

# REGISTRATION REPORT

## **Part B**

### **Section 9**

#### **Ecotoxicology**

Detailed summary of the risk assessment

Product code: FLORAS 50 SC

Product name(s): Floras 50 SC, HerbiFlo 50 SC

Chemical active substance:

Florasulam, 50 g/L

Central

Zonal Rapporteur Member State: POLAND

#### **CORE ASSESSMENT**

(authorization)

Applicant: Elvita Sp. z o.o.

Submission date: 30/11/2023, updated March 2024

MS Finalisation date: April 2024 (initial Core Assessment)

June 2024 (final Core Assessment)

### Version history

When	What
19.01.2024	Appendix 2, point 2.3.1.2. Amendment – study B-124-22 by the Applicant.
March 2024	Applicants' update.
April 2024	Initial zRMS assessment  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are <del>struck through</del> and shaded for transparency.
June 2024	Final report (Core Assessment updated following the commenting period)  No additional information or assessments after the commenting period.

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## **9 Ecotoxicology (KCP 10)**

This document reviews the ecotoxicology for the product Floras 50 SC containing Florasulam as active substances. A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

Florasulam was reviewed as part of the renewal of approval procedure by the Member States and the Commission and the Commission review report finalised on 14.08.2015 approved Florasulam in accordance with Regulation (EC) No. 1107/2009 (Regulation 2015/1397).

Note: this Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II data must only be included if they are considered essential for the evaluation and in this case a full study summary must be provided.

This product was not the representative formulation and has not been previously evaluated according to Uniform Principles.

The EFSA Report of Florasulam (EFSA Journal 2015; 13(1):3984) is considered to provide the relevant review information or a reference to where such information can be found. The following table provides the EU endpoints to be used in the evaluation.

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Florasulam, and in particular Appendices I and II thereof, shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

- the risk to aquatic organisms and non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate.

These concerns have been addressed within the current submission in the respective sections.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

## 9.1 Critical GAP and overall conclusions

**Table 9.1-1: Table of critical GAPs**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use- No. *	Member state(s)	Crop and/ or situa- tion  (crop destination / purpose of crop)	F, Fn, G, Gn, Gnp 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, other dose rate expres- sion, dose range (min- max)	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g 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	Poland	Winter wheat	F	<i>Anthemis arvensis</i> , <i>Brachiaria nana</i> , <i>Brassica napus</i> , <i>Capsella bursa-pastoris</i> , <i>Descurainia sophia</i> , <i>Fallopia convolvulus</i> , <i>Galium aparine</i> , <i>Tripleurospermum inodorum</i> , <i>Myosotis arvensis</i> , <i>Papaver rhoeas</i> , <i>Fallopia convolvulus</i> , <i>Sinapis arvensis</i> , <i>Stellaria media</i> , <i>Thlaspi arvense</i> , <i>Veronica persica</i> .	Foliar spraying; small drops	BBCH 12-32	1	-	a) 0,1	Florasulam: 5,0	200- 400	-	Herbicide for use with field sprayers	A	A	R Aquatic R1, R3***	A	A	A	R
														A	A	A Remained species				
2	Poland	Spring barley	F	<i>Anthemis arvensis</i> , <i>Amaranthus retroflexus</i> , <i>Brassica napus</i> , <i>Capsella bursa-pastoris</i> , <i>Chenopodium album</i> , <i>Descurainia sophia</i> , <i>Fallopia convolvulus</i> , <i>Galeopsis tetrahit</i> , <i>Galium aparine</i> , <i>Galinsoga parviflora</i> , <i>Tripleurospermum inodorum</i> , <i>Silene latifolia subsp. Alba</i> , <i>Myosotis arvensis</i> , <i>Polygonum aviculare</i> , <i>Fallopia convolvulus</i> , <i>Persicaria maculosa</i> , <i>Sinapis arvensis</i> , <i>Stellaria media</i> , <i>Thlaspi arvense</i> , <i>Veronica persica</i> .	Foliar spraying; small drops	BBCH 12-32	1	-	a) 0,1	Florasulam: 5,0	200- 400	-	Herbicide for use with field sprayers	A	A	A	A	A	A	R

\* 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, Fnp: 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

\*\*\* not relevant for PL

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/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
- (11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
- (12) If water volume range depends on application equipments (*e.g.* ULVA or LVA) it should be mentioned under “application: method/kind”.
- (13) PHI - minimum pre-harvest interval
- (14) Remarks may include: Extent of use/economic importance/restrictions



## **9.1.1 Overall conclusions**

An estimation of risk indicate acceptable risk for each organism of each range of assessed issues, taking into consideration adequate mitigation measures.

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

An estimation of risk indicate low risk for birds and mammals of each range of assessed issues.

### **9.1.1.2 Effects on aquatic organisms (KCP 10.2)**

An estimation of risk indicate accepted risk for aquatic organisms, taking into consideration adequate mitigation measures.

- Winter Cereals: 10 m vegetative buffer zone to surface water bodies for R1 scenario
- Winter Cereals: 20 m vegetative buffer zone to surface water bodies for R3 scenario

### **9.1.1.3 Effects on bees (KCP 10.3.1)**

An estimation of risk indicate low risk for bees of each range of assessed issues.

### **9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)**

An estimation of risk indicate accepted risk for arthropods other than bees.

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

An estimation of risk indicate accepted risk for microbial activity.

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

An estimation of risk indicate accepted risk when 5-meter buffer zone to non-crop land is applied for use in cereals (winter and spring)

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

No studies submitted.

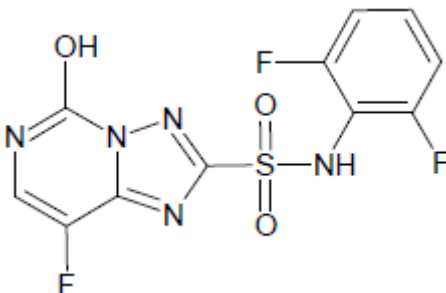
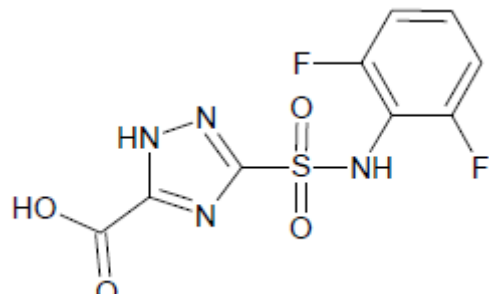
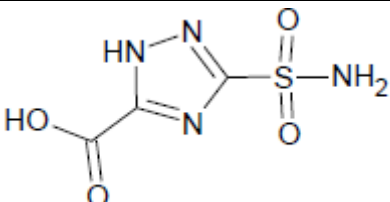
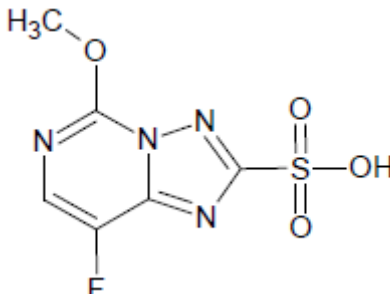
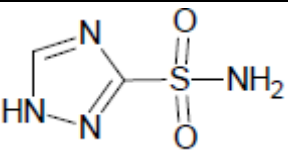
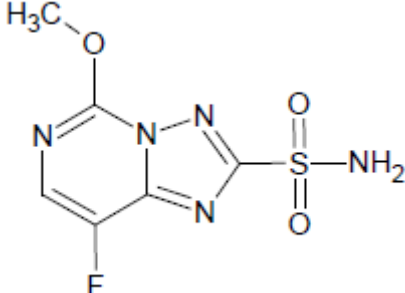
## **9.1.2 Grouping of intended uses for risk assessment**

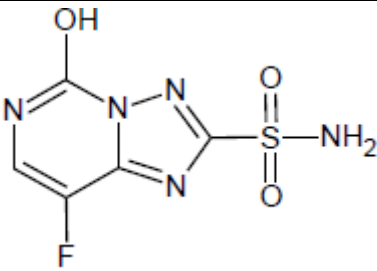
Floras 50 SC is intended to use in winter and spring cereals. ~~and winter rape.~~

## **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 Floras 50 SC is indicated in the table.

**Table 9.1-32-1 Metabolites of Florasulam**

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
<b>5-OH Florasulam;</b> N-(2,6-difluorophenyl)-8-fluoro-5-oxo-5,6-dihydro[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonamide	345.3		71,6 % 99,0 %	Soil Water/Sediment
<b>DFP-ASTCA;</b> 3-[(2,6-difluorophenyl)sulfamoyl]-1H-1,2,4-triazole-5-carboxylic acid	304.2		47,8 % 8,9 %	Soil Water/Sediment
<b>ASTCA;</b> 3-sulfamoyl-1H-1,2,4-triazole-5-carboxylic acid	192.1		40 % 53,8 %	Soil Water/Sediment
<b>TPSA;</b> 8-fluoro-5-methoxy[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonic acid	248.2		0,0001 % 58,0 %	Soil Water/Sediment
<b>TSA;</b> 1H-1,2,4-triazole-3-sulfonamide	148.1		45,9 % 0,0001 %	Soil Water/Sediment
<b>ASTP;</b> 8-fluoro-5-methoxy[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonamide	247.2		0,0001 % 21,0 %	Soil Water/Sediment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
<b>5-OH ASTP;</b> 8-fluoro-5-oxo-5,6-dihydro[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonamide	233.2		0,0001 % 29,0 %	Soil Water/Sediment

#### zRMS comments:

Metabolites relevant for soil and water compartment listed in Table 9.1-3 are the same as indicated in EFSA Scientific EFSA Journal 2015; 13(1):3984).

The maximum occurrence is relevant for exposure evaluation, for more information agreed in this area please refer to the Core Assessment, Part B, Section 8, where all respective data are provided and used in calculation of PEC<sub>soil</sub> and PEC<sub>sw/sed</sub> values, considered further in the risk assessment.

## 9.2 Effects on birds (KCP 10.1.1)

### 9.2.1 Toxicity data

Avian toxicity studies have been carried out with active substances. Full details of these studies are provided in the respective EU DAR and related documents.  
Effects on birds of formulation were not evaluated.

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

Species	Substance	Time scale	Results [mg/kg bw]	Reference
Japanese quails	Florasulam	Acute	1046 <sup>ab</sup>	EFSA Conclusion, 2015
Japanese quails	Florasulam	Short-term	> 938	EFSA Conclusion, 2015
Bobwhite quail	Florasulam	Long-term	150 (factor 0.1)	EFSA Conclusion, 2015

<sup>a</sup> The worst case acute oral LD<sub>50</sub> value

<sup>b</sup> Endpoint use in long-term risk assessment is LD<sub>50</sub> 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.

#### zRMS comment:

Avian toxicity data for florasulam are in line with the EU agreed endpoints reported EFSA Journal 2015; 13(1):3984).

### 9.2.1.1 Justification for new endpoints

Studies with the formulation were not performed.

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active substances:

- Florasulam (EFSA Journal 2015; 13(1):3984) and Draft Assessment Report for Florasulam.

### 9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment

for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

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

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

**Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of Floras 50 SC in Cereals ( wheat; barley) regarding Florasulam data.**

Intended use		Cereals				
Active substance/product		Florasulam				
Application rate (kg/ha)		1 × 0.005				
Acute toxicity (mg/kg bw)		1046				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Cereals	Small omnivorous bird	158.8	1	0.794	1317	
Reprod. toxicity (mg/kg bw/d)		104.6-150				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>t</sub>	
Growth stage						
Cereals	Small omnivorous bird	64.8	1.0 x 0.53	0.172	608.14 372	

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

#### zRMS comment:

##### Screening step in the risk assessment

The acute screening step risk assessment for florasulam is validated by zRMS.

In case of long-term risk assessment zRMS amended the toxicity endpoint used in the risk assessment.

According to recommendation given in EFSA Journal 2015; 13(1):3984), the lowest LD<sub>50</sub> value for florasulam of 1046 mg/kg bw divided by 10 (104.6 mg a.s./kg bw) is lower than the NOEC from reproductive study for florasulam of 1500 mg/kg diet multiplied by a factor 0.1.

Therefore, the relevant value for the long-term risk assessment is NOEL = 104.6 mg a.s./kg bw.

TER<sub>A</sub> and TER<sub>LT</sub> values for the exposure to florasulam for cereals are above the trigger of 10 and 5, respectively indicating acceptable risk for birds.

Overall, based on calculations acceptable risk to birds from compound active substance florasulam may be concluded from the intended uses of Floras 50 SC.

### 9.2.2.2 Higher-tier risk assessment

Not relevant.

### 9.2.2.3 Drinking water exposure

#### Leaf scenario

There's no risk from leafy scenario.

The leaf scenario is not relevant for the intended uses.

### 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 ( $K_{oc} < 500$  L/kg) or 3000 in the case of more sorptive substances ( $K_{oc} \geq 500$  L/kg).

Active substance Florasulam has  $K_{oc}$  below 500 L/kg.

Active substance	Time scale	Toxicity endpoint	Effective application rate [g a.s./ha]	Ratio ( $AR_{eff}/\text{endpoint}$ )
Florasulam	Acute	1046 mg a.s./kg bw	5	0.0047
	Chronic	104.6 mg a.s./kg bw/d		0.047

There's no risk from puddle scenario.

#### zRMS comment:

As a generic approach, the EFSA Guidance Document states that no specific calculations of exposure and TER are necessary for the puddle scenario when the ratio of effective application rate (in g/ha) to relevant end-point (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ( $K_{OC} < 500$  L/kg) or 3000 in the case of more sorptive substances ( $K_{OC} \geq 500$  L/kg). The ratio is below the trigger value ( $K_{oc} < 500$  L/kg) for a.s. - florasulam, indicating an acceptable risk and no further consideration is needed.

### 9.2.2.4 Effects of secondary poisoning

According to EFSA Guidance Document on Risk Assessment for Birds and Mammals, 2009, substances with a log POW lower than 3 haven't potential for bioaccumulation. Florasulam has a log Pow below 3, and not indicating a potential risk of secondary poisoning, therefore a risk assessment is not required.

#### zRMS comment:

zRMS agrees that the risk assessment for effects due to secondary poisoning is not required for birds. The log Kow of florasulam amounts to -1.22 (EFSA Journal 2015; 13 (1):3984) and thus does not exceed the trigger value of 3.

### 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

An estimation of risk indicate low risk for birds of each range of assessed issues.

## 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 formulation Floras 50 SC and active substances. 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).

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

Species	Substance	Time scale	Results [mg/kg bw/day]	Reference
Rat	Florasulam	Acute	> 5000	EFSA Conclusion, 2015
Rat	Florasulam	Long-term	100	EFSA Conclusion, 2015

**zRMS comments:**

Mammalian toxicity data for florasulam are in line with the EU agreed endpoints reported EFSA Journal 2015; 13(1):3984).

### 9.3.1.1 Justification for new endpoints

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active sub-stances:  
- Florasulam (EFSA Journal 2015; 13(1):3984) and Draft Assessment Report for Florasulam.

### 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 first-tier risk assessments are summarised in the following tables.

**Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Floras 50 SC in Cereals (wheat; barley) - Florasulam.**

Intended use		Cereals				
Active substance/product		Florasulam				
Application rate (kg/ha)		1 × 0.005				
Acute toxicity (mg/kg bw)		5000 <sup>12.4</sup>				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Cereals	Small herbivorous mammal	118.4	1.0	0.59	8474.58 <sup>21.02</sup>	
Reprod. toxicity (mg/kg bw/d)		100				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>it</sub>	
Growth stage						
Cereals	Small herbivorous mammal	48.3	1.0 x 0.53	0.128	781	

**zRMS comments:**

Screening step in the risk assessment

The acute screening step risk assessment for florasulam is not validated by zRMS. According to recommendation given in EFSA Journal 2015; 13(1):3984), the acute LD50 >5000 mg a.s./kg bw should be used for the active substance in the risk assessment. For is unknown reason the Applicant used value of 12.4 mg a.s./kg bw.

TER<sub>A</sub> and TER<sub>LT</sub> values for the exposure to florasulam for cereals are above the trigger of 10 and 5, respectively indicating acceptable risk for mammals.

The risk assessment for formulation is not required as the active substance data is sufficient in case of solo formulation.

Overall, based on calculations acceptable risk to mammals from compound active substance florasulam may be concluded from the intended uses of Floras 50 SC.

### 9.3.2.2 Higher-tier risk assessment

Further risk assessment is not necessary for long term toxicity.

### 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).

Active substance Florasulam has Koc below 500 L/kg.

Active substance	Time scale	Toxicity endpoint	Effective application rate [g a.s./ha]	Ratio (AR <sub>eff</sub> /endpoint)
Florasulam	Acute	5000 mg a.s./kg bw/d	5	0.001
	Chronic	100 mg a.s./kg bw/d		0.05

There's no risk from puddle scenario.

#### zRMS comments:

As a generic approach, the EFSA Guidance Document states that no specific calculations of exposure and TER are necessary for the puddle scenario when the ratio of effective application rate (in g/ha) to relevant end-point (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). The ratio is below the trigger value (Koc<500 L/kg) for a.s. - florasulam, indicating an acceptable risk and no further consideration is needed.

### 9.3.2.4 Effects of secondary poisoning

According to EFSA Guidance Document on Risk Assessment for Birds and Mammals, 2009, substances with a log POW lower than 3 haven't potential for bioaccumulation. Active substance of Floras 50 SC have a log Pow of 2.5, and not indicating a potential risk of secondary poisoning, therefore a risk assessment is not required.

#### zRMS comment:

zRMS agrees that the risk assessment for effects due to secondary poisoning is not required for mammals. The log K<sub>ow</sub> of florasulam amounts to - 1.22 (EFSA Journal 2015; 13 (1):3984) and thus does not exceed the trigger value of 3.

### 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

An estimation of risk indicate low risk for mammals of each range of assessed issues.

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

There is no additional data.

## 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 Floras 50 SC, active substances and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents, as well as in Appendix 2 of this document (new studies).

Effects on aquatic organisms of Floras 50 SC were not evaluated in EU. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

**Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – active substances.**

Species	Substance	Exposure System	Results [mg/L]	Reference
Oncorhynchus mykiss	Florasulam	96 h (acute)	LC <sub>50</sub> = 100	EFSA Conclusion
Pimephales promelas	Florasulam	28 d (longterm)	NOEC = 2.9	EFSA Conclusion
Daphnia magna	Florasulam	48 h	EC <sub>50</sub> = 292	EFSA Conclusion
Daphnia magna	Florasulam	21 d	NOEC = 23.4	EFSA Conclusion
Chironomus riparius	Florasulam	28 d	NOEC = 10	EFSA Conclusion
Pseudokirchneriella subcapitata	Florasulam	72 h	ErC <sub>50</sub> = 0.00894	EFSA Conclusion
Lemna gibba	Florasulam	14 d	EC <sub>50</sub> = 0.00118	EFSA Conclusion

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

Species	Substance	Exposure System	Results [mg/L]	Reference
Oncorhynchus mykiss	5-OH Florasulam	96 h (acute)	LC <sub>50</sub> = 91	EFSA Conclusion
Daphnia magna	5-OH Florasulam	48 h	EC <sub>50</sub> = 96.7	EFSA Conclusion



Species	Substance	Exposure System	Results [mg/L]	Reference
Daphnia magna	DFP-ASTCA	48 h	EC <sub>50</sub> = 0.03	EFSA Conclusion
Daphnia magna	ASTCA	48 h	EC <sub>50</sub> = 0.03	EFSA Conclusion
Daphnia magna	TSA	48 h	EC <sub>50</sub> = 0.03	EFSA Conclusion
Pseudokirchneriella subcapitata	5-OH Florasulam	72 h	ErC <sub>50</sub> = 21.57	EFSA Conclusion
Pseudokirchneriella subcapitata	DFP-ASTCA	72 h	ErC <sub>50</sub> = 96	EFSA Conclusion
Pseudokirchneriella subcapitata	ASTCA	72 h	ErC <sub>50</sub> = 9.2	EFSA Conclusion
Pseudokirchneriella subcapitata	TPSA	72 h	ErC <sub>50</sub> = 100	EFSA Conclusion
Pseudokirchneriella subcapitata	TSA	72 h	ErC <sub>50</sub> = 94	EFSA Conclusion
Pseudokirchneriella subcapitata	5-OH-ASTP	72 h	ErC <sub>50</sub> = 100	EFSA Conclusion
Pseudokirchneriella subcapitata	ASTP	72 h	ErC <sub>50</sub> = 100	EFSA Conclusion
Lemna gibba	5-OH Florasulam	7 d	EC <sub>50</sub> = 0.0378	EFSA Conclusion
Lemna gibba	DFP-ASTCA	7 d	EC <sub>50</sub> = 100	EFSA Conclusion
Lemna gibba	ASTCA	14 d	EC <sub>50</sub> = 10.2	EFSA Conclusion
Lemna gibba	TPSA	7 d	EC <sub>50</sub> = 100	EFSA Conclusion
Lemna gibba	TSA	7 d	EC <sub>50</sub> = 100	EFSA Conclusion
Lemna gibba	5-OH-ASTP	7 d	EC <sub>50</sub> = 100	EFSA Conclusion
Lemna gibba	ASTP	7 d	EC <sub>50</sub> = 88	EFSA Conclusion

**zRMS comments:**

Aquatic toxicity data for florasulam and its metabolites are in line with the EU agreed endpoints reported EFSA Journal 2015; 13(1):3984).

**Table 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – formulation Floras 50 SC.**

Species	Substance	Exposure System	Results [mg/L]	Reference
Daphnia magna	Floras 50 SC	48 h	EC <sub>50</sub> > 100 <sub>nom</sub>	IPO Pszczyna Report W-18-22
Pseudokirchneriella subcapitata	Floras 50 SC	72 h	ErC <sub>50</sub> = 10.01 <sub>nom</sub> EyC <sub>50</sub> = 2.75 NOEC = 0.37	IPO Pszczyna Report W-20-22
Lemna gibba	Floras 50 SC	7 d	ErC <sub>50</sub> = 0.062 <sub>nom</sub> NOEC = 0.0064	IPO Pszczyna Report W-19-22

**zRMS comments:**

Studies on effects of the formulated product on aquatic organisms listed in Table 9.5-3 were evaluated by the zRMS and considered acceptable. Summaries of the performed studies together with zRMS evaluation may be found in Appendix 2.

### **9.5.1.1 Justification for new endpoints**

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active sub-stances:

- Florasulam (EFSA Journal 2015; 13(1):3984) and Draft Assessment Report for Florasulam.

### **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  $PEC_{SW}$  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<sub>SW</sub>, PEC<sub>SED</sub>) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

**Table 9.5-4-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Florasulam for each organism group based on FOCUS Steps 1-2, 3 calculations for the use of Floras 50 SC in Winter Cereals**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. pro- longed	Aquatic Plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>
Endpoint (µg/L)		LC <sub>50</sub> 100000	NOEC 2900	EC <sub>50</sub> 292000	NOEC 23400	E <sub>r</sub> C <sub>50</sub> 8,94	NOEC 10000	EC <sub>50</sub> 1.18
AF		100	10	100	10	10	10	10
RAC (µg/L)		1000	290	2920	2340	0.894	1000	0.118
FOCUS Sce- nario	PEC <sub>gl-max</sub> (µg/L)	PEC/RAC						
Step 1 N-EU								
March-May	1.69	0.0017	0.0058	0.0006	0.0007	1.8904	0.0017	14.3220
Oct-Feb	1.69	0.0017	0.0058	0.0006	0.0007	1.8904	0.0017	14.3220
Step 2 N-EU								
March-May	<div>0.090.08</div>	<div>0.00090.0001</div>	0.0003	0.0000	0.0000	<div>0.10.0895</div>	<div>0.00090.0001</div>	<div>0.760.678</div>
Oct-Feb	<div>0.180.15</div>	<div>0.000180.0002</div>	<div>0.000620.0005</div>	<div>0.000160.0001</div>	<div>0.000790.0001</div>	<div>0.200.1678</div>	<div>0.000180.0002</div>	<div>1.521.2712</div>
Step 3 *								
D3 Ditch	0.031590	0.0000	0.0001	0.0000	0.0000	0.0353	0.0000	0.2677
D4 Pond	0.001094	0.0000	0.0000	0.0000	0.0000	0.0012	0.0000	0.0093
D4 Stream	0.027410	0.0000	0.0001	0.0000	0.0000	0.0307	0.0000	0.2323
D5 pond	<div>0.001</div>	<div>0.000001</div>	<div>0.0000034</div>	<div>0.000000342</div>	<div>0.000000427</div>	<div>0.0011</div>	<div>0.000001</div>	<div>0.0084</div>
D5 stream	<div>0.029</div>	<div>0.000029</div>	<div>0.0001</div>	<div>0.0000099</div>	<div>0.0000123</div>	<div>0.032</div>	<div>0.000029</div>	<div>0.254</div>
R1 Pond	<div>0.0230.001749</div>	<div>0.0000230.0000</div>	<div>0.0007930.0000</div>	<div>0.00000780.0000</div>	<div>0.00000980.0000</div>	<div>0.0250.0020</div>	<div>0.0000230.0000</div>	<div>0.190.0148</div>

R1 Stream	<b>0.130</b> 0.126500	<b>0.00013</b> 0.0001	<b>0.000448</b> 0.0004	<b>0.000044</b> 0.0000	<b>0.000055</b> 0.0001	<b>0.145</b> 0.1415	<b>0.00013</b> 0.0001	<b>1.10</b> 1.0720
R3 stream	<b>0.319</b>	<b>0.000319</b>	<b>0.0011</b>	<b>0.000109</b>	<b>0.000136</b>	<b>0.35</b>	<b>0.00013</b>	<b>2.70</b>
R4 stream	<b>0.028</b>	<b>0.000028</b>	<b>0.000096</b>	<b>0.0000095</b>	<b>0.0000119</b>	<b>0.0313</b>	<b>0.000028</b>	<b>0.237</b>

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

\* - Scenarios required for Poland

#### zRMS comment:

At Step 3 obtained PEC<sub>sw</sub> values for D3 and D4 scenarios for florasulam were in good agreement with values obtained by the Applicant, for R1 scenario obtained results were slightly higher from values obtained by the Applicant and were corrected by the e- ate expert in Section 8.

In addition to that it is noted that scenarios D5, R3 and R4 were not included in Applicant's simulations for winter

cereals, although these scenarios are indicated as relevant for the Central Zone in the guidance for evaluation in area of environmental fate and behaviour<sup>1</sup>.

Accordingly, respective simulations were performed by the e fate expert in Section 8 for missing scenarios and obtained results are presented in table above with PEC/RAC values calculated by zRMS.

Based on the PEC/RAC values >1 for winter cereals further calculations with consideration PEC<sub>sw</sub> at STEP 4 are required for R1 and R3 scenarios.

**Table 9.5-4-2: 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 Floras 50 SC in Spring Cereals**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. pro- longed	Aquatic Plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>
Endpoint (µg/L)		LC <sub>50</sub> 100000	NOEC 2900	EC <sub>50</sub> 292000	NOEC 23400	E <sub>r</sub> C <sub>50</sub> 8.94	NOEC 10000	EC <sub>50</sub> 1.18
AF		100	10	100	10	10	10	10
RAC (µg/L)		1000	290	2920	2340	0,894	1000	0.118
FOCUS Sce- nario	PEC <sub>gl-max</sub> (µg/L)	PEC/RAC						
Step 1 N-EU								
March-May	1.69	0.0017	0.0058	0.0006	0.0007	1.8904	0.0017	14.3220

<sup>1</sup> Working Document of the Central Zone in the Authorisation of Plant Protection Products - Part B section 8 - Environmental fate and behaviour, Version 1 rev. 1, June 2018

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged	Aquatic Plants
<b>Step 2 N-EU</b>								
March-May	<b>0.09</b> 0.08	<b>0.00009</b> 0.0001	<b>0.00031</b> 0.0003	0.0000	0.0000	0.0895	0.0001	<b>0.762</b> 0.678

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 9.5-4-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites for each organism group based on FOCUS Steps 1-2 calculations for the use of Floras 50 SC in Winter cereals**

Group		Fish acute	Inverteb. acute	Algae	Aquatic Plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Selenastrum capricornutum</i>	<i>Lemna gibba</i>
Endpoint		LC <sub>50</sub>	EC <sub>50</sub>	ErC <sub>50</sub>	EC <sub>50</sub>
AF		100	100	10	10
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)				
5-OH Florasulam					
PEC/RAC		910	967	2157	3.78
Step 1 N-EU					
March-May	2.72	0.003	0.003	0.001	0.720
Oct-Feb	2.72	0.003	0.003	0.001	0.720
Step 2 N-EU					
March-May	<div>0.280.23</div>	<div>0.00280.00025</div>	<div>0.00280.00024</div>	<div>0.0280.000107</div>	<div>0.0280.061</div>
Oct-Feb	<div>0.640.52</div>	<div>0.00640.00057</div>	<div>0.00640.00054</div>	<div>0.0640.00024</div>	<div>0.0640.138</div>
DFP-ASTCA					
PEC/RAC		-	0.3	9600	10000
Step 1 N-EU					
March-May	0.34	-	1.133	0.000035	0.000034
Oct-Feb	0.34	-	1.133	0.000035	0.000034
Step 2 N-EU					

Group		Fish acute	Inverteb. acute	Algae	Aquatic Plants
March-May	0.04	-	0.13	0.0000042	0.000004
Oct-Feb	0.09	-	0.3	0.0000094	0.000009
ASTCA					
PEC/RAC		-	0.3	920	1020
Step 1 N-EU					
March-May	0.75	-	2.5	0.00082	0.00074
Oct-Feb	0.75	-	2.5	0.00082	0.00074
Step 2 N-EU					
March-May	0.09 0.07	-	0.3 0.23	0.000097 0.000076	0.000294 0.000069
Oct-Feb	0.20 0.16	-	0.66 0.53	0.000217 0.00017	0.000196 0.00016
TPSA					
PEC/RAC		-	-	10000	10000
Step 1 N-EU					
March-May	0.65 0.63	-	-	0.000065 0.000063	0.000065 0.000063
Oct-Feb	0.65 0.63	-	-	0.000065 0.000063	0.000065 0.000063
Step 2 N-EU					
March-May	0.04 0.10	-	-	0.000004 0.00001	0.000004 0.00001
Oct-Feb	0.07 0.25	-	-	0.000007 0.000025	0.000007 0.000025
TSA					
PEC/RAC		-	0.3	9400	10000
Step 1 N-EU					
March-May	0.11	-	0.3667	0.000012	0.000011
Oct-Feb	0.11	-	0.3667	0.000012	0.000011

Group		Fish acute	Inverteb. acute	Algae	Aquatic Plants
<b>Step 2 N-EU</b>					
March-May	0.02	-	0.067	0.0000002	0.000002
Oct-Feb	<b>0.05</b> 0.04	-	<b>0.16</b> 0.133	<b>0.0000053</b> 0.0000043	<b>0.000005</b> 0.000004
<b>5-OH ASTP</b>					
<b>PEC/RAC</b>		-	-	10000	10000
<b>Step 1 N-EU</b>					
March-May	0.28	-	-	0.000028	0.000028
Oct-Feb	0.28	-	-	0.000028	0.000028
<b>Step 2 N-EU</b>					
March-May	<b>0.03</b> 0.05	-	-	<b>0.000003</b> 0.000005	<b>0.000003</b> 0.000005
Oct-Feb	<b>0.02</b> 0.11	-	-	<b>0.000002</b> 0.000011	<b>0.000002</b> 0.000011
<b>ASTP</b>					
<b>PEC/RAC</b>		-	-	10000	8800
<b>Step 1 N-EU</b>					
March-May	0.22	-	-	0.000022	0.000025
Oct-Feb	0.22	-	-	0.000022	0.000025
<b>Step 2 N-EU</b>					
March-May	<b>0.01</b> 0.04	-	-	<b>0.000001</b> 0.000004	<b>0.000001</b> 0.0000045
Oct-Feb	<b>0.02</b> 0.09	-	-	<b>0.000002</b> 0.000009	<b>0.000002</b> 0.0000102

**Table 9.5-4-4:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites for each organism group based on FOCUS Steps 1-2 calculations for the use of Floras 50 SC in Spring cereals

Group		Fish acute	Inverteb. acute	Algae	Aquatic Plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Selenastrum capricornutum</i>	<i>Lemna gibba</i>
Endpoint		LC <sub>50</sub>	EC <sub>50</sub>	ErC <sub>50</sub>	EC <sub>50</sub>
AF		100	100	10	10
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)				
5-OH Florasulam					
PEC/RAC		910	967	2157	3.78
Step 1 N-Europe	2.72	0.0030	0.0028	0.0013	0.7196
Step 2 N-Europe	<u>0.28</u> 0.23	<u>0.00025</u> 0.00025	<u>0.00029</u> 0.00024	<u>0.000129</u> 0.000107	<u>0.074</u> 0.061
DFP-ASTCA					
PEC/RAC		-	0.3	9600	10000
Step 1 N-Europe	0.34	-	1.1333	0.0000	0.0000
Step 2 N-Europe	0.04	-	0.13	0.0000042	0.000004
ASTCA					
PEC/RAC		-	0.3	920	1020
Step 1 N-Europe	0.75	-	2.5000	0.0008	0.0007
Step 2 N-Europe	<u>0.09</u> 0.07	-	<u>0.3</u> 0.23	<u>0.0000978</u> 0.000076	<u>0.000088</u> 0.000069
TPSA					
PEC/RAC		-	-	10000	10000
Step 1 N-Europe	<u>0.65</u> 0.63	-	-	<u>0.000065</u> 0.0001	<u>0.000065</u> 0.0001



Group		Fish acute	Inverteb. acute	Algae	Aquatic Plants
Step 2 N-Europe	0.04 0.10	-	-	0.000004 0.00001	0.000004 0.00001
TSA					
PEC/RAC		-	0.3	9400	10000
Step 1 N-Europe	0.11	-	0.3667	0.0000	0.0000
Step 2 N-Europe	0.02	-	0.067	0.0000002	0.000002
5-OH ASTP					
PEC/RAC		-	-	10000	10000
Step 1 N-Europe	0.28	-	-	0.000028	0.000028
Step 2 N-Europe	0.02 0.05	-	-	0.000002 0.000005	0.000002 0.000005
ASTP					
PEC/RAC		-	-	10000	8800
Step 1 N-Europe	0.22	-	-	0.000022	0.000022
Step 2 N-Europe	0.01 0.04	-	-	0.000001 0.000004	0.00000113 0.0000045

**Table 9.5-5: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Florasulam based on FOCUS Step 4 calculations and toxicity data for *Lemna gibba* with mitigation of run-off for the use of Floras 50 SC in Winter Wheat.**

Intended use		Winter cereals	
Active substance		Florasulam	
Application rate (g/ha)		1 x 5	
Nozzle reduction	Vegetated strip (m)	-	
	No spray buffer (m)	10	
None	R1 stream	PEC <sub>sw</sub> =0.05666	
50 %		-	
75 %		-	
90 %		-	
RAC (µg/L)		PEC/RAC ratio	
0.118			
None	R1 stream	0.48	
50 %		-	
75 %		-	
90 %		-	

#### zRMS comments:

At Step 3 the maximum PEC<sub>sw</sub> values of 0.130 µg/L and 0.319 µg/L were obtained in the run-off scenarios R1 stream and R3, respectively. Since values are above the RAC value of 0.118 µg/L, further calculation at Step 4 were required for R1 and R3 scenarios. The application of run-off mitigation in the form of a vegetated filter strip according to the values proposed in the FOCUS Landscape and Mitigation report leads to a reduction of these maximum PEC values to around 0.058 µg/L and 0.075 µg/L, occurring in the R1 stream and R3 stream scenarios.

Please note that for spring cereals Step 3 was not necessary.

Based on these results the updated risk assessment has been performed by zRMS.

#### FOCUS Step 4 Max PEC<sub>sw</sub> (µg/L) for florasulam considering application of 5 g a.s./ha.

FOCUS SCENARIOS	Step 4	
	Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sw</sub> (µg/L)
	10m VFS	20m VFS
R1 stream	0.058	-
R3 stream	<b>0.144</b>	0.075
RAC= 0.118 µg a.s./L	STEP 4 PEC/RAC	
R1 stream	0.49	
R3 stream		0.63

Maximum PEC<sub>sw</sub> values highlighted in **bold** exceed the lowest RAC of 0.118 µg a.s./L

Based on the results with consideration FOCUS STEP 4 the acceptable risk for aquatic organism is concluded with the following risk mitigation measures:

- Winter Cereals: 10 m vegetative buffer zone to surface water bodies for R1 scenario
- Winter Cereals: 20 m vegetative buffer zone to surface water bodies for R3 scenario

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

### 9.5.3 Overall conclusions

According to presented at point 9.5. assessment, use of Floras 50 SC cause accepted effect to aquatic organisms with the following risk mitigation measures:

~~— Winter Cereals: 10 m no spray buffer zone, using nozzle reduction is not needed.~~

Based on the results with consideration FOCUS STEP 4 the acceptable risk for aquatic organism is concluded with the following risk mitigation measures:

- Winter Cereals: 10 m vegetative buffer zone to surface water bodies for R1 scenario
- Winter Cereals: 20 m vegetative buffer zone to surface water bodies for R3 scenario

## 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 active substance and formulation Floras 50 SC. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

**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 <sub>50</sub> > 100 µg/bee	EFSA Conclusion 2015
Apis mellifera	Florasulam	Contact	LD <sub>50</sub> > 100 µg/bee	EFSA Conclusion 2015
Apis mellifera	Floras 50 SC	Oral	LD <sub>50</sub> > 200 µg/bee	IPO Pszczyna Study code: B-127-22 OECD 213
Apis mellifera	Floras 50 SC	Contact	LD <sub>50</sub> > 200 µg/bee	IPO Pszczyna Study code: B-129-22 OECD 214
Apis mellifera	Floras 50 SC	Chronic adult	LDD <sub>50</sub> > 12.4 µg product/bee/day LC <sub>50</sub> > 666.7 mg product/kg food	IPO Pszczyna B-126-22
Apis mellifera	Floras 50 SC	Chronic larvae (OECD239)	ED <sub>50</sub> > 100.0 µg test item/larva EC <sub>50</sub> > 649.4 mg/kg NOED ≥ 100.0 µg test item/larva NOEC ≥ 649.4 mg/kg	IPO Pszczyna B-124-22

#### zRMS comments:

Acute bee toxicity endpoints provided in Tables 9.6 - 1 above are in line with EU agreed endpoints reported in EFSA Journal 2015; 13(1):3984).

Studies on effects of the formulated product to bees listed in Table 9.6 - 1 were evaluated by the zRMS and considered acceptable. The reported endpoints are confirmed. Summary of the performed studies together with zRMS evaluation may be found in Appendix 2.

It is noted that in order to fulfil the data requirements as set by Commission Regulation (EU) No 284/2013, studies on chronic adult bees and larvae toxicity were performed with the formulated product Floras 50 SC.

### 9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the “EFSA Guidance Document on the risk assessment of plant protection products on bees”, as provided in EFSA Journal 2013;11(7):3295.

### 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 Floras 50 SC regarding Florasulam.**

Intended use		Cereals	
Active substance		Florasulam	
Application rate (g/ha)		1 × 5	
Test design	LD <sub>50</sub> (lab.) (µg/bee)	Single application rate (g/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	100	5	0.05
Contact toxicity	100		0.05
Product		Floras 50 SC	
Application rate (g/ha)		1 × 104	
Test design	LD <sub>50</sub> (lab.) (µg/bee)	Single application rate (g/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	200	104	0.52
Contact toxicity	200		0.52

Q<sub>HO</sub>, Q<sub>HC</sub>: Hazard quotients for oral and contact exposure. Q<sub>H</sub> values shown in bold breach the relevant trigger.

#### **zRMS comments:**

The acute risk assessment for bees presented in Table 9.6 - 2 is agreed by the zRMS.  
HQ<sub>oral</sub>, contact values for the active substances and the formulated product are below the trigger of 50, indicating a low acute risk for bees.  
Please note that the evaluation has been performed in line with SANCO/10329/2002 rev 2 final.  
  
Overall, acceptable risk to bees may be concluded from the intended uses of Floras 50 SC.

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

Not relevant.

### 9.6.3 Effects on bumble bees

Studies on the toxicity to Bumblebees have been carried out with formulation Floras 50 SC. Full details of these studies are provided in Appendix 2 of this document (new studies).

**Table 9.6-3: Endpoints and effect values relevant for the risk assessment for Bumblebees**

Species	Substance	Exposure System	Results	Reference
Bombus spp.	Floras 50 SC	Oral	LD <sub>50</sub> > 100 µg/bee	IPO Pszczyna Study code: B-128-22 OECD 247
Bombus spp.	Floras 50 SC	Contact	LD <sub>50</sub> > 100 µg/bee	IPO Pszczyna Study code: B-130-22 OECD 246

**Table 9.6-4: First-tier assessment of the risk for Bumblebees due to the use of Floras 50 SC regarding Florasulam.**

<b>Intended use</b>	Cereals
<b>Active substance</b>	Florasulam
<b>Application rate (g/ha)</b>	1 × 5

<b>Product</b>		Floras 50 SC	
<b>Application rate (g/ha)</b>		1 × 104	
<b>Test design</b>	<b>LD<sub>50</sub> (lab.) (µg/bee)</b>	<b>Single application rate (g/ha)</b>	<b>Q<sub>HO</sub>, Q<sub>HC</sub> criterion: Q<sub>H</sub> ≤ 50</b>
Oral toxicity	100	104	1.04
Contact toxicity	100		1.04

Q<sub>HO</sub>, Q<sub>HC</sub>: Hazard quotients for oral and contact exposure. Q<sub>H</sub> values shown in bold breach the relevant trigger.

#### **zRMS comments:**

The studies for bumble bees were evaluated by the zRMS and used in the risk assessment but it should be noted that currently there is not data requirement in this area.

The acute oral and contact risk is considered acceptable to bees after application of Floras 50 SC.

### **9.6.4 Effects on solitary bees**

Tests are not required as the test substance is of low toxicity to honey bees.

### **9.6.5 Overall conclusions**

The test substance is of low toxicity to honey bees. Both criteria are met.

## **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 active substances and formulation Floras 50 SC. Full details of these studies are provided in the respective EU DAR and related documents.

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

Species	Substance	Exposure System	Results [g/ha]	Reference
<i>Typhlodromus pyri</i> (protonymphs)	Florasulam	Laboratory test glass plates (2D)	LR <sub>50</sub> = 15	EFSA Conclusion
<i>Aphidius rhopalosiphi</i> (adults)	Florasulam	Laboratory test glass plates (2D)	LR <sub>50</sub> = 15	EFSA Conclusion
<i>Typhlodromus pyri</i> (protonymphs)	Floras 50 SC	Laboratory test glass plates (2D)	LR <sub>50</sub> > 104	IPO Pszczyna Study code: B-122-22 Escort
<i>Aphidius rhopalosiphi</i> (adults)	Floras 50 SC	Laboratory test glass plates (2D)	LR <sub>50</sub> > 104	IPO Pszczyna Study code: B-123-22 Escort

#### **zRMS comments:**

The studies performed with the formulated product Floras 50 SC were evaluated and agreed by the zRMS (for details, please refer to respective points in Appendix 2). The active substance data are not relevant for the risk assessment as according to EU Reg. 284/2009 the risk should be based on formulation study in case of NTA and NTP. Endpoints reported in Table 9.7-1 are confirmed to be correct.

## 9.7.1.1 Justification for new endpoints

## 9.7.2 Risk assessment

Risk assessment strategy used here follow recommendations in the ESCORT 2 guidance document (Candolfi et al. 2001) and opinion (EFSA Journal 2015;13(2):3996).

### 9.7.2.1 Risk assessment for in-field exposure

**Table 9.7-2: Assessment of the in-field risk for non-target arthropods due to the use of Floras 50 SC (0.1 ltr/ha)**

<b>Intended use</b>	Winter and Spring cereals		
<b>Active substance/product</b>	Floras 50 SC		
<b>Application rate (g/ha)</b>	1 × 104		
<b>MAF</b>	1		
<b>Test species Tier I</b>	<b>LR<sub>50</sub> (lab.) (g/ha)</b>	<b>PER<sub>in-field</sub> (g/ha)</b>	<b>HQ<sub>in-field</sub> criterion: HQ ≤ 2</b>
<i>Typhlodromus pyri</i>	104	104	1
<i>Aphidius rhopalosiphi</i>	104		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<sub>50</sub> or ER<sub>50</sub> 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: Assessment of the off-field risk for non-target arthropods due to the use of Floras 50 SC (0.1 ltr/ha)**

<b>Intended use</b>	Winter and Spring cereals				
<b>Active substance/product</b>	Floras 50 SC				
<b>Application rate (g/ha)</b>	1 × 104				
<b>MAF</b>	1				
<b>vdf</b>	10				
<b>Test species Tier I</b>	<b>LR<sub>50</sub> (lab.) (g/ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>CF</b>	<b>HQ<sub>off-field</sub> criterion: HQ ≤ 2</b>
<i>Typhlodromus pyri</i>	104	2.77	0.29	10	0.003
<i>Aphidius rhopalosiphi</i>	104				0.003

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<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

#### zRMS comments:

The risk assessment presented in Table 9.7-2 and Table 9.7-3 is validated by the zRMS.

Based on calculations performed with consideration of the Tier I laboratory for formulated product Floras 50 SC data acceptable in-field and off-field risk to non-target arthropods from all intended uses of Floras 50 SC may be concluded with no need for risk mitigation measures.

### 9.7.2.3 Additional higher-tier risk assessment

Not relevant.

### 9.7.2.4 Risk mitigation measures

No risk mitigation needed.

### 9.7.3 Overall conclusions

Use of Floras 50 SC indicate low risk for non-target arthropods other than bees.

## 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 active substances (plus certain metabolite) and Floras 50 SC. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

**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
<b>Earthworms</b>				
<i>Eisenia fetida</i>	Florasulam	14 d, acute	LC <sub>50</sub> = 1320 mg/kg dw	EFSA Conclusion
<i>Eisenia fetida</i>	Florasulam	Chronic	NOEC = 0.203 mg/kg dw	EFSA Conclusion 2015
<i>Eisenia andrei</i>	Floras 50 SC Florasulam	56 d	NOEC = 180 mg product/kg dw correspond to NOEC = 8.71 mg a.s./kg dw EC <sub>10</sub> = 106 mg product/kg dws	IPO Pszczyna Study code: G-10-22
<i>Eisenia fetida</i>	5-OH Florasulam DFP-ASTCA ASTCA TSA	14 d, acute	LC <sub>50</sub> = 1120 mg/kg dw LC <sub>50</sub> = 0.1 mg/kg dw LC <sub>50</sub> = 100 mg/kg dw LC <sub>50</sub> = 0.1 mg/kg dw	EFSA Conclusion
<i>Eisenia fetida</i>	5-OH Florasulam DFP-ASTCA ASTCA TSA	Chronic	NOEC = 0.14 mg/kg dw NOEC = 0.0304 mg/kg dw NOEC = 1.0 mg/kg dw NOEC = 10.0 mg/kg dw	EFSA Conclusion 2015
<b>Other non-target soil organisms</b>				
<i>Folsomia candida</i>	5-OH Florasulam DFP-ASTCA ASTCA TSA	Chronic	NOEC = 2.5 mg/kg dw NOEC = 10 mg/kg dw NOEC = 12.5 mg/kg dw NOEC = 50 mg/kg dw	EFSA Conclusion 2015
<i>Hypoapis accu.</i>	5-OH Florasulam DFP-ASTCA ASTCA TSA	Chronic	NOEC = 1.25 mg/kg dw NOEC = 10 mg/kg dw NOEC = 100 mg/kg dw NOEC = 50 mg/kg dw	EFSA Conclusion 2015

#### zRMS comments:

Soil organism toxicity endpoints provided in Tables 9.8-1 above are in line with EU agreed endpoints reported in

EFSA Journal 2015; 13(1):3984). It should be noted that no data for that a.s florasulam, only for florasulam's metabolites. According to REG.284/2009 only for plant protection products applied as soil treatments directly to soil either as a spray or as a solid formulation, then testing shall be required on both *Folsomia candida* and *Hypoaspis aculeifer*. For this reason the study for formulation Floras 50 SC is not required.

Studies on effects of the formulated product for earthworm listed in Table 9.8 - 1 were evaluated by the zRMS and considered acceptable. The reported endpoints are confirmed. Summary of the performed studies together with zRMS evaluation may be found in Appendix 2. The acute toxicity data to earthworms has been struck through in tables above as being no longer a data requirement.

It is noted that in order to fulfil the data requirements as set by Commission Regulation (EU) No 284/2013, studies on chronic toxicity to earthworm were performed with the formulated product Floras 50 SC.

## 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<sub>soil</sub> for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2 and data for metabolites from DAR.

**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 Floras 50 SC.**

Intended use	Cereals		
Acute effects on earthworms			
Product/active substance	LC <sub>50</sub> (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>a</sub> (criterion TER ≥ 10)
Florasulam	1320	0.007	188571
5-OH Florasulam	1120	0.005	224000
DFP-ASTCA	0.1	0.001	100
ASTCA	100	0.003	33333
TSA	0.1	0.001	100
Chronic effects on earthworms			
Product/active substance	NOEC/EC10 (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>lt</sub> (criterion TER ≥ 5)
Florasulam	0.203 8.71	0.007	1294 1244
Floras 50 SC	106 180	0.139 0.007	762.6 25714
5-OH Florasulam	0.14	0.00465	30.4628
DFP-ASTCA	0.0304	0.001	30.4
ASTCA	1	0.00143	714.3333
TSA	10	0.00041	25 00010000
Chronic effects on other non-target soil organisms			
5-OH Florasulam	2.5	0.0046	543.5
DFP-ASTCA	10	0.001	10000
ASTCA	12.5	0.0014	8928.6
TSA	50	0.0004	125000



5-OH Florasulam	1.25	0.0046	271.7
DFP-ASTCA	10	0.001	10 000
ASTCA	100	0.0014	71428.6
TSA	50	0.0004	125 000

TER values shown in bold fall below the relevant trigger.

#### zRMS comments:

The chronic risk assessment for earthworms provided in the Table 9.8-2 has been amended by zRMS taking into account the PEC<sub>soil</sub> values for product Floras 50 SC and its metabolites agreed by e-fate expert in Section 8.

The acute risk assessment to earthworms has been struck through in tables above as being no longer a data requirement.

Overall, no unacceptable effects on earthworm and other soil non-target soil organism are expected from the intended Central Zone uses of Floras 50 SC, TER<sub>LT</sub> values are above trigger of 5.

### 9.8.2.2 Higher-tier risk assessment

Not relevant.

### 9.8.3 Overall conclusions

Use of Floras 50 SC indicate low risk for earthworms and other macroorganisms.

## 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 active substances and Floras 50 SC. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Floras 50 SC	28 d 42-d, aerobic soil type	0.104-0.52 mg/kg < 25 % effect	IPO Pszczyna Study code: G-11-22
	Florasulam	100 days	0.005 mg as/kg < 25 % effect	EFSA Conclusion 2015
	5-OH Florasulam		0.036 < 25 % effect	
	DFP-ASTCA		0.0076 < 25 % effect	
	ASTCA		1 < 25 % effect	
	TSA		0.05 < 25 % effect	

#### zRMS comments:

Soil micro-organism endpoints provided in Tables 9.9-1 above are in line with EU agreed endpoints reported in EFSA Journal 2015; 13(1):3984).

Study on effects of the formulated product Floras 50 SC to soil-micro-organism listed in Table 9.9 - 1 were evaluated by the zRMS and considered acceptable. The reported endpoints are confirmed. Summary of the performed studies together with zRMS evaluation may be found in Appendix 2.

## 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<sub>soil</sub> for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

**Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of Floras 50 SC.**

Intended use	Cereals		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	Risk acceptable?
Florasulam	0.005 (at 42 d)	0.007	Yes
Floras 50 SC	0.104 -0.52 (at 28 d)	0.139 0.007	Yes
5-OH Florasulam	0.036	0.0046	Yes
DFP-ASTCA	0.0076	0.001	Yes
ASTCA	1	0.0014	Yes
TSA	0.05	0.0004	Yes

### zRMS comments:

The risk assessment for soil microorganism provided in the Table 9.9-2 has been amended by zRMS taking into account the relevant PEC<sub>soil</sub> values for product Floras 50 SC and florasulam’s metabolites agreed by e-fate expert in Section 8.

Overall, no unacceptable effects on soil microbial activity are expected from the intended Central Zone uses of Floras 50 SC, TER<sub>LT</sub> values are above trigger of 5.

## 9.9.3 Overall conclusions

On the basis of the results, it was concluded that Floras 50 SC at the concentrations corresponding to 5 x PEC (0.520 mg/kg of soil), did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

## 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 Floras 50 SC. Full details of these studies are provided in the respective EU DAR.

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

Species	Substance	Exposure System	Results	Reference
Cabbage ( <i>Brassica oleracea</i> var. <i>capitata</i> ) Flax ( <i>Linum usitatissimum</i> ) Carrot ( <i>Daucus carota</i> ), Onion ( <i>Allium cepa</i> ),	Floras 50 SC (expressed as g a.s/ha)	Seedling emergence	ER <sub>50</sub> emergence = 0.22 g s.a./ha ( cabbage , shoot length) >104 g/kg soil	IPO Pszczyna Study code: G- 13-22

Species	Substance	Exposure System	Results	Reference
Oats ( <i>Avena sativa</i> ), Perennial ryegrass ( <i>Lolium perenne</i> )				
Cabbage ( <i>Brassica oleracea</i> var. <i>capitata</i> ) Flax ( <i>Linum usitatissimum</i> ) Carrot ( <i>Daucus carota</i> ), Onion ( <i>Allium cepa</i> ), Oats ( <i>Avena sativa</i> ), Perennial ryegrass ( <i>Lolium perenne</i> )	Floras 50 SC expressed as g a.s./ha	Vegetative vigour	ER <sub>50</sub> emergence=0.32 g s.a./ha (carrot, plant dry weight) > 104 g/kg soil	IPO Pszczyna Study code: G- 12-22

#### zRMS comments:

The studies performed with the formulated product Floras 50 SC listed in the Table 9.10-1 were evaluated and agreed by the zRMS (for details, please refer to respective points in Appendix 2).

Endpoints reported in Table 9.10-1 has been amended by zRMS according to results obtained from these studies.

## 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”, (SAN-CO/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 Floras 50 SC**

<b>Intended use</b>	Cereals		
<b>Active substance/product</b>	Floras 50 SC		
<b>Application rate [g/ha]</b>	5 g a.s./ha-104		
<b>MAF</b>	1		
<b>ER<sub>50</sub></b> (mg/ha) g a.s./ha	<b>Drift rate</b>	<b>PER<sub>off-field</sub></b> (mg/kg)	<b>TER</b> <b>Criterion: TER ≥ 5</b>
0.22	0.0277 (1 m)	0.14	1.57
104	0.0057 (5 m)	0.028	7.85

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

#### zRMS comments:

Deterministic risk assessment performed by the Applicant for non-target terrestrial plants has not been validated by zRMS.

Based on the results from seedling emergence test the ER<sub>50</sub> value for the most sensitive species-cabbage is estimated as 0.22 g a.s./ha. This value has been used by zRMS in the risk assessment which covering also risk from visual toxicity.

Based on the results performed in the Table 9.10-2 the risk for NTP is considered acceptable as TER<sub>LT</sub> is above trigger value of 5, when 5-meter buffer zone to non-crop land is applied.

### 9.10.2.3 Higher-tier risk assessment

Not relevant.

### 9.10.2.4 Risk mitigation measures

No risk mitigation needed.

### 9.10.3 Overall conclusions

Use of Floras 50 SC is accepted concerning effects on non-target terrestrial plants when 5-meter buffer zone is applied to non-crop land.

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

No additional data.

### 9.12 Monitoring data (KCP 10.8)

No additional data.

### 9.13 Classification and Labelling

With regard to ecotoxicological data – H410 - Very toxic to aquatic life with long lasting effects.


#### zRMS comments:

Endpoint from studies on acute toxicity of Floras 50 SC to algae is <1.0 mg product/L ( $ErC_{50}=0.062$  mg product/L) and on this basis the formulation should be classified for aquatic hazard as Acute 1 with hazard statement H400.

Based on chronic formulation data for Lemna sp. with  $NOEC=0.0064$  mg product/L and taking into account that a.s. is not rapidly degradable, formulation Floras 50 SC should be classified as chronic 1 with hazard statement H410.

Following classification and labelling are considered relevant for Floras 50 SC:

In accordance with indication of CLP, when formulation is classified as H410, hazard statement regarding acute classification (i.e. H400) may be omitted.

<b>Hazard pictograms:</b>	GHS09 
<b>Signal word:</b>	Warning
<b>Hazard statement(s):</b>	H410 - Very toxic to aquatic life with long lasting effects
<b>Precautionary statement(s):</b>	P391: Collect spillage P501: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

## 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 10.2.1/01	Grażyna Hodorek	2022	FLORAS 50 SC Daphnia magna, Acute Immobilization Test IPO Pszczyna W-18-22 GLP/No Published	<del>N</del> Y	Elvita Sp. z o.o.
KCP 10.2.1/02	Grażyna Hodorek	2022	FLORAS 50 SC Anabaena flos-aquae UTEX B 1444 Growth Inhibition Test IPO Pszczyna W-20-22 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.2.1/03	Grażyna Hodorek	2022	Floras 50 SC Lemna gibba CPCC 310, Growth inhibition test IPO Pszczyna W-19-22 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.3.1.1.1/01	Marcin Dybek	2022	FLORAS 50 SC Honeybees (Apis mellifera L.), Acute Oral Toxicity Test IPO Pszczyna B-127-22 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.3.1.1.2/01	Marcin Dybek	2022	FLORAS 50 SC Honeybees (Apis mellifera L.), Acute Contact Toxicity Test IPO Pszczyna B-129-22 GLP/No Published	N	Elvita Sp. z o.o.
<del>KCP 10.3.1.2/01</del>	<del>Marcin Dybek</del>	<del>2022</del>	<del>FLORAS 50 SC Honeybees (Apis mellifera L.), Larval Toxicity Test, Single Exposure IPO Pszczyna B-125-22 GLP/No Published</del>	<del>N</del>	<del>Elvita Sp. z o.o.</del>
KCP 10.3.1.2/02	Marcin Dybek	2023	FLORAS 50 SC Honeybees (Apis mellifera L.), Larval Toxicity Test, Repeated Exposure IPO Pszczyna B-124-22 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.3.1.2/03	Marcin Dybek	2023	FLORAS 50 SC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test IPO Pszczyna	N	Elvita Sp. z o.o.

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-126-22 GLP/No Published		
KCP 10.3.1.3/01	Marcin Dybek	2022	FLORAS 50 SC Bumblebees (Bombus spp.), Acute Oral Toxicity Test IPO Pszczyna B-128-22 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.3.1.3/02	Marcin Dybek	2022	FLORAS 50 SC Bumblebees (Bombus spp.), Acute Contact Toxicity Test IPO Pszczyna B-130-22 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.3.2/01	Marcin Dybek	2022	A laboratory test for evaluating the effects of Floras 50 SC on the parasitic wasp, Aphidius rhopalosiphi (De Stefani - Perez) IPO Pszczyna B-123-22 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.3.2/02	Marcin Dybek	2022	A laboratory test for evaluating the effects of Floras 50 SC on the predatory mite, Typhlodromus pyri (Sch.) IPO Pszczyna W-122-22 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.4.1.1/01	Paweł Pieczka	2022	FLORAS 50 SC Earthworm Reproduction Test IPO Pszczyna G-10-22 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.5/01	Paweł Pieczka	2022	FLORAS 50 SC Soil Microorganisms: Nitrogen Transformation Test IPO Pszczyna G-11-22 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.6/01	Paweł Pieczka	2022	Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test IPO Pszczyna G-13-22 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.6/02	Paweł Pieczka	2022	Terrestrial Plant Test: Vegetative Vigour Test IPO Pszczyna	N	Elvita Sp. z o.o.

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
			G-12-22 GLP/No Published		

## Appendix 2 Detailed evaluation of the new studies

### A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

#### A 2.1.1 KCP 10.1.1 Effects on birds

No studies submitted.

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

Please refer to Section 6 this registration documentation - Acute Oral Toxicity Study on Rats.

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

No additional studies submitted.

### A 2.2 KCP 10.2 Effects on aquatic organisms

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

##### zRMS comments:

The study of acute toxicity to *Daphnia magna* is agreed by zRMS. No significant deviation from OECD 202 were noted. The validity criteria were met. Derived endpoint may be used in the risk assessment.

48 h EC<sub>50</sub>> 100 mg product/L

Reference:	KCP 10.2.1/01
Report:	<i>Daphnia magna</i> , Acute Immobilisation Test. STUDY CODE: [REDACTED]
Guideline(s):	OECD 202
Deviations:	No
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	-

## Executive summary

### I. Materials and methods

#### A. Materials

1. Test material: Floras 50 SC  
Lot/Batch no.: RFEAR0501  
Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

2. Test organisms.  
Species: *Daphnia magna* Straus  
Age: < 24 h old  
Source: [REDACTED]



Acclimatisation: Cultured in glass beakers with a capacity of 150 mL (16 h light : 8 h dark)  
Feeding: suspension of algae, *Raphidocelis subcapitata* : *Desmodesmus subspicatus* (in 2:1 ratio)  
No of organisms: 5

3. Test units and exposure.

Type and size: glass beakers with a capacity of 150 mL  
Test procedure: demonstrate that the test item concentration causing 50% immobilisation of the *Daphnia magna* is higher than the test item concentration used for exposure i.e. 100 mg/L (limit test).  
Test duration: 48 h

4. Test conditions -

Test medium: Elendt M7  
Water temperature: 18.5 – 20.2°C  
Aeration: No  
Photoperiod: 16 h light : 8 h dark  
Light intensity: fluorescent light source  
Dissolved oxygen: dissolved oxygen concentration in the control: 9.0 – 9.2 mg/L  
pH value: pH of the control: 7.09 – 7.19

## B. Study design and method

1. In life dates:

Study initiation date: September 14, 2022  
Start of the preliminary test: July 11, 2022  
End of the preliminary test: July 13, 2022  
Experimental starting date: September 20, 2022  
Experimental completion date: September 22, 2022  
Draft report: October 20, 2022  
Final report: November 29, 2022

2. Test design:

Static test (48 h of exposure); 4 replicates per test item concentration and the control; 5 *Daphnia magna* in each replicate.

3. Analytical verification:

The concentration of florasulam in the test item concentration was determined using a validated high performance liquid chromatographic method with DAD.

4. Statistics: ToxRat Professional Version 3.3.0

## II. Results and discussion

### A. Analytical data

Nominal test item concentration [mg/L]	Nominal concentration of florasulam [mg/L]	Average determined concentration of florasulam (n=3) in samples collected			
		at exposure initiation [mg/L]	[%] of nominal concentration	at exposure termination [mg/L]	[%] of nominal concentration
Control	---	< LoD	---	< LoD	---
100	4.84	4.852	100.2	4.837	99.9

LOQ = 0.2 mg/L

LOD = 0.1 mg/L

### B. Mortality

Endpoint value [mg/L]	Time of exposure	
	24 h	48 h
EC50	>100	>100
LOEC	>100	>100
NOEC	≥100	≥100

### C. Toxicological symptoms

-

### D. Validity of the test:

In the definitive test, the validity criteria were met according to the OECD Guideline No. 202 (2004) and EU Method C.2.:

- 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 8.8 – 9.3 mg/L (criterion: not less than 3 mg/L).

### III. Assessment and conclusion

The endpoint values were determined based on the nominal test item concentrations. In the test item concentration of 100 mg/L and in the control, no immobilisation of *Daphnia magna* was observed during exposure. Since the immobilisation of *Daphnia magna* was less than 10%, no statistical analysis was needed. The EC50/48 h value is higher than 100 mg/L.

#### zRMS comments:

The study of toxicity to algae is agreed by zRMS. No significant deviation from OECD 201 were noted. The validity criteria were met. Derived endpoints may be used in the risk assessment.

72 h E<sub>r</sub>C<sub>50</sub> = 10.01 mg/L (95% confidence interval: 8.25 – 12.96)

72 h E<sub>r</sub>C<sub>20</sub> = 2.77 mg/L (95% confidence interval: 2.05 – 3.42)

72 h E<sub>r</sub>C<sub>10</sub> = 1.41 mg/L (95% confidence interval: 0.88 – 1.93), NW=0.74 according to EFSA GD 2019 reliable value

72 h LOEC = 3.3 mg/L

72 h NOEC = 1.1 mg/L

Reference:	KCP 10.2.1/02
Report:	Anabaena flos-aquae UTEX B 1444, Growth inhibition Test. STUDY CODE: W-20-22.
Guideline(s):	OECD 201
Deviations:	No
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	-

### Executive summary

#### I. Materials and methods

##### A. Materials

1. Test material: Floras 50 SC  
Lot/Batch no.: RFEAR0501  
Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

2. Test organisms.

Species: The freshwater cyanobacteria, *Anabaena flos-aquae*

Age: 3 d

Source: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna

Acclimatisation: in Erlenmeyer flasks, incubated at temp. 21 – 24°C under constant illumination

Feeding: -

No of organisms: cell density:  $1 \times 10^4$  cells/mL.

3. Test units and exposure.

Type and size: Erlenmeyer flasks with a capacity of 250 mL

Test procedure: The aim of the study was to determine the test item concentrations causing 50% inhibition of growth rate and yield of the cyanobacteria, *Anabaena flos-aquae* (ErC50 and EyC50 after 72 hours of exposure, respectively). The LOEC and NOEC values after 72 hours of exposure were also determined.

Test duration: 72 h

4. Test conditions -

Test medium: AAP

Water temperature: 22.6 – 22.9°C

Aeration: No

Photoperiod: constant

Light intensity: 4070 - 4140 lux

Dissolved oxygen: -

pH value: pH of the control: 7.38 – 8.05

## B. Study design and method

1. In life dates:

Start of the preliminary test: 03.08.2022

End of the preliminary test: 06.08.2022

Study initiation date: 13.09.2022

Experimental starting date: 07.11.2022

Experimental completion date: 10.11.2022

Draft report: 06.12.2022

Final report: 09.12.2022

2. Test design:

72 hours of exposure; three replicates per each test item concentration; six replicates per the control; initial cyanobacterial cell density:  $1 \times 10^4$  cells/mL.

3. Analytical verification:

The concentrations of florasulam was chemically analysed with a validated liquid chromatographic method (HPLC) with Diode Array Detection.

4. 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.

## II. Results and discussion

### A. Analytical data

The concentrations of active substance florasulam in test item concentrations was chemically determined using the validated high performance liquid chromatographic methods with DAD detection. Samples of each treatment were collected at exposure initiation and at exposure termination.

At exposure initiation, the determined concentrations of florasulam were in the range of 92.7 – 100.6% of the 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 93.9 – 112.6% of the nominal concentration. Therefore, the concentrations of florasulam were stable under test conditions.

## B. Mortality

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
<b>EyC50</b>	0.78 (0.58 – 1.00)	2.03 (1.22 – 3.60)	2.75 (2.20 – 3.44)
<b>EyC20</b>	0.47 (0.27 – 0.62)	0.37 (0.11 – 0.69)	1.06 (0.69 – 1.40)
<b>EyC10</b>	0.37 (0.17 – 0.51)	0.15 (0.03 – 0.35)	0.65 (0.36 – 0.93)
<b>LOEC</b>	1.1	1.1	1.1
<b>NOEC</b>	0.37	0.37	0.37

## C. Toxicological symptoms

-

## D. Validity of the test:

In the definitive test, the following validity criteria specified in the OECD Guideline No. 201 (2006) were met:

- the biomass in the control increased by a factor of 31.5 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 4.7% (criterion: it must not exceed 10%).
- the mean coefficient of variation for the section-by-section growth rate in the control culture was 30.8% (criterion: it must not exceed 35%).

## III. Assessment and conclusion

The endpoint values are based on the nominal test item concentrations. The ECx values were calculated with a probit method. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were estimated on the basis of statistical analyzes. To conduct statistical analyses, the ToxRat Professional commercial software was used.

The median test item concentration causing 50% inhibition of the average specific growth rate of *Anabaena flos-aquae*, i.e. the ErC50/72 h value is 10.01 mg/L (95% confidence interval: 8.25 – 12.96). The ErC20/72 h value is 2.77 mg/L (95% confidence interval: 2.05 – 3.42) and the ErC10/72 h value is 1.41 mg/L (95% confidence interval: 0.88 – 1.93).

Statistical tests based on the growth rate data were the Shapiro-Wilk's Test on Normal Distribution which confirm normal distribution of the data, the Levene's Test on Variance Homogeneity (with Residuals) which showed that the variances were homogeneous. The Williams Multiple Sequential t-test Procedure showed significant differences between the test item concentrations in the range of 3.3 – 10 mg/L and the control. Therefore, the LOEC/72 h value is 3.3 mg/L and the NOEC/72 h value is 1.1 mg/L.

The median test item concentration causing 50% yield inhibition of *Anabaena flos-aquae*, i.e. the

EyC50/72 h value is 2.75 mg/L (95% confidence interval: 2.20 – 3.44). The EyC20/72 value is 1.06 mg/L (95% confidence interval: 0.69 – 1.40) and EyC10/72 h value is 0.65 mg/L (95% confidence interval: 0.36 – 0.93).

Statistical tests based on the yield data were the Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, the Levene's Test on Variance Homogeneity (with Residuals) which showed that the variances were homogeneous. The Williams Multiple Sequential t-test Procedure showed significant differences between the test item concentrations in the range of 1.1 - 10 mg/L and the control. Therefore, the LOEC/72 h value is 1.1 mg/L and the NOEC/72 h value is 0.37 mg/L.

**zRMS comments:**

The study of toxicity to algae is agreed by zRMS. No significant deviation from OECD 221 were noted. The validity criteria were met. Derived endpoints may be used in the risk assessment.

72 h ErC<sub>50</sub> = 0.062 mg product/L  
72 h ErC<sub>20</sub> = 0.020 mg product/L  
72 h LOEC = 0.032 mg product/L  
NOEC = 0.0064 mg product/L

The 72 ErC<sub>10</sub> = 0.011 mg product/L, (CI: 0.005-0.02) with NW>1 value calculated by zRMS.  
This value is not reliable according to EFSA 2019 and can be not used in the risk assessment.

Reference:	KCP 10.2.1/03
Report:	Lemna gibba CPCC 310, Growth inhibition test. STUDY CODE: W-19-22.
Guideline(s):	OECD 221
Deviations:	No
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	-

## Executive summary

### I. Materials and methods

#### A. Materials

1. Test material: Floras 50 SC  
Lot/Batch no.: RFEAR0501  
Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL  
Control: Yes.  
Toxic reference: -

2. Test organisms.

Species: Freshwater aquatic plant *Lemna gibba* L.  
Age: -  
Source: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna  
Acclimatisation: in Erlenmeyer flasks, incubated at temp. 21 – 24°C under constant illumination  
Feeding: -  
No of organisms: cell density: 9.

3. Test units and exposure.

Type and size: glass beakers with a capacity of 600 mL containing 400 mL of each treatment  
Test procedure: The aim of the study was to determine the test item concentrations causing 50% inhibition of growth rate and yield of duckweed *Lemna gibba* (Linné) CPCC 310 (ErC50, EyC50 after 7

days of exposure, respectively based on frond number and dry weight). The LOEC and NOEC values were also determined.

Test duration: 10 d

4. Test conditions -

Test medium: 20 x AAP

Water temperature: 22.9 – 23.2°C

Aeration: No

Photoperiod: constant

Light intensity: 7690 – 7774 lux

Dissolved oxygen: -

pH value: pH of the control: 7.49 – 8.48

## **B. Study design and method**

1. In life dates:

Start of the preliminary test: August 22, 2022

End of the preliminary test: August 29, 2022

Study initiation date: September 27, 2022

Experimental starting date: September 30, 2022

Experimental completion date: October 09, 2022

Draft report: November 24, 2022

Final report: November 29, 2022

2. Test design:

Static system (7 days of exposure); three replicates for each test item concentration and six replicates for the control.

3. Analytical verification:

The concentrations of florasulam in the test item were chemically determined using the validated high performance liquid chromatographic method with Diode Array Detection. The validation of analytical method will be performed according to SANTE/2020/12830, rev.1.

4. Statistics: ToxRat Professional Version 3.3.0

## **II. Results and discussion**

### **A. Analytical data**

At exposure initiation, the determined concentrations of florasulam, were in the range of 89.2 – 99.2% of the 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 81.4 – 101.3% of the nominal concentration. Therefore, the concentrations of florasulam were stable under test conditions.

Nominal test item concentration [mg/L]	Nominal concentration of active substance [mg/L]	Mean concentration determined (n=3) in samples collected			
		at day 0 (30.09.2022) [mg/L]	% ± RSD of nominal concentration	at day 7 (07.10.2022) [mg/L]	% ± RSD of nominal concentration
Control	0.00000	< LOD	---	< LOD	---
0.032	0.00155	0.00149	96.1 ± 0.0	0.00128	82.6 ± 2.3
0.16	0.00774	0.00768	99.2 ± 1.2	0.0063	81.4 ± 2.9
0.8	0.0387	0.0365	94.3 ± 5.5	0.0351	90.7 ± 0.6
4.0	0.194	0.173	89.2 ± 0.0	0.163	84.0 ± 0.0
20.0	0.968	0.948	97.9 ± 0.4	0.981	101.3 ± 0.1

## B. Mortality

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

Endpoint value [mg/L]	Frond number			Dry weight
	0-3 d	0-5 d	0-7 d	0-7 d
E <sub>r</sub> C <sub>10</sub>	0.009 (0.003 – 0.028)	0.009 (0.005 – 0.019)	0.011 (0.005 – 0.022)	n.d.
E <sub>r</sub> C <sub>20</sub>	0.016 (0.005 – 0.049)	0.016 (0.008 – 0.032)	0.020 (0.010 – 0.039)	0.006 (n.d. – 11.275)
E <sub>r</sub> C <sub>50</sub>	0.053 (0.014 – 0.207)	0.044 (0.019 – 0.101)	0.062 (0.028 – 0.141)	>20
LOEC	0.032	0.032	0.032	0.032
NOEC	0.0064	0.0064	0.0064	0.0064

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

Endpoint value [mg/L]	Frond number			Dry weight
	0-3 d	0-5 d	0-7 d	0-7 d
E <sub>y</sub> C <sub>10</sub>	0.012 (0.001 – 0.106)	0.028 (n.d.)	0.007 (0.004 – 0.012)	n.d.
E <sub>y</sub> C <sub>20</sub>	0.017 (0.002 – 0.136)	0.029 (n.d.)	0.012 (0.007 – 0.019)	0.001 (n.d. – 0.044)
E <sub>y</sub> C <sub>50</sub>	0.029 (0.002 – 0.389)	0.031 (n.d.)	0.030 (0.017 – 0.053)	0.053 (0.0002 – 12.657)
LOEC	0.032	0.032	0.032	≤0.0064
NOEC	0.0064	0.0064	0.0064	<0.0064

### C. Toxicological symptoms

-

### D. Validity of the test:

In the definitive test, the following validity criteria specified in the OECD Guideline No. 221/ EU method C.26. were met:

- the doubling time of frond number in the control was 2.2 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 9.0),
- the average specific growth rate in the control between day 0 and day 7 was 0.314 d<sup>-1</sup> (minimum requirement: higher than 0.275 d<sup>-1</sup>).

### III. Assessment and conclusion

The endpoint values determined based on the nominal test item concentrations:

The median concentration causing 50% inhibition of the mean specific growth rate of *Lemna gibba* determined on the basis of the frond number ErC50/7 d value is 0.062 mg/L (95% confidence interval: 0.028 – 0.141). The ErC20/7 d value is 0.020 mg/L (95% confidence interval: 0.010 – 0.039) and the ErC10/7 d value is 0.011 mg/L (95% confidence interval: 0.005 – 0.022).

The growth rate data based on the frond number were analyzed using Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) which showed that the variances were homogeneous, and the Williams Multiple Sequential t-test Procedure which showed significant differences between nominal test item concentrations in the range of 0.032 – 20 mg/L and the control. The lowest concentration of the test item causing an effect on growth rate, i.e. the LOEC/7 d value is 0.032 mg/L and the highest concentration of the test item not causing any effect on growth rate, i.e. the NOEC/7 d value is 0.0064 mg/L.

The median concentration causing 50% inhibition of yield of *Lemna gibba* determined on the basis of the frond number EyC50/7 d value is 0.030 mg/L (95% confidence interval: 0.017 – 0.053). The EyC20/7 d value is 0.012 mg/L (95% confidence interval: 0.007 – 0.019) and the EyC10/7 d value is 0.007 mg/L (95% confidence interval: 0.004 – 0.012).

The yield data based on the frond number were analyzed using Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) which showed that the variances were homogeneous, and the Williams Multiple Sequential t-test Procedure which showed significant differences between nominal test item concentrations in the range of 0.032 – 20 mg/L and the control. The lowest test item concentration causing a yield inhibition effect, i.e. the LOEC/7 d value is 0.032 mg/L. The highest test item concentration at which no yield inhibition effects are observed, i.e. the NOEC/7 d value is lower than 0.0064 mg/L.

The median concentration causing 50% inhibition of the mean specific growth rate of *Lemna gibba* determined on the basis of the dry weight ErC50/7 d value is higher than 20 mg/L. The ErC20/7 d value is 0.006 mg/L (95% confidence interval: not determined – 11.275) and the ErC10/7 d value is not determined.

The growth rate data based on the dry weight were analyzed using Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) which showed that the variances were homogeneous, and the Williams Multiple Sequential t-test Procedure which showed significant differences between nominal test item concentrations in the range of 0.032 – 20 mg/L and the control. The lowest concentration of the test item causing an effect on growth rate, i.e. the LOEC/7 d value is 0.032 mg/L. The highest concentration of the test item not causing any effect on growth rate, i.e. the NOEC/7 d value is 0.0064 mg/L.

The median concentration causing 50% inhibition of yield of *Lemna gibba* determined on the basis of the dry weight EyC50/7 d value is 0.053 mg/L (95% confidence interval: 0.0002 – 12.657). The EyC20/7 d value is 0.001 mg/L (95% confidence interval: not determined – 0.044) and the EyC10/7 d value is not determined.

The yield data based on the dry weight were analyzed using the Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, the Levene's Test on Variance Homogeneity (with Residuals) which showed that the variances were homogeneous, and the Williams Multiple Sequential t-test Procedure which showed significant differences between nominal test item concentrations in the



range of 0.064 – 20 mg/L and the control. The lowest test item concentration causing a yield inhibition effect, i.e. the LOEC/7 d value is lower than or equal to 0.0064 mg/L. The highest test item concentration at which no yield inhibition effects are observed, i.e. the NOEC/7 d value is lower than 0.0064 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 KCP 10.3.1.1 Acute toxicity to bees**

**A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees**

**zRMS comments:**

In general, the study was performed in line with recommendations of OECD 213. All validity criteria were met. The study is acceptable with following endpoint relevant for the risk assessment:

48 h LD<sub>50</sub> > 100 µg product/honeybee

Reference:	KCP 10.3.1.1.1/01
Report:	Honeybees ( <i>Apis mellifera</i> L.), Acute Oral Toxicity Test. STUDY CODE: B-127-22.
Guideline(s):	OECD 213
Deviations:	No
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	-

**Executive summary**

**I. Materials and methods**

**A. Materials**

- Test material: Floras 50 SC  
Lot/Batch no.: RFEAR0501  
Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

- Test organisms.

Species: *Apis mellifera* L.

Age: 3 weeks

Source: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna

Acclimatisation: Honeybees were removed from the comb and starved for up to two hours before the initiation of the treatment.

Feeding: 50% sucrose solution

No of organisms: 15.

3. Test units and exposure.

Type and size: Honeycomb

Test procedure: The aims of the study were to determine the acute oral toxicity of Floras 50 SC a laboratory method to adult worker honeybees and to calculate the LD<sub>50</sub> values with, if possible or to demonstrate that the LD50 value is higher than the highest dose used in the test.

Test duration: 48 h

4. Test conditions -

Test medium: 50% solution of sucrose in water

Temperature: 25°C

Aeration: No

Photoperiod: dark room

Light intensity: \_\_\_\_\_

Dissolved oxygen: \_\_\_\_\_

pH value: \_\_\_\_\_

relative humidity: 63-65%

## B. Study design and method

1. In life dates:

Study initiation date: 27.06.2023

The experimental starting date: 14.07.2023

The experimental completion date: 16.07.2023

Draft Report: 28.07.2023

Study completion date: 04.08.2023

2. 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

3. Analytical verification: -

The study was carried out according to the OECD Guideline for the Testing of Chemicals No. 213 [1], the EU Method C.16. [2], the SOP/B/47.

4. Statistics: ToxRat Professional 3.3.0. Probit analysis using linear max. likelihood regression

## II. Results and discussion

### A. Analytical data

Since the test guideline does not require the necessity of checking the concentration, homogeneity and stability of the test material, such analyses will not be carried out by the study director.

## B. Mortality\*\*

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48 h after the beginning of the treatment			LD <sub>50</sub>	
		Total			[µg/bee]	Florasulam [µg a.i./ bumblebee]
		[no.]	[%]	Corr. [%] <sup>a</sup>		
<b>0.0 (Control)</b>	30	2	<b>6.7</b>	-	<b>&gt;200.0</b>	<b>&gt;9.67</b>
<b>12.5</b>	30	0	<b>0.0</b>	<b>(-7.1)*</b>		
<b>25.0</b>	30	0	<b>0.0</b>	<b>(-7.1)*</b>		
<b>50.0</b>	30	2	<b>6.7</b>	<b>0.0</b>		
<b>100.0</b>	30	1	<b>3.3</b>	<b>(-3.6)*</b>		
<b>200.0</b>	30	2	<b>6.7</b>	<b>0.0</b>		

[%]<sup>a</sup>: mortality corrected according to the formula of Abbott [9],

\*: the negative value means that in the tested doses mortality was lower than control

\*\*for honeybee not bumblebee

## C. Toxicological symptoms

-

## D. Validity of the test:

The following validity criteria were met during the test:

- the mortality for the control was 6.7% at the end of the experiment (criterion: it must not exceed 10%).
- the LD<sub>50</sub>/24 h of the reference item (dimethoate) was 0.117 µg a.i./bee (criterion: 0.10 – 0.35 µg a.i./bee).

## III. Assessment and conclusion

The median lethal doses LD<sub>50</sub>/24 h and LD<sub>50</sub>/48 h are higher than the highest dose used in the test, i.e. 200.0 µg/honeybee, i.e. > 9.67 µg a.i./bee.

### A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

#### zRMS comments:

In general, the study was performed in line with recommendations of OECD 214.  
The study is acceptable with following endpoints relevant for the risk assessment:

48 h LD<sub>50</sub> > 200 µg product/honeybee

Reference:	KCP 10.3.1.1.2/01
Report:	Honeybees (Apis mellifera L.), Acute Contact Toxicity Test. STUDY CODE: B-129-22.
Guideline(s):	OECD 214
Deviations:	<del>No</del> Yes 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.
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication	-

(if vertebrate study)	
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## Executive summary

### I. Materials and methods

#### A. Materials

1. Test material: Floras 50 SC  
Lot/Batch no.: RFEAR0501  
Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

2. Test organisms.

Species: *Apis mellifera* L.

Age: 3 weeks

Source: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna

Acclimatisation: Honeybees were removed from the comb and starved for up to two hours before the initiation of the treatment.

Feeding: -

No of organisms: 15.

3. Test units and exposure.

Type and size: Honeycomb

Test procedure: The aims of the study were to use a laboratory method to determine the acute contact toxicity of Floras 50 SC to adult worker honeybees and to determine the LD50 values or to demonstrate that the LD50 values are higher than the highest dose used in the test.

Test duration: 48 h

4. Test conditions -

Test medium: 1% water solution of surfactant, Triton(R) X -100

Temperature: 25°C

Aeration: No

Photoperiod: dark room

Light intensity: \_\_\_\_\_

— Dissolved oxygen: —

— pH value: —

#### B. Study design and method

1. In life dates:

Study initiation date: 27.06.2023

The experimental starting date: 14.07.2023

The experimental completion date: 16.07.2023

Draft Report: 27.07.2023

Study completion date: 04.08.2023

2. 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

### 3. Analytical verification:

Since the test guideline does not require the necessity of checking the concentration, homogeneity and stability of the test material, such analyses will not be carried out. The waiver of these analyses constitutes.

### 4. Statistics: ToxRat Professional 3.3.0.

Probit analysis using linear max. likelihood regression

## II. Results and discussion

### A. Analytical data

Since the test guideline does not require the necessity of checking the concentration, homogeneity and stability of the test material, such analyses will not be carried out.

### B. Mortality\*

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48 h of exposure		LD <sub>50</sub>	
		Total		[µg/bee]	Florasulam [µg a.i./ bumblebe]
		[no.]	[%]		
0.0 (water control)	30	0	0.0		
0.0 (1% Triton control)	30	0	0.0		
12.5 with surfactant	30	0	0.0		
25.0 with surfactant	30	0	0.0	>200.0	>9.67
50.0 with surfactant	30	0	0.0		
100.0 with surfactant	30	0	0.0		
200.0 with surfactant	30	0	0.0		

\*for honeybee not bumblebee

### C. Toxicological symptoms

-

### D. Validity of the test:

The following validity criteria were met during the test:

- the mortality for the both control was 0.0% after 48 h (criterion: it must not exceed 10.0%),
- the LD<sub>50</sub>/24 h of the reference item (dimethoate) was 0.221 µg a.i./bee (criterion: 0.10 – 0.30 µg a.i./bee).

## III. Assessment and conclusion

The median lethal doses LD<sub>50</sub>/24 h and LD<sub>50</sub>/48 h are higher than the highest dose used in the test, i.e. 200.0 µg/honeybee, i.e. > 9.67 µg a.i./bee.

## A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

### zRMS comments:

The acute toxicity test for larva has not been considered in the risk assessment and it is not evaluated by zRMS. The relevant study for chronic exposure according to OECD 239 has been performed and evaluated by zRMS.

Reference:	KCP 10.3.1.2/01
Report:	Honeybees ( <i>Apis mellifera</i> L.), Larval Toxicity Test, Single Exposure. STUDY CODE: B-125-22.
Guideline(s):	OECD 237
Deviations:	No
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	-

### Executive summary

#### I. Materials and methods

##### A. Materials

- Test material: Floras 50 SC  
— Lot/Batch no.: RFEAR0501  
— Content: Florasulam: 50.3 g/L  
—  
— Density: 1.04 g/mL  
— Control: Yes.  
— Toxic reference:

- Test organisms.  
— Species: *Apis mellifera* L.  
— Age: 1 d  
— Source: Lukasiiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna  
— Acclimatisation: Before the experiment grafting cells were disinfected (in a 70% ethanol bath) followed by drying of the cells under laminar flow hood. Sterile equipment was used (48 well plates from NEST and pipette filter tips). Before and during the transfer of larvae, grafting tools were disinfected in 70% ethanol regularly. Surfaces in the laboratory, as well as desiccators and incubator were disinfected with 70% ethanol regularly.  
— Feeding: Diet C  
— No of organisms: 36.

- Test units and exposure.  
— Type and size: Incubator  
— Test procedure: The aim of the study was to demonstrate that the median lethal dose, i.e. the LD50 after 72 h of exposure of honeybees (*Apis mellifera* L.) larvae to the test item Floras 50 SC is higher than the dose used in the test, i.e. 100.0 µg/ larva (limit test).  
— Test duration: 72 h

- Test conditions  
— Test medium: Diet C  
— Temperature: 34.0 – 34.6°C  
— Aeration: No  
— Photoperiod:  
— Light intensity:

—Dissolved oxygen:—  
—pH value:—

## B. Study design and method

### 1. In life dates:

Study initiation date: 05.06.2023

The experimental starting date: 17.06.2023

The experimental completion date: 23.06.2023

Draft report: 19.09.2023

Study completion date: 09.10.2023

### 2. Test design:

—the test item: exposure: 72 hours; number of doses: 1 and a control; number of replicates: 3; number of larvae: 12/replicate

—the reference item: exposure: 72 hours; number of doses: 1; number of replicates: 3; number of larvae: 12/replicate

### 3. Analytical verification:—

4. Statistics: Chi<sup>2</sup> rx2 Contingency Table, STUDENT t test for Homogeneous Variances, One-way Analysis of Variance.

## II. Results and discussion

### A. Analytical data

—

### B. Mortality

Dose [µg/larva]	Number of tested larvae [no.]	Mortality after 72 h of exposure (D7)			LD <sub>50</sub> 72 h	
		Total			[µg/larva]	florasulam [µg a.i. / larva]
		[no.]	[%]	Corr. <sup>a</sup> [%]		
Floras 50 SC						
0.0 (Control)	36	3	8.3	–	> 100.0	> 4.84
100.0	36	3	8.3	0.0		
Dimethoate (reference item)						
8.8	36	32	88.9	87.9	not determined	

<sup>a</sup>: Mortality corrected according to the Abbott formula

### C. Toxicological symptoms

—

### D. Validity of the test:

The following validity criteria were met:

—Mortality of the control group was 8.3% at the end of the test (criterion: ≤ 15%).

~~= Abbott corrected mortality of the larvae treated with the reference item (dimethoate) was 87.9% (criterion:  $\geq 50\%$ ).~~

### III. Assessment and conclusion

~~Mortality of the control group at the end of the test was 8.3% (criterion:  $\leq 15\%$ ). The percentage of mortality of the honeybee larvae, exposed to the test item, Floras 50 SC at the dose of 100.0 µg/larva, corrected according to the formula of Abbott [7], at the end of the test (D7) was 0.0%. The percentage of larval mortality on D7 in the reference item group, corrected according to the formula of Abbott [7], was 87.9%. The median lethal doses after 24, 48 and 72 h of exposure, for the test item (LD50/24, LD50/48 and LD50/72 h) are higher than 100.0 µg test item/larva.~~

#### zRMS comments:

The study was conducted in line with OECD 239 with no deviations.

All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:

ED<sub>50</sub> > 100.0 µg test item/larva  
EC<sub>50</sub> > 649.4 mg/kg  
NOED  $\geq$  100.0 µg test item/larva  
NOEC  $\geq$  649.4 mg/kg

Reference:	KCP 10.3.1.2/02
Report:	Honeybees ( <i>Apis mellifera</i> L.), Larval Toxicity Test, Repeated Exposure. STUDY CODE: B-124-22.
Guideline(s):	OECD 239
Deviations:	No
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	-

## Executive summary

### I. Materials and methods

#### A. Materials

- Test material: Floras 50 SC  
Lot/Batch no.: RFEAR0501  
Content: Florasulam: 50.3 g/L  
Density: 1.04 g/mL  
Control: Yes.  
Toxic reference: -

- Test organisms.

Species: *Apis mellifera* L.  
Age: 1 d

Source: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna  
Acclimatisation: Before the experiment grafting cells were disinfected (in a 70% ethanol bath) followed by drying of the cells under laminar-flow hood. Sterile equipment was used (48- well plates from NEST and pipette filter tips). Before and during the transfer of larvae, grafting tools were disinfected in 70% ethanol regularly. Surfaces in the laboratory, as well as desiccators and incubator were disinfected with 70% ethanol regularly.

Feeding: Diet B



No of organisms: 36.

3. Test units and exposure.

Type and size: Incubator

Test procedure: The aims of the study were to determine the toxicity of the test item to honeybee larvae (*Apis mellifera* L.) after repeated exposure of the test item using a laboratory method and to demonstrate that the median effective concentration/dose, i.e. EC50/ED50 is higher than the test item concentration used for exposure (limit test).

Test duration: 22 d

4. Test conditions -

Test medium: Diet B

Temperature: 34.0 – 35.0°C

Aeration: No

Photoperiod: \_\_\_\_\_

— Light intensity: \_\_\_\_\_

— Dissolved oxygen: \_\_\_\_\_

— pH value: -

## B. Study design and method

1. In life dates:

Study initiation date: 23.06.2023

The experimental starting date: 01.07.2023

The experimental completion date: 22.07.2023

Draft report: 06.12.2023

Study completion date: 18.12.2023

2. Test design:

– the test item: number of cumulative dose: 1 and a control; number of replicates: 3; number of larvae: 12/replicate

– the reference item: number of cumulative doses: 1; number of replicates: 3; number of larvae: 12/replicate

3. Analytical verification:

The concentrations of florasulam was chemically determined using the validated high performance liquid chromatographic method with DAD detection. Fresh samples of the test item concentration and the control were chemically analyzed at test initiation and at the end of the maximum storage period (i.e. after 4 days).

4. Statistics: ToxRat Professional 3.3.0.

## II. Results and discussion

### A. Analytical data

At exposure initiation, in the fresh sample of the test item of 666.7 mg/kg, the determined concentration of florasulam was 93.2% of nominal concentration. The results confirm that the test item concentration was prepared correctly. After 4 days of the storage period, in the sample of the test item of 666.7 mg/kg, the determined concentration of florasulam was 94.0% of nominal concentration. Based on the results of chemical analyses, the concentrations of florasulam were stable under storage conditions.

### B. Mortality

Dose [µg test item/larva]	Concen- tration [mg test item/kg food]	Number of tested larvae [no.]	Total mortality (larval and pupal) on day 22 (D22)				
			Number [no.]	[%]	Corr <sup>a</sup> [%]	Number of emerged adults [No.]	Emergence rate [%]
Test item: Floras 50 SC							
0.0 (Control)		36	9	25.0	–	27	75.0
100.0	649.4	36	6	16.7	(-11.1)*	30	83.3
ED <sub>50</sub> [µg test item/larva]		> 100.0					
EC <sub>50</sub> [mg/kg]		> 649.4					
NOED [µg test item/larva]		≥ 100.0					
NOEC [mg/kg]		≥ 649.4					
Reference item: Technical dimethoate mortality on day 8 (D8)							
7.39	48.0	36	36	100.0	100.0	not determined	

Corr<sup>a</sup>: Mortality corrected according to the Abbott formula

\*: the negative value means that in the tested doses mortality was lower than control

### C. Toxicological symptoms

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### D. Validity of the test:

The following validity criteria were met:

- Cumulative larval mortality in the control group was 2.8% at day 8 (D8) (criterion: ≤ 15%).
- Abbott corrected mortality of the larvae treated with the reference item at day 8 (D8) (dimethoate) was 100.0% (criterion: ≥ 50%).
- Emergence rate in the control group on D22 was 75.0% (criterion: ≥ 70%).

### III. Assessment and conclusion

Mortality of the control group on day 8 (D8) of the test was 2.8% (criterion: ≤ 15%). The percentage of mortality of the honeybee larvae, exposed to the test item, Floras 50 SC at the cumulative dose of 100.0 µg test item/larva at D8, after Abbott's correction, was 0.0%. The percentage of larval mortality on D8 in the reference item group was 100.0%.

Pupal mortality of the control group on day 15 (D15) of the test was 11.1%. The percentage of mortality of the honeybee pupae corrected using Abbott's formula, exposed to the test item, Floras 50 SC at the cumulative dose of 100.0 µg/larva at D15 was (-6.3)%. The percentage of pupal mortality, corrected using Abbott's formula, on D15 in the reference item group was 100.0%.

Cumulative mortality (larval and pupal) of the control group on day 22 (D22) of the test was 25.0%. The percentage of mortality of the honeybee pupae corrected using Abbott's formula, exposed to the test item,

Floras 50 SC at the cumulative dose of 100.0 µg/larva at D22 was (-11.1)%. The percentage of pupal mortality, corrected using Abbott's formula, on D22 in the reference item group was 100.0%.

The emergence of adults (emergence rate) at the end of the test (on D22) in the control group was 75.0%. In the groups treated with the test item at the cumulative dose of 100.0 µg test item/larva the adult emergence rates were: 83.3%, respectively.

The endpoint values for Floras 50 SC at the end of the assessment (D22):

- ED50 value is higher than 100.0 µg test item/larva,
- EC50 value is higher than 649.4 mg/kg,
- NOED value is higher than or equal to 100.0 µg test item/larva,
- NOEC value is higher than or equal to 649.4 mg/kg.

#### **zRMS comments:**

The study was conducted in line with OECD 245 with no deviation.

The concentrations of the active substance in the applied test item feeding solutions were within the required range of  $\pm 20\%$  of the nominal concentrations.

All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:

LDD<sub>50</sub> > 12.4 µg product/bee/day

LC<sub>50</sub> > 666.7 mg product/kg food

Reference:	KCP 10.3.1.2/03
Report:	Honeybees ( <i>Apis mellifera</i> L.), Chronic Oral Toxicity Test. STUDY CODE: B-126-22.
Guideline(s):	OECD 245
Deviations:	No
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	-

## **Executive summary**

### **I. Materials and methods**

#### **A. Materials**

##### **1. Test material: Floras 50 SC**

Lot/Batch no.: RFEAR0501

Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

##### **2. Test organisms.**

Species: *Apis mellifera* L.

Age: 2 d

Source: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna

Acclimatisation: One day before the experiment, brood frames were transferred from the apiary to the experimental room. Afterwards, they were placed in hatching boxes in an incubator. After hatching, the bees were acclimated to the test conditions for about one day.

Feeding: 50% sucrose solution

No of organisms: 50.

3. Test units and exposure.

Type and size: Incubator

Test procedure: The aims of the study were to determine the chronic oral toxicity of the test item, Floras 50 SC to honeybees (*Apis mellifera* L.) and to demonstrate that the median lethal concentration, i.e. the LC50 and median lethal dietary dose, i.e. LDD50 are higher than the test item concentration used for exposure (limit test).

Test duration: 10 d

4. Test conditions -

Test medium: 50% sucrose solution

Temperature: 33.9 – 34.9°C

Aeration: No

Photoperiod: -

Light intensity: -

Dissolved oxygen: -

pH value: -

## B. Study design and method

1. In life dates:

Study initiation date: 27.06.2023

The experimental starting date: 06.07.2023

The experimental completion date: 16.07.2023

Draft Report: 22.09.2023

Completion of the study: 18.10.2023

2. Test 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

3. Analytical verification: -

In the stability and definitive test, the concentrations of florasulam in sucrose solution were chemically determined by the high-performance liquid chromatography (HPLC) with Diode Array Detection [SOP/C/328, SOP/C/439].

In the stability test the samples of the test item concentration of 666.7 mg of test item/kg and the 50% sucrose solution control were transferred for chemical determinations at test initiation, after 3 and 4 days of the storage period.

4. Statistics: Range-to-standard-deviation-ratio and Levene's test, Chi2 rxr 2-Contingency Table.

The percentages of honeybees mortality in the group treated with the reference item were calculated [SOP/OG/7].

Food consumption (mg/bee/day) in each study group was determined by weighing the feeders with a sucrose solution and dividing the amount of food by the number of surviving bees in the previous observation time. The doses of the test item (µg/bee/day) consumed by the bees were calculated directly from treated 50% sucrose solution consumption and the concentrations of the test item [SOP/OG/7].

Mortality results were analysed in order to demonstrate that the LC50 (median lethal concentration, expressed in mg per kg of diet) and the LDD50 (median lethal dietary dose, expressed in µg/bee/day), after 10 days of exposure, are higher than the test item dose used for exposure.

Due to the occurred mortality in the group treated with the test item, the statistical analysis was performed.

## II. Results and discussion

### A. Analytical data

Based on the chemical determinations results, the concentrations of florasulam in sucrose solution were stable under storage conditions. Therefore, in the definitive test fresh feeding solutions of test item were prepared twice during the exposure. The results of the stability and definitive tests are summarized in Table 1 and 7.

In the definitive test fresh samples of the control, the feeding solution at the concentration of 666.7 mg/kg were chemically analyzed directly after preparation and once after 4 days of the storage (i.e. at D0 and D4) [SOP/B/75]. The aim was to make sure that the solution of the test item was prepared properly.

### B. Mortality

Nominal test item concentration/ dose		Ingested <sup>a</sup> dose [µg of test item/bee/day]	Number of tested bees [no]	Total mortality			LC <sub>50</sub> [mg of test item/kg of diet]	LDD <sub>50</sub> [µg of test item/bee/day]
[µg of test item/30 mg of diet/day] [µg of test item/bee/day]	[mg of test item/kg of diet]			No.	[%]	Corr <sup>b</sup> [%]		
Floras 50 SC								
0.0 (Control)			50	1	2.0	-	> 666.7	> 12.4
20.0	666.7	12.4	50	0	0.0	(-2.0)		
Dimethoate (reference item)								
0.024	0.8	0.012	30	30	100.0	not determined		

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

<sup>b</sup>: Mortality corrected according to the Abbott formula

### C. Toxicological symptoms

-

### D. Validity of the test:

The following validity criteria were met during the test:

- At the end of the experiment average mortality of the control groups was 2.0% (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 (0.012 µg/bee/day) was 100% (criterion: it must be ≥ 50% on day 10 of exposure).

## III. Assessment and conclusion

The validity criterion concerning mortality was met, because mortality in the control was 2.0% after 10 days of exposure.

The percentage of mortality of the honeybees exposed to the test item, at the concentration of 666.7 mg/kg (dietary dose 12.4 µg of test item/bee/day) at exposure termination (after 10 days), corrected according to the formula of Abbott, was (-2.0) %. The negative value indicates that mortality in the group

treated with the test item was lower than in the control group.

On the basis of the obtained mortality results the LC50 is higher than 666.7 mg/kg, and the LDD50 value is higher than 12.4 µg of test item/bee/day, there is no statistically significant difference in mortality between group treated with the test item at the dose of 666.7 mg/kg (dietary dose 12.4 µg of test item/bee/day) and the control group (Chi2-Contingency test,  $p(\text{Chi}) > \text{Alpha } 0.05$ ).

The validity criterion concerning mortality of the honeybees exposed to the reference item, dimethoate was met, because mortality was equal to 100% after 10 days of exposure. The results obtained in the reference item group showed that the insects were sensitive to dimethoate.

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

#### zRMS comments:

The study is considered valid. All validity criteria were met.

48 h LD<sub>50</sub> > 100 µg test item/bumblebee, corresponding to > 4.84 µg/florasulam (oral toxicity)

Reference:	KCP 10.3.1.3/01
Report:	Bumblebees (Bombus spp.), Acute Oral Toxicity Test. STUDY CODE: B-128-22.
Guideline(s):	OECD 247
Deviations:	According to the OECD Guideline No. 247 it is recommended to use plastic syringes for the test item administration. However, in the experiment they were replaced by calibrated glass pipettes. The obtained deviation had no impact on the quality, integrity and final results of the study. No
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	-

## Executive summary

### I. Materials and methods

#### A. Materials

- Test material: Floras 50 SC  
Lot/Batch no.: RFEAR0501  
Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

- Test organisms.

Species: bumblebee, Bombus spp.

Age: adult worker bumblebees

Source: Koppert Polska sp. z o.o.

Acclimatisation: The adult bumblebees were collected from the hives under a red light and individually placed in plastic isolators of known weight. There was 1 bumblebee in each isolator. Very small or very large individuals were excluded by visual inspection. After that, they were acclimatized to the test conditions for about 24 hours before starting the experiment. Food, i.e. 50% sucrose solution was provided. To determine the weight of each bumblebee, the isolator was weighed.

Feeding: 50% sucrose solution

No of organisms: 50.

3. Test units and exposure.

Type and size: Isolator.

Test procedure: The aims of the study were to determine the acute oral toxicity of Floras 50 SC to bumblebees (*Bombus* spp.) with a laboratory method and to demonstrate that the median lethal dose, i.e. the LD50 at the end of exposure, is higher than the dose used in the test, i.e. 100.0 µg test item/bumblebee (limit test).

Test duration: 48 h

4. Test conditions -

Test medium: 50% solution of sucrose in water

Temperature: 25°C

Aeration: No

Photoperiod: dark room

Light intensity: -

Dissolved oxygen: -

pH value: -

Relative humidity: 59-60%

**B. Study design and method**

1. In life dates:

Study initiation date: 17.01.2023

Experimental starting date: 31.01.2023

Experimental completion date: 03.02.2023

Draft report: 12.02.2023

Completion of the study: 23.02.2023

2. Test design:

– a control (50% sucrose solution w/v)

number of replicates: 50;

number of insects: 1 insect/replicate;

– test item:

number of doses: 1,

number of replicates: 50;

number of insects: 1 insect/replicate;

– the reference item: 4.0 µg/bumblebee

number of doses: 1,

number of replicates: 30;

number of insects: 1 insect/replicate

3. Analytical verification: -

The aim of the analytical part of the definitive test was to determine the concentrations of florasulam using a validated high performance liquid chromatographic method with DAD detection [SOP/C/304, SOP/C/439]. The validated analytical method was performed according to SANTE/2020/12830, Rev. 1 [7] [SOP/

4. Statistics: -

The percentage of bumblebee mortality in the group treated with the reference item was calculated [SOP/OG/7]. Statistical analysis was not conducted due to the lack of mortality in the group treated with the test item

**II. Results and discussion**

**A. Analytical data**

At exposure initiation, in the fresh test item sample, the concentration of florasulam was 107.4% of the nominal concentration. The results confirm that the test item concentration was prepared correctly.

## B. Mortality

Dose		Number of tested bumblebees [no.]	Mortality after 48 h		LD <sub>50</sub> /48 h	
Test item [µg/bum-blebee]	Florasulam [µg a.i. / bumblebee]		[no.]	[%]	[µg/ bumblebee]	Florasulam [µg a.i./bumblebe]
Control		50	0	0.0	> 100.0	> 4.84
100.0	4.84	50	0	0.0		
Reference item: dimethoate						
Dose [µg/bumblebee]	4.0	30	29	96.7	–	

## C. Toxicological symptoms

–

## D. Validity of the test:

The following validity criteria were met:

- Mortality of the control groups was 0.0% at the end of the test (criterion: ≤ 10%).
- Mortality in the toxic reference item group (dimethoate) at the end of the test was 96.7% (criterion: ≥ 50%).

## III. Assessment and conclusion

The median lethal doses (LD<sub>50</sub>/24 h, LD<sub>50</sub>/48 h) are higher than the dose used in the test, i.e. > 100.0 µg test item/bumblebee, i.e. > 4.84 µg/florasulam.

### zRMS comments:

The study is considered valid. All validity criteria were met.  
48 h LD<sub>50</sub> > 100 µg product/bumblebee, i.e. > 4.84 µg florasulam/bumblebee (contact toxicity)

Reference:	KCP 10.3.1.3/02
Report:	Bumblebees (Bombus spp.), Acute Contact Toxicity Test. STUDY CODE: B-130-22.
Guideline(s):	OECD 246
Deviations:	<del>Yes</del> No According to the OECD Guideline No. 246 the bumblebees may be anesthetized with carbon dioxide or chilled for the application of the test item. Anesthesia with carbon dioxide or chilling was replaced with mechanical immobilisation. The obtained deviation had no impact on the quality, integrity and final results of the study.
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	–



## Executive summary

### I. Materials and methods

#### A. Materials

1. Test material: Floras 50 SC  
Lot/Batch no.: RFEAR0501  
Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

2. Test organisms.

Species: *Apis mellifera* L.

Age: 3 weeks

Source: Koppert Polska sp. z o.o.

Acclimatisation: The adult bumblebees were collected from the hives under a red light and individually placed in plastic isolators of known weight. There was 1 bumblebee in each isolator. Very small or very large individuals were excluded by visual inspection. After that, they were acclimatized to the test conditions for about 24 hours before starting the experiment. Food, i.e. 50% sucrose solution was provided. To determine the weight of each bumblebee, the isolator was weighed.

Feeding: -

No of organisms: 15.

3. Test units and exposure.

Type and size: Honeycomb

Test procedure: The aims of the study were to determine the acute contact toxicity of Floras 50 SC to bumblebees (*Bombus* spp.) with a laboratory method and to demonstrate that the median lethal dose, i.e. the LD50 at the end of exposure, is higher than the dose used in the test, i.e. 100.0 µg test item/bumblebee (limit test).

Test duration: 48 h

4. Test conditions -

Test medium: 1% water solution of surfactant, Triton(R) X -100

Temperature: 24-25°C

Aeration: No

Photoperiod: dark room

Light intensity: \_\_\_\_\_

~~Dissolved oxygen: \_\_\_\_\_~~

~~pH value: \_\_\_\_\_~~

Humidity: 58-61%

#### B. Study design and method

1. In life dates:

Study initiation date: 17.01.2023

Experimental starting date: 30.01.2023

Experimental completion date: 02.02.2023

Draft report: 12.02.2023

Completion of the study: 23.02.2023

2. Test design:

– control with surfactant

(distilled water with 1% of Triton(R) X-100)

number of replicates: 50;

number of insects: 1 insect/replicate;  
– test item with surfactant:  
number of doses: 1,  
number of replicates: 50;  
number of insects: 1 insect/replicate;  
– the reference item with surfactant:  
number of doses: 1,  
number of replicates: 30;  
number of insects: 1 insect/replicate

### 3. Analytical verification:

The aim of the analytical part of the definitive test was to determine the concentration of florasulam using a validated high performance liquid chromatographic method with DAD detection [SOP/C/304, SOP/C/439]. The validated analytical method was performed according to SANTE/2020/12830, Rev. 1 [7] [SOP/C/9]. Fresh samples of the test item concentration of 50.0 g/L (i.e. 100 µg/2 µL) with surfactant and control with surfactant (distilled water with 1% Triton X-100) at exposure initiation were chemically analysed [SOP/B/75].

### 4. Statistics:

The percentage of bumblebee mortality in the group treated with the reference item was calculated [SOP/OG/7]. Statistical analysis was not conducted due to the lack of mortality in the group treated with the test item.

## II. Results and discussion

### A. Analytical data

At exposure initiation, in the fresh test item sample, the concentration of florasulam was 105.0±0.4% of the nominal concentration. The results confirm that the test item concentration was prepared correctly.

### B. Mortality

Dose		Number of tested bumblebees [no.]	Mortality after 48 h		LD <sub>50</sub> /48 h	
Test item [µg/bum-blebee]	Florasulam [µg a.i. / bumblebee]		[no.]	[%]	[µg/ bumble-bee]	Florasulam [µg a.i. / bumblebe]
Control + 1% surfactant		50	0	0.0	> 100.0	> 4.84
100.0	4.84	50	0	0.0		
Reference item: dimethoate [µg/bumblebee]						
10.0 + 1% surfactant		30	30	100.0	–	

### C. Toxicological symptoms

–

### D. Validity of the test:

The following validity criteria were met:

- Mortality of the control groups was 0.0% at the end of the test (criterion: ≤ 10%).
- Mortality in the toxic reference item group (dimethoate) at the end of the test was 100.0% (criterion: ≥ 50%).

### III. Assessment and conclusion

The median lethal doses (LD50/24 h, LD50/48 h) are higher than the dose used in the test, i.e. > 100.0 µg test item/bumblebee, i.e. > 4.84 µg florasulam/bumblebee.

#### A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

No additional studies submitted.

#### A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

No additional studies submitted.

#### A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

No additional studies submitted.

#### A 2.3.2. KCP 10.3.2 Effects on arthropods other than bees

##### zRMS comments:

The study was conducted in line with the respective guideline with no deviations.

All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:

LR<sub>50</sub>>0.1 L prod/ha

ER<sub>50</sub> = 0.052 L prod./ha

NOER<sub>fecundity</sub> = 0.025 Lprod./ha

Reference:	KCP 10.3.2/01
Report:	A laboratory test for evaluating the effects of Floras 50 SC on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani - Perez). STUDY CODE: B-123-22.
Guideline(s):	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)
Deviations:	No
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	-

### Executive summary

#### I. Materials and methods

##### A. Materials

- Test material: Floras 50 SC  
Lot/Batch no.: RFEAR0501  
Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

2. Test organisms.

Species: *Aphidius rhopalosiphi* (De Stefani-Perez).

Age: adult wasps (24 - 48 hours after emerging from mummies)

Source: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna

Acclimatisation: The wasps, *A. rhopalosiphi* were reared on the barley, *Hordeum vulgare* L. infested with the bird cherry-oat aphid, *Rhopalosiphum padi*. Cages were covered with nylon mesh. Honey drops applied to the nylon mesh served as supplementary food for the wasps.

Feeding: -

No of organisms: 10 wasps/replicate.

3. Test units and exposure.

Type and size: Common barley plants (*Hordeum vulgare* L., Gramineae).

Test procedure: The aim of the study was to determine the effect of Floras 50 SC on mortality and fecundity of the parasitic wasp, *Aphidius rhopalosiphi*. The endpoint of this test was mortality of the wasps after 48 hours of exposure and fecundity reduction (Pr) 12 days after the oviposition phase.

Test duration: 14 d

4. Test conditions -

Test medium: -

Temperature: 19-20°C

Aeration: No

Photoperiod: 16 hours light: 8 hours dark

Light intensity: mortality assessment and oviposition: 950 lx; fecundity assessment: 4913 lx

~~Dissolved oxygen: -~~

~~pH value: -~~

Humidity: 65-80%

## B. Study design and method

1. In life dates:

Start of the preliminary non-GLP test: 10.08.2022

End of the preliminary non-GLP test: 12.08.2022

Study initiation date: 01.09.2022

Experimental starting date (definitive test): 27.09.2022

Experimental completion date (definitive test): 12.10.2022

Draft report: 03.02.2023

Study completion date: 23.02.2023

2. Test design:

test groups:

– a control group (0.0 L/ha)

– the test item at the rate of 0.025 L/ha

– the test item at the rate of 0.05 L/ha

– the test item at the rate of 0.1 L/ha

– dimethoate at the rate of 0.2 g/ha

number of replicates: 4 replicates/group

number of wasps: 10 wasps/replicate

3. Analytical verification: -

4. Statistics: Probit analysis using linear weighted regression, Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Multiple Sequentially-rejective Welch-t-test After Bonferroni-Holm.

## II. Results and discussion

## A. Analytical data

## B. Mortality

Study group	Test item: Floras 50 SC					
	Mortality after 48 h		Reproduction after 12 days after the oviposition			
Test item [kg/ha]	Total [%]	LR <sub>50</sub> [L/ha]	Test item [L/ha]	Mean no. of mummies /female	Fecundity reduction Pr [%]	ER <sub>50</sub> [L/ha]
Control (0.0)	0.0	> 0.1	Control (0.0)	21.1	–	<b>0.052</b> (0.042 – 0.066)*
0.025	0.0		0.025	17.1	18.9	
0.05	0.0		0.05	7.7	63.7	
0.1	0.0		0.1	6.7	68.5	
NOER <sub>mortality</sub> ≥ 0.1 [L/ha]			NOER <sub>fecundity</sub> 0.025 [L/ha]			
Reference item: dimethoate						
Rate [g/ha]			Mortality after 24 h, Total [%]			
0.2			77.5			

\*: the ER<sub>50</sub> value (with 95% confidence limits) was calculated using ToxRat 3.3.0

## C. Toxicological symptoms

–

## D. Validity of the test:

The following validity criteria were met during the study [3]:

- the mortality of the control group after 48 hours was 0.0% (criterion: a maximum of 13.0%),
- mortality of the reference item group after 24 hours of the treatment was 77.5% (criterion: from 75 to 100%),
- 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 21.1 (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).

## III. Assessment and conclusion

In the definitive test, mortality of the control group, after 48 hours, was 0.0%. After 48 hours of the exposure to Floras 50 SC, at the all rates the percentages mortality of *A. rhopalosiph* was 0.0%.

Based on the obtained mortality results it can be assumed that the LR<sub>50</sub> is higher than 0.1 L/ha. The NOER<sub>mortality</sub> is higher or equal to 0.1 L/ha of the test item.

Mortality the wasps exposed to dimethoate (after 24 hours of exposure) at the rate of 0.2 g/ha was 77.5%. Therefore, the validity criterion specified in the method description was met. 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 21.1. As for the wasps treated with Floras 50 SC at the rates of 0.025, 0.05 and 0.1 L/ha the mean number of mummies per female were 17.1, 7.7, and 6.7 respectively. Fecundity reduction (Pr) in the group treated with the test item at the rates of 0.025, 0.05 and 0.1 L/ha were 18.9, 63.7 and 68.5%, respectively.

At the significance level of 0.05, there were no statistically significant differences in fecundity between the wasps exposed to the test item at the rate of 0.025 L/ha and the control group (Multiple Sequentially-rejective Welsh-t-test After Bonferroni-Holm,  $p(t) > \text{Alpha}$ ).

At the significance level of 0.05, there were statistically significant differences in fecundity between the wasps exposed to the test item at the rates of 0.05 and 0.1 L/ha and the control group (Multiple Sequentially-rejective Welsh-t-test After Bonferroni-Holm,  $p(t) < \text{Alpha}$ ).

Based on the obtained fecundity results it can be assumed that the ER50 is 0.052 L/ha (95% confidence limits: 0.042 – 0.066) of the test item. The NOER<sub>fecundity</sub> is 0.025 L/ha of the test item.

On the basis of the obtained results, it can be concluded that Floras 50 SC at the rates of 0.025, 0.05 and 0.1 L/ha has no effect on mortality of the wasps.

The test item, Floras 50 SC, at the rate of 0.025 L/ha has no adverse effect on fecundity of the wasps.

The test item, Floras 50 SC, at the rates of 0.05 and 0.1 L/ha has adverse effect on fecundity of the wasps.

#### zRMS comments:

The study was conducted in line with the respective guideline with no deviations.

All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:

LR<sub>50</sub> > 0.1 L prod./ha

ER<sub>50</sub> > 0.1 L prod./ha

NOER<sub>mortality</sub> = 0.01 L/ha

NOER<sub>fecundity</sub> = 0.05 L/ha

Reference:	KCP 10.3.2/02
Report:	A laboratory test for evaluating the effects of Floras 50 SC on the predatory mite, Typhlodromus pyri (Sch.). STUDY CODE: B-122-22.
Guideline(s):	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)
Deviations:	Yes According to the guideline developed by the IOBC, BART, EPPO Joint Initiative, as a food source only pollen is 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. The obtained deviation had no impact on the quality, integrity and final results of the study.
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	-

## Executive summary

### I. Materials and methods

#### A. Materials

##### 1. Test material: Floras 50 SC

Lot/Batch no.: RFEAR0501

Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

2. Test organisms.

Species: *Typhlodromus pyri* (Sch.)

Age: 24-hour-old protonymphs

Source: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna

Acclimatisation: the mites are reared on the bean, *Phaseolus vulgaris* L. (Fabaceae) infested with the two-spotted spider mite, *Tetranychus urticae* Koch.,.

Feeding: -

No of organisms: 20 wasps/replicate.

3. Test units and exposure.

Type and size: Each test set consisted of a glass tray filled with water and a glass bench containing 5 test units. Artificial discs (Ø 45 mm) were floating on the water surface in glass Petri dishes ('island dishes', Ø 54 mm) with central holes at the bottom (Ø 6 mm). Water in the test units prevented the mites from escaping.

Test procedure: The aim of the study was to determine the impact of Floras 50 SC on mortality and reproduction of the predatory mite, *Typhlodromus pyri* under laboratory conditions. The endpoint of this test was mortality of the mites after 7 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment.

Test duration: 14 d

4. Test conditions -

Test medium: -

Temperature: 24-26°C

Aeration: No

Photoperiod: 16 hours light: 8 hours dark

Light intensity: 627 lx

~~Dissolved oxygen: -~~

~~pH value: -~~

- Humidity: 63-76.5%

## B. Study design and method

1. In life dates:

Start of the preliminary non-GLP test: 23.09.2022

End of the preliminary non-GLP test: 30.09.2022

Study initiation date: 02.11.2022

The experimental starting date: 24.11.2022

The experimental completion date: 08.12.2022

Draft Report: 03.02.2023

Study completion date: 23.02.2023

2. Test design:

5 study groups:

– a control group (0.0 L/ha)

– the test item at the rate of 0.025 L/ha

– the test item at the rate of 0.05 L/ha

– the test item at the rate of 0.1 L/ha

– dimethoate at the rate of 4.0 g/ha

number of replicates: 3 replicates/group

number of mites in each replicate: 20

3. Analytical verification: -

4. Statistics: Probit analysis using linear max. likelihood regression, Qualitative Trend Analysis by Contrasts (Monotonicity of Rate/Response), Chi2 2x2 Table Test with Bonferroni Correction, Shapiro-Wilk's

Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure.

## II. Results and discussion

### A. Analytical data

-

### B. Mortality

Study group [application rate]	Parameter (endpoint)						
	Mortality (dead + escape mites)			Reproduction			
Test item [L/ha]	Total [%]	Corr. <sup>a</sup> [%]	LR <sub>50</sub> [L/ha]	Test item [L/ha]	Mean number of eggs per female (Rr) [no.]	Repro- duction reduction (Pr) [%]	ER <sub>50</sub> [L/ha]
Control	3.3	–	–	Control	7.6	–	–
Floras 50 SC							
0.025	6.7	3.5	> 0.1	0.025	7.3	4.3	> 0.1
0.05	5.0	1.7		0.05	7.9	(-4.4)*	
0.1	10.0	6.9		0.1 <sup>+</sup>	5.8	23.6	
NOER <sub>mortality</sub> [L/ha]			≥ 0.1	NOER <sub>reproduction</sub> [L/ha]			0.05
Reference item							
[g/ha]	Total [%]	Corr. <sup>a</sup> [%]		Dimethoate			
4.0	100.0	100.0		not assessed			

<sup>a</sup>: mortality corrected according to the Abbott formula

\*: the negative value means that in the tested rate there was higher the cumulative mean reproduction value than in the control group

<sup>+</sup>: statistically significant differences

### C. Toxicological symptoms

-

### D. Validity of the test:

The following validity criteria were met during the study [1]:

- mortality of the control group was 3.3% on day 7 of exposure (criterion: a maximum of 20%),
- corrected mortality of the mites exposed to the reference item at the rate of 4.0 g/ha was 100.0% on day 7 of exposure (criterion: from 50 to 100%),
- the mean number of eggs per female in the control group was 7.6 (required: ≥ 4 eggs per female).



### III. Assessment and conclusion

In the definitive test, mortality of the control group after 7 days of exposure was 3.3%. After 7 days of exposure to Floras 50 SC at the rates of 0.025, 0.05 and 0.1 L/ha, the *T. pyri*, percentages of mortality, corrected according to the Abbott formula, were equal to 3.5, 1.7 and 6.9%, respectively.

There were no statistically significant differences in mortality between the group treated with the test item at the all rates in comparison to the control group (Chi2-2 x 2 Test with Bonferroni Correction,  $p(z) > \text{Alpha}$ ).

On the basis of the obtained results the LR50 value is higher than 0.1 L/ha. The NOERMortality value is higher or equal to 0.1 L/ha.

After 7 days of exposure to dimethoate at the rate of 4.0 g/ha, the Abbott corrected mortality was 100.0%. 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.

Due to the mortality in each group was lower than 50%, all the groups treated with the test item, were included in reproduction assessment.

The mean reproduction rate (Rr) in the control group was 7.6 eggs/female. The mean Rr after 14 days of exposure to Floras 50 SC at rates of 0.025, 0.05 and 0.1 L/ha were 7.3, 7.9 and 5.8 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by the test item at the rates of 0.025, 0.05 and 0.1 L/ha were 4.3, -4.4 and 23.6%, respectively. There were no statistically significant differences in reproduction between the groups treated with the test item at the rates of 0.025 and 0.05 L/ha and the control group (Williams Multiple Sequential t-test Procedure,  $|t| < |t^*|$ ). There were statistically significant differences in reproduction between the groups treated with the test item at the rate of 0.1 L/ha and the control group (Williams Multiple Sequential t-test Procedure,  $|t| > |t^*|$ ).

On the basis of the obtained reproduction results, the ER50 value is higher than 0.1 L/ha and the NOERreproduction value is equal to 0.05 L/ha.

Based on the results it can be stated that Floras 50 SC has no an adverse effect on mortality of the tested organisms at the rates of 0.025, 0.05 and 0.1 L/ha. The test item has no adverse effect on reproduction of the mites at the rates of 0.025 and 0.05 L/ha. The test item has adverse effect on reproduction of the mites at the rate of 0.1 L/ha.

## 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

##### zRMS comments:

The study was conducted in line with OECD 222 with no deviation.  
All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:

56d NOEC<sub>rep</sub> = 180 mg prod./kg dw soil

56d EC<sub>10</sub> = **106 mg prod./kg dw soil** (CI: 55.8 – 157.2) NW=0.95, reliable value according to EFSA 2019 and should be used in the risk assessment as its value is lower than NOEC value.

Reference:	KCP 10.4.1.1/01
Report:	Earthworm reproduction test (Eisenia andrei). STUDY CODE: G-10-22.
Guideline(s):	OECD 222
Deviations:	No
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	-

## Executive summary

### I. Materials and methods

#### A. Materials

- Test material: Floras 50 SC  
Lot/Batch no.: RFEAR0501  
Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

- Test organisms.

Species: Eisenia andrei

Age: Adult

Source: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna

Acclimatisation: It takes place in plastic boxes placed in a special room. The dimensions of the bases of the boxes are 35 cm x 50 cm x 30 cm. There are some holes at the bottom of each box in order to drain off excess water. A 50:50 mixture of cattle manure and straw with the pH between  $7 \pm 1$  serves as a culture medium. During the process, the boxes are covered with black foil. The room temperature was  $20 \pm 2^\circ\text{C}$ .

Feeding: fresh substrate

No of organisms: 10 earthworms/replicate.

- Test units and exposure.

Type and size: plastic box.

Test procedure: The aims of the study were to assess the impact of the test item, i.e. Floras 50 SC on reproduction of the earthworm, *Eisenia andrei* and to determine the EC10, EC20, EC50, and NOEC.

Test duration: 8 weeks

4. Test conditions -

Test medium: -

Temperature: 20.1-22.0°C

Aeration: No

Photoperiod: light-dark cycle: 16h : 8h;

Light intensity: light intensity at the beginning of the experiment: 549.4 – 628.3 lux

light intensity at the end of the experiment: 563.5 to 612.8 lux

Dissolved oxygen:—

pH value: at the beginning: 5.61 – 5.75; 5.61 – 5.75; at the end of the experiment: 5.57 – 5.82;

## B. Study design and method

1. In life dates:

Start of the study: August 16, 2022

Experimental starting date: August 25, 2022

Experimental completion date: October 23, 2022

Draft Report: November 28, 2022

End of the study: November 30, 2022

2. Test design:

test duration: 8 weeks; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate.

The test item in the form of an aqueous suspensions was mixed with a suitable amount of the artificial soil.

During the experiment, the earthworms were fed on air-dried finely ground cow manure.

One day after the beginning of the experiment, it was spread on the soil surface (5 g food/ container) and moistened. The food prepared in this way was provided once a week during the four-week period (5 g food/container). After 4 weeks (when the adult earthworms were removed from the soil), the juvenile earthworms were fed only once (5 g food/container).

3. Analytical verification: Chromatografic – DAD detection.

4. Statistics:

EC10, EC20, EC50, LC50 – probit analysis using linear max. likelihood regression

NOEC (reproduction):

- Shapiro-Wilk's Test on Normal Distribution,

- Levene's Test 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

## II. Results and discussion

### A. Analytical data

#### Results from analysis of active substance in the test sample

Time/ date of analysis	Concentration of test item [mg/kg d.w.]	Nominal concentration of florasulam [mg/kg d.w.]	Mean concentration of florasulam determined (n=3) in samples [mg/kg d.w.]	% ± RSD of nominal concentration
Day 0 (25.08.2022)	control	---	< LoD	---
	1000	48.4	45.80	94.6 ± 6.3
Day 28 (22.09.2022)	control	---	< LoD	---
	1000	48.4	34.18	70.6 ± 0.3
Day 56 (20.10.2022)	control	---	< LoD	---
	1000	48.4	24.09	49.8 ± 14.5

LOQ = 10.0 mg florasulam/kg; LOD = 5.0 mg florasulam/kg;  
--- not calculated; ND – not detected

### B. Mortality

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of florasulam/kg dry weight of artificial soil]
EC10	106.0 (55.8 – 157.2)	5.13 (2.70 – 7.60)
EC20	356.1 (260.3 – 480.5)	17.22 (12.59 – 23.24)
EC50	>1000.0	48.37
NOEC (reproduction)	180.0	8.71
LOEC (reproduction)	320.0	15.48
LC50	>1000.0	>48.37
NOEC (survival)	≥1000.0	≥48.37
LOEC (survival)	>1000.0	>48.37

### C. Toxicological symptoms

-

### D. Validity of the test:

The results are considered valid because the following criteria were satisfied in the controls:

- each replicate produced from 40 to 87 juveniles (64.5 mean) at the end of the exposure period (criterion: ≥ 30 juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 22.3% (criterion: ≤ 30%),
- adult mortality over the initial 4 weeks of the experiment was 6.3% (criterion: ≤ 10%).

### III. Assessment and conclusion

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 12.5%. As for the control group, mortality of the adult earthworms was equal to 6.3%.

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 48.37 mg of florasulam/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 change was between -4.3 and 6.9%. As for the control group, the body weight increase was equal to 3.5%.

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 42.8 and 64.8 per replicate. The mean number of juveniles in the control group was equal to 64.5 per replicate.

After 8 weeks of the experiment, it was concluded that Floras 50 SC had a statistically significant impact on reproduction of the earthworms at the concentrations ranging from 320.0 to 1000.0 mg/kg dry weight of the artificial soil.

#### A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

No studies submitted.

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

No studies submitted.

##### A 2.4.2.1 KCP 10.4.2.1 Species level testing

No studies submitted.

##### A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

No studies submitted.

#### A 2.5 KCP 10.5 Effects on soil nitrogen transformation

##### zRMS comments:

The study was conducted in line with OECD 216 with minor deviations.

All the validity criteria were met.

It may be concluded that the effects of the test item on soil nitrogen formation rates were < 25 % at the end of the study period (28 days) up to 0.52 mg product/kg soil dw.

Reference:	KCP 10.5/01
Report:	Soil Microorganisms: Nitrogen Transformation Test. STUDY CODE: G-11-22.
Guideline(s):	OECD 216
Deviations:	<p>Yes <del>No</del></p> <p>According to the Guideline, the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm and time duration between 18 to 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.</p>

	This deviation did not affect the results of the study.
GLP:	Yes
Acceptability/Reliability:	Yes
Duplication (if vertebrate study)	-

## Executive summary

### I. Materials and methods

#### A. Materials

1. Test material: Floras 50 SC  
Lot/Batch no.: RFEAR0501  
Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

2. Test organisms.

Species: Soil

Age: -

Source: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna

Acclimatisation: The collected soil was manually cleared of large objects (e.g. stones, parts of plants, etc.), sieved to a particle size equal to 2 mm and thus the laboratory soil sample was obtained. Next, a batch of soil weighing 4.5 kg was separated. The soil, prepared in that way, was thoroughly mixed and divided into three equal portions (1.5 kg each). Each portion was amended with a suitable organic substrate, i.e. lucerne (N – 3.14%, C – 43.36% dry weight). The C/N content was equal to 13.8/1. The lucerne-soil ratio was 5 g of lucerne per kg of soil (dry weight). Lucerne was sieved to a particle size equal to 0.3 mm. It was obtained from TAMS II Obrót Nasionami, Koźyczkowo 64, 83 – 333 Chmielno.

Feeding: -

No of organisms: 3 x 500 g

3. Test units and exposure.

Type and size: plastic box.

Test procedure: The aim of this study was to detect long-term adverse effects of Floras 50 SC on the process of nitrogen transformation in aerobic surface soils.

Test duration: 28 d

4. Test conditions -

Test medium: -

Temperature: 18.9-22.0°C

Aeration: No

Photoperiod: incubation in darkness

Light intensity: —————

—Dissolved oxygen:—

—pH value:—

#### B. Study design and method

1. In life dates:

Start of the study: August 18, 2022

Experimental starting date: September 01, 2022

Experimental completion date: September 30, 2022

Draft Report: November 15, 2022

End of the study: November 24, 2022

## 2. Test design:

Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. After adding the deionized water, every portion was divided into three replicates (3 x 500 g). Exposure period: 28 days.

## 3. Analytical verification: -

Soil samples (10 g of dry weight) were weighed into the flasks with a capacity of 250 mL. Next, 50 mL of deionized water was added. The contents of the flasks were shaken at 90 rpm and time duration between 18 to 24 hours (a deviation from the OECD Guideline No. 216 (2000)). After that, the soil suspensions were centrifuged and the supernatants were used to determine the concentrations of nitrate nitrogen. The nitrate ion concentration was measured using the pH/ION 7320 digital meter and the NO 800 nitrate electrode.

At each day of analysis, the standard solutions were prepared using a basic solution. Before the measurement the nitrate electrode was calibrated using standard solutions. Then, flasks containing the soil extracts and blank sample were prepared. The results of the measurements were given in mg/L.

## 4. Statistics:

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

# II. Results and discussion

## A. Analytical data

Concentration of the test item [mg/kg dry weight of the soil]	Quantity of the test item [mg/1299 g dry soil]	Concentration of stock suspension [mg/mL]*	Volume of stock suspension [mL]	Volume of deionized water [mL]	Total volume of water stock suspension introduced to the sample weight of soil [mL]
<b>0.0</b>	-	-	-	48.0	-
<b>0.104</b>	0.14	1	0.14	47.86	48.0
<b>0.520</b>	0.70	1	0.70	47.30	48.0

\* **1 mg of the test item/mL**: 50 mg of the test item was mixed with small volume of deionised water, the volume was made up to 50 mL with deionised water [SOP/G/11].

## B. Mortality

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: 0.104 mg test item/kg dry weight of soil (0.005 mg of florasulam/kg dry weight of soil) and 5 x PEC: 0.520 mg test item/kg dry weight of soil (0.025 mg of florasulam/kg dry weight of soil) did not exceed 25% on 28 day of analysis.

## C. Toxicological symptoms

-

## D. Validity of the test:

The coefficients of variation (CV) in the control group were 7.9, 8.9, 5.9 and 2.5%, after 0, 7, 14 and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than 15%.

### III. Assessment and conclusion

Concentration	Control			PEC			5 x PEC		
Replicate	I	II	III	I	II	III	I	II	III
Reading* [mg/L]	42.673	37.343	36.213	36.733	36.333	36.053	38.423	39.443	39.453
Nitrate ion concentration [mg/kg of dry soil]	213.365	186.715	181.065	183.665	181.665	180.265	192.115	197.215	197.265
Mean nitrate ion concentration [mg/kg of dry soil] ± SD	193.72 ± 17.25			181.87 ± 1.71			195.53 ± 2.96		
CV	8.9			0.9			1.5		

\* - values adjusted for the value of the blank sample

On the basis of the results, it was concluded that Floras 50 SC at the concentrations corresponding to the PEC: 0.104 mg test item/kg dry weight of soil (0.005 mg of florasulam/kg dry weight of soil) and 5 x PEC: 0.520 mg test item/kg dry weight of soil (0.025 mg of florasulam/kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

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

### zRMS comments:

The study was conducted in line with OECD 208 with slight deviation in environmental conditions.

All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:

The most sensitive species is cabbage with ER<sub>50</sub>=0.22 g florasulam/ha (shoot length)

### Visual phytotoxicity

During the experiment the phytotoxic symptoms of the test item were noticed in cultivation of cabbage, flax, carrot, onion and oats. The most sensitive species id cabbage with ER<sub>50</sub>=0.28 g florasulam/ha

Reference:	KCP 10.6/01
Report:	Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test. STUDY CODE: G-13-22.
Guideline(s):	OECD 208
Deviations:	Yes No 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 119.5 and 186.7 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing.
GLP:	Yes
Acceptability/Reliability:	Yes



Duplication (if vertebrate study)	-
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## Executive summary

### I. Materials and methods

#### A. Materials

1. Test material: Floras 50 SC

Lot/Batch no.: RFEAR0501

Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

2. Test organisms.

Species: Plants: cabbage (*Brassica oleracea* var. *capitata*), flax (*Linum usitatissimum*), carrot (*Daucus carota*), onion (*Allium cepa*), perennial ryegrass (*Lolium perenne*), oats (*Avena sativa*)

Age: -

Source:

- Cabbage (*Brassica oleracea* var. *capitata*) - PNOS Sp. z o.o., Żeromskiego 3, 05 – 850 Ożarów Mazowiecki, Poland

- Flax (*Linum usitatissimum*) - W. Legutko, Przedsiębiorstwo Hodowlano – Nasienne Sp. z o.o., Nad Stawem 1F, 63 – 930 Jutrosin, Poland

- Carrot (*Daucus carota*) - „BIOPON” BROS Sp. z o.o, Sp.k., Karpia 24, 61 – 619 Poznań, Poland

- Onion (*Allium cepa*) - Przedsiębiorstwo Nasienne TORAF, L. T. R. Węgrzynowscy sp. j., Grundwaldzka 24b, 46 – 203 Kluczbork, Oddział Maciejów, Maciejów 34, 46 – 211 Kujakowice Górne, Poland

- Perennial ryegrass (*Lolium perenne*) - „DANKO” Hodowla Roślin Sp. z o.o., Zakład Hodowli Roślin, Oddział Szelejewo, Szelejewo Drugie 39, 63 – 820 Piaski, Poland

- Oats (*Avena sativa*) - DANKO Hodowla Roślin Sp. z o.o., Choryń 27, 64 – 000 Kościan, Zakład Hodowli Roślin – Oddział Modzurów, Ks. Strzybnego 23, 47 – 411 Rudnik, Poland

Acclimatisation: Six plant species were used. These were: cabbage (*Brassica oleracea* var. *capitata*), flax (*Linum usitatissimum*), carrot (*Daucus carota*), onion (*Allium cepa*), perennial ryegrass (*Lolium perenne*), oats (*Avena sativa*). The test species were selected from the list given in the OECD Guideline No. 208. Before the experiment started, seeds had been kept under dry conditions, at ambient temperature and with no access to light. The seed viability had also been examined.

Feeding: -

No of organisms: The total number of seeds per application rate: 21 (cabbage) or 20 (flax, carrot, onion, perennial ryegrass and oats).

3. Test units and exposure.

Type and size: plastic pots, pot's diameter – 15 cm, pot's surface area – about 177 cm<sup>2</sup>.

Test procedure: The aims of this study were to assess the impact of the test item, i.e. Floras 50 SC on seedling emergence and seedling growth of selected terrestrial plant species and to determine the ER10, ER25, ER50 and NOER for chosen parameters of the test.

Test duration: 23 d

4. Test conditions -

Test medium: Soil

Temperature: 16.7-26.8°C

Aeration: No

Photoperiod: 16 h light : 8 h dark

Light intensity: 119.5 – 186.7 µE/m<sup>2</sup>/s

Dissolved oxygen: -

pH value: -

## B. Study design and method

### 1. In life dates:

Start of the study: September 13, 2022

Experimental starting date: September 27, 2022

Experimental completion date: October 19, 2022

Draft Report: December 9, 2022

End of the study: December 9, 2022

### 2. Test design:

number of rates: 8 + control; number of replicates/rate: 7 (cabbage), 4 (flax, carrot, onion, perennial ryegrass and oats). The total number of seeds per application rate: 21 (cabbage) or 20 (flax, carrot, onion, perennial ryegrass and oats).

Exposure termination:

14 days after the emergence of 50% of the control seedlings;

Application rates:

- a control,
- 0.2 mL of the test item /ha (0.01 g of florasulam/ha),
- 0.4 mL of the test item /ha (0.02 g of florasulam/ha),
- 1.0 mL of the test item /ha (0.05 g of florasulam/ha),
- 2.6 mL of the test item /ha (0.13 g of florasulam/ha),
- 6.4 mL of the test item /ha (0.32 g of florasulam/ha),
- 16.0 mL of the test item /ha (0.80 g of florasulam/ha),
- 40.0 mL of the test item /ha (2.01 g of florasulam/ha),
- 100.0 mL of the test item /ha (5.03 g of florasulam/ha).

### 3. Analytical verification: Chromatographic – DAD detection.

### 4. Statistics:

ER10, ER25 and ER50 (number of plants) – Probit analysis using linear max. likelihood regression, Logit analysis using linear max. likelihood regression

ER10, ER25 and ER50 (shoot length) – 4-param. normal CDF, 3-param. normal CDF,

ER10, ER25 and ER50 (plants dry weight) – 4-param. normal CDF, 3-param. normal CDF, Logit analysis using linear max. likelihood regression

ER50 (visual phytotoxicity effects) – probit analysis using linear max. likelihood regression, 3-param. normal CDF

NOER:

- number of plants: Qualitative Trend Analysis by Contrasts (Monotonicity of Rate/Response), Chi2 2x2 Table Test with Bonferroni Correction, Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure, Fisher's Exact Binomial Test with Bonferroni Correction, Non-parametric Trend analysis by Contrasts (Monotonicity of Rate/Response), Step-down Jonckheere-Terpstra Test Procedure

- shoot length: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure, Non-parametric Trend analysis by Contrasts (Monotonicity of Rate/Response), Step-down Jonckheere-Terpstra Test Procedure

- shoot dry weight: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Multiple Sequentially-rejective Welch-t-test After Bonferroni-Holm, Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure, Non-parametric Trend analysis by Contrasts (Monotonicity of Rate/Response), Step-down Jonckheere-Terpstra Test Procedure

## II. Results and discussion

## A. Analytical data

### Results from analysis of active substance in test samples

Dose of test item [mL/ha]	Nominal concentration of florasulam [mg/L]	Mean concentration of florasulam determined (n=3) in samples collected		
		at start of experiment (27.09.2022) [mg/L]	%± RSD of nominal concentration	
100	16.8	17.0	101.2	± 0.6
40	6.72	6.75	100.4	± 0.6
16	2.69	2.76	102.6	± 0.7
6.4	1.08	1.21	112.0	± 9.1
2.6	0.432	0.443	102.5	± 2.5
1	0.173	0.170	98.3	± 0.6
0.4	0.0692	0.0685	99.0	± 0.7
0.2	0.0277	0.0264	95.3	± 1.1
Control	0.0000	< LoD	---	

## B. Mortality

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 and ER50 values for plant damages at the end of the exposure period expressed as **mL of the test item/ha for all test species**.

	<b>Cabbage</b> <i>Brassica oleracea var. capitata</i>	<b>Flax</b> <i>Linum usitatissimum</i>	<b>Carrot</b> <i>Daucus carota</i>	<b>Onion</b> <i>Allium cepa</i>	<b>Perennial ryegrass</b> <i>Lolium perenne</i>	<b>Oats</b> <i>Avena sativa</i>
<b>Plant number at the end of the experiment</b>						
<b>ER<sub>50</sub></b>	> 100.0	>100.0	> 100.0	> 100.0	> 100.0	> 100.0
<b>NOER</b>	> 100.0	16.0	≥ 100.0	16.0	≥ 100.0	≥ 100.0
<b>Shoot length</b>						
<b>ER<sub>50</sub></b>	4.6	46.7	49.4	>100.0	> 100.0	> 100.0
<b>NOER</b>	1.0	6.4	6.4	16.0	40.0	40.0
<b>Plant dry weight</b>						
<b>ER<sub>50</sub></b>	5.6	52.9	20.6	>100.0	>100.0	>100.0
<b>NOER</b>	2.6	6.4	6.4	40.0	40.0	6.4
<b>Plant Damage</b>						
<b>ER<sub>50</sub></b>	12.5	34.3	25.5	>100.0	>100.0	>100.0

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 and ER50 values for plant damages at the end of the exposure period expressed as g of florasulam/ha for all test species.

	<b>Cabbage</b> <i>Brassica oleracea var. capitata</i>	<b>Flax</b> <i>Linum usitatissimum</i>	<b>Carrot</b> <i>Daucus carota</i>	<b>Onion</b> <i>Allium cepa</i>	<b>Perennial ryegrass</b> <i>Lolium perenne</i>	<b>Oats</b> <i>Avena sativa</i>
<b>Plant number at the end of the experiment</b>						
<b>ER<sub>50</sub></b>	> 5.03	>5.03	> 5.03	> 5.03	> 5.03	> 5.03
<b>NOER</b>	> 5.03	0.81	≥ 5.03	0.81	≥ 5.03	≥ 5.03
<b>Shoot length</b>						
<b>ER<sub>50</sub></b>	0.23	2.35	2.49	>5.03	> 5.03	> 5.03
<b>NOER</b>	0.05	0.32	0.32	0.81	2.01	2.01
<b>Plant dry weight</b>						
<b>ER<sub>50</sub></b>	0.28	2.66	1.04	>5.03	>5.03	>5.03
<b>NOER</b>	0.13	0.32	0.32	2.01	2.01	0.32
<b>Plant Damage</b>						
<b>ER<sub>50</sub></b>	0.63	1.73	1.29	>5.03	>5.03	>5.03

### C. Toxicological symptoms

-

### D. Validity of the test:

On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of Floras 50 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:
  - 100.0% – cabbage
  - 100.0% – flax,
  - 95.0% – carrot,
  - 85.0% – onion,
  - 100.0% – perennial ryegrass,
  - 90.0% – oats,
- the mean survival of the emerged control seedlings was 100% for each tested plant species (validity criterion: 90%);
- the control seedlings did not exhibit any visible phytotoxic effects;
- environmental conditions for all plants of the same species were identical.

### III. Assessment and conclusion

On the basis of the obtained results it was proved that the test item i.e. Floras 50 SC had varied impact on seedling emergence and seedling growth of the tested plant species. The delayed seedling emergence of carrot and onion was observed when compared with the control. The accidental death of cabbage and flax was observed during the experiment. On the basis of NOER, ER10, ER25 and ER50 values determined from the plant number it was proved that the test item inhibited the seedling emergence and the process of growth of flax and onion. No influence was observed in cultivation of cabbage, carrot, perennial ryegrass and oats. On the basis of NOER, ER10, ER25 and ER50 values determined from the shoot length it was proved that the test item inhibited the process of growth of cabbage, flax, carrot and onion. Slight effect was observed in cultivation of perennial ryegrass and oats. On the basis of NOER, ER10, ER25 and ER50 values determined from the dry shoot weight it was proved that the test item inhibited the process of growth of cabbage, flax and carrot. Moderate effect was observed in cultivation of onion, perennial ryegrass and oats. During the experiment the phytotoxic symptoms of the test item were noticed in cultivation of cabbage, flax, carrot, onion and oats.

#### **zRMS comments:**

The study was conducted in line with OECD 227 with slight deviation in environmental conditions.

All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:

The lowest value of ER<sub>50</sub> = 0.32 g a.s./ha, carrot (plant dry weight) is estimated for carrot, the most sensitive species.

#### Visual phytotoxicity:

During the experiment the phytotoxic symptoms of the test item were noticed in cultivation of all tests plant species. The most sensitive species was carrot with ER<sub>50</sub>=0.44 g a.s./ha.

Reference:	KCP 10.6/02
Report:	Terrestrial Plant Test: Vegetative Vigour Test. STUDY CODE: G-12-22.
Guideline(s):	OECD 227
Deviations:	<p><b>Yes</b></p> <p><b>No</b></p> <p>According to OECD Guideline No. 227 (2006), the light intensity should be <math>350 \pm 50 \mu\text{E}/\text{m}^2/\text{s}</math>. However, these values are recommended for tests conducted in green-houses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between <math>96.4 - 277.3 \mu\text{E}/\text{m}^2/\text{s}</math>. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviation did not affect the results of the experiment.</p>
GLP:	Yes
Acceptability/Reliability:	<b>Yes</b>
Duplication (if vertebrate study)	-

## **Executive summary**

### **I. Materials and methods**

#### **A. Materials**

1. Test material: Floras 50 SC  
Lot/Batch no.: RFEAR0501  
Content: Florasulam: 50.3 g/L

Density: 1.04 g/mL

Control: Yes.

Toxic reference: -

## 2. Test organisms.

Species: Plants: cabbage (*Brassica oleracea* var. *capitata*), flax (*Linum usitatissimum*), carrot (*Daucus carota*), onion (*Allium cepa*), perennial ryegrass (*Lolium perenne*), oats (*Avena sativa*)

Age: -

Source:

- Cabbage (*Brassica oleracea* var. *capitata*) - PNOS Sp. z o.o., Żeromskiego 3, 05 – 850 Ożarów Mazowiecki, Poland

- Flax (*Linum usitatissimum*) - W. Legutko, Przedsiębiorstwo Hodowlano – Nasienne Sp. z o.o., Nad Stawem 1F, 63 – 930 Jutrosin, Poland

- Carrot (*Daucus carota*) - „BIOPON” BROS Sp. z o.o., Sp.k., Karpia 24, 61 – 619 Poznań, Poland

- Onion (*Allium cepa*) - Przedsiębiorstwo Nasienne TORAF, L. T. R. Węgrzynowscy sp. j., Grunwaldzka 24b, 46 – 203 Kluczbork, Oddział Maciejów, Maciejów 34, 46 – 211 Kujakowice Górne, Poland

- Perennial ryegrass (*Lolium perenne*) - „DANKO” Hodowla Roślin Sp. z o.o., Zakład Hodowli Roślin, Oddział Szelejewo, Szelejewo Drugie 39, 63 – 820 Piaski, Poland

- Oats (*Avena sativa*) - DANKO Hodowla Roślin Sp. z o.o., Choryń 27, 64 – 000 Kościan, Zakład Hodowli Roślin – Oddział Modzurów, Ks. Strzybnego 23, 47 – 411 Rudnik, Poland

Acclimatisation: Six plant species were used. These were: cabbage (*Brassica oleracea* var. *capitata*), flax (*Linum usitatissimum*), carrot (*Daucus carota*), onion (*Allium cepa*), perennial ryegrass (*Lolium perenne*), oats (*Avena sativa*). The test species were selected from the list given in the OECD Guideline No. 208. Before the experiment started, seeds had been kept under dry conditions, at ambient temperature and with no access to light. The seed viability had also been examined.

Feeding: -

No of organisms:

- cabbage: 3 plants/pot – 21 plants/ application rate (7 pots/ application rate);

- flax: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);

- carrot: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);

- onion: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);

- perennial ryegrass: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);

- oats: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate).

## 3. Test units and exposure.

Type and size: plastic pots, pot's diameter – 15 cm, pot's surface area – about 177 cm<sup>2</sup>.

Test procedure: The aims of this study were to assess the impact of the test item, i.e. Floras 50 SC on vegetative vigour of selected terrestrial plant species and to determine ER10, ER25, ER50 and NOER for chosen parameters of the test.

Test duration: 23 d

## 4. Test conditions -

Test medium: Soil

Temperature: 18.7-24.8°C

Aeration: No

Photoperiod: 16 h light : 8 h dark

Light intensity: 96.4 – 277.3  $\mu\text{E}/\text{m}^2/\text{s}$

Dissolved oxygen: -

pH value: -

## B. Study design and method

### 1. In life dates:

Start of the study: September 13, 2022

Experimental starting date: September 27, 2022

Experimental completion date: October 20, 2022

Draft Report: December 14, 2022

End of the study: December 19, 2022

## 2. Test design:

number of rates: 8 + control; number of replicates/rate: 7 (cabbage), 4 (flax, carrot, onion, perennial ryegrass and oats). The total number of seeds per application rate: 21 (cabbage) or 20 (flax, carrot, onion, perennial ryegrass and oats).

Exposure termination:

14 days after the emergence of 50% of the control seedlings;

Application rates:

- a control,
- 0.2 mL of the test item /ha (0.01 g of florasulam/ha),
- 0.4 mL of the test item /ha (0.02 g of florasulam/ha),
- 1.0 mL of the test item /ha (0.05 g of florasulam/ha),
- 2.6 mL of the test item /ha (0.13 g of florasulam/ha),
- 6.4 mL of the test item /ha (0.32 g of florasulam/ha),
- 16.0 mL of the test item /ha (0.80 g of florasulam/ha),
- 40.0 mL of the test item /ha (2.01 g of florasulam/ha),
- 100.0 mL of the test item /ha (5.03 g of florasulam/ha).

## 3. Analytical verification: Chromatografic – DAD detection.

## 4. Statistics:

Because no change in mortality of plants was to be observed, no computations in plant number have been performed for carrot, onion, perennial ryegrass and oats.

In order to determine ER10, ER25, ER50 the following test were used:

- plant number: Probit analysis using linear max. likelihood regression
- shoot length: Probit analysis using linear max. likelihood regression, 3-param. Normal CDF
- shoot dry weight: Probit analysis using linear max. likelihood regression, 3-param. Normal CDF, 3-param. logistic CDF, Logit analysis using linear max. likelihood regression
- ER50 (plant damages) - Probit analysis using linear max. likelihood regression;

In order to determine the NOER values, the following tests were used:

- for the plant number - Qualitative Trend Analysis by Contrasts (Monotonicity of Rate/Response), Tarone's Test Procedure, Multiple Sequentially-rejective Fisher Test After Bonferroni-Holm, Fisher's Exact Binomial Test with Bonferroni Correction;
- for the shoot length: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Multiple Sequentially-rejective Welch-t-test After Bonferroni-Holm, Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure;
- for the plant shoot dry weight: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Dunnett's Multiple t-test Procedure, Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure.

# II. Results and discussion

## A. Analytical data

### Results from analysis of active substance in test samples

Dose of test item [mL/ha]	Nominal concentration of florasulam [mg/L]	Mean concentration of florasulam determined (n=3) in samples collected		
		at start of experiment (27.09.2022) [mg/L]	%± RSD of nominal concentration	
100	16.8	17.0	101.2	± 0.6
40	6.72	6.75	100.4	± 0.6
16	2.69	2.76	102.6	± 0.7
6.4	1.08	1.21	112.0	± 9.1
2.6	0.432	0.443	102.5	± 2.5
1	0.173	0.170	98.3	± 0.6
0.4	0.0692	0.0685	99.0	± 0.7
0.2	0.0277	0.0264	95.3	± 1.1
Control	0.0000	< LoD	---	

## B. Mortality

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 and ER50 values for plant damages at the end of the exposure period expressed as mL of the test item/ha for all test species.

	<b>Cabbage</b> <i>Brassica oleracea var. capitata</i>	<b>Flax</b> <i>Linum usitatissimum</i>	<b>Carrot</b> <i>Daucus carota</i>	<b>Onion</b> <i>Allium cepa</i>	<b>Perennial ryegrass</b> <i>Lolium perenne</i>	<b>Oats</b> <i>Allium cepa</i>
<b>Plant number at the end of the experiment</b>						
ER <sub>50</sub>	>100.0	>100.0	>100.0	>100.0	>100.0	>100.0
NOER	≥100.0	≥100.0	>100.0	>100.0	>100.0	>100.0
<b>Shoot length</b>						
ER <sub>50</sub>	>100.0	9.6	17.3	64.2	>100.0	>100.0
NOER	2.6	2.6	1.0	2.6	16.0	6.4
<b>Plant dry weight</b>						
ER <sub>50</sub>	29.5	14.8	6.4	33.4	>100.0	>100.0
NOER	2.6	2.6	0.4	0.4	40.0	≥100.0
<b>Plant Damage</b>						
ER <sub>50</sub>	22.5	11.7	8.7	>100.0	>100.0	>100.0



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 and ER50 values for plant damages at the end of the exposure period expressed as g of florasulam/ha for all test species.

	<b>Cabbage</b> <i>Brassica oleracea var. capitata</i>	<b>Flax</b> <i>Linum usitatissimum</i>	<b>Carrot</b> <i>Daucus carota</i>	<b>Onion</b> <i>Allium cepa</i>	<b>Perennial ryegrass</b> <i>Lolium perenne</i>	<b>Oats</b> <i>Allium cepa</i>
<b>Plant number at the end of the experiment</b>						
<b>ER<sub>50</sub></b>	>5.03	>5.03	>5.03	>5.03	>5.03	>5.03
<b>NOER</b>	≥5.03	≥5.03	>5.03	>5.03	>5.03	>5.03
<b>Shoot length</b>						
<b>ER<sub>50</sub></b>	>5.03	0.48	0.87	3.23	>5.03	>5.03
<b>NOER</b>	0.13	0.13	0.05	0.13	0.81	0.32
<b>Plant dry weight</b>						
<b>ER<sub>50</sub></b>	1.48	0.74	0.32	1.68	>5.03	>5.03
<b>NOER</b>	0.13	0.13	0.02	0.02	2.01	≥5.03
<b>Plant Damage</b>						
<b>ER<sub>50</sub></b>	1.13	0.59	0.44	>5.03	>5.03	>5.03

### C. Toxicological symptoms

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### D. Validity of the test:

On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of Floras 50 SC on vegetative vigour of terrestrial plants were met:

- the seedling emergence of plants (validity criterion: at least 70%) was as follows:

88.1 – 97.6 – cabbage,

87.5 – 100.0 – flax,

90.0 – 97.5 – carrot,

87.5 – 97.5 – onion,

87.5 – 95.0 – perennial ryegrass,

92.5 – 97.5 – oats,

- 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.

### III. Assessment and conclusion

The test item, i.e. Floras 50 SC, applied at rates ranging from 0.2 to 100.0 mL/ha, had a varied impact on vegetative vigour of all tested plant species.

On the basis of NOER, ER10, ER25 and ER50 values determined from the plant number at the end of the experiment it was proved that the test item did not inhibit the process of growth of all tested plants species.

On the basis of NOER, ER10, ER25 and ER50 values determined from the shoot length it was proved that the test item inhibited the process of growth of cabbage, flax, carrot, onion. Slight effect was observed in cultivation of perennial ryegrass and oats.

On the basis of NOER, ER10, ER25 and ER50 values determined from the dry shoot weight it was proved that the test item inhibited the process of growth of cabbage, flax, carrot, onion. Slight effect was observed in cultivation of perennial ryegrass. No influence was observed in cultivation of oats.

During the experiment the phytotoxic symptoms of the test item were noticed in cultivation of all tested plant species.

In the study, the most sensitive plant to influence of the test item was carrot.

The most resistant species was oats.

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

No studies submitted.

## **A 2.8                      KCP 10.8 Monitoring data**

No additional information.