Winter cereals Flufencet 1 × 124.8	PEC/RAC ratio (trigger <1)
Nozzle reduction	**No-spray buffer (m)**	10	
	Vegetated filter strip (m)	10	

None	D3/ditch	0.1134	0.0945
None	D4/pond	0.01696	0.0141
None	D4/stream	0.1325	0.1104
None	D5/pond	0.3550	0.2958
None	D5/stream	0.4940	0.4117
None	R1/pond	0.03775	0.0315
None	R1/stream	0.9162	0.7635
None	R3/stream	1.173	0.9775
None	R4/stream	1.096	0.9133

Table 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite FOE sulfonic acid for each organism based on FOCUS Steps 1 calculations for the use of CHR/H/FDF 574 SC in winter cereals

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Selenastrum capricornutum***	***Lemna Gibba***
Endpoint		LC_{50}	EC_{50}	EbC50	EC50
(µg/L)		86700	87300	86700	86700
AF		100	100	10	10
RAC (µg/L)		867	873	8670	8670
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**				
Step 1					
PEC/RAC	8.12	0.00937	0.00930	0.00094	0.00094

Table 9.5-20: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite FOE thiadone of Flufenacet for each organism based on FOCUS Steps 1 calculations for the use of CHR/H/FDF 574 SC in winter cereals**

Group		**Fish acute**	**Inverteb. acute**	**Algae**

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Selenestrum capricornutum***
Endpoint **(µg/L)**		LC_{50} 9100	EC_{50} 31700	EbC50 4100
AF		100	100	10
RAC (µg/L)		91	317	410
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
PEC/RAC	16.41	0.18033	0.05177	0.04002

Table 9.5-21: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite FOE methylsulfide of flufenacet for each organism based on FOCUS Steps 1 calculations for the use of CHR/H/FDF 574 SC in winter cereals**

Group		**Algae**
Test species		***S. capricornutum***
Endpoint **(µg/L)**		EC50 83800
AF		10
RAC (µg/L)		838
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**	
Step 1		
PEC/RAC	3.67	0.00438

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

9.5.2.1 Risk assessment for formulation to aquatic organisms

Table 9.5-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites of CHR/H/FDF 574 SC for each organism group based on Drift Calculator SWASH MODEL ver 5.3 calculations for the use of CHR/H/FDF 574 SC in winter cereals

Intended use	Winter cereals
Formulation	CHR/H/FDF 574 SC
Application rate (g[prod]/ha)	1 x 483.08
Entry into surface water via spraydrift (Drift alculator from SWASH)	
Buffer zone (m)	**PECsw [µg prod/L**
1	3.1036
Entry into surface water via spraydrift (Drift alculator from SWASH)	
Buffer zone (m)	**For Fish risk assessment → please refer to the active substance risk assessment**
1	
Buffer zone (m)	**PEC/RAC ratio** **Daphnia magna =EC50 100 000 µg/L** **RAC=1000 (AF=100)**
1	0.003104
Buffer zone (m)	**PEC/RAC ratio** **Anabaena flos-aquae =EC_{50}=790 ~~1180~~ µg/L** **RAC=79 ~~118~~ (AF=10)**
1	0.0393 ~~0.0263~~
Buffer zone (m)	**PEC/RAC ratio** **Pseudokircheneriella subcapitata** **ErC50= 0.75 µg test item/L** **RAC=** **RAC=0.075 (AF=10)**
1	41
65	0.99
Buffer zone (m)	**PEC/RAC ratio** **Lemna Gibba =EC_{50} 134 g/L** **RAC=13.4 (AF=10)**
1	0.232

Table 9.5-23: Risk refinment for for CHR/H/FDF 574 SC for most sensitive species

Buffer strip (m)	**PERsw (g/ha)**	**PERsw 50 % drift red. (g/ha)**	**PERsw 75 % drift red. (g/ha)**	**PERsw 90 % drift red. (g/ha)**
1	3.1036	1.5518	0.7759	0.3103
6	0.7139	0.3570	0.1785	0.0714
16	0.2867	0.1434	0.07168	0.02867
20	0.2318	0.1159	0.05795	0.02318
30	0.1572	0.0786	0.0393	0.01572
35	0.1355	0.0678	-	-
65	0.0744			
Toxicity value RAC= 0.075 µg/L	**TER** **criterion: TER < 1**			
1	41	21	10	4
6	9	4.76	2.38	**0.952**
16	3.8	1.912	**0.96**	**0.382**
20	3.1	1.55	**0.773**	**0.31**
30	2.1	1.05	**0.77**	**0.31**
35	1.81	**0.904**		
65	**0.99**			

Based on the calculated concentrations of the formulation CHR/H/FDF 574 SC (spray drift) respectively its active ingredients Florasulam, Diflufenican and Flufenacet (run-off and drainage) in surface water (PECSW according to FOCUS STEP 1-2, STEP 3), the calculated RAC/PEC (mix) values for the risk resulting from an exposure of aquatic organisms to CHR/H/FDF 574 SC according to the GAP of the formulation achieve the acceptability criterium <1 for run-off exposure, therefore no risk mitigations are required.

The following formula was used to derive the surrogate EC50 for the mixture of active substances with known toxicity assuming dose additivity:

Decision scheme for mixture toxcitiy risk assessment for CHR/H/FDF 574 SC

Step 1. Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?

Only for the a.s. (ECxa.s.): Go to 7
For both formulation (EC_{xPPP}) and a.s. ($EC_{xa.s.}$): Go to 2

Answer: Measured toxicity data for the formulation and the a.s. are available for daphnia, algae and macrophytes. As these are the most sensitive aquatic organisms, it is justified to conduct the mixture toxicity risk assessment only for these two organism groups. → Go to 2

STEP 2. Check the plausibility of the measured formulation toxicity (EC_xPPP) against the calculated mixture toxicity EC_{xmix}-CA (assuming CA, Equation 13) for exactly the mixture

composition of the a.s. in the formulation (EC_xPPP) by means of the model deviation ratio (MDR = EC_{xmix}-CA/EC_xPPP).

If MDR = 0.2–5 (CA approximately holds for the mixture)
If MDR > 5 (mixture more toxic than CA)
If MDR < 0.2 (mixture less toxic than CA)

Equation 13:

$$EC_{X_{mix-CA}} = \left(\sum_{i=1}^{n} \frac{p_i}{EC_{X_i}} \right)^{-1}$$

Equation 15:

$$MDR = \frac{EC_{X_{mix-CA}}\ (calculated\ mixture\ toxicity)}{EC_{X_{PPP}}\ (measured\ mixture\ toxicity)}$$

Calculation of the acute mixture toxicity of the formulation

Table 1. Composition of CHR/H/FDF 574 SC

Name/code of the product	CHR/H/FDF 574 SC		
Name of the active substance A	Florasulam		
Name of the active substance B	diflufenican		
Name of the active substance C	flufenacet		
Density [g product/cm^3]	1.2077		
	Nominal [g a.s./kg or L product]	Fraction considering density [%]	$p_{i\ mix}$ = Fraction of active substance i in the mixture with $\sum p_{i\ mix}$ = 100 [%]
Concentrations of the active substance florasulam in the product	12	1.0%	2.1%
Concentrations of the active substance diflufenican in the product	250	20.7%	43.6%
Concentrations of the active substance flufenacet in the product	312	25.8%	54.4%

Table 2. Toxicity of CHR/H/FDF 574 SC and active substance

Endpoint/Test species	Toxicity of the product [mg product/L]	Toxicity of the product (a.s. based) ($EC_{x\ PPP}$) [mg a.s./L]	Toxicity of the a.s. florasulam (ECx A) [mg a.s./L]	Toxicity of the a.s. diflufenican (ECx B) [mg a.s./L]	Toxicity of the a.s. flufenacet (ECx C) [mg a.s./L]	Triggers (from EFSA Journal 2013;11(7):3290)
EC_{50} daphnids	100	47.528	292	0.24	30.9	0.01
E_rC_{50} algae	0.00075	0.000	0.00894	0.0042	0.00204	0.1
E_rC_{50} higher plant	0.134	0.064	0.00118	0.056	0.00243	0.1

Table 3. Calculation of toxicity exposure in CHR/H/FDF 574 SC

Toxicity per fraction of the a.s. florasulam (1/TUA) [mg a.s./L]	Toxicity per fraction of the a.s. diflufenican (1/TUB) [mg a.s./L]	Toxicity per fraction of the a.s. flufenacet (1/TUC) [mg a.s./L]	Calculated mixture toxicity (a.s. in product) ($EC_{x\ mix\text{-}CA} = 1/\sum(TU_i)$) [mg a.s./L]	Model deviation ratio (MDR = $EC_{x\ mix\text{-}CA}/EC_{x\ PPP}$)	$EC_{x\ mix\text{-}CA}$ (a.s. in product)/$EC_{x\ mix\text{-}CA}$ (a.s. in PEC_{mix}) (at lower exposure tier)
13967.33333	0.55104	56.84807692	0.546	0.011	0.557
0.42763	0.0096432	0.003753077	0.003	**7.531**	1.034
0.056443333	0.128576	0.004470577	0.004	0.063	1.479

Answer: MDRs for dpahnias and lemnas are below <0.2 Therefore , go to Step 9 MDRs for algaes are above 5. Therefore, go to Step 9 and 10

Step 10 . Carefully recheck the apparent synergism as observed in the measured mixture toxicity data (ECx PPP) regarding potential impacts of heterogeneous input data (a.s.) and of co-formulants ignored in the CA calculation. Does the apparent synergism remain?

Answer: Yes. Therefore go to step 3

Step 9. Carefully recheck the apparent antagonism as observed in the measured mixture toxicity data (ECx PPP) regarding potential impacts of the default assumption of CA and/or heterogeneous input data used for the CA calculation. Does the apparent antagonism remain and no toxicologically plausible explanation is available (e.g. special feature of the formulation type)?

Yes (measured mixture toxicity not plausible):	Go to step 8
No (measured mixture toxicity plausible):	Go to step 3

Answer: NO. → Go to step 3

Step 3. Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECx PPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PECmix. As a direct comparison on the basis of the relative proportions of the a.s. at the ECx PPP with the relative proportion at the PECmix is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECx mix-CA (see Equation 13) for the mixture composition of the a.s. at the PECmix and compare with the estimate calculated for the formulation (as already done in step 2 above).

Table 4. Results of compare ECmix-CA(a.s. in PPP) to ECmix-CA (a.s. in PECmix)

		Triggers	
Endpoint/Test species	**ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix)**	**0.8-1.2**	**<0.8 or >1.2**
EC50 daphnids	0.557		**Yes**
E_rC_{50} algae	1.034	**Yes**	
EC_{50} higher plant	1.479		**Yes**

Answer: Calculated factors gives results outside 0.8-1.2 dor daphnias and plants and between 0.8 and 1.2 for algae Therefore, go to step 5 for daphnias and plants and step 4 for algae.

STEP 4 Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETRmix) being defined as the PECmix divided by the measured

Equation 13: $$ECx_{mix-CA} = \left(\sum_{i=1}^{n} \frac{p_i}{ECx_i} \right)^{-1}$$

where:

n: number of mixture components
i: index from 1…n mixture components
p_i: the i^{th} component as a relative fraction of the mixture composition (note: $\Sigma\, p_i$ must be 1)
ECx_i: concentration of component i provoking x % effect (pragmatically, $NOEC_i$ may be inserted, too).

STEP 4 Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETRmix) being defined as the PECmix divided by the measured ECxPPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.

Exposure		(lower exposure tier)	(higher exposure tier)									
Exposure tier (FOCUS step)	Florasulam	Step 2	Step 3 (D3 ditch)	Step 3 (D4 pond)	Step 3 (D4 stream)	Step 3 (D5 pond)	Step 3 (D5 stream)	Step 3 (R1 pond)	Step 4 (20 m i 90% nozzle reduction, R1 stream)	Step 4 (20 m, R3 stream)	Step 4 (20 m i 90% nozzle reduction, R4 stream)	
PECsw [mg a.s./L]		0.002350	0.000030	0.000001	0.000026	0.000001	0.000028	0.000002	0.000021	0.000003	0.000005	
Exposure tier (FOCUS step)	Diflufenican	Step 2	Step 4 (10 m, D3 ditch)	Step 4 (10 m, D4 pond)	Step 4 (10 m, D4 stream)	Step 4 (10 m, D5 pond)	Step 4 (10 m, D5 stream)	Step 4 (10 m, R1 pond)	Step 4 (20 m, R1 stream)	Step 4 (20 m, R3 stream)	Step 4 (20 m, R4 stream)	
PECsw [mg a.s./L]		0.004790	0.000090	0.000045	0.000166	0.000014	0.000114	0.000027	0.000091	0.000102	0.000139	
Exposure tier (FOCUS step)	Flufenacet	Step 2	Step 4 (20 m, D3 ditch)	Step 4 (20 m, D4 pond)	Step 4 (20 m, D4 stream)	Step 4 (20 m, D5 pond)	Step 4 (20 m, D5 stream)	Step 4 (20 m, R1 pond)	Step 4 (20 m, R1 stream)	Step 4 (20 m, R3 stream)	Step 4 (20 m, R4 stream)	

PECsw [mg a.s./L]		0.012 840	0.000 113	0.000 017	0.000 133	0.000 355	0.000 494	0.000 038	0.000 477	0.000 613	0.000 573	
Total exposure concen-tration of the mixture (a.s. based) (PECmix) [mg/L]		0.019 980	0.000 233	0.000 063	0.000 325	0.000 370	0.000 636	0.000 067	0.000 589	0.000 718	0.000 717	
End-point/Test spe-cies	Toxici-ty of the product (a.s. based) ($EC_{x\ PPP}$) [mg a.s./L]	$ETR_{mix} = PEC_{mix}/EC_{x\ PPP}$										Trig gers
ERc50 algae	0.000	56.05 1	0.654	0.177	0.912	1.038	1.784	0.188	1.652	2.014	2.011	0.10

STEP 5. Check whether one mixture component clearly drives the toxicity if considering the measured mixture toxicity (ECx PPP), that is, does the largest part of the sum of toxic units (Equation 14) calculated for the formulation (≥ 90 %) comes from a single a.s. (TUi)?

Table 6. Results of toxicity driver's calculation

		Florasulam		Diflufenican		Flufenacet		**Triggers**	
Endpoint/Test species	Calculated mixture toxicity (a.s. in product) ($EC_{x\ mix\text{-}CA}$) [mg a.s./L]	Toxicity per fraction ($1/TU_i$) [mg a.s./L]	Deviation from mixture toxicity = 1-$EC_{x\ mix\text{-}CA}$ x (1/$EC_{x\ mix\text{-}CA}$-TU_i) [%]	Toxicity per fraction ($1/TU_i$) [mg a.s./L]	Deviation from mixture toxicity = 1-$EC_{x\ mix\text{-}CA}$ x (1/$EC_{x\ mix\text{-}CA}$-TU_i) [%]	Toxicity per fraction ($1/TU_i$) [mg a.s./L]	Deviation from mixture toxicity = 1-$EC_{x\ mix\text{-}CA}$ x (1/$EC_{x\ mix\text{-}CA}$-TU_i) [%]	>=90% for one a.s.	>=90% for no a.s.
EC50 daphnids	0.546	13967.333	0.0%	0.551	99.04%	56.848	1.0%	Yes	
EC50 higher plant	0.004	0.056	7.1%	0.129	3.1%	0.004	89.8%		Yes

Equation 14:

$$\sum_{i=1}^{n} TU_i = \sum_{i=1}^{n} \frac{c_i}{EC_{X_i}}$$

Answer: No toxicity drivers were found for higher plant. Therefore, got to Step 8. Toxicity drivers for daphnias is Diflufenican.

STEP 8. Conduct a mixture RA based on calculated mixture toxicity

Table 7. Results of exposure of mixture toxicity's calculation to aquatic species

Exposure		**(lower exposure tier)**	**(higher exposure tier)**									
Exposure tier (FOCUS step)	Florasulam	Step 2	Step 3 (D3 ditch)	Step 3 (D4 pond)	Step 3 (D4 stream)	Step 3 (D5 pond)	Step 3 (D5 stream)	Step 3 (R1 pond)	Step 4 (20 m i 90% nozzle reduction, R1 stream)	Step 4 (20 m, R3 stream)	Step 4 (20 m i 90% nozzle reduction, R4 stream)	
PECsw [mg a.s./L]		0.002350	0.000030	0.000001	0.000026	0.000001	0.000028	0.000002	0.000021	0.000003	0.000005	
Exposure tier (FOCUS step)	Diflufenican	Step 2	Step 4 (10 m, D3 ditch)	Step 4 (10 m, D4 pond)	Step 4 (10 m, D4 stream)	Step 4 (10 m, D5 pond)	Step 4 (10 m, D5 stream)	Step 4 (10 m, R1 pond)	Step 4 (20 m, R1 stream)	Step 4 (20 m, R3 stream)	Step 4 (20 m, R4 stream)	
PECsw [mg a.s./L]		0.004790	0.000090	0.000045	0.000166	0.000014	0.000114	0.000027	0.000091	0.000102	0.000139	
Exposure tier (FOCUS step)	Flufenacet	Step 2	Step 4 (20 m, D3 ditch)	Step 4 (20 m, D4 pond)	Step 4 (20 m, D4 stream)	Step 4 (20 m, D5 pond)	Step 4 (20 m, D5 stream)	Step 4 (20 m, R1 pond)	Step 4 (20 m, R1 stream)	Step 4 (20 m, R3 stream)	Step 4 (20 m, R4 stream)	
PECsw [mg a.s./L]		0.012840	0.000113	0.000017	0.000133	0.000355	0.000494	0.000038	0.000477	0.000613	0.000573	

Total exposure concentration of the mixture (a.s. based) (PECmix) [mg/L]		0.019980	0.000233	0.000063	0.000325	0.000370	0.000636	0.000067	0.000589	0.000718	0.000717	
End-point/Test species		Calculated mixture toxicity (a.s. in PEC_{mix}) ($EC_{x\ mix\text{-}CA} = \sum (p_{i\ PEC}/EC_{x\ i})$) [mg a.s./L]										
EC50 higher plant		0.003	0.003	0.007	0.004	0.003	0.003	0.004	0.003	0.003	0.003	
End-point/Test species		$ETR_{mix} = PEC_{mix}/EC_{x\ PPP}$										Trig-gers
EC50 higher plant		7.361	0.074	0.009	0.080	0.147	0.229	0.018	0.216	0.257	0.243	0.10

Answer: ETRmix for higher exposure tier are below the triggers. Therefore, CHR/H/FDF 574 SC no poses unacceptable mixture toxicity to aquatic species in Poland relevant scenario with applaying:

- 20m vegetative filter strip and 20m unsprayed buffer with 90% nozzle reduction to surface water bodies

~~20 meters buffer zone (vfs mode).~~

~~For risk refinement mixture toxicity for all scenario in Central Zone used endpoint of microcosm study for Flufenacet with assessment factor 10. Therefore, mentioned endpoint for higher study on Flufenacet replaced the endpoint for algae and lemna. New calculation are presented below:~~

~~**Decision scheme for mixture toxcitiy risk assessment for CHR/H/FDF 574 SC**~~

~~**Step 1. Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?**~~

~~**Only for the a.s. (ECxa.s.): Go to 7**~~
~~**For both formulation (ECx_{PPP}) and a.s. ($ECx_{a.s.}$): Go to 2**~~

~~Answer: Measured toxicity data for the formulation and the a.s. are available for daphnia, algae and macrophytes. As these are the most sensitive aquatic organisms, it is justified to conduct the mixture toxicity risk assessment only for these two organism groups. → Go to 2~~

~~**STEP 2. Check the plausibility of the measured formulation toxicity (EC_xPPP) against the calculated mixture toxicity EC_{xmix}-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC_xPPP) by means of the model deviation ratio (MDR = EC_{xmix}-CA/EC_xPPP).**~~

~~**If MDR = 0.2–5 (CA approximately holds for the mixture)**~~
~~**If MDR > 5 (mixture more toxic than CA)**~~
~~**If MDR < 0.2 (mixture less toxic than CA)**~~

~~Equation 13:~~

$$EC_{X_{mix-CA}} = \left(\sum_{i=1}^{n} \frac{p_i}{EC_{X_i}} \right)^{-1}$$

Equation 15:

$$MDR = \frac{EC_{X_{mix-CA}}\ (calculated\ mixture\ toxicity)}{EC_{X_{PPP}}\ (measured\ mixture\ toxicity)}$$

Calculation of the acute mixture toxicity of the formulation

Table 1. Composition of CHR/H/FDF 574 SC

Name/code of the product	CHR/H/FDF 574 SC	-	
Name of the active substance A	florasulam	-	
Name of the active substance B	diflufenican	-	
Name of the active substance C	flufenacet	-	
Density [g product/cm^3]	1.2077	-	-
-	Nominal [g a.s./kg or L product]	Fraction considering density [%]	$p_{i\ mix}$ = Fraction of active substance i in the mixture with $\sum p_{i\ mix}$ = 100 [%]
Concentrations of the active substance florasulam in the product	12	1.0%	2.1%
Concentrations of the active substance diflufenican in the product	250	20.7%	43.6%
Concentrations of the active substance flufenacet in the product	312	25.8%	54.4%

Table 2. Toxicity of CHR/H/FDF 574 SC and active substance

-

Endpoint/Test species	Toxicity of the product [mg product/L]	Toxicity of the product (a.s. based) ($EC_{x\ PPP}$) [mg a.s./L]	Toxicity of the a.s. Flufenacet (ECx A) [mg a.s./L]	Toxicity of the a.s. Diflufenican (ECx B) [mg a.s./L]	Toxicity of the a.s. Penoxulam ($EC_{x\ C}$) [mg a.s./L]	Triggers (from EFSA Journal 2013;11(7):3290)
EC50 daphnids	100	47.528	292	0.24	30.9	0.01
NOEC algae	0.0001	0.000	0.02	0.00015	0.012	0.1
NOEC higher plant	0.0024	0.001	0.00062	0.015	0.012	0.1

Table 3. Calculation of toxicity exposure in CHR/H/FDF 574 SC

Toxicity per fraction of the a.s. florasulam (1/TUA) [mg a.s./L]	Toxicity per fraction of the a.s. diflufenican (1/TUB) [mg a.s./L]	Toxicity per fraction of the a.s. flufenacet (1/TUC) [mg a.s./L]	Calculated mixture toxicity (a.s. in product) ($EC_{x\ mix-CA}$ = 1/$\sum$ (TU_i)) [mg a.s./L]	Model deviation ratio (MDR = $EC_{x\ mix-CA}$/$EC_{x\ ppp}$)	$EC_{x\ mix-CA}$ (a.s. in product)/$EC_{x\ mix-CA}$ (a.s. in PEC_{mix}) (at lower exposure tier)

Equation 13: $$ECx_{mix-CA} = \left(\sum_{i=1}^{n} \frac{p_i}{ECx_i} \right)^{-1}$$

where:

n: number of mixture components
i: index from 1…n mixture components
p_i: the i^{th} component as a relative fraction of the mixture composition (note: $\Sigma\, p_i$ must be 1)
ECx_i: concentration of component i provoking x % effect (pragmatically, $NOEC_i$ may be inserted, too).

13967.33333	0.55104	56.84807692	0.546	0.011	0.557
0.956666667	0.0003444	0.022076923	0.000	7.132	0.562
0.029656667	0.03444	0.022076923	0.009	8.113	2.399

Answer: MDRs for daphnias are below <0.2 Therefore , go to Step 9 MDRs for algaes and higher plants are higher than 5. Therefore, go to Step 10

Step 9. Carefully recheck the apparent antagonism as observed in the measured mixture toxicity data (ECx PPP) regarding potential impacts of the default assumption of CA and/or heterogeneous input data used for the CA calculation. Does the apparent antagonism remain and no toxicologically plausible explanation is available (e.g. special feature of the formulation type)?

Yes (measured mixture toxicity not plausible):	Go to step 8
No (measured mixture toxicity plausible):	Go to step 3

Answer: NO. → Go to step 3

Step 10. Carefully recheck the apparent synergism as observed in the measured mixture toxicity data (ECx PPP) regarding potential impacts of heterogeneous input data (a.s.) and of co-formulants ignored in the CA calculation. Does the apparent synergism remain?

Answer: Yes. → Go to step 3

Step 3. Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECx PPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PECmix. As a direct comparison on the basis of the relative proportions of the a.s. at the ECx PPP with the relative proportion at the PECmix is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECx mix-CA (see Equation 13) for the mixture composition of the a.s. at the PECmix and compare with the estimate calculated for the formulation (as already done in step 2 above).

Table 4. Results of compare ECmix-CA(a.s. in PPP) to ECmix-CA (a.s. in PECmix)

		Triggers

Endpoint/Test species	**ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix)**	**0.8-1.2**	**<0.8 or >1.2**
EC50 daphnids	0.557		Yes
NOEC algae	0.562		Yes
NOEC higher plant	2.399		Yes

Answer: Calculated factors for daphnias, algae and higher plants gives results outside 0.8-1.2 Therefore, go to step 5.

STEP 5. Check whether one mixture component clearly drives the toxicity if considering the measured mixture toxicity (ECx PPP), that is, does the largest part of the sum of toxic units (Equation 14) calculated for the formulation (≥ 90 %) comes from a single a.s. (TUi)?

Table 6. Results of toxicity driver's calculation

		Florasulam		Diflufenican		Flufenacet		Triggers	
Endpoint/Test species	Calculated mixture toxicity (a.s. in product) ($EC_{x\ mix\text{-}CA}$) [mg a.s./L]	Toxicity per fraction ($1/TU_i$) [mg a.s./L]	Deviation from mixture toxicity = 1-$EC_{x\ mix\text{-}CA}$ x (1/$EC_{x\ mix\text{-}CA}$-TU_i) [%]	Toxicity per fraction ($1/TU_i$) [mg a.s./L]	Deviation from mixture toxicity = 1-$EC_{x\ mix\text{-}CA}$ x (1/$EC_{x\ mix\text{-}CA}$-TU_i) [%]	Toxicity per fraction ($1/TU_i$) [mg a.s./L]	Deviation from mixture toxicity = 1-$EC_{x\ mix\text{-}CA}$ x (1/$EC_{x\ mix\text{-}CA}$-TU_i) [%]	>=90% for one a.s.	>=90% for no a.s.
EC50 daphnids	0.546	13967.333	0.0%	0.551	99.04%	56.848	1.0%	Yes	
NOEC algae	0.000	0.957	0.0%	0.000	98.4%	0.022	1.5%	Yes	
NOEC higher plant	0.009	0.030	31.2%	0.034	26.9%	0.022	41.9%		Yes

Equation 14:

$$\sum_{i=1}^{n} TU_i = \sum_{i=1}^{n} \frac{c_i}{EC_{X_i}}$$

Answer: No toxicity drivers were found for higher plan. Therefore, got to Step 8. Toxicity drivers for daphnias and algae is Diflufenican.

STEP 8. Conduct a mixture RA based on calculated mixture toxicity

Table 7. Results of exposure of mixture toxicity's calculation to aquatic species

Exposure	-	**(lower exposure tier)**	**(higher exposure tier)**									
Exposure tier (FOCUS	Florasulam	Step 2	Step 3 (D3 ditch)	Step 3 (D4 pond)	Step 3 (D4 stream)	Step 3 (D5 pond)	Step 3 (D5 stream)	Step 3 (R1 pond)	Step 4 (20 m i 90% nozzle reduc-	Step 4 (20 m, R3 stream)	Step 4 (20 m i 90% nozzle reduc-	

step)									tion, R1 stream)		tion, R4 stream)	
PECsw [mg a.s./L]		0.002350	0.000030	0.000001	0.000026	0.000001	0.000028	0.000002	0.000021	0.000003	0.000005	
Exposure tier (FOCUS step)	Diflufenican	Step 2	Step 4 (10 m, D3 ditch)	Step 4 (10 m, D4 pond)	Step 4 (10 m, D4 stream)	Step 4 (10 m, D5 pond)	Step 4 (10 m, D5 stream)	Step 4 (10 m, R1 pond)	Step 4 (20 m, R1 stream)	Step 4 (20 m, R3 stream)	Step 4 (20 m, R4 stream)	
PECsw [mg a.s./L]		0.004790	0.000090	0.000045	0.000166	0.000014	0.000114	0.000027	0.000091	0.000102	0.000139	
Exposure tier (FOCUS step)	Flufenacet	Step 2	Step 4 (20 m, D3 ditch)	Step 4 (20 m, D4 pond)	Step 4 (20 m, D4 stream)	Step 4 (20 m, D5 pond)	Step 4 (20 m, D5 stream)	Step 4 (20 m, R1 pond)	Step 4 (20 m, R1 stream)	Step 4 (20 m, R3 stream)	Step 4 (20 m, R4 stream)	
PECsw [mg a.s./L]		0.012840	0.000113	0.000017	0.000133	0.000355	0.000494	0.000038	0.000477	0.000613	0.000573	
Total exposure concentration of the mixture (a.s. based) (PECmix) [mg/L]	-	0.019980	0.000234	0.000063	0.000324	0.000370	0.000636	0.000067	0.000590	0.000717	0.000717	
-	-			-								
End-point/Test species	-	Calculated mixture toxicity (a.s. in PEC_{mix}) ($EC_{x\ mix\ CA} = \sum (p_{i\ PEC}/EC_{x\ i})$) [mg a.s./L] -										
NOEC higher plant	-	0.004	0.004	0.010	0.005	0.011	0.007	0.008	0.007	0.012	0.011	
End-point/Test species	-	$ETR_{mix} = PEC_{mix}/EC_{x\ ppp}$										Triggers
NOEC higher plant	-	5.180	0.064	0.006	0.064	0.032	0.094	0.008	0.080	0.062	0.066	0.10

Answer: ETRmix for higher exposure tier are below the triggers. Therefore, CHR/H/FDF 574 SC no poses unacceptable mixture toxicity to aquatic species with applayin 20 meters vegetative and no spray buffer zone with 90% nozzle reduction

9.5.1 Overall conclusions

The risk for the entry routes run-off and drainage is acceptable without buffer zones for the intended use of CHR/H/FDF 574 SC .
The use CHR/H/FDF 574 SC according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1) with applyain buffer zone:

- **65 meters zone or 35 meters buffer zone and 50% nozzle reduction or 16 meters and 75% nozzle reduction or 6 meters buffer zone and 90% nozzle reduction for Poland**
- **65 meters zone or 35 meters buffer zone and 50% nozzle recuction or 20 meters buffer zone and 90% nozzle reduction for other countries**

Based on the calculated concentrations of the formulation CHR/H/FDF 574 SC (spray drift) respectively its active ingredients Florasulam, Diflufenican and Flufenacet (run-off and drainage) in surface water (PEC_{SW} according to FOCUS STEP 1-2, STEP 3), the calculated RAC/PEC (mix) values for the risk resulting from an exposure of aquatic organisms to CHR/H/FDF 574 SC according to the GAP of the formulation achieve the acceptability criterium <1 for run-off exposure, therefore no risk mitigations are required.

The following formula was used to derive the surrogate EC_{50} for the mixture of active substances with known toxicity assuming dose additivity:

9.5.2 Overall conclusions

The risk for the entry routes run-off and drainage is acceptable without buffer zones for the intended use of CHR/H/FDF 574 SC .
The use CHR/H/FDF 574 SC according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1).

Review comments:

The evaluation of the risk for aquatic was performed in accordance with Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009(EFSA Journal 2013;11(7):3290).

For the active substance florasulam, calculated PEC/RAC ratios for winter cereals indicate an acceptable risk in all FOCUS Steps 3 scenarios. For florasulam relevant metabolites PEC/RAC ratios for winter cereals indicate an acceptable risk in Focus Step 1 and Step 2.

For the active substance diflufenican, PEC/RAC ratios are below the trigger value of 1 at step 4 for when 10 meters vegetative buffer zone and 10 meters no-spray buffer zone is used.
Calculated PEC/RAC values for diflufenican metabolites (IN-AE B10737, AE 0542291) were below the trigger value of 1 already at step 1, indicating low risk to aquatic organisms.

For the active substance flufenacet, calculated PEC/RAC ratios for flufenacet did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for *Selenastrum capricornutum* as characterised by an EC_{50} for species of 2.04 µg/L and form Lemna 2.43µg/L in connection with an assessment factor of 10) in FOCUS Step 4 with 10 m buffer zone scenarios. Therefore, higher tier study was necessary. Such study was performed on Annex I inclusion and was used in risk refinement. For flufenacet, the higher tier risk assessment is based on the NOEC of 12 µg a.s./L from the microcosm study (macophyte, duckweed and periphyton).
Calculated PEC/RAC values for flufenacet are below the trigger value of 1 at step 4, indicating low risk to aquatic organisms when 10 meters vegetative buffer zone and 10 meters no-spray buffer zone is used.
Calculated PEC/RAC values for flufenacet metabolites (FOE sulfonic acid, FOE thiadone, FOE methyl-

sulfide) are below the trigger value of 1 at step 1, indicating low risk to aquatic organisms.

PEC_{sw} values of formulation CHR/H/FDF 574 SC were calculated in SWASH drift calculator the ratio PEC/RAC were below 1 for all aquatic organisms. For the formulated product, no potential risks are identified for aquatic organisms following application of CHR/H/FDF 574 SC to winter cereals with appropriate mitigation measures. For mixture toxicity an acceptable risk was concluded without mitigation measures.

Concluding the risk to aquatic organisms caused by the application of CHR/H/FDF 574 SC for all uses foreseen in critical GAP is acceptable with appropriate mitigation measures.

To protect aquatic organisms for relevant PL scenarios D3, D4, R1 following mitigation measures are required:

- 20m vegetative filter strip and 20m unsprayed buffer with 90% nozzle reduction to surface water bodies

Concerned Member States must decide on the applicability of indicated risk mitigation measures at the product authorization.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Florasulam, Diflufenican and Flufenacet. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of CHR/H/FDF 574 SC were not evaluated as part of the EU assessment of Florasulam, Tribenuron-methy and Flufenacet. New data submitted with this application are listed in table below ~~**Błąd! Nie można odnaleźć źródła odwołania.**~~ and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Florasulam	Oral	LD_{50} > 100 µg a.s/bee	EFSA Journal 2015; 13(1):3984
Apis mellifera	Florasulam	Contact	LD_{50} >100 µg a.s/bee	EFSA Journal 2015; 13(1):3984
Apis mellifera	Diflufenican	Oral	LD_{50} > 112.3 µg a.s./bee	EFSA Scientific Report (2004) 15, 1-52
Apis mellifera	Diflufenican	Contact	LD_{50} > 100 µg a.s./bee	EFSA Scientific Report (2004) 15, 1-52
Apis mellifera	Flufenacet ~~sodium~~	Oral	‘LD_{50}> 170 µg a.s./bee	SANCO/7469/VI/98-Final 7469/VI/98-Final 3 July 2003

Species	Substance	Exposure System	Results	Reference
				~~EFSA Journal 2016;14(4):4453~~
Apis mellifera	Flufenacet ~~sodium~~	Contact	LD_{50} > 194 µg /bee	SANCO/7469/VI/98-Final 7469/VI/98-Final 3 July 2003 ~~EFSA Journal 2016;14(4):4453~~
Apis mellifera	CHR/H/FDF 574 SC	Acute Oral	LD_{50} > 200 µg/bee	M. Knapik, Study code: B-08-21
Apis mellifera	CHR/H/FDF 574 SC	Acute Contact	LD_{50} > 200 µg/bee	M. Knapik, Study code: B-09-21
Apis mellifera	CHR/H/FDF 574 SC	Chronic Oral	LC50 > 666.7 mg/kg LDD50 > 17.2 µg/bee/day	M. Knapik, Study code: B-07-21
Higher-tier studies (tunnel test, field studies)				

9.6.2 Risk assessment

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

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of CHR/H/FDF 574 SC in winter cereals

Intended use	Cereals winter		
Active substance	Florasulam		
Application rate (g/ha)	1 × 4.8		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	100	4.8	0.048
Contact toxicity	100		0.048
Intended use	Cereals winter/spring		
Active substance	Diflufenican		
Application rate (g/ha)	1 × 100		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	112.3	100	0.89
Contact toxicity	100		1
Intended use	Cereals winter/spring		

Active substance	Flufenacet		
Application rate (g/ha)	1 × 124.8		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	170	124.8	0.73
Contact toxicity	194		0.64
Product	CHR/H/FDF 574 SC		
Application rate (g/ha)	1 × 483.08		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	200	483.08	2.41
Contact toxicity	200		2.41

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

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

Not relevant.

Review Comments:

Since acceptable acute risk have been concluded for bees exposed to CHR/H/FDF 574 SC at the Tier 1 level, a higher-tier risk assessment is not required for the proposed uses of CHR/H/FDF 574 SC.

9.6.3 Effects on bumble bees

Not available

Review Comments:

According to SANCO/10329/2002 rev 2 final, the risk assessment for bumblebees is not required.

9.6.4 Effects on solitary bees

Not available

Review Comments:

According to SANCO/10329/2002 rev 2 final, the risk assessment for solitary bees is not required.

9.6.5 Overall conclusions

All hazard quotients (HQ) are considerably less than 50, indicating that CHR/H/FDF 574 SC applied at the maximum use rate in cereals winter/spring poses low risk to bees.

Review Comments:

The evaluation has been performed in line with SANCO/10329/2002 rev 2 final.
The risk assessment performed for active substance florasulam and the formulated product CHR/H/FDF 574 SC is agreed by the zRMS.
All hazard quotients calculated are lower than 50, indicating that the acute oral and contact risk to bees is acceptable following the use according to the proposed use pattern CHR/H/FDF 574 SC.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees): Applicant should provide chronic test on bees and evaluation of effects on honey bee development with formulated product. Only Test No. 245: Honey Bee (*Apis Mellifera* L.), Chronic Oral Toxicity Test (10-Day Feeding) was performed. Therefore, for Poland, the deficiencies need to be fill till EFSA bee guidance will come in to the force.
Nevertheless, such studies were deemed not necessary to finalize the risk assessment. Since the risk assessment was performed according to SANCO/10329/2002 rev 2.
Concerned Member States must decide on the consideration of data requirements of the EFSA Bee guidance (2013) on national level.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with florasulam, diflufenican, flufenacet and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of CHR/H/FDF 574 SC were not evaluated as part of the EU assessment of Florasulam, Diflufenican and Flufenacet. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	CHR/H/FDF 574 SC	Extended Laboratory test glass plates (2D)	LR_{50} = 0.09 L formulation//ha which is equivalent to 108.7 g/ha $ER_{50=}$ 0.07 L formulation/ha	M. Knapik, Study code: B-04-21
Aphidius rhopalosiphi (adults)	CHR/H/FDF 574 SC	Extended Laboratory test glass plates (3D)	LR50 > 0.4L/ha which is equicalent to > 489.72 g/ha $ER_{50=}$ 0.22 L formulation/ha	M. Knapik, Study code: B-05-21
Chrysoperla Carnea	CHR/H/FDF 574 SC	Extended Laboratory test glass plates (2D)	LR50 > 0.4L/ha which is equicalent to > 483.08 g/ha	M. Kanpik, Study code: B-06-21
Coccinella	CHR/H/FDF 574 SC	Extended	LR > 0.4L/ha which	M. Knapik, Study

Species	Substance	Exposure System	Results	Reference
septempunctata		Laboratory test glass plates (2D)	is equivalent to > 483.08 g/ha	code: B-03-21
Field or semi-field tests				
Aged-residue study Typhlodromus pyri	CHR/H/FDF 574 SC	Aged-residue Extended Laboratory Tests	The effects of freshly-dried and field-aged foliar residues of CHR/H/FDF 574 SC on the predatory mite Typhlodromus pyri were evaluated in a series of extended laboratory tests. When applied to sweetcorn plants at a rate equivalent to 0.4 L test item/ha, fresh-dried residues and 14-day field-aged residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the mites, (i.e. < 50% corrected mortality and < 50% reduction in reproduction, relative to the control).	L. Fallowfield, Study code: CHR-21-06, 2021

9.7.2 Risk assessment

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

9.7.2.1 Risk assessment for in-field exposure

Table 9.7-2: The Tier II based on extended laboratory studies ~~First- and higher-tier~~ assessment of the in-field risk for non-target arthropods due to the use of CHR/H/FDF 574 SC in cereals winter~~/spring~~

Intended use	Cereals winter~~/spring~~		
Active substance/product	CHR/H/FDF 574 SC		
Application rate (g/ha)	1 ×483.08		
MAF	1		
Test species Tier II	**LR_{50} (lab.)/ER_{50} (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 1**

Typhlodromus pyri	108.7/84.54	483.08	4.44/5.71
Aphidius rhopalosiphi	>483.08/269.34		1/1.8
Chrysoperla Carnea	>483.08		1
Coccinella septempunctata	>483.08		1

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.2 Risk assessment for off-field exposure

Table 9.7-3: The Tier II based on extended laboratory studies ~~First- and higher tier~~ assessment of the off-field risk for non-target arthropods due to the use of CHR/H/FDF 574 SC in cereals winter

Intended use	Cereals winter
Active substance/product	CHR/H/FDF 574 SC
Application rate (g/ha)	1 x 483.08
MAF	1
vdf	10 For 3D study no vdf is used

Test species Tier II	**LR_{50} (lab.)/ /ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 1**
Typhlodromus pyri (2D)	108.7/84.54	2.77	1.3 (2D) /13.38(3D)	5	0.061/0.08
Aphidius rhopalosiphi (3D)	>483.08/269.34				0.14/0.25
Chrysoperla Carneo (2D)	>483.08				0.14
Coccinella septempunctata (2D)	>483.08				0.14

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Since some MS accept vdf of 5, additional calculation with this parameter has been done I table below.

Table 9.7-4: The Tier II based on extended laboratory studies ~~First- and higher tier~~ assessment of the off-field risk for non-target arthropods due to the use of CHR/H/FDF 574 SC in cereals winter

Intended use	Cereals winter
Active substance/product	CHR/H/FDF 574 SC
Application rate (g/ha)	1 x 483.08
MAF	1

vdf	5 For 3D study no vdf is used

Test species Tier II	**LR_{50} (lab.)/ /ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 1**
Typhlodromus pyri (2D)	108.7/84.54	2.77	2.67 (2D)/ 13.38(3D)	5	0.12/0.16
Aphidius rhopalosiphi (3D)	>483.08/269.34				0.14/0.25
Chrysoperla Carneo (2D)	>483.08				
Coccinella septempunctata (2D)	>483.08				

Review comments:

Off-field risk was recalculated and updated by zRMS. For PL vdf of 10 is used. However for countries were vdf of 5 is accepted zRMS presented also these calculations. Concerned MS should decide of use of vdf 5 or 10 on the National Level.

9.7.2.3 Additional higher-tier risk assessment

According to GL aged residue study provided on the most sensitive species from laboratory studies – T.pyri the effects of freshly-dried and field-aged foliar residues of CHR/H/FDF 574 SC on the predatory mite *Typhlodromus pyri* were evaluated in a series of extended laboratory tests. When applied to sweetcorn plants at a rate equivalent to 0.4 L test item/ha, fresh-dried and 14-day field-aged residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the mites, (i.e. < 50% corrected mortality and < 50% reduction in reproduction, relative to the control).

Bioassay initiated	Treatment	Test item rate (L/ha)	Mean % mortality at 7 DAI [a)]	Corrected % mortality at 7 DAI [b)]	Mean number eggs/female (7-14 DAI) [c)]	Reduction in reproduction [%] [d)]
0 DAT	Control	-	13	-	10.4	-
	CHR/H/FDF 574 SC	0.4	38 *	28.7	6.1 *	41.0
	Toxic reference	-	100 *	100	~	-
14 DAT	Control	-	5	-	9.9	-
	CHR/H/FDF 574 SC	0.4	23 *	18.9	9.3	5.4

a) For each bioassay, treatment mortalities were compared to the control using chi^2 2x2 table test ($\alpha = 0.05$, one-sided, > control), a statistically significant effect is denoted by an asterisk (*).

b) Mortality corrected for respective control treatment deaths using Abbott's formula. A positive value indicates an increase.

c) Treatments were compared to the respective control by Student's t-test for homogenous variances ($\alpha = 0.05$, one-sided, < control), a statistically significant effect is denoted by an asterisk (*).

d) Percentage reduction in numbers of eggs per female, relative to the respective control. A positive value indicates a decrease.

~ indicates no assessments were made for this treatment.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

All hazard quotients (HQ) are considerably less than 2, indicating that CHR/H/FDF 574 SC applied at the maximum use rate in cereals winter~~/spring~~ poses no risk to non-target arthropods. No risk mitigation needed.

Review comments:

At TIER 2 not acceptable in-field risk for Typhlodromus pyri and Aphidius was indicated. Additional study for *Chrysoperla carnea and Cocciella septapunctata* was performed indicated low risk for arthropods.
On the basis of the risk assessment results also with additional species *Chrysoperla carnea and Coccinella septapunctata* it is clear that the most sensitive species was T.pyri. That is why additional age residue study on T. pyri was performed. For Tyhlodromus pyri TIER 3 assessent was performed on the basis of age residues studies. During aged residue studies, it was shown that after application of product, reduction of reproduction for T.pyri is less than 50%, what indicate acceptable risk.
The HQ for recommended species: *Typhlodromus pyri , Aphidius rhopalosiphi, Chrysoperla carnea and Cocciella* septapunctata is below the ESCORT 2 trigger value of 1 indicating acceptable off-field risk to non-target arthropods at tier II level.
On this basis acceptable risk for in-field and off-field habitats may be concluded with no need for risk mitigation measures.

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

9.8.1 Toxicity data

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

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of CHR/H/FDF 574 SC were not evaluated as part of the EU assessment of florasulam, diflufenican and flufenacet. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
Eisenia foetida	Florasulam	Acute (14d) Incorporated into soil / 10% OM	LC50 > 1320 mg a.s./kg d.w.soil	EFSA Journal 2015; 13(1):3984
Eisenia foetida	Florasulam	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 0.203 mg a.s./kg d.w.soil	EFSA Journal 2015; 13(1):3984
Eisenia foetida	5-OH-florasulam	Acute (14d) Incorporated into soil / 10% OM	LC50 > 1120 mg a.s./kg d.w.soil	EFSA Journal 2015; 13(1):3984
Eisenia foetida	5-OH-florasulam	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 0.14 mg /kg d.w.soil	EFSA Journal 2015; 13(1):3984
Eisenia foetida	DFP-ASTCA	Acute (14d) Incorporated into soil / 10% OM	LC50 > 0.1 mg /kg d.w.soil	EFSA Journal 2015; 13(1):3984
Eisenia foetida	DFP-ASTCA	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 0.0304 mg /kg d.w.soil	EFSA Journal 2015; 13(1):3984
Eisenia foetida	ASTCA	Acute (14d) Incorporated into soil / 10% OM	LC50 > 100 mg /kg d.w.soil	EFSA Journal 2015; 13(1):3984
Eisenia foetida	ASTCA	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 1.0 mg /kg d.w.soil	EFSA Journal 2015; 13(1):3984
Eisenia foetida	TSA	Acute (14d) Incorporated into soil / 10% OM	LC50 > 0.1 mg /kg d.w.soil	EFSA Journal 2015; 13(1):3984
Eisenia foetida	TSA	Mixed into	NOEC = 10.0 mg	EFSA Journal 2015;

Species	Substance	Exposure System	Results	Reference
		substrate 56 d, chronic 10 % peat content	/kg d.w.soil	13(1):3984
Falsomia candida	5-OH-florasulam	Mixed into sub-strate 28 d, chronic 5 % peat content	NOEC = 2.5 mg/kg d.w. soil	EFSA Journal 2015; 13(1):3984
Falsomia candida	DFP-ASTCA	Mixed into sub-strate 28 d, chronic 5 % peat content	NOEC = 10 mg/kg d.w.soil	EFSA Journal 2015; 13(1):3984
Falsomia candida	ASTCA	Mixed into sub-strate 28 d, chronic 5 % peat content	NOEC = 12.5 mg/kg d.w.soil	EFSA Journal 2015; 13(1):3984
Eisenia fetida	Diflufenican	14 d, acute 10 % peat content	LC50, corr > 500 mg/kg dw *	EFSA Scientific Report (2007) 122, 1-84
Eisenia fetida	Metabolite AE B107137	14 d, acute 10 % peat content	LC50, corr > 500 mg/kg dw *	EFSA Scientific Report (2007) 122, 1-84
Eisenia fetida	Metabolite AE 0542291	14 d, acute 10 % peat content	LC50, corr > 500 mg/kg dw *	EFSA Scientific Report (2007) 122, 1-84
Eisenia fetida	Diflufenican	56 d, chronic 10 % peat content	NOECcorr = 500 mg/kg dw *	EFSA Scientific Report
Eisenia fetida	Flufenacet	Mixed into sub-strate 14 d, acute 10 % peat content	LC50 = 219 mg /kg soil LC50 = 109.5 mg /kg soil corrected*	7469/VI/98-Final 3 July 2003
Eisenia fetida	Flufenacet	Mixed into sub-strate 56 d, chronic 10 % peat content	NOEC > 4 mg /kg soil NOEC > 2 mg /kg soil corrected*	7469/VI/98-Final 3 July 2003
Eisenia fetida	flufenacet-sulfonic acid	Mixed into sub-strate 14 d, acute 10 % peat content	LC50 > 1000 mg/kg LC50 > 500 mg/kg corrected *	7469/VI/98-Final 3 July 2003
Eisenia fetida	flufenacet oxalate	Mixed into sub-strate 14 d, acute 10 % peat content	LC50 > 1000 mg/kg LC50 > 500 mg/kg corrected *	7469/VI/98-Final 3 July 2003
Eisenia andrei	CHR/H/FDF 574 SC	Mixed into sub-strate 56 d, chronic 10 % peat content	EC10 = 99.44 mg/kg dw (day 56 reproduction) EC10corr = 49.72 mg/kg dw*	A. Gierbuszewska, Study code: G-77-20
Folsomia candida	CHR/H/FDF 574 SC	Mixed into sub-strate 28 d, chronic 5 % peat content	NOEC = 32 mg/kg dw NOEC = 16 mg/kg dw*	A. Arendarczyk, Study code: G-78-20

Species	Substance	Exposure System	Results	Reference
Hypoaspis aculeifer	CHR/H/FDF 574 SC	Mixed into substrate 14 d, chronic 5 % peat content	NOEC= 18 mg/kg dw NOEC= 9 mg/kg dw*	A. Giebuszewska, Study code: G-79-20
Field studies				
Litter bag test				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

9.8.2 Risk assessment

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

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for florasulam, diflufenican and flufenacet.

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of CHR/H/FDF 574 SC in cereals winter~~/spring~~

Intended use			
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Not required.			
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Florasulam	0.203	0.0064	31.7
5-OH-florasulam	0.14	0.0032	43.8
DFP-ASTCA	0.0304	0.0008	38
ASTCA	1.0	0.0013	769
TSA	10.0	0.0004	25 000
Diflufenican	500	0.3985	1 255
Flufenacet-sodium	2	0.1680	12
CHR/H/FDF 574 SC	49.72	0.644	77
Chronic effects on other soil macro- and mesofauna Folsomia candida			

Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Florasulam	-	0.0064	-
5-OH-florasulam	2.5	0.0032	781
DFP-ASTCA	10	0.0008	12 500
ASTCA	12.5	0.0013	9 6156
TSA	50	0.0004	12 500
Diflufenican	-	0.3985	-
Flufenacet-	-	0.1680	-
CHR/H/FDF 574 SC	16	0.644	25
Chronic effects on other soil macro- and mesofauna *Hypoaspis aculeifer*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Florasulam	-	0.0064	-
5-OH-florasulam	1.25	0.0032	391
DFP-ASTCA	10	0.0008	12 500
ASTCA	100	0.0013	76 923
TSA	50	0.0004	125 000
Diflufenican	-	0.3985	-
Flufenacet	-	0.1680	-
CHR/H/FDF 574 SC	9	0.644	13.9

TER values shown in bold fall below the relevant trigger.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

~~The acute and~~ Long term risk to earthworms and other non-target soil organisms (meso- and macrofauna) was assessed as low for CHR/H/FDF 574 SC in a first-tier risk assessment.

Review comments:

The risk assessment for soil macro- and meso-fauna presented in Table 9.8-2 and 9.9-3 has been accepted. PECsoil values for active substances and their metabolites were agreed in Section 8.
The long-term risk to earthworms and non-target soil organisms (meso- and macro-fauna) is acceptable for use of CHR/H/FDF 574 SC/ Cezaro 574 SC, Huron 574 in cereals. No further assessment is deemed necessary.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with florasulam, diflufenican, iodosulfuron-methy and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of CHR/H/FDF 574 SC were not evaluated as part of the EU assessment of florasulam, diflufenican and flufenacet. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below..

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Florasulam	28 d, aerobic soil type	Treatment causing <25% deviation from control: 0.05 mg/kg dry soil	EFSA Journal 2016;14(3):4419
N-mineralisation	5-OH-florasulam	28 d, aerobic soil type	Treatment causing <25% deviation from control: 0.036 mg/kg dry soil	EFSA Journal 2016;14(3):4419
N-mineralisation	DFP-ASTCA	28 d, aerobic soil type	Treatment causing <25% deviation from control: 0.00760 mg/kg dry soil	EFSA Journal 2015; 13(1):3984
N-mineralisation	ASTCA	28 d, aerobic soil type	Treatment causing <25% deviation from control: 1.0 mg/kg dry soil	EFSA Journal 2015; 13(1):3984
N-mineralisation	TSA	28 d, aerobic soil type	Treatment causing <25% deviation from control: 0.05 mg/kg dry soil	EFSA Journal 2015; 13(1):3984
N-mineralisation	Diflufenican	28 d, aerobic soil type	Nitrate formation rate 1.25 mg/kg soil dw < ± 25 %	EFSA Scientific Repor EFSA Scientific Report (2007) 122, 1-84
N-mineralisation	Metabolite AE B107137	28 d, aerobic soil type	Nitrate formation rate 0.36 mg/kg soil dw < ± 25 %	EFSA Scientific Report (2007) 122, 1-84
N-mineralisation	Metabolite AE 0542291	28 d, aerobic soil type	Nitrate formation rate 0.36 mg/kg soil dw < ± 25 %	EFSA Scientific Report (2007) 122, 1-84
N-mineralisation C-mineralisation	Flufenacet	28 d/14d, aerobic soil type	0.8 and 4 mg /kg soil: no significant effect	7469/VI/98-Final 3 July 2003
N-mineralisation	CHR/H/FDF 574 SC	28 d, aerobic soil type	On the basis of the results, it was concluded that CHR/H/FDF 574 SC at the concentrations corresponding to the	A. Arendarczyk, Study code: G-80-20

Endpoint	Substance	Exposure System	Results	Reference
			PEC: 3.22 mg of the test item/kg dry weight of soil (i.e. 0.03 mg of florasulam + 0.81 mg of flufenacet + 0.66 mg of diflufenican/kg dry weight of soil) and 5xPEC: 16.08 mg of the test item/kg dry weight of soil (i.e. 0.16 mg of florasulam + 4.06 mg of flufenacet + 3.30 mg of diflufenican/kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils..	

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of CHR/H/FDF 574 SC in winter/spring cereals

Intended use			
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Florasulam	Treatment causing <25% deviation from control: 0.05 mg/kg dry soil	0.0064	YES
5-OH-florasulam	Treatment causing <25% deviation from control: 0.036 mg/kg dry soil	0.0032	YES
DFP-ASTCA	Treatment causing <25% deviation from control: 0.00760 mg/kg dry soil	0.0008	YES
ASTCA	Treatment causing <25% deviation from control: 1.0 mg/kg dry soil	0.0013	YES
TSA	Treatment causing <25% deviation from control: 0.05 mg/kg dry soil	0.0004	YES

Diflufenican	Nitrate formation rate 1.25 mg/kg soil dw < ± 25 %	0.3985	YES
Metabolite AE B107137	Nitrate formation rate 0.36 mg/kg soil dw < ± 25 %	0.0008	YES
Metabolite AE 0542291	Nitrate formation rate 0.36 mg/kg soil dw < ± 25 %	0.0030	YES
Flufenacet	0.8 and 4 mg /kg soil: no significant effect	0.1680	YES
CHR/H/FDF 574 SC	On the basis of the results, it was concluded that CHR/H/FDF 574 SC at the concentrations corresponding to the PEC: 3.22 mg of the test item/kg dry weight of soil (i.e. 0.03 mg of florasulam + 0.81 mg of flufenacet + 0.66 mg of diflufenican/kg dry weight of soil) and 5xPEC: 16.08 mg of the test item/kg dry weight of soil (i.e. 0.16 mg of florasulam + 4.06 mg of flufenacet + 3.30 mg of diflufenican/kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.	0.644	YES
C-mineralisation: Not required			

9.9.3 Overall conclusions

The Predicted Environmental Concentrations of the formulation CHR/H/FDF 574 SC and its active substances Florasulam, Diflufenican, Flufenacet in soil are below the concentrations at which no una acceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days or more of exposure, indicating that the proposed use of CHR/H/FDF 574 SC poses an acceptable risk to soil microorganisms.

Review comments:

The risk assessment for soil micro-organisms exposed to CHR/H/FDF 574 SC, following the proposed uses of the formulation, was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology" (SANCO/10329/2002).

The risk assessment presented in Table 9.9-2 is agreed by the zRMS. The relevant PECsoil for risk assessments is taken from Section 8 (Environmental Fate), for details please, refer to Section 8.
Based on the obtained results, soil nitrate formation rates were below the 25% trigger value. Thus, it is concluded that CHR/H/FDF 574 SC had no significant impact on soil microorganisms when applied at test item concentrations up 16.08 mg formulation/kg soil dry weight.

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

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with florasulam, diflufenican and flufenacet. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of CHR/H/FDF 574 SC were not evaluated as part of the EU assessment of florasulam, diflufenican and iodosulfurn-methyl. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
Pisum sativum	CHR/H/FDF 574 SC	21 d Seedling emergence	ER50 = 0.045 L test item/ha which is eqivalent to 54.3 g prod/ha	A. Gierbuszewska, Study code: G-82-20
Helianthus annuus	CHR/H/FDF 574 SC	21 d Seedling emergence	ER50 = 0.152 L test item/ha which is eqivalent to 183.54 g prod/ha ~~ER50 = 0.226 L test item/ha which is eqivalent to 272.9g prod/ha~~	
Daucus carota	CHR/H/FDF 574 SC	21 d Seedling emergence	ER50 = 0.128 L test item/ha which is eqivalent to 154.6 g prod/ha	
Linum usitatissimum	CHR/H/FDF 574 SC	21 d Seedling emergence	ER50 = 0.135 L test item/ha which is eqivalent to 163.01 g prod/ha ~~ER50 = 0.147 L test item/ha~~ which is eqivalent ~~to 177.5 g prod/ha~~	
Allium cepa	CHR/H/FDF 574 SC	21 d Seedling emergence	ER50 = 0.040 L test item/ha which is eqivalent 48.3 g prod/ha	
Zea mays	CHR/H/FDF 574 SC	21 d Seedling emergence	ER50 = 0.375 L test item/ha which is eqivalent to 452.84 g prod/ha ~~ER50 = 0.395 L test item/ha~~ which is eqivalent to 477 g prod/ha	
Pisum sativum	CHR/H/FDF 574 SC	21 d Vegetative vigour	ER50 = 0.1197 L test item/ha which is eqivalent to 144.57 g prod/ha ~~ER50 = 0.1819 L test item/ha which is eqivalent to 219.7 g prod/ha~~	A. Arendarczyk, Study code: G-81-20

Species	Substance	Exposure System	Results	Reference
Helianthus annuus	CHR/H/FDF 574 SC	21 d Vegetative vigour	ER50 = 0.019 L test item/ha, which is eqivalent to 22.9 g prod/ha	
Daucus carota	CHR/H/FDF 574 SC	21 d Vegetative vigour	**ER50 = 0.0069 L test item/ha, which is eqivalent to 8.3 g prod/ha**	
Linum usitatissimum	CHR/H/FDF 574 SC	21 d Vegetative vigour	ER50 = 0.0347 L test item/ha which is eqivalent to 41.87 g prod/ha ~~ER50 = 0.0392 L test item/ha which is eqivalent to 47.3 g prod/ha~~	
Allium cepa	CHR/H/FDF 574 SC	21 d Vegetative vigour	ER50 = 0.0563 L test item/ha, which is eqivalent 68 7 g prod/ha ~~ER50 = 0.1811 L test item/ha, which is eqivalent to 218.7 g prod/ha~~	
Zea mays	CHR/H/FDF 574 SC	21 d Vegetative vigour	ER50 > 0.4 ~~400~~ L test item/ha which is eqivalent to 483.08 g prod/ha	

m: monocotyledonous; d: dicotyledonous

Review comments:

The lowest endpoints derived in the studies for each examinetd species were used for RA purposes. zRMS updated table with lowest endpoints.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

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

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of CHR/H/FDF 574 SC in winter cereals

Intended use **Active substance/product**	Winter cereals CHR/H/FDF 574 SC

Application rate (g/ha) **MAF**	1 x 483.08 1				
Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**	
Lowest endpoint ER50 = 0.0069 L test item/ha, which is eqivalent to 8.3 g prod/ha	8.3 g prod/ha	0.0277	13.38	0.62	21 d Vegetative vigour
~~*Pisum sativum*~~	~~54.3 g prod/ha~~	~~0.0277~~	~~13.38~~	~~4.06~~	~~21 d Seedling emergence~~
~~*Helianthus annuus*~~	~~272.9g prod/ha~~	~~0.0277~~	~~13.38~~	~~20.4~~	~~21 d Seedling emergence~~
~~*Daucus carota*~~	~~154.6 g prod/ha~~	~~0.0277~~	~~13.38~~	~~11.55~~	~~21 d Seedling emergence~~
~~*Linum usitatissimum*~~	~~177.5 g prod/ha~~	~~0.0277~~	~~13.38~~	~~13.27~~	~~21 d Seedling emergence~~
~~*Allium cepa*~~	~~48.3 g prod/ha~~	~~0.0277~~	~~13.38~~	~~3.61~~	~~21 d Seedling emergence~~
~~*Zea mays*~~	~~477 g prod/ha~~	~~0.0277~~	~~13.38~~	~~35.65~~	~~21 d Seedling emergence~~
~~*Pisum sativum*~~	~~219.7 g prod/ha~~	~~0.0277~~	~~13.38~~	~~16.42~~	~~21 d Vegetative vigour~~
~~*Helianthus annuus*~~	~~22.9 g prod/ha~~	~~0.0277~~	~~13.38~~	~~1.71~~	~~21 d Vegetative vigour~~
~~*Daucus carota*~~	~~8.3 g prod/ha~~	~~0.0277~~	~~13.38~~	~~0.62~~	~~21 d Vegetative vigour~~
~~*Linum usitatissimum*~~	~~47.3 g prod/ha~~	~~0.0277~~	~~13.38~~	~~3.54~~	~~21 d Vegetative vigour~~
~~*Allium cepa*~~	~~218.7 g prod/ha~~	~~0.0277~~	~~13.38~~	~~16.35~~	~~21 d Vegetative vigour~~
~~*Zea mays*~~	~~483.08 g prod/ha~~	~~0.0277~~	~~13.38~~	~~36.11~~	~~21 d Vegetative vigour~~

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.10.2.3 Higher-tier risk assessment

Not required

9.10.2.4 Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to un-sprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

Table 9.10-3: Risk assessment for non-target terrestrial plants due to the use of CHR/H/FDF 574 SC in cereals winter/~~spring~~ considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use **Active substance/product** **Application rate (g/ha)** **MAF**		Cereals winter CHR/H/FDF 574 SC 1 × 483.08 1			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
1	2.77	13.38	6.69	3.35	1.34
5	0.57	2.76	1.38	0.69	0.28
10	0.27	1.30	-	-	-
Toxicity value ER_{50} = 8.3 g/ha		**TER** **criterion: TER ≥ 5**			
1		0.62	1.24	2.48	6.19
5		3.01	6.01	12.03	29.64
10		6.38	-	-	-

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

9.10.3 Overall conclusions

Based on the predicted rates of CHR/H/FDF 574 SC in off-field areas, the TER values describing the risk for non-target plants following exposure to CHR/H/FDF 574 SC according to the GAP of the formulation CHR/H/FDF 574 SC achieve the acceptability criteria TER ≥ 5 ~~1 based on SSD~~ risk refinement, with applying:

- 10 m buffer zone
- 5 m and use of 50 % drift reducing nozzles
- 1 m and use of 90 % drift reducing nozzles

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

Not available.

9.12 Monitoring data (KCP 10.8)

Please refer to the point 9.5 (KCP 10.2)

9.13 Classification and Labelling

CHR/H/FDF 574 SC was classified and labeled according to REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Classification according tu CLP Regulation:

CLASSIFICATION	
Hazard classes, categories:	Aquatic Acute 1 Aquatic Chronic 1,
LABELLING	
Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statements:	H400: Very toxic to aquaitic life. H410: Very toxic to aquatic life with long lasting effects
Precautionary statements:	P391 – Collect spillage. P501 - Dispose of contents/container to an approved waste disposal plant.
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

Standard phrases under Regulation (EU) No 547/2011

SPe 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).
SPe3	To protect aquatic organisms respect a: - 20m vegetative filter strip and 20m unsprayed buffer with 50% nozzle reduction to surface water bodies is respected for PL ~~- 65 meters zone or 35 meters buffer zone and 50% nozzle reduction or 16 meters and 75% nozzle reduction or 6 meters buffer zone and 90% nozzle reduction for Poland~~ 65 meters zone or 35 meters buffer zone and 50% nozzle recuction or 20 meters buffer zone and 90% nozzle reduction for other countries To protect non target terrestrial plants respect a: - 10 m buffer zone - 5 m and use of 50 % drift reducing nozzles - 1 m and use of 90 % drift reducing nozzles

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.1	K. Florynski	2018	CHR/H/FDF 574 SC - TER Calculations for Terrestial Verterbrates Chemirol GLP No Unpublished	N	Chemirol
KCP 10.1.2	K. Florynski	2018	CHR/H/FDF 574 SC - TER Calculations for Terrestial Verterbrates Chemirol GLP No Unpublished	N	Chemirol
KCP 10.2/01	E. Nierzędska	2021	CHR/H/FDF 574 SC Daphnia magna, Acute Immobilisation Test W-65-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.2/05	E. Nierzędska	2021	CHR/H/FDF 574 SC Raphidocelis subcapitata SAG 61.81 (formerly Pseudokirchneriella subcapitata), Growth inhibition test W-68-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.2/03	E. Nierzędska	2021	CHR/H/FDF 574 SC Anabaena flos-aquae UTEX B 1444 Growth inhibition test W-66-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/04	E. Nierzędska	2021	CHR/H/FDF 574 SC Lemna gibba CPCC 310, Growth inhibition test W-67-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.3/01	M. Knapik	2021	CHR/H/FDF 574 SC Honeybees (Apis mellifera L.), Acute Oral Toxicity Test B-08-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.3/02	M. Knapik	2021	CHR/H/FDF 574 SC Honeybees (Apis mellifera L.), Acute Contact Toxicity Test B-09-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.3/03	M. Knapik	2021	CHR/H/FDF 574 SC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test B-07-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.3/04	M. Knapik	2021	An extended laboratory test for evaluating the effects of CHR/H/FDF 574 on the predatory mite, Typhlodromus pyri (Sch.) B-04-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.3/05	M. Knapik	2021	An extended laboratory test for evaluating the effects of CHR/H/FDF 574 on the parasitic wasp, Aphidius rhopalosiphi (De Stefani-Perez)	N	Chemirol

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
			B-05-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished		
KCP10.3/06	M. Knapik	2021	An extended laboratory test for evaluating effects of CHR/H/FDF 574 on the green lacewing, Chrysoperla carnea (Steph.) B-06-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.3/08	M. Knapik	2021	An extended laboratory test for evaluating effects of CHR/H/FDF 574 on the ladybird beetle, Coccinella septempunctata (L.) B-03-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.3/09	L. Fallowfield	2021	CHR/H/FDF 574 SC – Aged-Residue Extended Laboratory Tests to Determine Effects on the Predatory Mite Typhlodromus pyri (Acari: Phytoseiidae) CHR-21-06 Mambo-Tox A Division of Cawood Scientific Ltd. 2 Venture Road, University Science Park, Southampton SO16 7NP, UK GLP Unpublished	N	Chemirol
KCP 10.4/01	A. Gierbuszewska	2021	CHR/H/FDF 574 SC Earthworm reproduction test (Eisenia andrei) G-77-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4/02	A. Arendarczyk	2021	CHR/H/FDF 574 SC Collembolan (Folsomia candida) Reproduction Test G-78-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.4/03	A. Gierbuszewska	2021	CHR/H/FDF 574 Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil G-79-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.5/01	A. Arendarczyk	2021	CHR/H/FDF 574 Soil Microorganisms: Nitrogen Transformation Test G-80-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.6/01	A. Gierbuszewska	2021	CHR/H/FDF 574 Terrestial Plant Test: Seedling Emergence and Seedling Growth Test G-82-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.6/02	A. Arendarczyk	2021	CHR/H/FDF 574 Terrestial Plant Test: Vegetative Vigour Test G-81-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol

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
KCP 10.1.1/01	Austin, FTM	1997	A Laboratory Study to Evaluate the Effects of XDE-570 on the Predatory Mite, Typhlodromus pyri GHE-P-6706 Ecotox Limited GLP Yes Unpublished	N	DAS
KCP 10.1.1/02	Austin, FTM	1997	A Laboratory Study to Evaluate the Effects of XDE-570 on the Parasitic Wasp, Aphidius Rhopalosiphi Ecotox Limited GHE-P-6707 GLP Yes Unpublished	N	DAS
KCP 10.1.1/03	Austin, FTM	1996	A Laboratory Study to Evaluate the Effects of XDE-570 on the Carabid Beetle Poecilus cupreus Ecotox Limited GHE-P-6709 GLP Yes Unpublished	N	DAS
KCP 10.1.1/04	Baxter, I.	1999	An extended laboratory test to evaluate the effects of florasulam 50 SC (EF-1343), a suspension concentrate formulation containing 50 g/L DE-570, on the foliar-active arthropod, Episyrphus balteatus. DAS Report No.: EA99D5A088 (Accession Number) 73609 Mambo-Tox Limited GLP Yes Unpublished	N	DAS
KCP	-	1995	XDE-570 Herbicide: A Pilot Reproduction Study with the Mallard	Y	DAS

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**
10.1.1/05			DECO-ES-2821 GLP No Unublished		
KCP 10.1.1/06		1995	XDE-570 Herbicide: A Pilot Reproduction Study with the Northern Bobwhite DECO-ES-2820 GLP Yes Unublished	N	DAS
KCP 10.1.1/07	Beech, P	1996	A Determination of the Oral LD50s for XDE-570 against the Honey Bee, Apis mellifera Agrochemical Evaluation Unit, Department of Biology, The University, Southampton, UK GHE-P-6705 GLP Yes Unpublished	N	DAS
KCP 10.1.1/08	Boeri, RL, Magazu, JP, Ward, TJ	1994	XDE-570 Herbicide: Acute Toxicity to the Earthworm, Eisenia foetida TR Wilbury Laboratories Inc, DECO-ES-2798 GLP Yes Unpublished	N	DAS
KCP 10.1.1/09		1994	XDE-570: An Acute Oral Toxicity Study with the Japanese Quail DECO-ES-2799 GLP Yes Unpublished	N	DAS
KCP 10.1.1/11	Ehr, RJ, Alexander, AL	1997	The Activity of DE-570 in Herbicide, Insecticide and Fungicide Screening Tests and the Herbicidal Activity of DE-570 Soil Metabolites DERBI# 60600 DowElanco	N	DAS

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**
			GLP Yes Unpublished		
KCP 10.1.1/12	Ehr, RJ, Schmitzer, PR, Gray, JA	1997	The Activity of DE-570 and Soil Metabolites on Acetolactate Synthase, Lemna minor, and Agrostis palustris DERBI # 60598 DowElanco GLP No Unpublished	N	DAS
KCP 10.1.1/13	Feil, N.	2010	Effects of 5-hydroxy-florasulam on the activity of the soil microflora in the laboratory DAS Report No.: 101342 (Accession Number) 2007411 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DAS
KCP 10.1.1/14	Feil, N.	2011	Effects of DFP-ASTCA metabolite of florasulam on the activity of the soil microflora in the laboratory. DAS Report No.: 101343 (Accession Number) 2009901 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DAS
KCP 10.1.1/15	Feil, N.	2008	Effects of ASTCA metabolite of florasulam on the activity of the soil microflora in the laboratory DAS Report No.: 080039 (Accession Number) 2000205 Institut fiir Biologische Analytik und Consulting IBACON GmbH	N	DAS

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**
			GLP Yes Unpublished		
KCP 10.1.1/16	Feil, N.	2011	Effects of TSA metabolite of florasulam on the activity of the soil microflora in the laboratory DAS Report No.: 110143 (Accession Number) 2010747 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DAS
KCP 10.1.1/17	Forster, J	1997	A Laboratory Assessment of the Effects of XDE-570 on Soil Microflora Respiration and Nitrogen Turnover According to BBA Guidelmes VI 1-1 (1990) Euro Laboratories Limited GHE-T-713 GLP Yes Unpublished	N	DAS
KCP 10.1.1/18	-	1995	XDE-570: A Reproduction Study with the Northern Bobwhite (Colinus virginianus) DECO-ES-2911 GLP Yes Unpublished	Y	DAS
KCP 10.1.1/19	-	1995	XDE-570: A Reproduction Study with the Mallard (Anas platyrhynchos) DECO-ES-2912 GLP Yes Unpublished	Y	DAS
KCP 10.2/01	-	2011	Florasulam technical: an early life-stage toxicity test with the fathead minnow (Pimephales promelas) DAS Report No.: 101334 (Accession Number) 2007801	Y	DAS

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**
			GLP Yes Unpublished		
KCP 10.2/02	Hancock, G.A. Arnold, B.H., Carr, M.S., Najar, J.R.	2007	5-Hydroxy-florasulam: growth inhibition test with the aquatic plant duckweed, Lemna gibba DAS Report No.: 071032 (Accession Number) 245034 The Dow Chemical Company GLP Yes Unpublished	N	DAS
KCP 10.2/03	Hastings, M	1997	Preparation of Soil Extracts for Determination of the Algal Toxicity of XDE-570 Metabolites GHE-P-6616 DowElanco Europe GLP Yes Unpublished	N	DAS
KCP 10.2/04	-	1994	XDE-570 Herbicide: 8-day Acute Dietary LC50 Study in Japanese Quail DECO-ES-2797 GLP Yes Unpublished	Y	DAS
KCP 10.2/05	-	1994	XDE-570 Herbicide: 8-day Acute Dietary LC50 Study in Mallard Ducklings DECO-ES-2796 GLP Yes Unpublished	Y	DAS
KCP 10.2/06	Hughes, JS, Williams, TL, Conder, LA	1995	The Toxicity of XDE-570 to Skeletonema costatum Carolina Ecotox Inc DECO-ES-3021 GLP Yes	N	DAS

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**
			Unpublished		
KCP 10.2/07	Jenkins, CA	1997	Two Aqueous Soil Extracts Containing XDE-570 Metabolites: Growth Inhibition of Selenastrum capricornutum (Preliminary Toxicity Screen) Huntingdon Life GHE-T-837 GLP Yes Unpublished	N	DAS
KCP 10.2/08	Kelly, CR	1997	To Assess the Toxicity to the Sediment Dwelling Phase of the Midge, Chironomus riparius Huntingdon Life Sciences Ltd, GHE-T-838 GLP Yes Unpublished	N	DAS
KCP 10.2/09	-	1996	Evaluation of the Acute Toxicity of 5-hydroxy XDE-570 to the Rainbow Trout, Oncorhynchus mykiss Walbaum DECO-ES-3118 GLP Yes Unpublished	Y	DAS
KCP 10.2/10	Kirk, HD, Landre, AM, Hugo, JM	1996	Evaluation of the Acute Toxicity of 5-Hydroxy XDE-570 to the Daphnid, Daphnia magna Straus The Dow Chemical Company DECO-ES-3117 GLP Yes Unpublished	N	DAS
KCP 10.2/11	Kirk, HD, Landre, AM, Hugo, JM,	1996	Evaluation of the Chronic Toxicity of XDE-570 Herbicide to the Daphnid, Daphnia magna Straus The Dow Chemical Company	N	DAS

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
	Stahl, DC		DECO-ES-2944 GLP Yes Unpublished		
KCP 10.2/12	Kirk, HD, Landre, AM, Massaro, LM, Hugo, JM, Stahl, DC	1995	Evaluation of the Acute Toxicity of XDE-570 Herbicide to the Daphnid, Daphnia magna Straus. The Dow Chemical Company DECO-ES-2938 GLP Yes Unpublished	N	DAS
KCP 10.2/13	-	1995	Evaluation of the Acute Toxicity of XDE-570 Herbicide to the Rainbow Trout, Oncorhynchus mykiss Walbaum DECO-ES-2940 GLP Yes Unpublished	Y	DAS
KCP 10.2/14	-	1995	Evaluation of the Acute Toxicity of XDE-570 Herbicide to the Bluegill, Lepomis macrochirus Rafinesque. DECO-ES-2939 GLP Yes Unpublished	Y	DAS
KCP 10.2/15	Kirk, H.D. Gilles, M.M., Rick, D.L., McFadden, L.G.	2000	5-(Aminosulfonyl)-1H-1,2,4-triazole-3-carboxylic acid (florasulam M4 metabolite): growth inhibition test with the freshwater green alga, Selenastrum capricornutum DAS Report No.: 001019 Accession Number) 76271 (PRINTZ Toxicology & Environmental Research and Consulting The Dow Chemical Company GLP Yes Unpublished	N	DAS
KCP 10.2/16	Kirk, H.D.	2000	5-(Aminosulfonyl)-1H-1,2,4-triazole-3-carboxylic acid (florasulam M4 metabolite):	N	DAS

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**
	Gilles, M.M., Rick, D.L., McFadden, L.G.		growth inhibition test with the freshwater aquatic plant, duckweed, Lemna gibba L. G-3 DAS Report No.: 001021 (Accession Number) 76666 The Dow Chemical Company GLP Yes Unpublished		
KCP 10.2/17	Kirk, H.D.and Marino, T.A	1998	Toxicity of metabolites of XDE-570 to DaphniaMagna DAS Report No.: 981157 (Accession Number) 66206 The Toxicology Research Laboratory Health and Environmental Research Laboratories GLP Yes Unpublished	N	DAS
KCP 10.2/18		1995	Evaluation of the Prolonged (28-day) Toxicity of XDE-570 Herbicide to the Rainbow trout, Oncorhynchus mykiss walbaum DECO-ES-2973 GLP Yes Unpublished	N	DAS
KCP 10.2/19	Lührs, U.	2008	Acute toxicity (14 days) of ASTCA metabolite of florasulam to the earthworm Eisenia fetida in artificial soil DAS Report No.: 080037 (Accession Number) 259941 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP No Unpublished	N	DAS
KCP 10.2/20	Lührs, U.	2008	Effects of ASTCA metabolite of florasulam on reproduction and growth of earthworms Eisenia fetida in artificial soil	N	DAS

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
			DAS Report No.: 080038 (Accession Number) 2001599 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished		
KCP 10.2/21	Lührs, U.	2011	Effects of DFP-ASTCA metabolite of florasulam on reproduction of the Collembola Folsomia candida in artificial soil with 5% peat DAS Report No.: 101345 (Accession Number) 2009902 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DAS
KCP 10.2/22	Lührs, U.	2011	Effects of TSA metabolite of florasulam on reproduction of the Collembola Folsomia candida in artificial soil with 5% peat DAS Report No.: 110133 (Accession Number) 2009861 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DAS
KCP 10.2/23	Lührs, U.	2011	Effects of DFP-ASTCA metabolite of florasulam on reproduction of the predatory mite Hypoaspis aculeifer in artificial soil with 5% peat DAS Report No.: 101348 (Accession Number) 2009903 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP No Unpublished	N	DAS
KCP 10.2/24	Milazzo, DP, Hugo, JM,	1996	XDE-570 5-Hydroxy: The Toxicity to the Freshwater Green Alga. Selenastrum capricor-	N	DAS

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**
	McFadden, L		nutum Printz ES-3115 The Dow Chemical Company GLP Yew Unpublished		
KCP 10.2/25	Milazzo, DP, Martin, MD, Kirk, HD, Hugo, JM	1995	The Toxicity of XDE-570 Herbicide to the Aquatic Plant, Duckweed, Lemna gibba L. G-3 The Dow Chemical Company ES-2988 GLP Yes Unpublished	N	DAS
KCP 10.2/26	Milazzo, DP, Landre, AM, Rick, DL, Martin, MD	1995	XDE-570 Herbicide: The Toxicity to the Blue-Green Alga, Anabaena flos-aquae DECO-ES-3005 The Dow Chemical Company GLP Yes Unpublished	N	DAS
KCP 10.2/27	Milazzo, DP, Landre, AM, Hugo, JM, Martin, MD	1996	XDE-570 Herbicide: The Toxicity to the Freshwater Diatom, Navicula pelliculosa. DECO-ES-3045 The Dow Chemical Company GLP Yes Unpublished	N	DAS
KCP 10.2/28	Milazzo, DP, Humbert, LM, Hugo, JM, Martin, MD	1995	XDE-570 Herbicide: The Toxicity to the Green Alga, Selenastrum capricornutum Printz. DECO-ES-2946 The Dow Chemical Company GLP Yes Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/29	Nickless, A	1996	A Laboratory Study to Evaluate the Effects of XDE-570 on the Green Lacewing, Chrysoperla carnea Ecotox Limited GHE-P-6708 GLP Yes Unpublished	N	DAS
KCP 10.2/30	Palmer, SJ, Beavers, JB	1994	XDE-570: An Acute Contact Study with the Honey Bee DECO-ES-2819 Wildlife International Ltd, GLP Yes Unpublished	N	DAS
KCP 10.2/31	Paterson, E.	1999	Evaluation of the phytotoxicity of florasulam (based on OECD guideline 208) vegetative vigour terrestrial non target plants DAS Report No.: GHE-P-7957 (Accession Number) 69843 Dow AgroSciences Europe, Letcombe Laboratory GLP Yes Unpublished	N	DAS
KCP 10.2/32	Paterson, E.	2000	Evaluation of the phytotoxicity of florasulam (based on OECD guideline 208) seedling emergence test terrestrial non target plants DAS Report No.: GHE-P-8401 (Accession Number) 74191 Dow AgroSciences Europe, Letcombe Laboratory GLP Yes Unpublished	N	DAS
KCP 10.2/33	Porch, J.R., Kendall, T.Z.,	2011	TPSA metabolite of florasulam: a 96-hour toxicity test with the freshwater alga (Pseudo-	N	DAS

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**
	Krueger, H.O		kirchneriella subcapitata) DAS Report No.: 101350 (Accession Number) 2008420 Wildlife International, Ltd. GLP Yes Unpublished		
KCP 10.2/34	Porch, J.R., Kendall, T.Z., Krueger, H.O.	2011	Florasulam (TPSA metabolite): a 7-day staticrenewal toxicity test with duckweed (Lemna gibba G3) DAS Report No.: 101351 (Accession Number) 2008814 Wildlife International, Ltd. GLP Yes Unpublished	N	DAS
KCP 10.2/35	Rebstock, M	2011	DFP-ASTCA metabolite of florasulam (X12239339): growth inhibition test with the uni-cellular green alga, Pseudokirchneriella subcapitata DAS Report No.: 110046 (Accession Number) 2010085 ABC Laboratories, Inc. GLP Yes Unpublished	N	DAS
KCP 10.2/36	Rebstock, M.	2011	TSA metabolite of florasulam (X634074): growth inhibition test with the unicellular green alga, Pseudokirchneriella subcapitata DAS Report No.: 110043 (Accession Number) 2010859 ABC Laboratories, Inc. GLP Yes Unpublished	N	DAS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner
KCP 10.2/37	Rebstock, M.	2011	5-OH-ASTP metabolite of florasulam (X12251401): growth inhibition test with the uni-cellular green alga, Pseudokirchneriella subcapitata DAS Report No.: 110044 (Accession Number) 2010120 ABC Laboratories, Inc. GLP Yes Unpublished	N	DAS
KCP 10.2/38	Rebstock, M	2011	ASTP metabolite of florasulam (X516274): growth inhibition test with the unicellular green alga, Pseudokirchneriella subcapitata DAS Report No.: 110045 ABC Laboratories, Inc. GLP Yes Unpublished	N	DAS
KCP 10.2/39	Rebstock, M.	2011	DFP-ASTCA metabolite of florasulam (X12239339): growth inhibition test with the freshwater aquatic plant, duckweed, Lemna gibba DAS Report No.: 110039 (Accession Number) 2010084 ABC Laboratories, Inc. GLP Yes Unpublished	N	DAS
KCP 10.2/40	Rebstock, M.	2011	TSA metabolite of florasulam (X634074): growth inhibition test with the freshwater aquatic plant, duckweed, Lemna gibba DAS Report No.: 110040 (Accession Number) 2010161 ABC Laboratories, Inc. GLP Yes	N	DAS

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**
			Unpublished		
KCP 10.2/41	Rebstock, M.	2011	5-OH-ASTP metabolite of florasulam (X12251401): growth inhibition test with the freshwater aquatic plant, duckweed, Lemna gibba DAS Report No.: 110041 (Accession Number) 2010087 ABC Laboratories, Inc. GLP Yes Unpublished	N	DAS
KCP 10.2/42	Rebstock, M.	2011	ASTP Metabolite of Florasulam (X516274): Growth Inhibition Test with the Freshwater Aquatic Plant, Duckweed, Lemna gibba DAS Report No.: 110042 (Accession Number) 2010018 ABC Laboratories, Inc. GLP Yes Unpublished	N	DAS
KCP 10.2/43	-	1997	The Bioconcentration of XDE-570 by the Rainbow Trout, Oncorhychus mykiss Walbaum ES-3038 GLP Yes Unpublished	Y	DAS
KCP 10.2/44	Schaefer, E.C., Twilley, B.C.	2010	Florasulam technical: an activated sludge, respiration inhibition test DAS Report No.: 101336 (Accession Number) 2006412 Wildlife International, Ltd. GLP Yes Unpublished	N	DAS
KCP 10.2/45	Ward, T.J.,	1998	Toxicity of metabolites of XDE-570 to the earthworm, Eisenia foetida – Exposure-based	N	DAS

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
	Magazu, J.P., Boeri, R.L		screening investigation DAS Report No.: 980271 (Accession Number) 66907 T. R. Wilbury Laboratories, Inc. GLP Yes Unpublished		
KCP 10.2/46	Ward, TJ, Magazu, JP, Boen, RL	1995	XDE-570: Acute Toxicity to the Grass Shrimp, Palaemonetes pugio DECO-ES-2922 TR Wilbury Laboratories Inc GLP Yes Unpublished	N	DAS
KCP 10.2/47	Ward, TJ, Magazu, JP, Boeri, RL	1995	XDE-570: Acute Flow-Through Mollusc Shell Deposition Test DECO-ES-2923 TR Wilbury Laboratories Inc. GLP Yes Unpublished	N	DAS
KCP 10.2/48	Ward, TJ, Magazu, JP, Boen, RL	1995	Acute Toxicity to the Silverside, Menidia beryllina DECO-ES-2924 TR Wilbury Laboratories Inc GLP Yes Unpublished	N	DAS
KCP 10.4/01	Ward, TJ, Magazu, JP, Boeri, RL	1996	5-Hydroxy-XDE-570: Acute Toxicity to the Earthworm, Eisenia foetida DECO-ES-3120 TR Wilbury Laboratories Inc GLP Yes Unpublished	N	DAS
KCP 10.4/02	Witte, B.	2010	Effects of EF-1343 on reproduction and growth of earthworms Eisenia fetida in artificial	N	DAS

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**
			soil DAS Report No.: 101335 (Accession Number) 2006302 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished		
KCP 10.4/03	Witte, B.	2010	Effects of 5-hydroxy-florasulam on reproduction and growth of earthworms Eisenia fetida in artificial soil DAS Report No.: 101340 (Accession Number) 2006605 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DAS
KCP 10.4/04	Witte, B.	2011	Effects of DFP-ASTCA metabolite of florasulam on reproduction and growth of earth-worms Eisenia fetida in artificial soil with 5% peat DAS Report No.: 101341 (Accession Number) 2009374 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DAS
KCP 10.4/05	Witte, B.	2011	Effects of TSA metabolite of florasulam on reproduction and growth of earthworms Ei-senia fetida in artificial soil DAS Report No.: 110132 (Accession Number) 2009730 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DAS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP 10.4/06	Witte, B.	2010	Effects of 5-hydroxy-florasulam on reproduction of the Collembola Folsomia candida in artificial soil with 5% peat DAS Report No.: 101344 (Accession Number) 2011185 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DAS
KCP 10.4/07	Witte, B.	2010	Effects of ASTCA metabolite of florasulam on reproduction of the Collembola Folsomia candida in artificial soil with 5% peat DAS Report No.: 101346 (Accession Number) 2006243 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpulished	N	DAS
KCP 10.4/08	Witte, B.	2010	Effects of 5-hydroxy-florasulam on reproduction of the predatory mite Hypoaspis aculeifer in artificial soil with 5% peat DAS Report No.: 101347 (Accession Number) 2006681 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DAS
KCP 10.4/09	Witte, B.	2010	Effects of ASTCA metabolite of florasulam on reproduction of the predatory mite Hypoaspis aculeifer in artificial soil with 5% peat DAS Report No.: 101349 (Accession Number) 2006113 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DAS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner
KCP 10.4/10	Austin, HM	1996	A Laboratory Study to Evaluate the Effects of XDE-570 on the Carabid Beetle Poecilus cupreus GHE-P-6709 Ecotox Limited GLP Yes Unpublished	N	DAS
KCP 10.4/11	Austin, HM	1997	A Laboratory Study to Evaluate the Effects of XDE-570 on the Predatory Mite, Typh-lodromus pyri GHE-P-6706 Ecotox Limited GLP Yes Unpublished	N	DAS
KCP 10.4/12	Austin, HM	1997	A Laboratory Study to Evaluate the Effects of XDE-570 on the Parasitic Wasp, Aphidius rhopalosiphi GHE-P-6707 Ecotox Limited GLP Yes Unpublished	N	DAS
KCP 10.4/13	Beech, P	1996	Determination of Topical and Oral LD50s for EF-1343 (a 50 g/1 SC Formulation of XDE-570) agamst the Honey Bee, Apis mellifera GHE-P-5251 Agrochemical Evaluation Unit, Department of Biology, The University, Southampton GLP Yes Unpublished	N	DAS
KCP 10.4/14	Ehr, RJ, Alexander, AL	1997	The Activity of DE-570 in Herbicide, Insecticide and Fungicide Screening Tests and the Herbicidal Activity of DE-570 Soil Metabolites DowElanco	N	DAS

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**
			DERBI # 60600 GLP No Unpublished		
KCP 10.4/15	Feil, N.	2010	Effects of EF-1343 on the Activity of the Soil Microflora in the Laboratory DAS Report No.: 101332 (Accession Number) 2006493 Institut fir Biologische Analytik, und Consulting IBACON GmbH GLP Yes Unpublished	N	DAS
KCP 10.4/16		2010	EF-1343: an Acute Ooral Toxicity Study with the Mallard. DAS Report No.: 101331 (Accession Number) 2006117 GLP Yes Unpublished	N	DAS
KCP 10.4/17		1996	Acute Toxicity to Rainbow Trout 96/DES345/0351 GHE-T-654 GLP Yes Unpublished	N	DAS
KCP 10.4/18	Jenkins, CA	1996	Acute Toxicity to Daphnia magna 96/DES346/0352 GHE-T-655 Huntingdon Life Sciences Ltd GLP Yes Unpublished	N	DAS
KCP 10.4/19	Jenkins, CA	1996	Determination of 72-hour EC50 to Selenastrum capricornutum 96/DES366/0353	N	DAS

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
			GHE-T-656 Huntingdon Life Sciences Ltd GLP Yes Unpublished		
KCP 10.4/20	Kirk, H.D. Gilles, M.M., Hugo, J.M., McFadden, L.G	2000	Effect of EF-1343 (XDE-570 50 SC) on the growth of the freshwater aquatic plant, duck-weed, Lemna gibba L. G-3 DAS Report No.: 991190 (Accession Number) 73834 Toxicology & Environmental Research and Consulting, The Dow Chemical Company GLP Yes Unpublished	N	DAS
KCP 10.4/21	Kleiner, R, Haussmann, Brenner, P	1996	Testing Toxicity to Honeybee (Apis mellifera L.) According to BBA Guideline VI, 23-1 (1991) GHE-T-833 Biochem, D-76185 Karlsruhe, Germany GLP Yes Unpublished	N	DAS
KCP 10.4/22	Miihlen, Ackemeier, Rieger	1996	Assessment of Side Effects of EF-1343 on Honey Bees (Apis mellifera L.) Laboratory Test IPS AB D-48135 Munster, Germany GHE-T-835 GLP Yes Unpublished	N	DAS
KCP 10.5/01	Nengel, S.	1996	Assessment of Side Effects of EF-1343 to the Honey Bee, Apis mellifera L. in the La-boratory Following the EPPO Guideline No. 107 GHE-T-834	N	DAS

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**
			GAB, D75223 Niefern-Oschelbronn, Germany GLP Yes Unpublished		
KCP 10.5/02	Nickless, A	1996	A Laboratory Study to Evaluate the Effects of XDE-570 on the Green Lacewing, Chrysoperla Carnea GHE-P-6708 Ecotox Limited GLP Yes Unpublished	N	DAS
KCP 10.4/01	Rees, PB	1996	cute Toxicity Study in the Earthworm GHE-T-671 Huntingdon Life Sciences Ltd GLP Yes Unpublished	N	DAS
KCP 10.1/06	xxxxxxxxx	1984	Acute oral toxicity study with M&B 38,544 technical in bobwhite quail R006408 GLP Unpublished	Y	BCS
KCP 10.1/07	xxxxxxx	1984	The acute oral toxicity (LD50) of M&B38544 to the mallard duck R006406 GLP Unpublished	Y	BCS
KCP 10.1/08	xxxxxxxx	1992	Diflufenican Reproduction in the bobwhite quail R015190 GLP Unpublished	Y	BCS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	Owner
KCP 10.2/39	xxxxxxxxx	1998	Diflufenican Acute toxicity (96 hours) to rainbow trout (Oncorhynchus mykiss) under static conditions R006584 GLP Unpublished	Y	BCS
KCP 10.2/40	xxxxxxxxx	1996	MB38181 Cute toxicity (96 hours) to rainbow trout (Oncorhynchus mykiss) under static conditions R006576 GLP Unpublished	Y	BCS
KCP 10.2/41	xxxxxxxxx	1998	Diflufenican Acute toxicity (96 hours) to common carp (Cyprinus carpio) under static conditions R006586 GLP Unpublished	Y	BCS
KCP 10.2/42	xxxxxxxxxxx	1997	Diflufenican Fish, juvenile growth test (28 days) under flow-through conditions R005623 GLP Unpublished	Y	BCS
KCP 10.2/42	xxxxxxxxxx	1998	Diflufenican – Early life-stage toxicity test with feathed minnow (Pimephales promelas) R005752 GLP Unpublished	Y	BCS
KCP 10.2/43	xxxxxxxxxxx	1998	(14C)-Diflufenican Bioaccumulation and metabolism in rainbow trout R006596 Yes Unpublished	Y	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/44	Odin-Feurtet, M.	1999	Diflufenican Acute toxicity (48 hours) to daphnids (Daphnia magna) under static conditions R005989 Rhone-Poulenc; Rhone-Poulenc Agro, Sphia Antipolis; Centre de Recherche, Rhone-Poulenc Agro, Lyon GLP Unpublished	N	BCS
KCP 10.2/45	Suteau, P.	1996	MB38181 Cute toxicity (48 hours) to daphnids (Daphnia magna) under static conditions R006574 Rhone-Poulenc; Rhone-Poulenc Agro, Sphia Antipolis; Centre de Recherche, Rhone-Poulenc Agro, Lyon GLP Unpublished	N	BCS
KCP 10.2/46	Douglas, M.T. Handley, J.W.	1987	Diflufenican: The acute toxicity of diflufenican soil metabolite no.2. M&B 43,625 to Daphnia magna R008232 Rhone-Poulenc, Huntingdon Research Centre Ltd., Huntingdon, GBR May & Baker Ltd., Dagenham, Exxec, GBR GLP Unpublished	N	BCS
KCP 10.2/47	Putt, A.E.	2000	The chronic toxicity to Daphnia magna under static-renewal conditions Diflufenican Generated by: Springborn Laboratories, Inc., Wareham, USA; Rhone-Poulenc Agro, Sophia Antipolis, FRA; Document No: C009776 GLP / GEP Yes Unpublished	N	BCS
KCP 10.2/48	Odin-Feurtet M.	1997	Diflufenican Freshwater algal growth inhibition study (72 hours) Selenastrum capricornu-	N	BCS

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
			tum Generated by: Rhone-Poulenc; Rhone-Poulenc Agrochimie, Sophia Antipolis; Centre de Recherche Rhone-Poulenc Agro; Document No: R005609 GLP / GEP Yes Unpublished		
KCP 10.2/49	Hoberg J.R.	1998	Diflufenican - Toxicity to the freshwater blue-green alga, Microcystis aeruginosa Generated by: Rhone-Poulenc; Springborn Laboratories, Inc., Wareham, USA; Rhone-Poulenc Agro, Sophia Antipolis, FRA; Document No: R008300 GLP / GEP Yes unpublished	N	BCS
KCP 10.2/50	Hoberg J.R.	1998	Diflufenican - Toxicity to the freshwater blue-green alga, Anabaena flos-aquae Generated by: Rhone-Poulenc; Springborn Laboratories, Inc., Wareham, USA; Rhone-Poulenc Agrochimie, Sophia Antipolis, FRA; Rhone-Poulenc Secteur Agro; Document No: R008296 GLP / GEP Yes unpublished	N	BCS
KCP 10.2/50	Hoberg J.R.	1997	Diflufenican technical - Toxicity to the freshwater diatom, Navicula pelliculosa Generated by: Rhone-Poulenc; Springborn Laboratories, Inc., Wareham, USA; Rhone-Poulenc Secteur Agro, FRA; Document No: R008292 GLP / GEP Yes unpublished	N	BCS
KCP 10.2/51	Odin-Feurtet M.	1998	Diflufenican: Freshwater algal growth inhibition study (72 hours) Scenedesmus subspicatus	N	BCS

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**
			Generated by: Rhone-Poulenc; Rhone-Poulenc Agrochimie, Sophia Antipolis, FRA; Rhone-Poulenc Secteur Agro, Lyon, France; Document No: R015235 GLP / GEP Yes unpublished		
KCP 10.2/52	Odin-Feurtet M.	1998	Diflufenican: Freshwater algal growth inhibition study in the sediment water system (Scenedesmus subspicatus) Generated by: Rhone-Poulenc; Rhone-Poulenc Agrochimie, Sophia Antipolis; Centre de Recherche Rhone-Poulenc Agro, Lyon; Document No: R006582 GLP / GEP Yes unpublished	N	BCS
KCP 10.2/53	Odin-Feurtet M.	1998	Diflufenican Freshwater algal growth inhibition study in a sediment water system (Scenedesmus subspicatus) Generated by: Rhone-Poulenc; Rhone-Poulenc Agro, Sophia Antipolis; Centre de Recher-che Rhone-Poulenc Agro; Document No: R006589 GLP / GEP Yes unpublished	N	BCS
KCP 10.2/54	Odin-Feurtet M.	1998	Diflufenican Freshwater algal growth inhibition study and recovery phase Scenedesmus subspicatus Generated by: Rhone-Poulenc; Rhone-Poulenc Agrochimie, Sophia Antipolis, FRA; Centre de Recherche Rhone-Poulenc Secteur Agro; Rhone-Poulenc Agro, Lyon, FRA;	N	BCS

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
			W.E.Z. Document No: R008294 GLP / GEP Yes unpublished		
KCP 10.2/55	Suteau P.	1996	MB38181 Freshwater algal growth inhibition study (72 hours) Scenedesmus subspicatus Generated by: Rhone-Poulenc; Rhone-Poulenc Agrochimie, Sophia Antipolis; Centre de Recherche Rhone-Poulenc Secteur Agro; Document No: R006578 GLP / GEP Yes unpublished	N	BCS
KCP 10.2/56	Mead C., Mullee D.M.	2001	MB 43625: Algal inhibition test Generated by: Aventis CropScience GmbH, DEU; Ecotoxicology, Frankfurt Safepharm Laboratories Limited, Derby GBR; Document No: C021270 GLP / GEP Yes unpublished	N	BCS
KCP 10.2/57	Desjardins D., Kendall T.Z., Krueger H.O.	2002	A 72-hour toxicity test with the freshwater alga (Selenastrum capricornutum) Code: AE 0592370 (MB 44085) Generated by: Wildlife International Ltd.; BCS GmbH, DEU; Document No: C025824 GLP / GEP unpublished	N	BCS
KCP 10.2/58	Desjardins D., Kendall T.Z., Krueger H.O.	2002	A 72-hour toxicity test with the freshwater alga (Selenastrum capricornutum) Code: AE C522392 (MB40401) Generated by: Wildlife International Ltd.; BCS GmbH, DEU; Document No: C028238 GLP / GEP Yes	N	BCS

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**
			unpublished		
KCP 10.2/59	McElligott A.	1996	Diflufenican - Toxicity to the sediment dwelling chironomid larvae (Chironomus riparius) under static conditions - 28 days. Generated by: Rhone-Poulenc; Rhone-Poulenc Agrochimie, Sophia Antipolis, FRA; Centre de Recherche Rhone-Poulenc Agro GmbH, Koeln, Germany; Rhone-Poulenc Secteur Agro; Document No: R008288 GLP / GEP Yes unpublished	N	BCS
KCP 10.2/60	Krueger H.O., Platania S., Kendall T.Z., Jaber M.	2002	AE F088657 (diflufenican): A prolonged sediment toxicity test with Chironomus riparius using spiked sediment Generated by: BCS GmbH, DEU; Ecotoxicology, Frankfurt Wildlife International Ltd., Maryland, USA; Document No: C026642 GLP / GEP Yes unpublished	N	BCS
KCP 10.2/61	Krueger H.O., Thomas S., Kendall T.Z.	2003	AE C522392 (MB 40401): A prolonged sediment toxicity test with Chironomus riparius using spiked sediment Generated by: BCS GmbH, DEU; Ecotoxicology, Frankfurt Ecotoxicology, Frankfurt; Ecotoxicology, Frankfurt Wildlife International Ltd., Maryland, USA; Document No: C032889 GLP / GEP Yes unpublished	N	BCS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	Owner
KCP 10.2/62	Hoberg J.R.	1998	Diflufenican - Toxicity to the duckweed, Lemna gibba Generated by: Rhone-Poulenc; Springborn Laboratories, Inc., Wareham, USA; Rhone-Poulenc Agro, Sophia Antipolis, FRA; Document No: R008298 GLP / GEP Yes unpublished	N	BCS
KCP 10.3/03	Schmitzer S.	1998	Laboratory testing for toxicity (acute contact and oral LD50) of diflufenican on honey bees (Apis mellifera L.), (Hymenoptera, Apidae) Generated by: Rhone-Poulenc; IBACON GmbH, Rossdorf, DEU; Inst. f. Biologische Analytik und Consulting Rhone-Poulenc Agro, Sophia Antipolis, FRA; Ecotoxicology Department Document No: R008302 GLP / GEP Yes unpublished	N	BCS
KCP 10.4/02	Odin-Feurtet M.	1997	Diflufenican: Acute toxicity (14 day) to earthworms (Eisenia foetida) Artificial soil method Generated by: Rhone-Poulenc; Rhone-Poulenc Agro, Sophia Antipolis; Centre de Recherche Rhone-Poulenc Agro; Document No: R005596 GLP / GEP Yes unpublished	N	BCS
KCP 10.4/03	Staebler D.	2001	Acute toxicity of MB 38181 on earthworms, Eisenia foetida using an artificial soil test Generated by: Aventis CropScience GmbH, DEU; Arbeitsgemeinsch. GAB GmbH & IFU GmbH, DEU; Document No: C021267 GLP / GEP Yes unpublished	N	BCS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP 10.4/04	Wetton P.M.	2001	MB43625: Acute toxicity to earthworms (Eisenia foetida) Generated by: Aventis CropScience GmbH, DEU; Ecotoxicology, Frankfurt Safepharm Laboratories Limited, Derby GBR; Document No: C015390 GLP / GEP Yes	N	BCS
KCP 10.4/05	Lührs U.	1999	Effects of diflufenican on reproduction and growth of earthworms Eisenia fetida (Savigny 1826) in artificial soil. Generated by: Rhone-Poulenc; IBACON GmbH, Rossdorf, DEU; Rhone-Poulenc Secteur Agro; Document No: R005877 GLP / GEP Yes unpublished	N	BCS
KCP 10.5/02	Schaefer E.C., Siddiqui A.I.	2003	AE F088657 (dilfufenican): Soil microorganisms: Nitrogen transformation test Generated by: BCS GmbH, DEU; Ecotoxicology, Frankfurt Wildlife International Ltd., Maryland, USA; Document No: C031491 GLP / GEP Yes unpublished	N	BCS
KCP 10.5/03	Lamb L.S., Luscombe B.M.	1985	Diflufenican: Effects on soilrespiration and nitrification Generated by: Rhone-Poulenc; May & Baker Ltd., England; Document No: R008108 GLP / GEP unpublished	N	BCS
KCP 10.5/04	Koelzer U.	2002	Assessment of the side effects of MB 38181 on the activity of the soil microflora Generated by: Aventis CropScience GmbH, DEU; Arbeitsgemeinsch. GAB GmbH & IFU GmbH, DEU; Document No: C021268	N	BCS

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
			GLP / GEP Yes unpublished		
KCP 10.5/05	Koelzer U.	2002	Assessment of the side effects of MB 43625 on the activity of the soil microflora Generated by: Aventis CropScience GmbH, DEU; Arbeitsgemeinsch. GAB GmbH & IFU GmbH, DEU; Document No: C021269 GLP / GEP Yes unpublished	N	BCS
KCP 10.5/06	Schaefer E.C., Siddiqui A.I.	2003	AE F088657 (dilfufenican): Soil microorganisms: Carbon transformation test Generated by: BCS GmbH, DEU; Ecotoxicology, Frankfurt Wildlife International Ltd., Maryland, USA; Document No: C031490 GLP / GEP Yes Unpublished	N	BCS
KCP 10.1/09	xxxxxxxxxxx	1992	Technical FOE 5043: An acute oral LD50 with bobwhite quail. Source: Miles Inc. Bayer AG, Report No. 102642 GLP, Unpublished	Y	Bayer
KCP 10.1/10	xxxxxxxxxxxxx	1993	FOE 5043 technical: A subacute dietary LC50 with mallard duck. Source: Miles Inc. Bayer AG, Report No. 103814 GLP, Unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1/11	xxxxxxxxxxxxxxxxxxxxx	1994	FOE 5043 technical: A subacute dietary LC50 with northern bobwhite. Source: Miles Inc. Bayer AG, Report No. 106583 GLP, Unpublished	Y	Bayer
KCP 10.1/12	xxxxxxxxxxxxxxx	1994	Effects of a subchronic dietary exposure of FOE 5043 techn. on bobwhite quail including effects on reproduction and health. Bayer AG, Report No. SXR/REP 03 GLP, Unpublished	Y	Bayer
KCP 10.1/13	xxxxxxxxxxxxxxxxx	1994	Effect of technical FOE 5043 on mallard reproduction. Source: Miles Inc. Bayer AG, Report No. 106594 GLP, Unpublished	Y	Bayer
KCP 10.2/63	xxxxxxxxxxxxxxx	1995	Acute toxicity of FOE 5043 technical to the rainbow trout (*Oncorhynchus mykiss*) under static-renewal conditions. Source: Mobay Corp. Bayer AG, Report No. 106673 GLP, Unpublished	Y	Bayer
KCP 10.2/64	xxxxxxxxxxxxxxxxx	1995	Acute toxicity of FOE 5043 technical to the rainbow trout (*Oncorhynchus mykiss*) under static-renewal conditions. Source: Mobay Corp. Bayer AG, Report No. 106673 GLP, Unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/65	xxxxxxxxxx	1995	FOE 5043 sulfonic acid - Acute toxicity (96 hours) to rainbow trout (*Oncorhynchus mykiss*) in a static test. Bayer AG, Report No. DOM 95031 GLP, Unpublished	Y	Bayer
KCP 10.2/66	xxxxxxxxxxxxxxx	1995	Early life stage toxicity of FOE 5043 technical to the rainbow trout (*Oncorhynchus mykiss*) under flow-through conditions. Source: Miles Inc. Bayer AG, Report No. 106978 GLP, Unpublished	Y	Bayer
KCP 10.2/67	xxxxxxxxxx	1994	Uptake, depuration and bioconcentration of ^{14}C-FOE 5043 technical by bluegill (*Lepomis macrochirus*) under flow-through conditions. Source: Miles Inc. Bayer AG, Report No. 106760 GLP, Unpublished	Y	Bayer
KCP 10.2/68	Gagliano G.G Bowers,L.M	1994	Chronic toxicity of FOE 5043 technical to the water flea (*Daphnia magna*) under static renewal conditions. Source: Miles Inc. Bayer AG, Report No. 106762 GLP, Unpublished	N	Bayer
KCP 10.2/69	Anderson, J.P.E.	1995	Range Finding Test: Influence of FOE 5043 T on the Growth of the Green Alga, Selenastrum capricornutum Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: AJO/130095 Date: April 5, 1995	N	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**
			GLP not published		
KCP 10.2/70	Anderson, J.P.E.	1997	Growth of the green alga, *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*), during and after exposure to high concentrations of FOE 5043 Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: AJO/157097 Date: July 14,1997 GLP not published	N	Bayer
KCP 10.2/71	Dorgerloh, M.	1998	FOE 5043-Methylsulfide -Influence on the Growth of the Green Alga, *Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum)* Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: DOM 98011 Date: June 16, 1998 GLP not published	N	Bayer
KCP 10.2/72	Dorgerloh, M.	1998	Toxicity of 14C-FOE 5043 to the Green Alga *Selenastrum capricornutum* Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: DOM 98092 Date: September 9, 1998 originally reported as: Bowers, L.M.: Toxicity of 14C-FOE 5043 to the Green Alga *Selenastrum capricornutum.* Source: Bayer Corp., Kansas, USA; Bayer AG, Report No.: 107114, Date: October 19, 1995 GLP	N	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
			not published		
KCP 10.2/73	Hughes, J.S. Alexander, M.M.	1993	Acute toxicity of FOE 5043 (technical) to *Anabaena flos-aquae* Source: Malcolm Pirnie Inc., Tarrytown, NY 10591, USA Generated by: Miles Inc., Submitted by: Bayer AG, Bayer file No.: 105199 Date: December 17, 1993 GLP not published	N	Bayer
KCP 10.2/74	Dorgerloh, M.	1998	Acute toxicity of FOE 5043 (technical) to *Lemna gibba* G3 Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: DOM 98091 Date: September 1, 1998 GLP not published originally reported as: Hughes, J.S.; Alexander, M. M.: Acute Toxicity of FOE 5043 (technical) to *Lemna gibba* G3; Source: Miles, Kansas; Bayer AG, Report No.: 105198 Date: December 17, 1993	N	Bayer
KCP 10.2/75	Dorgerloh, M.	1995	FOE 5043-sulfonic acid - Toxicity (14 days) to *Lemna gibba* G3. Bayer AG, Report No. DOM 95072 GLP, Unpublished	N	Bayer
KCP 10.2/76	Foekema E.M. and Jak R.G.,	1999	The fate and biological effects of Flufenacet WG 60 in aquatic indoor microcosms Bayer AG, Report No. TNO-MEP – R 99/423 GLP Unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3/04	Mayer, D.F	1994	FOE 5043 / honey bees acute toxicity. Source: Washington State University Bayer AG, Report No. 106765 GLP, Unpublished	N	Bayer
KCP 10.3/05	Tornier, I.	1995	Results of the screening test on the honey bee *Apis mellifera* L. test substance: FOE 5043 (techn.). Source: GAB Biotechnologie GmbH Bayer AG, Report No. B-958264 Not GLP, Unpublished	N	Bayer
KCP 10.3/06	Nengel.S	1995	Assessment of side effects of FOE 5043 (techn.) to the honey bee, *Apis mellifera* L. in the laboratory following the EPPO Guideline No. 170. Source: GAB/IFU, Niedern Bayer AG, Report No. 94137/01-BLEU GLP, Unpublished	N	Bayer
KCP 10.4/06	Nienstedt, K.M.	1999	FOE 5043-Oxalate: A 14-day acute toxicity test with the earthworm (Eisenia fetida) Source: Springborn Laboratories, Horn, Switzerland Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 1022.006.630 Date: July 19, 1999 GLP not published	N	Bayer
KCP 10.4/07	Nienstedt, K.M.	1999	FOE 5043-Sulfonic acid Na-salt: A 14-day acute toxicity test with the earthworm (Eisenia fetida)	N	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
			Source: Springborn Laboratories, Horn, Switzerland Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 99-005-1022 Date: July 15, 1999 GLP not published		

Appendix 2 Detailed evaluation of the new studies

Review Comment:

In order to provide sufficient details, where appropriate, the study summaries have been adapted by the zRMS from the full study reports provided in the dossier. zRMS text is highlighted in grey. The comments on individual studies are provided in grey comment boxes.

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

2 KCP 10.1.1.2 Higher tier data on birds

A.2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.1.1 KCP 10.1.2.1 Acute oral toxicity to mammals

Summarised in Section 6 (Mammalian Toxicology)

A 2.2 KCP 10.2 Effects on aquatic organisms

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

A 2.2.1.1.1 Daphnia magna

Comments of zRMS:	The study was conducted according to OECD guideline 202 and principles of GLP. In the study, one deviation occurred from the OECD Test Guideline No. 202 (2004) 'Daphnia sp., Acute Immobilisation'/ EU method C.2: Acute Toxicity for Daphnia magna'. The temperature exceed 2°C by 0.1°C during exposure of the definitive test. The deviation did not have impact on the results generated in the study. In the definitive test all the validity criteria were met. The analytical measurements demonstrated that the test item concentrations of f florasulam, flufenacet and diflufenican throughout the test was within 80-120% of nominal and for this reason endpoints are expressed as nominal concentrations. The study is reliable and suitable for the risk assessment. EC_{50}/48 h values is > 100 mg product /L NOEC= ≥ 100 mg product/L

Reference: KCP 10.2/01

Report CHR/H/FDF 574 SC Daphnia magna, Acute Immobilisation Test.; E.

	Nierzędska, 2021, Study code: W-65-20, Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the OECD Guideline No. 202 (2004)
Deviations:	Yes~~No~~
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	CHR/H/FDF 574 SC; batch no. 042020, content of penoxulam is 38.7 g/L, diflufenican is 259.0 g/L and flufenacet is 318.8 g/L; production date: April 01, 2020, expiry date: April 01, 2022.
Test organism:	*Daphnia magna* Straus (< 24 h old at exposure initiation); not first brood progeny; neonates collected from a laboratory culture cultivated at the Łukasiewicz Research Network Institute of Industrial Organic Chemistry Branch Pszczyna.
Test design:	*Static test (48 h of exposure); 4 replicates per test item concentration and the control; 5 Daphnia magna in each replicate.*
Nominal test item concentrations:	*100 mg/L plus the control.*
Test conditions:	*Temperature: 19.5 – 21.6°C; pH of the control: 7.54 – 7.83; dissolved oxygen concentration in the control: 8.1 – 8.9 mg/L; daily cycle 16 h light : 8 h dark; fluorescent light source; no feeding; no aeration; medium: Elendt M7.*
Chemical determinations:	*Concentrations of florasulam, flufenacet and diflufenican weredetermined with a validated liquid chromatographic method with DAD detection..*
Endpoint values:	*EC50/48 h*

Summary
Immobilisation of Daphnia magna exposed to the test item, CHR/H/FDF 574 SC, was investigated during a 48-hour static test. The test was performed in glass beakers of 150 mL capacity, containing 100 mL of either the test item concentration or the control per replicate. The definitive test was performed with one test item concentration of 100 mg/L plus the control (limit test).

Analytical measurements
The concentrations of florasulam, flufenacet and diflufenican were determined using a validated liquid chromatographic method with DAD detection.
Samples of the test item concentration and the control were analysed at exposure initiation and at exposure termination. In samples at exposure initiation, the determined concentration of florasulam was 96.5% of the nominal concentration. The determined concentration of flufenacet was 95.6% of the nominal concentration. The determined concentration of diflufenican was 90.7% of the nominal concentration. The results confirm that the test item concentration was prepared correctly. In samples at exposure termina-

tion, the determined concentration of florasulam was 97.6% of the nominal concentration. The determined concentration of flufenacet was 96.0% of the nominal concentration. The determined concentration of diflufenican was 89.6% of the nominal concentration. Therefore, the concentrations of active substances were stable under test conditions.

Table 1. Concentration and stability of florasulam, definitive test

Nominal test item concentration [mg/L]	Nominal concentration of florasulam in the test item [mg/L]	Average determined concentration of florasulam (n=3) in samples collected [mg/L]			
		at exposure initiation	[%] of nominal concentration	at exposure termination	[%] of nominal concentration
Control	---	<LoD	---	<LoD	---
100	1.010	0.975	96.5	0.986	97.6

LoQ = 0.01 mg/L
LoD = 0.003 mg/L
--- no value

Table 2. Concentration and stability of flufenacet, definitive test

Nominal test item concentration [mg/L]	Nominal concentration of flufenacet in the test item [mg/L]	Average determined concentration of flufenacet (n=3) in samples collected [mg/L]			
		at exposure initiation	[%] of nominal concentration	at exposure termination	[%] of nominal concentration
Control	---	<LoD	---	<LoD	---
100	25.260	24.153	95.6	24.255	96.0

LoQ = 0.01 mg/L
LoD = 0.003 mg/L
--- no value

Table 3. Concentration and stability of diflufenican, definitive test

Nominal test item concentration [mg/L]	Nominal concentration of diflufenican in the test item [mg/L]	Average determined concentration of diflufenican (n=3) in samples collected [mg/L]			
		at exposure initiation	[%] of nominal concentration	at exposure termination	[%] of nominal concentration
Control	---	<LoD	---	<LoD	---
100	20.520	18.611	90.7	18.385	89.6

LoQ = 0.01 mg/L
LoD = 0.003 mg/L
--- no value

The endpoint values were determined based on nominal test item concentration..

Results and discussion:

Oxygen concentrations ans pH values are presented in table below.

Table 4. pH values and dissolved oxygen concentrations, definitive test

Nominal test item concentration [mg/L]	pH values		Dissolved oxygen concentrations [mg/L]	
	at exposure initiation#	at exposure termination*	at exposure initiation#	at exposure termination*
Control	7.54	7.83	8.9	8.1
100	7.47	7.61	9.0	8.0

#- pH values and dissolved oxygen concentrations measured in samples before split up into replicates
*- pH values and dissolved oxygen concentrations measured in samples of pooled replicates

Immobilisation of Daphnia magna exposed to the test item, CHR/H/FDF 574 SC, was investigated during a 48-hour static test. The test was performed in glass beakers of 150 mL capacity, containing 100 mL of either the test item concentration or the control per replicate. The definitive test was performed with one test item concentration of 100 mg/L plus the control (limit test).
The Daphnia magna were observed for immobilisation after 24 h and 48 h of exposure. The Daphnia magna should be considered immobile if they showed no ability to swim within 15 seconds after gentle swirling of the test vessel. In the test item concentration of 100 mg/L and the control no immobilisation of Daphnia
magna was observed during the exposure.

Immobilization

Table 5. Immobilisation of Daphnia magna, definitive test

Nominal test item concentration [mg/L]	Number of *Daphnia magna*	Number of immobilised *Daphnia magna*								Total of immobilised *Daphnia magna* [%]	
		24 h				48 h					
		Replicates									
		A	B	C	D	A	B	C	D	24 h	48 h
Control	20	0	0	0	0	0	0	0	0	0	0
100	20	0	0	0	0	0	0	0	0	0	0

Results:
The endpoint values based on nominal test item concentration are given below:
The EC_{50}/48 h is higher than 100 mg/L.
The LOEC/48 h is higher than 100 mg/L
The NOEC/48 h is higher than or equal to 100 mg/L

TEST VALIDITY CRITERIA
In the definitive test the validity criteria were met according to OECD Guideline No. 202 (2004):
– the percentage of immobilisation of Daphnia magna in the control was 0% (criterion: not more than 10%),
– the dissolved oxygen concentrations in the test vessels were within the range of 8.0 – 9.0 mg/L (criterion: not less than 3 mg/L).

A 2.2.1.1.2 Pseudokirchneriella subcapitata

Comments of zRMS:	The study was conducted according to OECD guideline 201 and principles of GLP. No deviations were noted during the study. In the definitive test all the validity criteria were met. The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason end-points are expressed as nominal concentrations. The study is reliable and suitable for the risk assessment. Following endpoints are relevant for risk assessment purposes: The concentration causing a 50% inhibition of the growth rate of *Raphidocelis subcapitata:* The ErC_{50}/72 h value is 0.75 µg/L NOEC of *Raphidocelis subcapitata:* NOEC = 0.1 µg test item/L

Reference:	KCP 10.2/05
Report	CHR/H/FDF 574 SC Raphidocelis subcapitata SAG 61.81 (formerly Pseudokirchneriella subcapitata), Growth inhibition test.; E. Nierzędska, 2021, Study code: W-68-20, Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxico-logical Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the OECD Guideline No. 201 (2006)/EU method C.3.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Materials and methods
Test item: CHR/H/FDF 574 SC; batch no. 052020, the (determined) content of florasulam: 12.2 g/L; the (determined) content of flufenacet: 304.7 g/L; the (determined) content of diflufenican: 247.5 g/L, density at 20°C: 1.2061 g/cm3; manufacturing date: April 01, 2020, expiry date: April 01, 2022.

Test system: The unicellular freshwater green algae, Raphidocelis subcapitata (formerly Pseudokirchneriella subcapitata (Reinsch) Korshikov (Selenastrum capricornutum Prinz.) SAG 61.81 cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Aquatic Organisms Toxicology. The culture was obtained from the Algal Collection at the University of Göttingen,Germany.

Test design: 72 hours of exposure; three replicates per each test item concentration; six replicates per the control; initial algael cell density: 1 x 104 cells/mL.

Nominal test item concentrations:
10, 3.13, 0.98, 0.31, 0.10 µg/L plus the control.
Test conditions: Temperature: 21.7 – 23.0°C; pH of the control: 7.69 – 8.43;
mean light intensity: 6400 - 6928 lux; constant illumination and shaking; medium: AAP.

Chemical determinations:
The concentrations of florasulam, flufenacet, and diflufenican were determined with the validated high performance liquid chromatographic method with MS/MS detection.

Statistics: Probit method calculations and analyses by: Shapiro-Wilk's Test on Normal Distribution,

Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, Step-down Jonckheere-Terpsta Test Procedure.

Endpoint values: ErC50/72 h, EyC50/72 h, NOEC/72 h, LOEC/72 h.

Results and discussion:

The growth of the algae Raphidocelis subcapitata SAG 61.81 (formerly Pseudokirchneriella subcapitata) exposed to the test item, CHR/H/FDF 574 SC was investigated during a 72-hour test. The test was performed in glass flasks with a capacity of 250 mL containing 100 mL of either the test item concentration, or the control, per replicate. The initial density of the algae was 1 x 104 cells/mL. The definitive test was performed using the following test item concentrations: 10, 3.13, 0.98, 0.31, 0.10 µg/L (with a spacing factor of 3.2) plus the control.
The number of algae cells was determined with an indirect method, which involves a spectrophotometric measurement of the absorbance of algal suspension at 670 nm and converting its value into the number of cells using a standard curve. The absorbance for each treatment was measured after 24, 48 and 72 hours of exposure. The microscopic observations of algae cells morphology were performed at exposure termination.
In the test item concentrations of 0.10 and 0.31 µg/L no differences in shape, size and colour of algal cells were reported as compared to the algae cells in the control. In the test item concentration of 0.98 µg/L bigger algal cells were reported as compared to the algae cells in the control. In the test item concentration of 3.13 µg/L bigger and deformed algal cells were reported as compared to the algae cells in the control. In the
test item concentration of 10 µg/L deformed algal cells were reported as compared to the algae cells in the control.
The concentrations of florasulam, diflufenican and flufenacet were chemically analysed with a validated high performance liquid chromatography with MS/MS detection. Samples of each test item concentration and the control were collected at exposure initiation and at exposure termination.
At exposure initiation, the determined concentrations of florasulam were in the range of 91.3 – 106.9% of the nominal concentration, the determined concentrations of flufenacet were in the range of 100.6 – 103.8% of the nominal concentration, the determined concentrations of diflufenican were in the range of 98.5 – 104.6% of nominal concentration. The results confirm that the test item concentrations were prepared correctly.
At exposure termination, the determined concentrations of florasulam were in the range of 87.1 – 102.0%, the determined concentrations of flufenacet were in the range of 99.1 – 103.0% of the nominal concentration, the determined concentrations of diflufenican were in the range of 81.9 – 92.3% of nominal concentration. Therefore, the concentrations of florasulam, flufenacet and diflufenican were stable under test conditions.
The endpoint values based on the nominal test item concentrations are given below:
The ErC50/72 h value is 0.75 µg/L (95% confidence interval: 0.50 – 1.11).
The LOEC/72 h value for growth rate is 0.31 µg/L.
The NOEC/72 h value for growth rate is 0.10 µg/L.
The EyC50/72 h value is 0.27 µg/L (95% confidence interval: 0.24 – 0.30).
The LOEC/72 h value for yield is 0.31 µg/L.
The NOEC/72 h value for yield is 0.10 µg/L.

TEST VALIDITY CRITERIA
In the definitive test, the following validity criteria specified in the OECD Guideline No. 201 (2006) and EU method C.3. were met:
the biomass in the control increased by a factor of 35.4 within the 72-hour test period (criterion: at least a 16-fold growth),
- the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 1.5% (criterion: it must not exceed 7%).
- the mean coefficient of variation for the section-by-section growth rate in the control culture was 14.4% (criterion: it must not exceed 35%).

A 2.2.1.1.3 Anabaena flos-aquae

Comments of zRMS:	The study was conducted according to OECD guideline 201 and to the principles of GLP. No deviations were noted during the study. In the definitive test all the validity criteria were met. The analytical measurements demonstrated that the test item concentrations throughout the test was mainly within 80-120% of nominal concentrations. However, since at exposure termination, the determined concentrations of florasulam were in the range of 61.4 – 75.3%, endpoints would be expressed as measured concentrations. The study is reliable and suitable for the risk assessment. Following endpoints are relevant for risk assessment purposes: The concentration causing a 50% inhibition of the growth rate of *Anabaena flos-aquae:* *ErC50/72 h= 0.79 mg formulation/L measured (taking to consideration % of florasulam, at least stable substance)* ErC_{50}/72 h= 1.18 mg formulation/L nom The concentration causing a 50% inhibition of yield of *Anabaena flos-aquae*: *EyC50/72 h= 0.29 mg formulation/L measured measured (taking to consideration % of florasulam, at least stable substance)* EyC_{50}/72 h = 0.43 mg formulation/L nom

Reference:	KCP 10.2/03
Report	CHR/H/FDF 574 SC Anabaena flos-aquae UTEX B 1444 Growth inhibition test.; E. Nierzędska, 2021, Study code: W-66-20, Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxico-logical Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the OECD Guideline No. 201 (2006)/EU method C.3.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item: CHR/H/FDF 574 SC; batch no. 052020, the (determined) content of florasulam: 12.2 g/L; the (determined) content of flufenacet:. 304.7 g/L; the (determined) content of diflufenican: 247.5 g/L, density at 20°C: 1.2061 g/cm3; manufacturing date: April 01, 2020, expiry date: April 01, 2022.

Test system: The freshwater cyanobacteria, Anabaena flos-aquae (Lyng.) Bréb UTEX B 1444 cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Aquatic Organisms Toxicology. The culture was obtained from the Culture Collection of Algae at the University of Texas at Austin, USA.

Test design: 72 hours of exposure; three replicates per each test item concentration; six replicates per the control; initial cyanobacterial cell density: 1 x 104 cells/mL.

Nominal test item concentrations:
5, 1.0, 0.2, 0.04, 0.008 and 0.0016 mg/L plus the control.

Test conditions: Temperature: 22.7 – 23.1°C; pH of the control: 7.64 – 8.10; mean light intensity: 3328 -

3510 lux; constant illumination and shaking; medium: AAP.

Chemical determinations:
The concentrations of florasulam, flufenacet, and diflufenican were determined with the validated high performance liquid chromatographic methods with MS/MS detection..

Statistics: Probit method calculations and analyses by: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, Step-down Jonckheere-Terpsta Test Procedure.

Endpoint values: ErC50/72 h, EyC50/72 h, NOEC/72 h, LOEC/72 h.

Results and discussion:

The growth of the cyanobacteria Anabaena flos-aquae exposed to the test item, CHR/H/FDF 574 SC was investigated during a 72-hour test. The test was performed in glass flasks with a capacity of 250 mL containing 100 mL of either the test item concentration, or the control, per replicate. The initial density of the cyanobacteria was 1 x 104 cells/mL. The definitive test was performed using the following test item concentrations: 5, 1.0, 0.2, 0.04, 0.008 and 0.0016 mg/L (with a spacing factor of 5.0) plus the control.
The number of cyanobacterial cells was determined with a direct method, which involves counting the number of cells in the Bürker chamber under a microscope. In case of each replicate, the number of cells was determined after 24, 48, and 72 h of exposure. Morphology observations of the cyanobacteria cells were performed at exposure termination.
In all test item concentrations, no differences in shape, size and colour of cyanobacterial cells were reported as compared to the cyanobacteria cells in the control. The concentrations of florasulam, diflufenican and flufenacet were chemically analysed with a validated high performance liquid chromatography with MS/MS detection. Samples of each test item concentration and the control were collected at exposure initiation and at exposure termination. At exposure initiation, the determined concentrations of florasulam were in the range of 91.6 – 108.3% of the nominal concentration, the determined concentrations of flufenacet were in the range of 96.2 – 108.8% of the nominal concentration, the determined concentrations of diflufenican were in the range of 84.1 – 95.9% of nominal concentration. The results confirm that the test item concentrations were prepared
correctly.
At exposure termination, the determined concentrations of florasulam were in the range of 61.4 – 75.3%, the determined concentrations of flufenacet were in the range of 82.1 –105.1% of the nominal concentration, the determined concentrations of diflufenican were in the range of 82.8 – 99.9% of nominal concentration. Therefore, the concentrations of flufenacet and diflufenican were stable under test conditions and the concentrations of florasulam were not stable under test conditions. The endpoint values were determined based on nominal test item concentrations..

The endpoint values based on the nominal test item concentrations are given below:
The ErC50/72 h value is 1.18 mg/L (95% confidence interval: 0.80 – 1.75).
The LOEC/72 h value for growth rate is 0.04 mg/L.
The NOEC/72 h value for growth rate is 0.008 mg/L.
The EyC50/72 h value is 0.43 mg/L (95% confidence interval: 0.29 – 0.63).
The LOEC/72 h value for yield is 0.2 mg/L.
The NOEC/72 h value for yield is 0.04 mg/L..

TEST VALIDITY CRITERIA
In the definitive test, the following validity criteria specified in the OECD Guideline No. 201 (2006) and EU method C.3. were met:
- the biomass in the control increased by a factor of 27.3 within the 72-hour test period (criterion: at least a 16-fold growth),
- the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 2.0% (criterion: it must not exceed 10%).
- the mean coefficient of variation for the section-by-section growth rate in the control culture was 34.6% (criterion: it must not exceed 35%).

A 2.2.1.1.4 Lemna Gibba

Comments of zRMS:	Growth inhibition test was conducted according to OECD guideline 221 and to the principles of GLP. No deviations were noted during the study. In the definitive test all the validity criteria were met. The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason endpoints are expressed as nominal concentrations. The study is reliable and suitable for the risk assessment. ErC_{50}= 0.134[mg test item/L]

Reference:	KCP 10.2/04
Report	CHR/H/FDF 574 SC Lemna gibba CPCC 310, Growth inhibition test.; E. Nierzędska, 2021, Study code: W-67-20, Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxico-logical Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the OECD Guideline No. 221 (2006)/ EU Method C.26.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item: CHR/H/FDF 574 SC; batch no. 052020, the (determined) content of florasulam: 12.2 g/L; the (determined) content of flufenacet: 304.7 g/L; the (determined) content of diflufenican: 247.5 g/L, density at 20°C: 1.2061 g/cm3; manufacturing date: April 01, 2020, expiry date: April 01, 2022..

Test system: Freshwater aquatic plant Lemna gibba L. specification CPCC 310, cultured in the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Aquatic Organisms Toxicology, stock G3 from Canadian Phycological Culture Centre (CPCC), Department of Biology, University of Waterloo, Ontario, Canada.

Test design: Semi-static system with daily renewals (7 days of exposure); three replicates for each test item concentration and six replicates for the control.

Nominal test item concentrations:
10, 2.5, 0.625, 0.156, 0.039, 0.010, 0.0024 mg/L plus control

Test conditions: Temperature: 22.6 – 23.0ºC; pH of the control: 7.41 – 8.87; light intensity: 7128 – 7354 lux; constant illumination; test vessels: glass crystallizers containing 150 mL of each treatment; initial frond number: 9, i.e. 3 plants per 3 fronds; medium: 20X AAP..

Chemical determinations:
The concentrations of florasulam, flufenacet, and diflufenican and were determined using the validated high performance liquid chromatographic methods with MS/MS detection.

Statistics: Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure.

Endpoint value: ErC50, EyC50, LOEC and NOEC, based on frond number and dry weight..

Results and discussion:
The growth of Lemna gibba exposed to the test item, CHR/H/FDF 574 SC, was investigated in a 7 day semi-static test with daily renewals. The test was performed in glass crystallizers containing 100 mL of either the test item concentration or the control. The initial frond number in each test item concentration and the control was nine. The following test item concentrations were used: 10, 2.5, 0.625, 0.156, 0.039, 0.010, 0.0024 mg/L plus the control. The total number of fronds in each test vessel was counted twice during exposure (day 2 and 5) and at exposure termination. The observations of plant development, i.e. size of fronds, necrosis, chlorosis, colony break-up, gibbosity, changes in the appearance of roots were performed at the same time. At exposure termination, in the test item concentration of 0.0024 mg/L, no distinctive changes from the normal development of plants in the control were observed. In the test item concentrations of 0.010, 0.039, and 2.5 mg/L bending down of colonies were observed. In the test item concentrations of 0.156 and 0.625 mg/L bending down of colonies and smaller younger fronds were observed. In the test item concentration of 10 mg/L separating of roots was observed. The concentrations of florasulam, diflufenican and flufenacet were chemically analysed with a validated high performance liquid chromatography with MS/MS detection. Samples of all fresh test item concentrations and the control collected at exposure initiation and all spent test item concentrations and the control collected at the first renewal were chemically determined. Moreover, fresh and spent samples of the highest (10 mg/L) and the lowest test item concentration (0.0024 mg/L) and the control at each renewal and at exposure termination were chemically analyzed. In fresh samples at exposure initiation and at renewals, the determined concentrations of flurasulam were in the range of 97.4 – 105.8% of the nominal concentration, the determined concentrations of flufenacet were in the range of 91.1 – 103.9% of the nominal concentration, and the determined concentrations of diflufenican were in the range of 96.9 – 106.0% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. In spent samples at renewals and at exposure termination, the determined concentrations of florasulam were in the range of 90.6 – 106.2% of the nominal concentration, the determined concentrations of flufenacet were in the range of 87.9 – 100.8% of the nominal concentration, the determined concentrations of diflufenican were in the range of 89.4 – 102.1% of the nominal concentration. The results showed that active substances were stable during exposure. The endpoint values were determined based on the nominal test item concentrations..

Inhibition of growth rate and yield – definitive test

Nominal test item concentration [mg/L]	Based on frond number		Based on dry weight	
	[%] inhibition at exposure termination of growth rate	[%] inhibition at exposure termination of yield	[%] inhibition at exposure termination of growth rate	[%] inhibition at exposure termination of yield
Control	0.0	0.0	0.0	0.0
0.0024	-4.5*	-11.0*	-6.9*	-17.5*
0.010	15.9	31.3	19.2	34.6
0.039	28.8	50.4	32.7	55.5
0.156	46.4	69.6	33.7	57.5
0.625	84.3	94.0	38.9	62.0
2.5	90.0	96.4	37.6	62.0
10	88.4	95.8	44.5	68.8

*Inhibition is lower than 0.0%, which means that the frond number at exposure termination was higher than the number of fronds in the control.

Growth rate endpoint values based on nominal test item concentration [mg/L] – definitive test

Endpoint value [mg/L]	Frond number			Dry weight
	0-2 d	0-5 d	0-7 d	0-7 d
E_rC_{10}	0.010 (0.003 – 0.023)	0.008 (0.004 – 0.013)	0.008 (0.004 – 0.013)	n.d.
E_rC_{20}	0.031 (0.012 – 0.058)	0.022 (0.013 – 0.032)	0.021 (0.013 – 0.030)	0.016 (0.001 – 0.060)
E_rC_{50}	0.259 (0.158 – 0.426)	0.156 (0.116 – 0.210)	0.134 (0.102 – 0.176)	> 10
LOEC	0.010	0.010	0.010	0.039
NOEC	0.0024	0.0024	0.0024	0.010

Calculations according to [9], [SOP/W/68]
(-) - 95% confidence interval
n.d. – not determined

Yield endpoint values based on nominal test item concentration [mg/L] – definitive test

Endpoint value [mg/L]	Frond number			Dry weight
	0-2 d	0-5 d	0-7 d	0-7 d
E_yC_{10}	0.007 (0.001 – 0.016)	0.003 (0.001 – 0.004)	0.003 (0.002 – 0.004)	n.d.
E_yC_{20}	0.019 (0.006 – 0.037)	0.007 (0.004 – 0.011)	0.007 (0.005 – 0.010)	0.002 (0.000 – 0.008)
E_yC_{50}	0.146 (0.085 – 0.251)	0.056 (0.042– 0.074)	0.040 (0.032 – 0.050)	0.165 (0.055 – 0.499)
LOEC	0.010	0.010	0.010	0.010
NOEC	0.0024	0.0024	0.0024	0.0024

Calculations according to [9], [SOP/W/68]
(-) - 95% confidence interval
n.d. – not determined

The endpoint values based on the nominal test item concentrations:

Endpoints based on the frond number:

The ErC50/7 d value is 0.134 mg/L (95% confidence interval 0.102 – 0.176)..
The ErC20/7 d value is 0.021 mg/L (95% confidence interval 0.013 – 0.030).
The ErC10/7 d value is 0.008 mg/L (95% confidence interval 0.004 – 0.013).
For growth rate, the NOEC/7 d value is 0.0024 mg/L, whereas LOEC/7 d value is 0.010 mg/L.
The EyC50/7 d value is 0.040 mg/L (95% confidence interval 0.032 – 0.050).
The EyC20/7 d value is 0.007 mg/L (95% confidence interval 0.005 – 0.010).
The EyC10/7 d value is 0.003 mg/L (95% confidence interval 0.002 – 0.004).
For yield, the NOEC/7 d value is 0.0024 mg/L, whereas LOEC/7 d value is 0.010 mg/L.

Endpoints based on the dry weight:
The ErC50/7 d value is higher than 10 mg/L.

The ErC20/7 d value is 0.016 mg/L (95% confidence interval 0.001 – 0.060).
The ErC10/7 d value is not determined.
For growth rate NOEC/7 d value is 0.010 mg/L, whereas the LOEC/7 d value is 0.039 mg/L.

The EyC50/7 d value is 0.165 mg/L (95% confidence interval 0.055 – 0.499).
The EyC20/7 d value is 0.002 mg/L (95% confidence interval 0.000 – 0.008).
EyC10/7 d value is not determined.
For yield, the NOEC/7 d value is lower than 0.0024 mg//L, whereas the LOEC/7 d value is 0.010 mg/L..

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

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1.1 KCP 10.3.1.1 Acute oral toxicity to bees

Comments of zRMS:	The study was conducted to OECD guideline 213 and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met. The study is reliable and suitable for the risk assessment. Overall, the study is considered acceptable with following endpoints: 48 h LD_{50} > 200.0 µg/honeybee

Reference:	KCP 10.3.1/01
Report	CHR/H/FDF 574 SC Honeybees (Apis mellifera L.), Acute Oral Toxicity Test.; M. Knapik, 2021, Study code: B-08-21, Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxico-logical Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the OECD Guideline for the Testing of Chemicals No. 213 (1998) and the EU Method C.16. (2008)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	CHR/H/FDF 574 SC content: 12.2 g/L of florasulam 304.7 g/L of flufenacet 247.5 g/L of diflufenican batch no.: 052020 production date: 01.04.2020

expiry date: 01.04.2022

Biological test system:	the honeybee, *Apis mellifera* L., strain: carnica
– age:	approximately 3 weeks
– source:	an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna,
Test design:	
	– the test item: - exposure duration: 48 hours - number of doses: 5 doses and a control - number of replicates: 3 replicates - number of bees: 10 bees/replicate – the reference item: - exposure duration: 24 hours - number of doses: 3 doses - number of replicates: 3 replicates - number of bees: 10 bees/replicate
Test item doses:	12.5, 25.0; 50.0; 100.0 and 200.0 µg test item/bee and a control (0.0 µg/bee)
Reference item doses:	0.1, 0.2 and 0.4 µg a.i./bee and a control (0.0 µg/bee)
Test conditions:	
– temperature:	24 − 26°C (required: 25 ± 2°C)
– relative air humidity:	63 − 66% (required: 50 – 70%)
Photoperiod:	24h darkness, except during application and assessments
Statistical analysis:	regression analysis using the probit method
Endpoints:	
	– honeybee mortality after 24 and 48 hours of the exposure, – the oral LD_{50}/24 h and LD_{50}/48 h of the test item, – the oral LD_{50}/24 h of the reference item (dimethoate).

Results and discussion

The acute oral toxicity study of CHR/H/FDF 574 SC was conducted to estimate the dose which cause 50% of mortality (LD50). Five doses of the test item were used. These included: 12.5, 25.0, 50.0, 100.0 and 200.0 µg/honeybee. The range of doses was selected on the basis of the preliminary non-GLP test results.
Each group of 10 bees (3 replicates containing 10 bees each) was fed with 100 µL of a 50% sucrose solution, containing the test item at the doses mentioned above, using a micropipette. During the entire experiment, the insects were caged in groups of 10.
The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the honeybees and the precision of the test procedure.
After the application, the insects were observed for mortality and signs of toxicity. These observations were made 4, 24 and 48 hours after the beginning of the treatment. The acute oral toxicity test finished after the 48-hour observation..

The acute oral toxicity study of the test item, CHR/H/FDF 574 SC on honeybees (Apis mellifera L.) in the laboratory test are summarized below..

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48h after the beginning of the treatment		LD_{50} [µg/bee]
		Total		
		[no.]	[%]	
0.0	30	0	0.0	>200.0*
12.5	30	0	0.0	
25.0	30	0	0.0	
50.0	30	1	3.3	
100.0	30	3	10.0	
200.0	30	1	3.3	

*: oral LD_{50} value was estimated with the Probit analysis using linear max. likelihood regression (ToxRat Proffesional 3.3.0 computer software), [9]

Conclusions:
The median lethal doses LD50/24 h and LD50/48 h are higher than the highest dose used in the test i.e. 200.0 µg/honeybee..

TEST VALIDITY CRITERIA
The following validity criteria were met during the test:
− the mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%).
− the LD50/24 h of the reference item (dimethoate) was 0.15 µg a.i./bee (criterion: 0.13 – 0.18 µg a.i./bee).

A 2.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study was conducted to OECD guideline 214 and according to the principles of GLP. According to the Guideline No. 214/ EU Method C.17., the honeybees may be anesthetized with carbon dioxide for application of the test item. Anesthesia was replaced with mechanical immobilisation. The mentioned deviation had not effect on the results of the stud In the definitive test all the validity criteria were met. The study is reliable and suitable for the risk assessment. Overall, the study is considered acceptable with following endpoints: 48 h LD_{50} > 200.0 µg/honeybee

Reference:	KCP 10.3.1/02
Report	CHR/H/FDF 574 SC Honeybees (Apis mellifera L.), Acute Contact Toxicity Test.; M. Knapik, 2021, Study code: B-09-21, Łukasiewicz Re-search Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxico-logical Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method C.17. (2008)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	CHR/H/FDF 574 SC content: 12.2 g/L of florasulam, 304.7 g/L of flufenacet, 247.5 g/L of diflufenican batch no.: 052020 production date: 01.04.2020 expiry date: 01.04.2022
Biological test system:	the honeybee, *Apis mellifera* L., strain: carnica
– age:	approximately 3 weeks
– source:	an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna,
Test design:	
	– the test item:

	- exposure duration: 48 hours - number of doses: 5 doses and one control - number of replicates: 3 replicates - number of bees: 10 bees/replicate – the reference item: - exposure duration: 24 hours - number of doses: 3 doses - number of replicates: 3 replicates - number of bees: 10 bees/replicate
Test item doses:	12.5, 25.0, 50.0, 100.0 and 200.0 µg test item/bee and a control (0.0 µg/bee)
Reference item doses:	0.1, 0.2 and 0.4 µg a.i./bee
Test conditions:	
– temperature:	24 − 25°C (required: 25 ± 2°C)
– relative air humidity:	67 − 69% (required: 50 – 70%)
16 hours light : 8 hours dark	
Place:	Dark room
Statistical analysis:	regression analysis using the log-probit method
Endpoints:	
	– honeybee mortality after 24 and 48 hours of the exposure, – the contact LD50 of the test item after 24 and 48 hours of the exposure, – the contact LD50/24 h of the reference item (dimethoate).

Results and discussion

The acute contact toxicity study of CHR/H/FDF 574 SC was conducted to estimate the dose which caused 50% of mortality (LD50) . Five doses of the test item were used. These included: 12.5, 25.0, 50.0, 100.0 and 200.0 µg/honeybee. The range of doses was selected on the basis of the preliminary non-GLP range-finding test results. A microapplicator was used to apply the test item. The volume was 1 µL/bee. During the experiment, the insects were caged in groups of 10. The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the honeybees and the precision of the test procedure. After the application, the insects were observed for mortality and signs of toxicity. These observations were made 4, 24 and 48 hours after the beginning of the treatment. The acute contact toxicity test finished after the 48-hour observation.

The acute contact toxicity study of the test item, CHR/H/FDF 574 SC on honeybees (Apis mellifera L.) in the laboratory test are summarized below:

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48 h after the beginning of the treatment			LD_{50} [µg/bee]
		Total			
		[no.]	[%]	[%]*	
0.0 (control)	30	3	10.0	-	> 200.0
12.5	30	0	0.0	-11.1	
25.0	30	0	0.0	-11.1	
50.0	30	0	0.0	-11.1	
100.0	30	0	0.0	-11.1	
200.0	30	2	6.7	-3.7	

*: mortality was corrected according Abbott's equation [9]

Conclusions:
The median lethal doses LD50/24 h and LD50/48 h are higher than the highest dose used in the test, i.e. 200.0 µg/honeybee

TEST VALIDITY CRITERIA
The following validity criteria were met during the test:
- the mortality for the control was 10.0% after 48 h (criterion: it must not exceed 10.0%),
- the LD50/24 h of the reference item (dimethoate) was 0.28 µg a.i./bee (criterion: 0.10 – 0.30 µg a.i./bee).

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

A 2.3.1.2.1 Chronic oral toxicity to bees

Comments of zRMS:	The study was conducted to OECD guideline 245 and according to the principles of GLP. No deviation were noted during the study. In the definitive test all the validity criteria were met. The study is reliable and suitable for the risk assessment. Overall, the study is considered acceptable with following endpoints: 48 h LD_{50} > 666.7 µg/honeybee LDD_{50} >17.2 µg/honeybee/day

Reference:	KCP 10.3.1/03
Report	CHR/H/FDF 574 SC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test.; M. Knapik, 2021, Study code: B-07-21, Łukasiewicz Re-search Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxico-logical Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the OECD Guideline No. 245 (2017)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	CHR/H/FDF 574 SC batch number: 052020 content: 12.2 g/L of florasulam, 304.7 g/L of flufenacet, 247.5 g/L of diflufenican production date: 01.04.2020 expiry date: 01.04.2022
Biological test system:	species: the honeybee, *Apis mellifera* L.; strain: carnica, source: an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; age: freshly emerged worker honeybees (max. 2 days old) from the same queen-right colony
Experimental design:	□ the test item: number of concentrations: 1 and the control number of replicates: 5 number of insects: 10 bees/replicate □ the reference item: number of concentrations: 1 number of replicates: 3 number of insects: 10 bees/replicate exposure duration: 10 days
Nominal concentration of the test item:	666.7 mg/kg
Nominal dose of the test item:	20.0 µg/bee/day
Test item dietary dose:	17.2 µg/bee/day
Nominal concentration of the reference item (dimethoate):	0.8 mg/kg
Nominal dose of the reference item (dimethoate):	0.024 µg/bee/day
Reference item dietary dose:	0.016 µg/bee/day
Test conditions:	temperature: 33.2 – 35.0ºC; relative humidity: 50.6 – 69.6%;
Statistical analysis:	Fisher's Exact Binomial Test
Endpoints:	Multiple Sequentially – rejective Fischer Test After Bonferroni - Holm

Aim of the study

The aims of the study were to determine the chronic oral toxicity of the test item, CHR/H/FDF 574 SC to honeybees (*Apis mellifera* L.) and to demonstrate that the median lethal concentration, i.e. the LC_{50} and median lethal dietary dose, i.e. LDD_{50} are higher than the test item concentration used for exposure (limit test).

Results and discussion

The validity criterion concerning mortality was met, because mortality in the control was 0.0% after 10 days of exposure.
The percentage of mortality of the honeybees exposed to the test item, CHR/H/FDF 574 SC at the concentration of 666.7 mg/kg (dietary dose 17.2 µg/bee/day) at exposure termination (after 10 days) was 4.0%. On the basis of the obtained mortality results the LC50 is higher than 666.7 mg/kg, and the LDD50 value is higher than 17.2 µg/bee/day. The validity criterion concerning mortality of the honeybees exposed to the reference item, dimethoate was met, because mortality was equal to 63.3% after 10 days of exposure. The results obtained in the reference item group showed that the insects were sensitive to dimethoate..

The effects of CHR/H/FDF 574 SC on mortality of honeybees are summarized below::

Table 1. Honeybee mortality and the LDD_{50} and LC_{50}/10 d – definitive test

Nominal test item concentration/ dose		Ingested[a] dose	Number of tested bees	Total mortality		LC_{50}	LDD_{50}
[µg/30 mg/day] [µg/bee/day]	[mg/kg]	[µg/bee/day]	[no]	No.	[%]	[mg/kg]	[µg/bee/day]
CHR/H/FDF 574 SC							
0.0 (Control)			50	0	0.0	> 666.7	> 17.2
20.0	666.7	17.2	50	2	4.0		
Dimethoate (reference item)							
0.024	0.8	0.016	30	19	63.3	not determined	

[a]: ingested doses (dietary doses) were calculated on the basis of the concentrations of the test item / reference item and average sucrose solution consumption

TEST VALIDITY CRITERIA
The following validity criteria were met during the test:
− At the end of the experiment average mortality of the control groups was 0.0% (criterion: it must not exceed 15%)
− After 10 days of exposure corrected mortality of the honeybees exposed to the reference item at the concentration of 0.8 mg/kg (0.016 µg/bee/day) was 63.3% (criterion: it must be ≥ 50% on day 10 of exposure).

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

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.4.1 Typhlodromus pyri

Comments of zRMS:	The study follows the guideline specified by Blümel et al. (2000) and according to the principles of GLP. According to the guideline developed by the IOBC, BART, EPPO Joint Initiative, as a food source only pollen was used. However, in the experiment additional food in the form of the two-spotted spider mite (T. urticae) eggs, was used. Another food source prevents the mites from escaping from discs. Since n the definitive test all the validity criteria were met it didn't impact the results of the study. Considering the current test guideline (Blümel et al., 2000) the study is considered valid. LR_{50}= 0.09 L formulation/ha NOERmortality < 0.008 L formulation/ha ER_{50}= 0.07 L formulation/ha NOERreproduction < 0.008 L formulation/ha

Reference:	KCP 10.3.1/04
Report	An extended laboratory test for evaluating the effects of CHR/H/FDF 574 SC on the predatory mite, Typhlodromus pyri (Sch.).; M. Knapik, 2021, Study code: B-04-21, Łukasiewicz Re-search Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxico-logical Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M. P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000))
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Name:	CHR/H/FDF 574 SC
Active substance:		12.2 g/L of florasulam 304.7 g/L of flufenacet 247.5 g/L of diflufenikan
Batch number:		052020
Manufacture date:		01.04.2020
Expiry date:		01.04.2022
Biological test system:		the predatory mite, *Typhlodromus pyri* (Sch.) (Acari: *Phytoseiidae)*
– age:		24-hour-old protonymphs
– source:		a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented from a commercial breeder
Experimental design:		6 study groups: - a control group (0.0 L/ha) - 0.008 L/ha - 0.021 L/ha - 0.052 L/ha

	- 0.13 L/ha - reference item: Bi 58 Top 400 EC at the rate of 9.0 mL/ha - number of replicates: 3 number of mites in each replicate: 20
Test conditions:	
– temperature:	23 – 26°C
– relative air humidity:	60 – 80%
– photoperiod:	16 h light : 8 h dark
– light intensity:	786 lux
Statistical analysis:	Logit analysis using max. likelihood regression, Probit analysis using linear weighted regression Step-down Cochran-Armitage Test Procedure, Shapiro Wilk's Test on Normal Distribution, Levene's Test on Variance Homogenity (with Residuals), Williams Multiple Sequential t-test Procedure, Chi2 2x2 Table Test with Bonferroni Correction
Endpoints:	
	– mite mortality after 7 days of the treatment – LR_{50} and $NOER_{mortality}$ – reproduction reduction (Pr) after 14 days of the treatment – ER_{50} and $NOER_{reproduction}$

Results and discussion

In the definitive test, mortality of the control group after 7 days of exposure was 0.0%. After 7 days of exposure to CHR/H/FDF 574 SC at rates of 0.008, 0.021, 0.052 and 0.13 L/ha, the percentages of T. pyri, mortality were 0.0, 13.3, 26.7 and 65.0%, respectively.
There were no statistically significant differences in mortality between group treated with the test item at the rate of 0.008 L/ha and the control group. There were statistically significant differences in mortality between group treated with the test item at the rates of 0.021, 0.052 and 0.13 L/ha (Step-down Cochran-Armitage Test Procedure, $p(trend)>\alpha$).
The LR50 value is equal to 0.09 L/ha (confidence limits: 0.07 – 0.12) of CHR/H/FDF 574 SC. NOER-mortality is 0.008 L/ha of CHR/H/FDF 574 SC.
After 7 days of exposure to Bi 58 Top 400 EC at the rate of 9.0 mL/ha mortality was 88.3%. Therefore, the validity criterion specified in the Method description was met. The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.
Reproduction of the surviving mites from the control group and the groups treated with CHR/H/FDF 574 SC at the rates of 0.008, 0.021 and 0.052 L/ha, was assessed since mortality of these groups was < 50.0%.
The mean reproduction rate (Rr) in the control group was 9.2 eggs/female. The mean Rr after 14 days of exposure to CHR/H/FDF 574 SC at the rates of 0.008, 0.021 and 0.052 L/ha were 7.7, 7.0 and 5.2 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by test item at the rates of 0.008, 0.021 and 0.052 L/ha were 16.5, 24.4 and 44.0 %, respectively.
There were statistically significant differences in reproduction between group treated with the test item at the rates of 0.008, 0.021 and 0.052 L/ha and the control group (Williams Multiple Sequential t-test Procedure,$|t|>|t^*|$).
On the basis of the obtained reproduction results, it could be assumend that the ER50 value is equal to 0.07 L/ha (confidence limits: 0.003 – 1.36) of CHR/H/FDF 574 SC. NOERreproduction is below 0.008 L/ha of CHR/H/FDF 574 SC..

The effects of CHR/H/FDF 574 on mortality and reproduction of *Typhlodromus pyri* in the definitive test are summarized in the table.

Test item rate [L/ha]	Parameter (endpoint)					
	Mortality		Reproduction			
	Total [%]	LR_{50} [L/ha]	Test item rate [L/ha]	Mean number of eggs/ female (Rr) [no.]	Repro-duction reduction Pr [%]	ER_{50} [L/ha]
Control (0.0)	0.0	0.09 (0.07 – 0.12*)	Control (0.0)	9.2	–	0.07 (0.003 – 1.36*)
0.008	0.0		0.008	7.7	16.5	
0.021*	13.3		0.021	7.0	24.4	
0.052*	26.7		0.052	5.2	44.0	
0.13*	65.0		0.13	–	–	
$NOER_{mortality}$ 0.008 [L/ha]			$NOER_{reproduction}$ < 0.008 [L/ha]			
Reference item: Bi 58 Top 400 EC						
Reference item [mL/ha]			9.0			
Mortality						
Total [%]			88.3			

*: statistically significant differences between control and groups exposed to test item; ToxRat Professional 3.3.0. software [12], [SOP/B/67]
*: 95%-confidence limits

Conclusions:
Based on the results it can be stated that CHR/H/FDF 574 SC, at the rates of 0.021, 0.052 and 0.13 L/ha has significant adverse effect on mortality of the mites. Based on the results it can be stated that CHR/H/FDF 574 SC, at the rates of 0.008, 0.021 and 0.052 L/ha has significant adverse effect on reproduction of the mites.

TEST VALIDITY CRITERIA
The following validity criteria were met during the study [3]:
− mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%),
− mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 88.3% on day 7 of exposure (criterion: from 50 to 100%),
− the mean number of eggs per female in the control group was 9.2 (required: ≥ 4 eggs per female).

A 2.3.1.4.2 Aphidius rhopalosiphi

Comments of zRMS:	The study follows the guideline specified by Mead Briggs M.A. et al. (2000) and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met Considering the current test guideline (Mead Briggs M.A. et al, 2000) the study is considered valid. Based on the obtained results the LR_{50} value could not be estimated. It could be assumend that LR_{50} is higher than 0.4 L/ha. The NOERmortality is higher than or equal to 0.4 L/ha LR_{50} > 0.4 L formulation /ha NOERmortality is ≥ 0.4 Lformulation/ha ER_{50}-0.22 L formulation/ha NOERfecundity is < 0.064 Lformulation/ha

Reference: KCP 10.3.1/05

Report	An extended laboratory test for evaluating the effects of CHR/H/FDF 574 on the parasitic wasp, Aphidius rhopalosiphi (De Stefani-Perez), M. Knapik, 2021, Study code: B-05-21 ~~10~~, Łukasiewicz Re-search Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000; Mead-Briggs M.A. et al., 2010)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Name:	CHR/H/FDF 574 SC
Active substance:		12.2 g/L of florasulam 304.7 g/L of flufenacet 247.5 g/L of diflufenican
Batch number:		052020
Manufacture date:		01.04.2020
Expiry date:		01.04.2022
Biological test system:		the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Hymenoptera: *Braconidae, Aphiidinae*
– age:		adult females (24 – 48 hours after emerging from mummies)
– source:		the culture was obtained from a commercial breeder (Katz Biotech AG)
Experimental design:		5 study groups: □ a control group (0.0 L/ha) – 0.064 L/ha – 0.16 L/ha – 0.4 L/ha □ Reference item: Bi 58 Top 400 EC at the rate of 5.0 mL/ha mortality assessment: 6 replicates/group; 5 females/replicate fecundity assessment: 15 replicates/group; 1 females/replicate
Test conditions:		
– temperature:		18 – 20°C
– relative air humidity:		62 –72%
– photoperiod:		16 hours light : 8 hours dark
– light intensity:		mortality and oviposition assessment: 2203 lx fecundity phase: 5504 lx
Statistical analyses:		– Probit analysis using linear max. likelihood regression, – Chi2 2x2 Table Test with Bonferroni Correction, – Shapiro-Wilk's Test on Normal Distribution, – Levene's Test on Variance Homogeneity, – Williams Multiple Sequential t-test Procedure.

Endpoints:

– wasp mortality after 48 hours of exposure,
– determination of the LR_{50} and the $NOER_{mortality}$,
– determination of the ER_{50} and the $NOER_{fecundity}$.
– reduction in fecundity (Pr) of the surviving female wasps exposed to CHR/H/FDF 574, 12 days after the oviposition period

Results and discussion

In the definitive test, after 48 hours mortality of the control wasps was 3.3%. The corrected mortality, in the groups treated with CHR/H/FDF 574 SC at the rates of 0.064, 0.16 and 0.4 L/ha were -3.5, -3.5 and -3.5%, respectively.
At the significance level of 0.05, there were no statistically significant differences in mortality between the wasps exposed to the test item at the rates of 0.064, 0.16 and 0.4 L/ha and the control group (Multiple Sequentially-rejective Fisher Test After Bonferroni-Holm, p>0.05).
Based on the obtained results the LR50 value could not be estimated. It could be assumend that LR50 is higher than 0.4 L/ha. The NOERmortality is higher than or equal to 0.4 L/ha.
The corrected mortality of the wasps exposed to Bi 58 Top 400 EC at the rate of 5.0 mL/ha was 75.9% after 48 hours. Therefore, the validity criterion specified in the Method description was met [6]. The results showed that the test organisms were sensitive to dimethoate.
The fecundity assessment showed that the mean number of mummies per female in the control group was 16.4 (after 12 days after oviposition). As for the wasps treated with CHR/H/FDF 574 SC at the rates of 0.064, 0.16 and 0.4 L/ha the mean number of mummies per female were 12.1, 10.7 and 9.9, respectively. Fecundity reduction (Pr) in the group treated with the test item at the rates of 0.064, 0.16 and 0.4 L/ha were 26.0, 34.6 and 39.5%, respectively.
At the significance level of 0.05, there were statistically significant differences in fecundity between the wasps exposed to the test item at the rate of 0.064, 0.16 and 0.4 L/ha and the control group (Williams Multiple Sequential t-test Procedure, p>0.05).
Based on the obtained fecundity results it could be assumed that the ER50 value is equal to 0.22 L/ha and the NOERfecundity is below 0.064 L/ha of the test item..

The effects of the test item, CHR/H/FDF 574 on mortality and fecundity of *Aphidius rhopalosiphi* in the extended laboratory test are summarized below.

Parametr (endpoint)						
Mortality			Fecundity			
Test item [L/ha]	Total [%]	LR_{50} [L/ha]	Test item [L/ha]	Mean no. of mummies/ female	Fecundity reduction Pr [%]	ER_{50} [L/ha]
Control	3.3	>0.4	Control	16.4	–	0.22
0.064	-3.5		0.064*	12.1	26.0	
0.16	-3.5		0.16*	10.7	34.6	
0.4	-3.5		0.4*	9.9	39.5	
$NOER_{mortality}$ ≥ 0.4 [L/ha]			$NOER_{fecundity}$ < 0.064 [L/ha]			
Reference item: Bi 58 Top 400 EC						
Reference item [mL/ha]	5.0					
Mortality (after 48 h)						
Total [%]	75.9					

*: statistically significant differences

Conclusion:
On the basis of the obtained mortality results it can be concluded that CHR/H/FDF 574 SC at the rates of 0.064, 0.16 and 0.4 L/ha has no adverse effect on the mortality of the wasps.
On the basis of the obtained fecundity results it can be concluded that CHR/H/FDF 574 SC at the rates of 0.064, 0.16 and 0.4 L/ha has an adverse effect on the fecundity of the wasps..

TEST VALIDITY CRITERIA
The following validity criteria were met during the study:
– after 48 hours, mortality of the control group was 3.3% (criterion: a maximum of 10.0%),
– after 48 hours, mortality of the group treated with the reference item at the rate of 5.0 mL/ha was 75.9% (criterion: a minimum of 50%),
– all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),
– the mean number of mummies per female in the control group was 16.4 (criterion: a minimum of 5.0 mummies/female),
– all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).).

A 2.3.1.4.3 Chrysoperla Carnea

Comments of zRMS:	The study follows the guideline specified by Vogt et al. and according to the principles of GLP. In the experimental part of the study a deviation from the guidelines developed by the IOBC, BART and EPPO Joint initiative (Vogt H. et al., 2000) occurred. This deviation is to use leaf discs as a surface instead of plastic discs. Since the definitive test all the validity criteria were met. The study is considered valid. $NOER_{mortality}$ is higher than or equal to 0.4 L/ha not 0.04 as is mentioned in the table with the results. Please, update the table with correct values.

Reference:	KCP 10.3.1/06
Report	An extended laboratory test for evaluating effects of CHR/H/FDF 574 on the green lacewing, Chrysoperla carnea (Steph.), M. Knapik, 2021, Study code: B-06-21, Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxico-logical Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Vogt H. et al., 2000)
Deviations:	Yes ~~/ No~~
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	CHR/H/FDF 574 SC content: 12.2 g/L of florasulam, 304.7 g/L of flufenacet, 247.5 g/L of diflufenican batch no.: 052020 production date: 01.04.2020 expiry date: 01.04.2022
Biological test system:	the green lacewing, *Chrysoperla carnea* (Steph.), Neuroptera: *Chrysopidae*
– age:	first instars' larvae (3 days old)
– source:	a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented by commercial breeder
Experimental design:	5 study groups: - a control group (0.0 L/ha) - CHR/H/FDF 574 at the rates of - 0.04 L/ha - 0.13 L/ha - 0.4 L/ha

- dimethoate at the rate of 15.0 g/ha

number of replicates: 30 replicates/group
number of larvae: 1 larva of *Chrysoperla carnea* /replicate

Test conditions:	
– temperature:	23.0 - 26.0°C
– relative air humidity:	60.1 - 89.8%
– photoperiod:	16 hours light : 8 hours dark
– light intensity	3011 lux
Statistical analysis:	Logit analysis using linear max. likelihood regression, Step-down Cochran-Armitage Test Procedure
Endpoints:	– cumulative mortality of larvae, pupae, and adults after emergence – LR50 value – reproduction of the lacewings: - fecundity (mean number of eggs/female/day) - fertility (mean hatching rate)

Results and discussion

The extended laboratory test involved the evaluation of the effects of the test item, CHR/H/FDF 574 SC on mortality and reproductive capacity of the green lacewing, Chrysoperla carnea. In a definitive test, three test item application rates of 0.04, 0.13 and 0.4 L/ha were used. To assess mortality, 3-day-old larvae of Chrysoperla carnea were exposed to dry residues of the test item on leaf discs. Eggs of the mill moth Ephestia kuehniella were offered as food. After emergence of adults, total mortality was calculated on the basis of the numbers of dead larvae, pupae, and adults which died during emergence. There were

30 replicates of each treated group. Each of them contained 1 larva of Chrysoperla carnea. To determine possible adverse effects of the test item on fecundity and fertility of the lacewings, reproductive performance was conducted during 8 days. Total mortality of the lacewings, the mean number of eggs laid per female lacewing per day, and the mean hatching rate were the endpoints. To control the sensitivity of the biological test system, an insecticide, dimethoate was used as a reference item. The rate of the reference item was 15.0 g/ha. Control lacewings had contact with discs sprayed with distilled water. The effects of the test item, CHR/H/FDF 574 on mortality and fecundity of *Aphidius rhopalosiphi* in the extended laboratory test are summarized below.

Study group [application rate]	Parameter (endpoints)				
	Mortality			Reproduction	
Test item [L/ha]	[%]	[%][a]	LR_{50} [L/ha]	Mean number of eggs/female /day [no.]	Mean hatching rate [%]
Control (0.0)	6.7	-	> 0.4	18.7	89.0
0.04	6.7	0.0		17.6	77.6
0.13	10.0	3.6		26.1	78.2
0.4	3.3	-3.6*		15.0	82.2
$NOER_{mortality}$	≥ 0.04 [L/ha]				
Reference item [g/ha]	Dimethoate				
15.0	70.0	67.9	-		

*: mortality was corrected according Abbott's equation [1]
*: the negative value indicates that the mortality in the control group was higher than in the group exposed to the test item

Conclusion:
The validity criterion concerning mortality was met, because mortality of the green lacewings, Chrysoperla carnea (Steph.) in the control group was 6.7%. The corrected mortality of the green lacewings exposed to the test item at the rates of 0.04, 0.13 and 0.4 L/ha of CHR/H/FDF 574 SC was 7.1, -3.6 and -3.6%, respectively. The negative values means that in the tested rates there were lower mortality than in the control group.
There were no statistically significant differences in mortality of the green lacewings in the groups treated with the test item at the rates of 0.04, 0.13 and 0.4 L/ha in comparison to the control group (Chi2 2x2 Table Test with Bonferroni Correction, $p(z) > \alpha$, (α=0.05)).
The LR50 value is higher than 0.4 L/ha. The NOERmortality value is higher or equal to 0.4 L/ha.
The percentage of mortality of Ch. carnea (Steph.) exposed to dimethoate at rate of 15.0 g/ha, after Abbott's corrections, was 67.9%. The results obtained in the reference item group indicated that the biological test system was sensitive to dimethoate.
The mean number of fertile eggs/female/day in the control group was equal to 18.7 (criterion: ≥ 15.0). The mean numbers of fertile eggs/female/day in the groups treated with CHR/H/FDF 574 SC at the rates of 0.04, 0.13 and 0.4 L/ha were equal to 12.3, 13.3 and 12.6, respectively. The mean hatching rate in the control group was 89.0% (criterion: ≥ 70%). The mean hatching rate in the groups treated with the test item at the rates of 0.04, 0.13 and 0.4 L/ha were 86.2, 73.4 and 84.1%, respectively.
Fecundity reduction (Pr) in the group treated with the test item at the rates 0.04, 0.13 and 0.4 L/ha were 3.1, 17.5 and 5.5%, respectively.
Based on the results, it can be presumed that CHR/H/FDF 574 SC at the rates of 0.04, 0.13 and 0.4 L/ha had adverse effect on the reproductive performance of the lacewings.

TEST VALIDITY CRITERIA
The following validity criteria were met during the study:
– pre-imaginal mortality of the control group was 6.7% (criterion: a maximum of 20.0%),

– mean mortality of the reference item group was 67.9% (criterion: a minimum of 50%),
– the mean number of eggs per female per day in the control group (fecundity) was 18.7 (criterion: ≥ 15.0),
– the mean hatching rate in the control group (fertility) was 89.0 (criterion: ≥ 70%).

A 2.3.1.4.4 Coccinella Septempunctata

Comments of zRMS:	The study follows the guideline specified by. Schmuck et al. (2000) in Candolfi (2000) guidelines according to the principles of GLP. In the experimental part of the study a deviation from the guidelines developed by the IOBC, BART and EPPO Joint initiative (Schmuck V., et al., 2000) occurred.This deviation is to use leaf discs as a surface instead of plastic discs. Since the definitive test all the validity criteria were met. The study is considered valid. In the definitive test all the validity criteria were met. LR_{50} > 0.4 L product/ha $NOER_{mortality}$ > 0.4 L product/ha

Reference:	KCP 10.3.1/07
Report	An extended laboratory test for evaluating effects of CHR/H/FDF 574 on the ladybird beetle, Coccinella septempunctata (L.), M. Knapik, 2021, Study code: B-03-21, Łukasiewicz Re-search Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxico-logical Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Schmuck et al., 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	CHR/H/FDF 574 SC content: 12.2 g/L of florasulam, 304.7 g/L of flufenacet, 247.5 g/L of diflufenican batch no.: 052020 production date: 01.04.2020 expiry date: 01.04.2022
Biological test system:	the ladybird beetle, *C. septempunctata* L. (Arthropoda: *Coccinellidae)*
– age:	4-day-old larvae
– source:	Beetles was obtained from commercial breeder (Katz Biotech AG, Germany)

Experimental design:	5 study groups: □ a control group (0.0 L/ha) □ CHR/H/FDF 574 at the rates of: - 0.064 L/ha - 0.16 L/ha - 0.4 L/ha □ dimethoate at the rate of 3.2 g/ha number of replicates: 40 replicates/group number of larvae: 1 larva of *Coccinella septempunctata* /replicate
Test conditions:	
– temperature:	23.0 – 26.9°C
– relative air humidity:	60.9 - 78.0%
– photoperiod:	16 hours light : 8 hours dark
– light intensity	3052 lx
Statistical analysis:	probit analysis using linear max. likelihood regression, Step-down Cochran-Armitage Test Procedure
Endpoints:	
	– preimaginal mortality of the ladybird beetles – LR_{50} – $NOER_{mortality}$ – reproductive performance of the moulted beetles over a period of 14 days (the mean number of fertile eggs/female/day) reproduction reduction (Pr)

Results and discussion

The extended laboratory test involved the evaluation of the effects of the test item, CHR/H/FDF 574 SC on mortality and reproductive capacity of the ladybird beetle, Coccinella septempunctata. In a definitive test, three test item application rates of 0.064, 0.16 and 0.4 L/ha were used. To assess mortality of the ladybird beetles, Coccinella septempunctata L., 4-day-old larvae were exposed to the test item applied to leaf discs. There were 40 replicates of each treated group. Each replicate contained 1 larva of C. septempunctata L. The larvae were fed with the fresh aphids, Acyrthosiphon pisum until pupation. During the exposure phase, survival, condition and development of the ladybird beetles were regularly assessed until the end of pupation. After emergence of the adults, pre-imaginal mortality was calculated on the basis of the numbers of dead larvae, pupae, and adults which died during emergence. After completion of mortality assessment, healthy hatched beetles from the control group and from group treated with the test item at the rates of application rates of 0.064, 0.16 and 0.4 L/ha were subjected to evaluate the reproductive performance. To allow egg-laying, adult ladybirds were transferred to separate reproduction units. The beetles had continuous access to food in the form of a honey-water solution (2:1), pine pollen (Pinus sp.) and the broad bean plants infested with the aphid, A. pisum. Reproductive performance observations, concerning the numbers of eggs laid and their fertility were made over a period of 14 days. To check the relative susceptibility of the test system and the sensitivity of the test method, an insecticide, dimethoate was used as a reference item. The rate of the reference item was 3.2 g/ha. Control beetles had contact with leaf discs sprayed with distilled water. The effects of the test item, CHR/H/FDF 574 SC on mortality and reproductive capacity of the ladybird beetle, Coccinella septempunctata L. in the laboratory test are summarized below.

Conclusion:
The validity criterion concerning mortality was met, because mortality of the ladybird beetle, Coccinella septempunctata L. in the control group was equal to 5.0% (≤ 30.0%). The mortality of the ladybird beetles exposed to the test item at the rates of 0.04, 0.13 and 0.4 L/ha, after Abbott's correction, were -2.6, -5.3 and -5.3%, respectively. The negative values means that in the tested rates there were lower mortality

than in the control group At the significance level of 0.05, there were no statistically significant differences in mortality between the ladybirds exposed to the test item at the rates of 0.04, 0.13 and 0.4 L/ha of CHR/H/FDF 574 and the control group (Step-down Cochran-Armitage Test Procedure, (α=0.05)). The LR50 value is above 0.4 L/ha of CHR/H/ PENDIF 599,5 SC. The NOERmortality is higher or equal to 0.4 L/ha of CHR/H/ PENDIF 599,5 SC. The mortality of the ladybird beetles exposed to the reference item at the rate of 3.2 g of dimethoate/ha, after Abbott's correction, was equal to 100.0%. Therefore, the validity criterion was met. The results showed that the insects were sensitive to dimethoate. The mean number of fertile eggs/female/day in the control group was 5.7 (criterion: ≥ 2 eggs/female/day). The mean numbers of fertile eggs/female/day in the group treated with the of CHR/H/FDF 574 at the rates of 0.04, 0.13 and 0.4 L/ha were equal to 7.5, 8.1 and 7.1 it refers to -31.6, -42.1 and -24.6% reproduction reduction. The negative values means that in the tested rates there were higher mean numbers of fertile eggs per viable female per day than in the control group. It can be concluded that CHR/H/FDF 574 at the rates of 0.04, 0.13 and 0.4 L/ha had no adverse effect on the reproduction capacity of the ladybird beetle.

Study group	Parameters (endpoints)					
	Mortality			Reproduction		
Test item [L/ha]	[%]	[%]*	LR_{50} [L/ha]	Mean no. of eggs/female/day	Mean no. of fertile eggs/female/day	Reproduction reduction Pr [%]***
Control (0.0)	5.0	–	> 0.4	7.7	5.7	–
0.064	5.0	0.0		8.1	6.6	-15.8
0.16	5.0	0.0		8.8	7.0	-22.8
0.4	3.0	-2.6		12.2	9.3	-63.2
$NOER_{mortality}$	> 0.4 [L/ha]					
dimethoate						
Reference item [g/ha]	100.0	100.0	–			
3.2						

*: mortality was corrected according Abbott's equation [1]
+: statistically significant differences
* - confidence limits
** - The negative values means that in the tested rates there were lower mortality than in the control group
*** - The negative values means that in the tested rates there were higher mean numbers of fertile eggs per viable female per day than in the control group

TEST VALIDITY CRITERIA

The following validity criteria were met during the study ~~[6]~~:
− pre-imaginal mortality of the control group was 5.0% (criterion: a maximum of 30.0%),
− mean corrected mortality of the reference item group was 100.0% (criterion: a minimum of 40%),
− fertility (the mean number of fertile eggs/female/day) in the control group was 5.7 (criterion: ≥ 2 fertile eggs/female).

A 2.3.1.4.5 Aged Residue study

Comments of zRMS:	The study follows the guideline specified by Blümel S. et al., 2000 and according to the principles of GLP. No deviations to the guideline were noted. All the validity criteria were met.

Reference:	KCP 10.3.1/08
Report	CHR/H/FDF 574 SC – Aged-Residue Extended Laboratory Tests to Determine Effects on the Predatory Mite Typhlodromus pyri (Acari: Phytoseiidae), L. Fallowfield, 2021, Study code: CHR-21-06, Mambo-Tox A Division of Cawood Scientific Ltd., 2 Venture Road, University Science Park Southampton SO16 7NP, UK
Guideline(s):	Blümel et al. (2000). Laboratory residual contact test with the predatory mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) for regulatory testing of plant protection products.)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Product code = CHR/H/FDF 574 SC
Formulation type = suspension concentrate (SC)
Sample identification = 220111704701
Batch number = 052020
Active substances = a) florasulam b) flufenacet c) diflufenican
Nominal content of a.s. = a) 12.0 g/L b) 312.0 g/L c) 250.0 g/L
Analysed content of a.s. = a) 12.2 g/L b) 304.7 g/L c) 247.5 g/L
Analysed density = 1.2061 g/cm3
Appearance = white opaque liquid
Storage at Test Facility = ambient laboratory conditions
Sample expiry date = 01 April 2022

CHR/H/FDF 574 SC was evaluated at a single application rate, equivalent to 0.4 L test item/ha. This treatment was compared to a water control. A toxic reference treatment of dimethoate (an EC formulation containing nominally 400 g a.s./L, applied at a rate of 60 mL product/ha) was also included in the study.
All treatments were applied to sweetcorn plants, (Zea mays L.), using a laboratory track-sprayer, at a volume rate equivalent to 400 L spray solution/ha. After treatment, the plants were placed under UV permeable rain protection and extended laboratory bioassays were carried out using leaves collected from the plants at 0 and 14 DAT (days after treatment).
For each bioassay, 5-cm leaf sections were cut from the treated leaves (n = 5 per treatment). These were each laid, with the treated upper (adaxial) surface exposed, onto a layer of water-saturated cotton wool lining a Petri dish. A line of a non-drying sticky insect gel was drawn around the edge of each leaf section, to serve as a barrier to mite dispersal. Twenty protonymphal mites were placed at the centre of each arena and untreated pollen and water were provided for nourishment. The survival of the mites was assessed after 7 days, by which time the mites in the control treatment were adult. The sex of the surviving mites was determined and they were then left in situ so that their reproduc-

tion could be assessed over a further 7 days. The mean number of eggs produced per female between 7 and 14 days after initiation (DAI) of the test was calculated. These reproduction assessments were made for the control and for the test-item treatment only.
The testing programme was to be continued until residues no longer resulted in unacceptable effects (i.e. where corrected mortality was ≤ 50% and any reduction in reproduction was ≤ 50% when compared to the control), in two consecutive bioassays..

Results and discussion

The test item CHR/H/FDF 574 SC is a suspension concentrate formulation containing florasulam (nominally 12.0 g/L), flufenacet (nominally 312.0 g/L) and diflufenican (nominally 250.0 g/L). The aim of this study was to determine the effects of both freshly-dried and field-aged residues of CHR/H/FDF 574 SC on the predatory mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae), in a series of extended laboratory tests.. The results for bioassays initiated at 0 and 14 DAT are summarised below.

Bioassay initiated	Treatment	Test item rate (L/ha)	Mean % mortality at 7 DAI [a)]	Corrected % mortality at 7 DAI [b)]	Mean number eggs/female (7-14 DAI) [c)]	Reduction in reproduction [%] [d)]
0 DAT	Control	-	13	-	10.4	-
	CHR/H/FDF 574 SC	0.4	38 *	28.7	6.1 *	41.0
	Toxic reference	-	100 *	100	~	-
14 DAT	Control	-	5	-	9.9	-
	CHR/H/FDF 574 SC	0.4	23 *	18.9	9.3	5.4

a) For each bioassay, treatment mortalities were compared to the control using chi² 2x2 table test (α = 0.05, one-sided, > control), a statistically significant effect is denoted by an asterisk (*).
b) Mortality corrected for respective control treatment deaths using Abbott's formula. A positive value indicates an increase.
c) Treatments were compared to the respective control by Student's t-test for homogenous variances (α = 0.05, one-sided, < control), a statistically significant effect is denoted by an asterisk (*).
d) Percentage reduction in numbers of eggs per female, relative to the respective control. A positive value indicates a decrease.

~ indicates no assessments were made for this treatment.

Conclusions
The effects of freshly-dried and field-aged foliar residues of CHR/H/FDF 574 SC on the predatory mite Typhlodromus pyri were evaluated in a series of extended laboratory tests. When applied to sweetcorn plants at a rate equivalent to 0.4 L test item/ha, fresh-dried residues and 14-day field-aged residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the mites, (i.e. < 50% corrected mortality and < 50% reduction in reproduction, relative to the control).

TEST VALIDITY CRITERIA
For a bioassay to be deemed valid (Blümel et al., 2000), it was considered that:
a) mortality in the control treatment over the initial 7 days of a bioassay should not exceed 20%. (was 5%)
b) corrected mortality in the toxic reference treatment should be 50-100%. (was 100%)
c) the mean cumulative number of eggs produced between 7 and 14 days should be equal to or exceed 4.0 per female in the control treatment. (was >4)
All of these criteria, where relevant, were met in the 0 and 14 DAT bioassays.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

A 2.4.1.1.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 222 and according to the principles of GLP. No deviation were noted during the study. In the definitive test all the validity criteria were met according to OECD Guideline No. 222: The study is reliable and suitable for the risk assessment. EC_{10}= 99.439 mg/kg dry weight of the artificial soil (equal to 1.006 mg of florasulam + 25.122 mg of flufenacet + 20.406 mg of diflufenican/kg dry weight of the artificial soil). NOEC=100 mg/kg dry weight of the artificial soil (equal to 1.012 mg of florasulam + 25.263 mg of flufenacet + 20.521 mg of diflufenican/kg dry weight of the artificial soil). EC_{50}= 188.136 mg/kg dry weight of the artificial soil (equal to 1.903 mg of florasulam + 47.529 mg of flufenacet + 38.607 mg of diflufenican/kg dry weight of the artificial soil).

Reference:	KCP 10.4/01
Report	CHR/H/FDF 574 SC Earthworm reproduction test (Eisenia andrei); A. Gierbuszewska, 2021, Study code: G-77-20, Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxico-logical Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	According to the OECD Guideline No. 222 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	**CHR/H/FDF 574 SC** batch no.: 052020
Active substances:	florasulam 12.2 g/L flufenacet 304.7 g/L diflufenican 247.5 g/LL

Artificial soil:	10% sphagnum peat, 20% kaolin clay, 70% air-dried quartz sand
Test organism:	the earthworm, *Eisenia andrei* obtained from a standard laboratory culture cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Soil Organisms Toxicology
Test design:	test duration: 8 weeks; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate
Concentrations of the test item:	control, 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0 and 1000.0 mg/kg dry weight of the artificial soil
Test conditions:	temperature: 19.0 – 22.0°C; pH at the beginning of the experiment: 5.56 – 5.63; pH at the end of the experiment: 5.50 – 5.75; soil moisture content at the beginning of the experiment: 23.1 – 25.6% (44.3 – 49.1% of the maximum water holding capacity); soil moisture content at the end of the experiment: 23.6 – 26.5% (45.3 – 50.8% of the maximum water holding capacity); light-dark cycle: 16h : 8h; light intensity at the beginning of the experiment: 552 – 624 lux light intensity at the end of the experiment: 584 – 624 lux
Statistical analysis:	EC10, EC20, EC50, LC50 – probit analysis using linear max. likelihood regression, NOEC (reproduction) – Shapiro-Wilk's Test on Normal Distribution, Bartlett's Test Procedure on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, NOEC (survival) – Fisher's Exact Binomial Test with Bonferroni Correction LOEC: a values suggested by the ToxRat Professional 2.10 statistical computer software
Endpoint:	EC10, EC20, EC50, NOEC, LOEC (reproduction) LC50, NOEC, LOEC (survival)

Results and discussion

The aims of the study were to assess the impact of CHR/H/FDF 574 SC on reproduction of the earthworm, Eisenia andrei and to determine EC10, EC20, EC50 and NOEC. The test item in the form of an aqueous suspension was mixed with a suitable amount of the artificial soil. The concentrations of the test item were: 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0 and 1000.0 mg/kg dry weight of the artificial soil. Each of them was divided into four replicates. There was also one untreated control group with the deionised water only. Control group was divided into eight replicates. The experiment lasted 8 weeks.
After 4 weeks, all of adult earthworms were removed from the test containers and observed. All changes in their behavior and morphology were recorded. The number of earthworms and their body weights were also determined. The impact of the test item on reproduction was evaluated after the additional 4 week period on the basis of the number of juveniles hatched from cocoons during the experiment..
At concentrations ranging from 5.6 to 1000.0 mg of the test item/kg dry weight of artificial soil, after 4 weeks of exposure to the test item, mortality of the adult earthworms was between 2.5 and 37.5%.
As for the control group, mortality of the adult earthworms was equal to 7.5%.
The concentration of the test item causing 50% mortality of the adult earthworms (LC50) is above 1000.0 mg/kg dry weight of the artificial soil (above 10.115 mg of florasulam + 252.632 mg of flufenacet + 205.207 mg of diflufenican/kg dry weight of the artificial soil). No changes in the appearance (morphology) and behaviour of the living adult earthworms were noticed.
After 4 weeks of the exposure period of the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of artificial soil, the body weight increase was between -61.2 and 2.6%. As for the control group, the body weight decrease was equal to 4.8%. After 8 weeks of the experiment, the obtained results led to the following conclusions:
After the application of the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 0.0 and 167.8 per replicate. The mean number of juveniles in the control group was equal to 123.1 per replicate.
After 8 weeks of the experiment, it was concluded that CHR/H/FDF 574 SC had a statistically significant impact on reproduction of the earthworms at the concentrations ranging from 180.0 to 1000.0 mg/kg dry weight of the artificial soil.

Mortality of the adult earthworms (Eisenia andrei) after 4 weeks of the experiment.

Concentration of the test item [mg/kg dry weight of the artificial soil]	Replicate	Number of tested earthworms [no.]	Number of alive earthworms [no.]	Total mortality	
				[no.]	[%]
0.0 (control)	1 2 3 4 5 6 7 8	10 10 10 10 10 10 10 10	10 9 9 9 9 9 9 10	6	7.5
5.6	1 2 3 4	10 10 10 10	10 9 10 9	2	5.0
10.0	1 2 3 4	10 10 10 10	9 9 8 9	5	12.5
18.0	1 2 3 4	10 10 10 10	9 10 9 9	3	7.5
32.0	1 2 3 4	10 10 10 10	10 10 10 9	1	2.5
56.0	1 2 3 4	10 10 10 10	9 10 10 9	2	5.0
100.0	1 2 3 4	10 10 10 10	9 9 9 8	5	12.5
180.0	1 2 3 4	10 10 10 10	9 9 9 9	4	10.0
320.0	1 2 3 4	10 10 10 10	9 10 9 8	4	10.0
560.0	1 2 3 4	10 10 10 10	9 9 8 9	5	12.5
1000.0	1 2 3 4	10 10 10 10	5 7 6 7	15*	37.5

* - statistically significant difference (Fisher's Exact Binomial Test with Bonferroni Correction, alpha = 0.05, one-sided greater)

Number of juvenile earthworms (Eisenia andrei) after 8 weeks of the experiment.

Concentration of the test item [mg/kg dry weight of the artificial soil]	Replicate	Number of juveniles [no.]	Mean ±SD	Comparison to the control [%]	CV* [%]
0.0 (control)	1 2 3 4 5 6 7 8	141 99 147 127 75 107 133 156	123.1 ± 27.4	-	22.2
5.6	1 2 3 4	142 166 132 133	143.3 ± 15.8	**116.3**	11.0
10.0	1 2 3 4	143 140 113 91	121.8 ± 24.5	**98.9**	20.2
18.0	1 2 3 4	137 123 157 180	149.3 ± 24.8	**121.2**	16.6
32.0	1 2 3 4	156 192 137 163	162.0 ± 22.8	**131.6**	14.1
56.0	1 2 3 4	159 133 146 233	167.8 ± 44.8	**136.2**	26.7
100.0	1 2 3 4	150 139 127 114	132.5 ± 15.5	**107.6**	11.7
180.0	1 2 3 4	74 41 58 43	54.0⁺ ± 15.3	**43.9**	28.4
320.0	1 2 3 4	28 35 31 20	28.5⁺ ± 6.4	**23.1**	22.3
560.0	1 2 3 4	0 0 0 0	0.0⁺ ± 0.0	**0.0**	-
1000.0	1 2 3 4	0 0 0 0	0.0⁺ ± 0.0	**0.0**	-

* coefficient of variation;

⁺ - statistically significant difference (Williams Multiple Sequential t- test Procedure, alpha = 0.05, one-sided smaller)

Results of the observations for changes in behaviour and in morphology of the juveniles earthworms.

Concentration of the test item [mg/kg dry weight of the artificial soil]	Replicate	Number of juveniles after 8 weeks of the experiment [no.]	Changes in behaviour and in morphology
0.0 (control)	1	141	nc
	2	99	nc
	3	147	nc
	4	127	nc
	5	75	nc
	6	107	nc
	7	133	nc
	8	156	nc
5.6	1	142	nc
	2	166	nc
	3	132	nc
	4	133	nc
10.0	1	143	nc
	2	140	nc
	3	113	nc
	4	91	nc
18.0	1	137	nc
	2	123	nc
	3	157	nc
	4	180	nc
32.0	1	156	nc
	2	192	nc
	3	137	nc
	4	163	nc
56.0	1	159	nc
	2	133	nc
	3	146	nc
	4	233	nc
100.0	1	150	nc
	2	139	nc
	3	127	nc
	4	114	nc
180.0	1	74	nc
	2	41	nc
	3	58	nc
	4	43	nc
320.0	1	28	nc
	2	35	nc
	3	31	nc
	4	20	nc
560.0	1	0	-
	2	0	-
	3	0	-
	4	0	-
1000.0	1	0	-
	2	0	-
	3	0	-
	4	0	-

nc – no changes

Endpoint	Value [mg/kg dry weight of the artificial soil]	Value [mg of florasulam/kg dry weight of the artificial soil]	Value [mg of flufenacet/kg dry weight of the artificial soil]	Value [mg of diflufenican/kg dry weight of the artificial soil]
EC_{10}	99.439 (64.009 – 123.256)	1.006 (0.647 – 1.247)	25.122 (16.171 – 31.138)	20.406 (13.135 – 25.293)
EC_{20}	123.770 (90.093 – 146.519)	1.252 (0.911 – 1.482)	31.268 (22.760 – 37.015)	25.398 (18.488 – 30.067)
EC_{50}	188.136 (162.027 – 218.094)	1.903 (1.639 – 2.206)	47.529 (40.933 – 55.098)	38.607 (33.249 – 44.754)
NOEC (reproduction)	100.000	1.012	25.263	20.521
LOEC (reproduction)	180.000	1.821	45.474	36.937
LC_{50}	> 1000.000	> 10.115	> 252.632	> 205.207
NOEC (survival)	560.000	5.665	141.474	114.916
LOEC (survival)	> 1000.000	> 10.115	> 252.632	> 205.207

VALIDITY CRITERIA
The results are considered valid because the following criteria were satisfied in the controls:
- each replicate produced from 75 to 156 juveniles (123.1 mean) at the end of the experiment (criterion: ≥ 30 juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 22.2% (criterion: ≤ 30%),
- adult mortality over the initial 4 weeks of the experiment was 7.5% (criterion: ≤ 10%).

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1.1 Folsomia candida

Comments of zRMS:	The study was conducted to OECD guideline 232 and according to the principles of GLP. Following deviations from the guideline 232 were noted: - culturing of collembolans takes place in plastic containers containing an artificial substrate consisting of plaster and charcoal in ratio 9:1 and not 10:1 or 8:1 as is mentioned in OECD Guideline No. 232

	- at the end of the test the soil moisture content was determined by drying small sample of the artificial soil in 105°C instead of weighing the test vessels as it is mentioned in OECD Guideline No. 232 (2016) Since all validity criteria were met these deviations did not affect the results of the study. The study is reliable and suitable for the risk assessment. NOECreproduction = 32 mg formulation/kg dw

Reference:	KCP 10.4/02
Report	CHR/H/FDF 574 SC Collembolan (Folsomia candida) Reproduction Test, A. Arendarczyk, 2021, Study code: G-78-20, Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Depart-ment of Ecotoxico-logical Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the OECD Guideline No. 232 (2016)
Deviations:	Yes ~~No~~
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item: CHR/H/FDF 574 SC
batch no.: 052020
Active substances: florasulam 12.2 g/L
flufenacet 304.7 g/L
diflufenican 247.5 g/L

Artificial soil: 5% sphagnum peat, 20% kaolin clay, and 75% air-dried
industrial sand

Test organism: the collembolan, Folsomia candida obtained from a standard laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Laboratory of Soil Organisms Toxicology. The collembolans used in the study were between 9 to 11 days old

Test design:
test duration: 28 days
number of replicates: 4 replicates / concentration + 8
replicates / control; number of collembolans: 10 / replicate

Concentrations of the test item:
a control, 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0, and 1000.0 mg of the test item/kg of dry weight of the artificial soil

Test conditions: temperature: 21.1 – 22.0°C;
pH at the beginning of the test: 5.21 – 5.58;
pH at the end of the test: 5.04 – 5.17;
soil moisture content at the beginning of the test: 14.0 – 15.6% (43.1 – 48.0% of the maximum water holding capacity);
soil moisture content at the end of the test: 13.3 – 14.9% (41.0 – 45.9% of the maximum water holding capacity);
lighting: 16 h light and 8h dark;
light intensity at the beginning of the experiment: 495.7 – 567.3 lux;

light intensity at the end of the experiment: 578.5 – 675.1 lux

Statistical analysis: EC10, EC20, EC50 – logit analysis using linear max. likelihood regression
LC10, LC20 and LC50 – probit analysis using linear weighted regression
NOEC (number of juveniles):
- Shapiro-Wilk's Test on Normal Distribution,
- Bartlett's Test Procedure on Variance Homogeneity,
- Williams Multiple Sequential t-test Procedure
NOEC (survival):
- Fisher's Exact Binomial Test with Bonferroni
Correction.
Endpoints: EC10, EC20, EC50, NOEC, LC10, LC20, LC50, NOEC

Results and discussion
The aims of the study were to assess the impact of CHR/H/FDF 574 SC on reproduction of the collembolans, Folsomia candida and to determine the EC10, EC20, EC50, and NOEC. Ten concentrations of the test item were used. These were 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0, and 1000.0 mg of the test item/kg of dry weight of the artificial soil. Each concentration was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in form of aqueous suspension was mixed with the artificial soil. The control artificial soil was mixed with deionized water alone. The exposure period lasted 28 days. After that, the collembolans were extracted from the artificial soil. The numbers of adults and juveniles were determined separately. At the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil, the mortality of adults ranged from 5.0 to 55.0%. As for the control group, it was equal to 7.5%.

Mortality of adult collembolans (Folsomia candida) after 28 days of the experiment.

Concentration [mg/kg dry weight of the artificial soil]	Replicate	Number of tested collembolans	Number of living collembolans after 28 days [no.]	Total mortality	
				No.	%
control	1 2 3 4 5 6 7 8	10 10 10 10 10 10 10 10	9 10 8 10 10 8 9 10	6	7.5
5.6	1 2 3 4	10 10 10 10	10 10 8 9	3	7.5
10.0	1 2 3 4	10 10 10 10	9 9 9 9	4	10.0
18.0	1 2 3 4	10 10 10 10	9 8 10 10	3	7.5
32.0	1 2 3 4	10 10 10 10	10 9 10 9	2	5.0
56.0	1 2 3 4	10 10 10 10	10 9 9 9	3	7.5
100.0	1 2 3 4	10 10 10 10	8 9 9 10	4	10.0
180.0	1 2 3 4	10 10 10 10	10 10 9 9	2	5.0
320.0	1 2 3 4	10 10 10 10	8 10 8 8	6	15.0
560.0	1 2 3 4	10 10 10 10	8 8 7 9	8	20.0
1000.0	1 2 3 4	10 10 10 10	6 4 2 6	22*	55.0

"+" - statistically significant differences between the control and the treatment group were noticed (Fisher's Exact Binomial Test with Bonferroni Correction, significance level = 0.05, one-sided greater)

The concentration of the test item causing a 50% mortality of adults within the exposure period (LC50) is above 1000.0 mg/kg dry weight of the artificial soil (above 10.12 mg of florasulam + 252.63 mg of flufenacet + 205.21mg of diflufenican/kg dry weight of the artificial soil). The endpoint values showing the impact of the test item on the survival of adult collembolans are presented in the table given below..

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of florasulam/kg dry weight of the artificial soil]	Value [mg of flufenacet/kg dry weight of the artificial soil]	Value [mg of diflufenican/kg dry weight of the artificial soil]
LC_{10}	273.03	2.76	68.98	56.03
LC_{20}	515.46	5.21	130.22	105.78
LC_{50}	>1000.00	>10.12	>252.63	>205.21
NOEC	560.00	5.66	141.47	114.92

After the exposure of collembolans to the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 13.0 – 749.3 per replicate. As for the control group, the number of juveniles was equal 742.1 per replicate. The endpoint values showing the impact of the test item on reproduction of Folsomia candida are presented in the table given below..

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of florasulam/kg dry weight of the artificial soil]	Value [mg of flufenacet/kg dry weight of the artificial soil]	Value [mg of diflufenican/kg dry weight of the artificial soil]
EC_{10}	38.47 (30.95 – 45.73)	0.39 (0.31 – 0.46)	9.72 (7.82 – 11.55)	7.90 (6.35 – 9.38)
EC_{20}	59.80 (50.90 – 68.23)	0.60 (0.51 – 0.69)	15.11 (12.86 – 17.24)	12.27 (10.44 – 14.00)
EC_{50}	139.07 (126.58 – 152.78)	1.41 (1.28 – 1.55)	35.13 (31.98 – 38.60)	28.54 (25.98 – 31.35)
NOEC	32.00	0.32	8.08	6.57

VALIDITY CRITERIA

The results are considered valid because the following criteria were satisfied in the controls:
- mean adult mortality: 7.5% (criterion: ≤ 20%),
- the mean number of juveniles per vessel at the end of the test: 742.1 (criterion: ≥100 juveniles at the end of the test),
- the coefficient of variation calculated for the number of juveniles: 12.0 (criterion: ≤ 30%).

A 2.4.2.1.2 Hypoaspis aculeifer

Comments of zRMS:	The study was conducted to OECD guideline 226 and according to the principles of GLP. Following deviations from the guideline 232 were noted, however they did not affect the results since all the validity criteria of the method were met: 1. According to the OECD Guideline No. 226 (2016) the water content of the soil substrate should be maintained throughout the test by weighing and if needed re-watering the vessels periodically. In the study to maintain proper moisture content, a small sample of soil was drying at 105°C and re-weighing at the beginning, after 7 days of the test and at the end of the test 2. Due to the use of the temperature extraction method, there was no need for euthanasia of the extracted organisms, since the mites are fixed in a 70% ethanol solution 3. Due to the use of the temperature extraction method, it was not possible to record the symptoms with behavioral and morphology changes of the extracted predatory mites. The study is reliable and suitable for the risk assessment. NOECsurvival= 18 mg formualtion/kg dw

Reference:	KCP 10.4/03
Report	CHR/H/FDF 574 SC Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil, A. Gierbuszewska, 2021, Study code: G-79-20, Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Depart-ment of Ecotoxico-logical Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the OECD Guideline No. 226 (2016)
Deviations:	Yes ~~No~~
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:
CHR/H/FDF 574 SC
batch number: 052020

Active substance:
florasulam 12.2 g/L
flufenacet 304.7 g/L
diflufenican 247.5 g/L

Artificial soil:
5% sphagnum peat, 20% kaolin clay, and 75% air-dried industrial sand

Test organism:
the predatory mites, Hypoaspis (Geolaelaps) aculeifer (adult female mites from a synchronized culture) obtained from a standard laboratory culture at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Soil Organisms Toxicology. The mites were introduced 7 – 14 days after becoming adult.

Test design:
Concentrations of the test item:
test duration: 14 days
number of replicates: 4 replicates / concentration + 8 replicates / control; number of mites: 10 mites / replicate

Concentrations of the test item:
a control, 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0 and 1000.0 mg test item/kg dry weight of the artificial soil..

Test conditions:
temperature: 21.1 – 22.0°C
pH at the beginning of the test: 5.59 – 5.72
pH at the end of the test: 5.58 – 5.66
soil moisture content at the beginning of the test: 14.4 – 15.9% (46.1 – 50.9% of the maximum water holding capacity)
soil moisture content in the middle of the test: 14.5 – 15.7% (46.4 – 50.2% of the maximum water holding capacity)
soil moisture content at the end of the test: 13.5 – 16.1% (43.2 – 51.5% of the maximum water holding capacity)
light-dark cycle: 16 h light and 8 h dark
light intensity at the beginning of the test: 507 – 521 lux
light intensity at end of the test: 524 – 563 lux

Statistical analysis:
EC10, EC20, EC50 – a probit analysis using linear max. likelihood regression
LC10, LC20, LC50 – a probit analysis using linear max. likelihood regression
NOEC:
- offspring number – Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Trend analysis by Contrast (Monotonicity of Response), Dunnett's Multiple Multiple t-test Procedure
- survival – Qualitative Trend Analysis by Contrast (Monotonicity of Response), Chi2×2 Table Test with Bonferroni Correction

Endpoints:
EC10, EC20, EC50, NOEC
LC10, LC20, LC50, NOEC

Results and discussion
The aims of the study were to assess the impact of CHR/H/FDF 574 SC on reproduction of the predatory mite, Hypoaspis (Geolaelaps) aculeifer and to determine the EC10, EC20, EC50, and NOEC.
Ten concentrations of the test item were used. These included: 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0 and 1000.0 mg/kg dry weight of the artificial soil. Each concentration was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in the form of aqueous suspension was mixed with the artificial soil. The control artificial soil was mixed with deionized water alone. The experiment lasted 14 days. After that, the mites were extracted from the artificial soil (48-hour extraction). The numbers of adults and juveniles were determined separately. Mortality of the predatory mites exposed to the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil was between 0.0% and 27.5%. Mortality of the control group was equal to 3.8%. After the application of the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil the mean number of juveniles was between 38.3 – 149.8 per replicate. The mean number of juveniles in the control group was equal to 141.0 per replicate.
The results are summarized in the table given below.

Concentration [mg/kg dry weight of the artificial soil]	Adult mites		Number of juveniles (mean)
	Number of tested mites	Number of dead mites after 14 days	
Control	80	3	141.0
5.6	40	3	141.5
10.0	40	1	149.8
18.0	40	7	139.3
32.0	40	9	131.5
56.0	40	3	127.3
100.0	40	2	117.5
180.0	40	0	116.3
320.0	40	4	96.0
560.0	40	8	77.3
1000.0	40	11	38.3

Mortality of adult mites (Hypoaspis aculeifer) after 14 days of the experiment.

Concentration [mg/kg dry weight of the artificial soil]	Replicate	Number of tested mites	Number of alive mites after 14 days [no.]	Mortality	
				no.	%
0.0 (control)	1 2 3 4 5 6 7 8	10 10 10 10 10 10 10 10	10 9 10 10 8 10 10 10	**3**	**3.8**
5.6	1 2 3 4	10 10 10 10	8 10 9 10	**3**	**7.5**
10.0	1 2 3 4	10 10 10 10	9 10 10 10	**1**	**2.5**
18.0	1 2 3 4	10 10 10 10	10 8 10 5	**7**	**17.5**
32.0	1 2 3 4	10 10 10 10	10 7 8 6	**9⁺**	**22.5**
56.0	1 2 3 4	10 10 10 10	9 10 10 8	**3**	**7.5**
100.	1 2 3 4	10 10 10 10	10 8 10 10	**2**	**5.0**
180.0	1 2 3 4	10 10 10 10	10 10 10 10	**0**	**0.0**
320.0	1 2 3 4	10 10 10 10	10 9 9 8	**4**	**10.0**
560.0	1 2 3 4	10 10 10 10	8 8 8 8	**8⁺**	**20.0**
1000.0	1 2 3 4	10 10 10 10	8 7 7 7	**11⁺**	**27.5**

⁺ - statistically significant difference between the control and the treatment group (Fisher's Exact Binominal Test with Bonferroni Correction, significance level = 0.05, one-sided greater)

Endpoint values – the impact of the test item on reproduction and on mortality of the predatory mites *(Hypoaspis aculeifer).*

Endpoint	Value [mg/kg dry weight of the artificial soil]	Value [mg of florasulam/kg dry weight of the artificial soil]	Value [mg of flufenacet/kg dry weight of the artificial soil]	Value [mg of diflufenican/kg dry weight of the artificial soil]
EC_{10}	**88.098** (50.026 – 125.550)	**0.891** (0.506 – 1.270)	**22.256** (12.638 – 31.718)	**18.078** (10.266 – 25.764)
EC_{20}	**165.914** (114.031 – 213.653)	**1.678** (1.153 – 2.161)	**41.915** (28.808 – 53.976)	**34.047** (23.400 – 43.843)
EC_{50}	**556.956** (455.176 – 715.825)	**5.634** (4.604 – 7.241)	**140.705** (114.992 – 180.841)	**114.291** (93.405 – 146.892)
NOEC (reproduction)	**56.000**	**0.566**	**14.147**	**11.492**
LC_{10}	**143.364**	**1.450**	**36.218**	**29.419**
LC_{20}	**> 1000.000**	**> 10.115**	**> 252.632**	**> 205.207**
LC_{50}	**> 1000.000**	**> 10.115**	**> 252.632**	**> 205.207**
NOEC (survival)	**18.000**	**0.182**	**4.547**	**3.694**

VALIDITY CRITERIA
The results are considered valid because the following criteria were satisfied in the control:
- mean adult mortality: 3.8% (criterion: ≤ 20%),
- the mean number of juveniles per vessel at the end of the test: 141.0 (criterion: ≥ 50 juveniles at the end of the test),
- the coefficient of variation for the number of juveniles: 16.8% (criterion: ≤ 30%).

A 2.4.2.2 KCP 10.4.2.1 Species level testing

A 2.4.2.3 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

A 2.5.1.1.1 Nitrogen transformation

Comments of zRMS:	The study was conducted to OECD guideline 216 and according to the prin-ciples of GLP. Following deviations from the OECD Guideline No. 216 (2000), the EU Method C.21were noted: - the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm for 24 hours. The modification resulted from the optimization of the nitrate extraction which showed that the extraction was more effective when the shaking rate was lower and the extraction lasted longer - The predicted environmental concentration (PEC) was calculated assuming 1 cm of the soil depth according to the German conditions for the active substances with the mobility in soil KFoc > 500 mL/g. Thus, the applied soil depth is a deviation from the OECD Guideline No. 216 (2000) and EU Method C.21 where the PEC is calculated by using 5 cm of the soil depth In the definitive test all the validity criteria were met as follows: The coefficients of variation (CV) in the control group were 5.2, 10.7, 0.7, 2.2 and 1.3%, after 0, 7, 14, 28 and 42 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than 15%. On the basis of the results, it was concluded that CHR/H/FDF 574 SC at the concentrations corresponding to the **PEC: 3.22 mg** of the test item/kg dry weight of soil (i.e. 0.03 mg of florasulam + 0.81 mg of flufenacet + 0.66 mg of diflufenican/kg dry weight of soil) and **5xPEC: 16.08 mg** of the test item/kg dry weight of soil (i.e. 0.16 mg of florasulam + 4.06 mg of flufenacet + 3.30 mg of diflufenican/kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils..

Reference:	KCP 10.5/01
Report	CHR/H/FDF 574 SC Soil Microorganisms: Nitrogen Transformation Test, A. Arendarczyk, 2021, Study code: G-80-20, Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	Organization for Economic Cooperation and Development (OECD), Guidelines for Testing of Chemicals, Guideline No. 216, “Soil Microorganisms: Nitrogen Transformation Test” adopted January 21, 2000
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material: CHR/H/FDF 574 SC
batch no.: 052020

Active substance: florasulam – 12.2 g/L,
flufenacet – 304.7 g/L,
diflufenican – 247.5 g/L

Soil: Agricultural soil collected from a place belonging to the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna

Test design: Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500 g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil.

Test duration: 42 days.

Concentrations of the test item:
control; PEC: PEC: 3.22 mg of the test item/kg dry weight of soil (i.e. 0.03 mg of florasulam + 0.81 mg of flufenacet + 0.66 mg of diflufenican/kg dry weight of soil)
5 x PEC: 16.08 mg of the test item/kg dry weight of soil (i.e. 0.16 mg of florasulam + 4.06 mg of flufenacet + 3.30 mg of diflufenican/kg dry weight of soil).)

Test conditions:
temperature: 18.8 – 21.5°C,
soil moisture: 44.6 – 51.8% of the maximum water holding capacity, incubation in darkness

Endpoints: The concentration of nitrate [mg/kg dry soil] after 0, 7, 14, 28 and 42 days of incubation.
The nitrate formation rate [mg/kg dry weight of soil/day]
for selected time intervals of soil incubation, i.e. 0 – 7, 0 – 14, 0 – 28, 0 – 42 days.
Percent deviation from the control in nitrate formation rate calculated for selected time intervals i.e. 0 – 7, 0 – 14, 0 – 28, 0 – 42 days.

Statistical analysis: - Shapiro-Wilk's test on Normal Distribution
- Levene's Test on Variance Homogeneity (with Residuals)
- Williams Multiple Sequential t-test Procedure

Results and discussion

The aim of the study was to detect long-term adverse effects of CHR/H/FDF 574 SC on the processes of nitrogen transformation in aerobic surface soils. The freshly collected agricultural soil was used in the experiment. It was manually cleared of large objects and sieved to a particle size of 2 mm. Two concentrations of the test item were used in the experiment:
- PEC: 3.22 mg of the test item/kg dry weight of soil (i.e. 0.03 mg of florasulam + 0.81 mg of flufenacet + 0.66 mg of diflufenican/kg dry weight of soil).
- 5 x PEC: 16.08 mg of the test item/kg dry weight of soil (i.e. 0.16 mg of florasulam + 4.06 mg of flufenacet + 3.30 mg of diflufenican/kg dry weight of soil).
The treated and the control soils were divided into three replicates. On days 0, 7, 14, 28 and 42 of incubation, soil samples were collected to determine the quantities of nitrate. The method involves a measurement of the nitrates ions concentration in a soil extract obtained by using deionised water. The pH/ION 7320 digital meter and the NO 800 nitrate electrode were used. The nitrate formation rate in each treated group was compared with that in the control, and the percent deviation of the treated from the control was calculated..

On 28 day of analysis the percent deviation from the control calculated on the basis of the nitrate formation rate of the soil treated with the test item at the concentration corresponding to the PEC and 5xPEC

exceeded 25%, therefore, according to the OECD No. 216, EU Method C.21 and the study plan, the experiment was continued.
The difference in the nitrate formation rate between the control soil and the ones treated with the test item at the concentrations corresponding to the PEC: 3.22 mg of the test item/kg dry weight of soil (i.e. 0.03 mg of florasulam + 0.81 mg of flufenacet + 0.66 mg of diflufenican/kg dry weight of soil) and 5xPEC: 16.08 mg of the test item/kg dry weight of soil (i.e. 0.16 mg of florasulam + 4.06 mg of flufenacet + 3.30 mg of diflufenican/kg dry weight of soil) did not exceed 25% on 42 day of analysis..

Nitrate formation rate* [mg nitrate/kg dry weight of soil/day] for selected time intervals

Time interval [d]	Control				PEC				5 x PEC			
	Replicate			Mean ± SD	Replicate			Mean ± SD	Replicate			Mean ± SD
	I	II	III		I	II	III		I	II	III	
0 – 7	-5.857	-11.114	-8.257	-8.409 ± 2.63	-12.726	-15.347	-14.761	-14.278 ± 1.38	-15.838	-10.938	-10.195	-12.323 ± 3.07
0 – 14	2.222	2.054	1.986	2.087 ± 0.12	0.094	1.994	1.505	1.198 ± 0.99	2.106	3.520	1.199	2.275 ± 1.17
0 – 28	2.406	2.362	1.990	2.253 ± 0.23	1.037	1.618	1.553	1.403* ± 0.32	1.427	1.524	1.493	1.481* ± 0.05
0 – 42	3.160	2.943	2.984	3.029 ± 0.12	2.552	2.645	3.906	3.034 ± 0.76	3.771	3.411	3.585	3.589 ± 0.18

* - Rate of nitrate ions formation per a day = [(mg nitrate / kg of soil dry weight on sampling day 'a') - (mg nitrate / kg of soil dry weight on day 0)]/ 'a' day; 'a' = 7, 14, 28 and 42 day

* - statistically significant difference between the control and the treatment group (Williams Multiple Sequential t-test Procedure, significance level = 0.05, two sided)

Deviations from the control based on nitrate formation rate for selected time intervals [%]

Time interval [d]	PEC	5 x PEC
0 – 7	-69.8	-46.5
0 – 14	42.6	-9.0
0 – 28	37.7	34.2
0 – 42	-0.2	-18.5

"-" - values of nitrate formation rate higher than the ones obtained for the control group

Values obtained using ToxRat 2.10. computer software.

Conclusions:
On the basis of the results, it was concluded that CHR/H/FDF 574 SC at the concentrations corresponding to the PEC: 3.22 mg of the test item/kg dry weight of soil (i.e. 0.03 mg of florasulam + 0.81 mg of flufenacet + 0.66 mg of diflufenican/kg dry weight of soil) and 5xPEC: 16.08 mg of the test item/kg dry weight of soil (i.e. 0.16 mg of florasulam + 4.06 mg of flufenacet + 3.30 mg of diflufenican/kg dry weight

of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

VALIDITY CRITERION
The coefficients of variation (CV) in the control group were 5.2, 10.7, 0.7, 2.2 and 1.3%, after 0, 7, 14, 28 and 42 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than 15%.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

A 2.6.2.1.1 Seedling Emergence

Comments of zRMS:	The seedling emergence study was conducted to OECD guideline 208 and according to the principles of GLP. In the definitive test all the validity criteria were met. Following deviation from OECD Guideline No. 208 was noted: According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 90.73 and 179.1 µE/m2 /s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. This deviation did not affect results of the experiment The study is acceptable and reliable for risk assessment purposes.

Reference:	KCP 10.6.1/01
Report	CHR/H/FDF 574 SC Terrestial Plant Test: Seedling Emergence and Seedling Growth Test, A. Gierbuszewska, 2021, Study code: G-82-20, Łukasiewicz Research Network – Institute of Industrial Organic Chemis-try, Branch Pszczyna Depart-ment of Ecotoxicological Studies, Doświ-adczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	OECD Guideline 208, 2006
Deviations:	Yes ~~No~~
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	**CHR/H/FDF 574 SC** batch number: 052020 active substances: florasulam 12.2 g/L flufenacet 304.7 g/L diflufenican 247.5 g/L
Test species:	sunflower (*Helianthus annuus)*, flax (*Linum usitatissimum*), pea *(Pisum sativum)*, carrot *(Daucus carota)*, onion *(Allium cepa)*, corn *(Zea mays)*
Soil:	Sandy loam
Study design:	number of rates: - 5 + control for corn, - 6 + control for carrot, - 7 + control for sunflower, pea, flax and onion, Number of seeds: - 4 for carrot, flax, onion, - 7 for pea, sunflower, - 10 for corn. The total number of seeds per application rate: - 20 for carrot, flax, onion and corn, - 21 for pea and sunflower; test termination: 14 days after the emergence of 50% of the control seedlings.
Application rates:	- corn: 0.0000 (control), 0.0100, 0.0260, 0.0640, 0,1600 and 0.4000 L/ha, - carrot: 0.0000 (control), 0.0041, 0.0100, 0.0260, 0.0640, 0,1600 and 0.4000 L/ha, - sunflower, pea, flax and onion: 0.0000 (control), 0.0016, 0.0041, 0.0100, 0.0260, 0.0640, 0,1600 and 0.4000 L/ha.
Volume of deionized water:	volume of deionized water used to prepare the highest rate corresponded to 300 L water/ha.
Test conditions:	temperature: 18.2 – 24.1°C, humidity: 47.5 – 83.9%, lighting: 16 h light : 8 h dark; light intensity: 90.73 – 179.10 µE/m2/s; carbon dioxide concentration: 348 – 391 ppm
Statistical analysis:	ER_{25}, ER_{50} – probit analysis with the linear max. likelihood regression (final number of plants), non-linear regression - 3 parametric normal Distribution Function (CDF) (plant shoot length and plant shoot weight). NOER (plant emergence): - Multiple Sequentially-rejective Fisher Test After Bonferroni – Holm, - Fisher's Exact Binomial Test with Bonferroni Cor-

	rection, - Tarone's Test Procedure, - Williams Multiple Sequential t-test Procedure were used. NOER (plant shoot length and plant shoot weight): - Shapiro-Wilk's Test on Normal Distribution, - Levene's Test on Variance Homogeneity (with Residuals), - Multiple Sequentially-rejective Welsch-t-test After Bonferroni – Holm, - Step-down Jonckheere-Terpstra Test Procedure, - Williams Multiple Sequential t-test Procedure.
Endpoints:	ER25, ER50, NOER

Results and discuss:

The study, aimed at evaluating the effect CHR/H/FDF 574 SC on seedling emergence and seedling growth of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. The test item was sprayed onto the soil surface. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots. There were 3 (pea, sunflower) or 5 (carrot, flax, onion) or 2 (corn) seeds/pot. The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for emergence (every 1 to 2 days to the emergence of 50% of the control seedlings and after then every 2 – 3 days) and visual phytotoxicity (after 7 and 14 days after the emergence of 50% of the control seedlings). The experiment finished 14 days after the emergence of 50% of the control seedlings. At the end of the experiment, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60ºC, and weighed. The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER25, ER50, and NOER..

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as L of the test item/ha for all test species are given below.

	Sunflower *Helianthus annuus*	**Flax** *Linum usitatissimum*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	>0.400*	0.447	0.049 (0.039 – 0.060)	>0.400*	0.369 (0.239 – 0.889)	> 0.400*
NOER	≥0.400*	0.160	0.026	≥0.400*	0.160	≥ 0.400*
Shoot length (plants without roots)						
ER_{50}	0.152 (0.075 – 0.444)	0.135	0.075 (0.058 – 0.126)	0.308 (0.173 – 1.681)	0.094 (0.060 – 0.159)	0.375
NOER	0.002	0.064	0.010	0.064	0.010	0.026
Plant dry weight (plants without roots)						
ER_{50}	0.226 (0.121 – 0.811)	0.147 (0.142 – 0.152)	0.045 (0.032 – 0.075)	0.128 (0.100 – 0.165)	0.040 (0.026 – 0.061)	0.395
NOER	0.002	0.064	0.004	0.026	0.004	0.160

The ER_{50} and NOER values were calculated using the ToxRat Professional 2.10 computer software.
*the value could not be dertermined, it can be probably higher than the highest rate of the test item used in the experiment, i.e. 0.400 L/ha

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of florasulam/ha for all test species are given below..

	Sunflower *Helianthus annuus*	**Flax** *Linum usitatissimum*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 4.880*	5.453	0.598 (0.476 – 0.732)	> 4.880*	4.502 (2.916 – 10.846)	> 4.880*
NOER	≥ 4.880*	1.952	0.317	≥ 4.880*	1.952	≥ 4.880*
Shoot length (plants without roots)						
ER_{50}	1.854 (0.915 – 5.417)	1.647	0.915 (0.708 – 1.537)	3.758 (2.111 – 20.508)	1.147 (0.732 – 1.940)	4.575
NOER	0.024	0.781	0.122	0.781	0.122	0.317
Plant dry weight (plants without roots)						
ER_{50}	2.757 (1.476 – 9.894)	1.793 (1.732 – 1.854)	0.549 (0.390 – 0.915)	1.562 (1.220 – 2.013)	0.488 (0.317 – 0.744)	4.819
NOER	0.024	0.781	0.049	0.317	0.049	1.952

The ER_{50} and NOER values were calculated using the ToxRat Professional 2.10 computer software.
*the value could not be dertermined, it can be probably higher than the highest rate of the test item used in the experiment, i.e. 0.400 L/ha

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of flufenacet/ha for all test species are given below..

	Sunflower *Helianthus annuus*	**Flax** *Linum usitatissimum*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 121.880*	136.201	14.930 (11.883 – 18.282)	> 121.880*	112.434 (72.823 – 270.878)	> 121.880*
NOER	≥ 121.880*	48.752	7.922	≥ 121.880*	48.752	≥ 121.880*
Shoot length (plants without roots)						
ER_{50}	46.314 (22.853 – 135.287)	41.135	22.853 (17.673 – 38.392)	93.848 (52.713 – 512.201)	28.642 (18.282 – 48.447)	114.263
NOER	0.609	19.501	3.047	19.501	3.047	7.922
Plant dry weight (plants without roots)						
ER_{50}	68.862 (36.869 – 247.112)	44.791 (43.267 – 46.314)	13.712 (9.750 – 22.853)	39.002 (30.470 – 50.276)	12.188 (7.922 – 18.587)	120.357
NOER	0.609	19.501	1.219	7.922	1.219	48.752

The ER_{50} and NOER values were calculated using the ToxRat Professional 2.10 computer software.
*the value could not be dertermined, it can be probably higher than the highest rate of the test item used in the experiment, i.e. 0.400 L/ha

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of diflufenican/ha for all test species are given below..

	Sunflower *Helianthus annuus*	**Flax** *Linum usitatissimum*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 99.000*	110.633	12.128 (9.653 – 14.850)	> 99.000*	91.328 (59.153 – 220.028)	> 99.000*
NOER	≥ 99.000*	39.600	6.435	≥ 99.000*	39.600	≥ 99.000*
Shoot length (plants without roots)						
ER_{50}	37.620 (18.563 – 109.890)	33.413	18.563 (14.355 – 31.185)	76.230 (42.818 – 416.048)	23.265 (14.850 – 39.353)	92.813
NOER	0.495	15.840	2.475	15.840	2.475	6.435
Plant dry weight (plants without roots)						
ER_{50}	55.935 (29.948 – 200.723)	36.383 (35.145 – 37.620)	11.138 (7.920 – 18.563)	31.680 (24.750 – 40.838)	9.900 (6.435 – 15.098)	97.763
NOER	0.495	15.840	0.990	6.435	0.990	39.600

The ER_{50} and NOER values were calculated using the ToxRat Professional 2.10 computer software.
*the value could not be dertermined, it can be probably higher than the highest rate of the test item used in the experiment, i.e. 0.400 L/ha

On the basis of the obtained results it was proved that the test item i.e. CHR/H/FDF 574 SC had varied impact on seedling emergence and seedling growth of the test plant species.

For the selected application rates, seedling emergence of flax, pea, carrot and onion was delayed when compared with the control. The death of pea at the rates between 0.0640 and 0.4000 L/ha was observed during the experiment. One incidental death of onion occurred at the rate equal to 0.1600 L/ha. The death of sunflower, flax, carrot and corn was not observed.

The lowest ER50 value determined on the basis of the plant emergence at the end of the experiment, was observed for pea and it was equal to 0.049 L of the test item/ha.

The lowest ER50 value determined on the basis of the plant shoot length at the end of the experiment, was observed for pea and it was equal to 0.075 L of the test item/ha.

The lowest ER50 value determined on the basis of the plant shoot weight at the end of the experiment, was observed for onion and it was equal to 0.040 L of the test item/ha.

Significant and moderate inhibition of plant shoot length was observed for sunflower, flax, pea, carrot, onion and corn.
Significant and moderate inhibition of plant shoot weight was observed for sunflower, flax, pea, carrot, onion and corn.

Phytotoxic symptoms of plants, at selected application rates, were observed during the experiment. It was stunted growth, spots, wilting, chlorosis, necrosis and mortality of plants.
The following order of the test plant sensitivity was noticed:

pea > onion > flax > sunflower > carrot > corn.

VALIDITY CRITERIA
On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of CHR/H/FDF 574 SC on seedling emergence and seedling growth of terrestrial plants were met:
- the seedling emergence in the control (validity criterion: at least 70%) was as follows:
100% – sunflower,
100% – flax,
100% – pea,
100% – carrot,
95% – onion,
100% – corn,
- the mean survival of the emerged control seedlings was 100% for sunflower, flax, pea, carrot, onion and corn (validity criterion: 90%);
- the control seedlings did not exhibit any visible phytotoxic effects;
- environmental conditions for all plants of the same species were identical.

A 2.6.2.1.2 Vegetative Vigour

Comments of zRMS:	The Vegetative vigour study was conducted to OECD guideline 227 and according to the principles of GLP. In the definitive test all the validity criteria were met. Following deviation from OECD 227 method was noted: - the light intensity, monitored twice during the experiment, between 50 and 400 µE/m2/s (deviation from the OECD Guideline no. 227). The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 61.66 and 225.3 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing.This deviation did not affect results of the experiment. The study is accepted and reliable for risk assessment purposes.

Reference:	KCP 10.6.1/02
Report	CHR/H/FDF 574 SC Terrestial Plant Test: Vegetative Vigour Test, A. Gierbuszewska, 2021, Study code: G-81-20, Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Depart-ment of Ecotoxicological Studies, Doświ-adczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	OECD Guideline 227, 2006
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:
CHR/H/FDF 574 SC
batch number: 052020
active substances: florasulam – 12.2 g/L
flufenacet – 304.7 g/L
diflufenican – 247.5 g/L

Test species:
pea (Pisum sativum), sunflower (Helianthus annuus), carrot (Daucus carota), flax (Linum usitatissimum), onion (Allium cepa), corn (Zea mays)

Soil: Sandy loam

Study design: number of rates: 9 + control (carrot), 8 + control (pea, flax sunflower, onion , corn); number of replicates/rate: 7 (pea, sunflower), 4 (carrot, flax, onion) or 10 (corn). The total number of plants per application rate – 21 (pea, sunflower) or 20 (carrot, flax, onion, corn)
exposure termination: 21 days after spraying

Application rates:
- control, 1.6, 3.2, 6.3, 12.5, 25.0, 50.0, 100.0, 200.0 and 400.0 mL of the test item / ha –carrot,
- control, 3.2, 6.3, 12.5, 25.0, 50.0, 100.0, 200.0 and 400.0 mL of the test item / ha – pea, flax sunflower, onion , corn,

volume of deionized water used to prepare the highest rate corresponded to 300 L spraying liquid/ha.
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Test conditions:
temperature: 17.2 – 24.1°C, humidity: 47.5 – 83.9%, lighting: 16 h light : 8 h dark; light intensity: 61.66 – 225.3 μE/m2/s; carbon dioxide concentration: 325 – 392 ppm

Statistical analysis:
ER25, ER50 – probit analysis using linear max. likelihood regression, Weibull analysis using linear max. likelihood regression, logit analysis using simple linear regression
NOER:
In order to determine the NOER values for the plant number at the end of the experiment of sunflower, carrot, flax, and onion the Fisher's Exact Binomial Test with Bonferroni Correction was used. In order to determine the NOER value for the plant number at the end of the experiment of pea and corn any computations had been perfomed because of no change in mortality of plants. In order to determine the NOER values for the shoot length at the end of the experiment (shoots cut down above the ground) the following statistical tests were used:
Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test
Procedure or Dunnett's Multiple t-test Procedure
In order to determine the NOER values for the plant weight at the end of the experiment (shoots cut down above the ground), the following statistical tests were used:
Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure or Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment

Endpoints: ER25, ER50, NOER

Results and discussion

The study, aimed at evaluating the effect of CHR/H/FDF 574 SC on vegetative vigour of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. Seeds of the test plant species were sown in plastic pots (6 seeds/pot for pea and sunflower; 10 seeds/pot for carrot, flax, onion and 4 seeds/pot for corn). The plants were grown to the 2- to 4- true leaf stage. Then, some of them were removed. As a result, the number of plants per pot as well as the total number of plants per concentration were:
- pea: 3 plants/pot – 21 plants/application rate (7 pots/application rate);
- sunflower: 3 plants/pot – 21 plants/application rate (7 pots/application rate);
- carrot: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- flax: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- onion: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- corn: 2 plants/pot – 20 plants/ application rate (10 pots/ application rate).

The pot is defined as a replicate. The test item was sprayed onto the plants. The experiment was conducted in a plant growth room where suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for visual phytotoxicity (7, 14 and 21 days after the test item application). The experiment finished 21 days after the spraying. At the end of the experiment, the number of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60ºC to a constant weight and weighed.
The results concerning the shoot length, the dry weight, and the number of plants at the end of the experiment were statistically analyzed to determine the ER25, ER50 and NOER..

The ER50 and NOER values, determined on the basis of plants number, shoot length and shoot dry weight measurements at the end of the experiment, expressed as L of the test item/ha for all test species are given below.

	Pea *Pisum sativum*	Sunflower *Helianthus annuus*	Carrot *Daucus carota*	Flax *Linum usitatissimum*	Onion *Allium cepa*	Corn *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 400.0*	97.3 (76.6 – 124.3)	> 400.0*	> 400.0*	134.0 (102.6 – 180.3)	> 400.0*
NOER	≥ 400.0*	25.0	≥ 400.0	≥ 400.0*	50.0	≥ 400.0*
Shoot length (plants without roots)						
ER_{50}	119.7 (83.6 – 174.7)	32.9 (19.9 – 55.4)	30.7 (15.5 – 62.0)	34.7 (24.3 – 50.1)	56.3 (34.5 – 93.8)	> 400.0*
NOER	6.3	3.2	1.6	3.2	3.2	100.0
Plant dry weight (plants without roots)						
ER_{50}	181.9 (128.8 – 258.3)	19.0 (13.5 – 27.1)	6.9 (3.2 – 14.9)	39.2 (26.1 – 59.6)	181.1 (60.0 – 544.1**)	> 400.0*
NOER	25.0	3.2	1.6	3.2	12.5	100.0

The ER_{10}, ER_{25}, ER_{50} and NOER values were calculated using the ToxRat Professional 3.3.0 computer software.

*the value could not be dertermined but it can be probably higher than the highest rate of the test item used in the experiment, i.e. 400.0 mL test item / ha

**the value determined as higher than the highest application rate, i.e. 400.0 mL / ha

The ER50 and NOER values, determined on the basis of plants number, shoot length and shoot dry weight measurements at the end of the experiment, expressed as g of florasulam/ha for all test species are given below.

	Pea *Pisum sativum*	**Sunflower** *Helianthus annuus*	**Carrot** *Daucus carota*	**Flax** *Linum usitatissimum*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 4.88*	1.19 (0.93 – 1.52)	> 4.88*	> 4.88*	1.64 (1.25 – 2.20)	> 4.88*
NOER	≥ 4.88*	0.31	≥ 4.88*	≥ 4.88*	0.61	≥ 4.88*
Shoot length (plants without roots)						
ER_{50}	1.46 (1.02 – 2.13)	0.40 (0.24 – 0.68)	0.37 (0.19 – 0.76)	0.42 (0.30 – 0.61)	0.69 (0.42 – 1.14)	> 4.88*
NOER	0.08	0.04	0.02	0.04	0.04	1.22
Plant dry weight (plants without roots)						
ER_{50}	2.22 (1.57 – 3.15)	0.23 (0.16 – 0.33)	0.08 (0.04 – 0.18)	0.48 (0.32 – 0.73)	2.21 (0.73 – 6.64**)	> 4.88*
NOER	0.31	0.04	0.02	0.04	0.15	1.22

The ER_{10}, ER_{25}, ER_{50} and NOER values were calculated using the ToxRat Professional 3.3.0 computer software.

*the value could not be dertermined but it can be probably higher than the highest rate of the test item used in the experiment, i.e. 4.88 g of florasulam / ha

**the value determined as higher than the highest application rate, i.e. 4.88 g of florasulam / ha

The ER50 and NOER values, determined on the basis of plants number, shoot length and shoot dry weight measurements at the end of the experiment, expressed as g of flufenacet/ha for all test species are given below.

	Pea *Pisum sativum*	Sunflower *Helianthus annuus*	Carrot *Daucus carota*	Flax *Linum usitatissimum*	Onion *Allium cepa*	Corn *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 121.88*	29.65 (23.33 – 37.88)	> 121.88*	> 121.88*	40.84 (31.25 – 54.94)	> 121.88*
NOER	≥ 121.88*	7.62	≥ 121.88	≥ 121.88*	15.24	≥ 121.88*
Shoot length (plants without roots)						
ER_{50}	36.48 (25.48 – 53.23)	10.01 (6.05 – 16.88)	9.34 (4.72 – 18.91)	10.57 (7.41 – 15.26)	17.15 (10.50 – 28.59)	> 121.88*
NOER	1.92	0.98	0.49	0.98	0.98	30.47
Plant dry weight (plants without roots)						
ER_{50}	55.42 (39.26 – 78.72)	5.78 (4.11 – 8.24)	2.09 (0.99 – 4.54)	11.93 (7.95 – 18.16)	55.17 (18.29 – 165.77**)	> 121.88*
NOER	7.62	0.98	0.49	0.98	3.81	30.47

The ER_{10}, ER_{25}, ER_{50} and NOER values were calculated using the ToxRat Professional 3.3.0 computer software.

*the value could not be dertermined but it can be probably higher than the highest rate of the test item used in the experiment, i.e. 121.88 g of flufenacet / ha

**the value determined as higher than the highest application rate, i.e. 121.88 g of flufenacet / ha

The ER50 and NOER values, determined on the basis of plants number, shoot length and shoot dry weight measurements at the end of the experiment, expressed as g of diflufenican/ha for all test species are given below.

	Pea *Pisum sativum*	Sunflower *Helianthus annuus*	Carrot *Daucus carota*	Flax *Linum usitatissimum*	Onion *Allium cepa*	Corn *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 99.00*	24.08 (18.95 – 30.77)	> 99.00*	> 99.00*	33.17 (25.38 – 44.63)	> 99.00*
NOER	≥ 99.00*	6.19	≥ 99.00	≥ 99.00*	12.38	≥ 99.00*
Shoot length (plants without roots)						
ER_{50}	29.63 (20.69 – 43.24)	8.13 (4.92 – 13.71)	7.59 (3.84 – 15.36)	8.58 (6.02 – 12.04)	13.93 (8.53 – 23.22)	> 99.00*
NOER	1.56	0.79	0.40	0.79	0.79	24.75
Plant dry weight (plants without roots)						
ER_{50}	45.02 (31.89 – 63.94)	4.69 (3.33 – 6.70)	1.70 (0.80 – 3.69)	9.69 (6.45 – 14.75)	44.81 (14.85 – 134.65**)	> 99.00*
NOER	6.19	0.79	0.40	0.79	3.09	24.75

The ER_{10}, ER_{25}, ER_{50} and NOER values were calculated using the ToxRat Professional 3.3.0 computer software.

*the value could not be dertermined but it can be probably higher than the highest rate of the test item used in the experiment, i.e. 99.00 g of diflufenican / ha

**the value determined as higher than the highest application rate, i.e. 99.00 g of diflufenican / ha

The test item, i.e. CHR/H/FDF 574 SC had an impact on vegetative vigour of pea, sunflower, carrot, flax onion and corn. The impact varied from significant and moderate to little inhibition of plants growth and depend on the test plant species.
The test item caused mortality of carrot (rates: 200.0 and 400.0 mL/ha), onion (rates: 25.0, 100.0, 200.0, 400.0 mL/ha), sunflower (rates: from 25.0 to 400 mL/ha). The death of pea, flax and corn plants was not observed during the experiment.
The lowest ER50 value determined on the basis of the plant shoot length at the end of the experiment, was observed for carrot and it was equal to 30.7 mL of the test item/ha.
The lowest ER50 value determined on the basis of the plant shoot weight at the end of the experiment, was observed for carrot and it was equal to 6.9 mL of the test item/ha.
Some phytotoxic symptoms as stunted growth, deformations, wilting, chlorosis, necrosis and mortality of plants were observed after 21 days of the exposure.
The following order of the test plant sensitivity was noticed (on the basis of plant shoot length and plant shoot dry weight):
carrot > sunflower > flax > onion > pea > corn.

VALIDITY CRITERIA
On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of CHR/H/FDF 574 SC on vegetative vigour of terrestrial plants were met:
- the seedling emergence of plants (validity criterion: at least 70%) was as follows:
85.7 – 92.9% – pea,

83.3 – 90.5% – sunflower,
90.0 – 100.0% – carrot,
85.0 – 100.0% – flax,
92.5 – 100.0% – onion,
80.0 – 90.0% – corn,
- the mean plant survival of the control was 100% for all tested species (validity criterion: at least 90%),
- the control plants did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.8 KCP 10.8 Monitoring data