REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: F7B-39-30

Product name: Rinpode

Chemical active substance: Florpyrauxifen-benzyl, 25 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Corteva Agriscience

Submission date: March 2023 Update April 2024

zRMS Assessment date: 15/11/2023

Following commenting round: 17/04/2024

References correction: 31/07/2024

Version history

When	What
March 2023	Submission to zRMS and concerned Member States
November 2023	zRMS assesment
April 2024	Updated by highlighting in green the new text and strikethrough the ~~text to be removed~~ to address comments from Member States
April 2024	Following commenting round
July 2024	References correction

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9 Ecotoxicology (KCP 10)

This application was submitted by Corteva Agriscience in March 2023.
The application is for the first approval of the formulation F7B-39-30 (trademark: Rinpode) as new post-emergence herbicide developed by Corteva Agriscience. The formulation is an EC (emulsion concentrate) containing 25 g/L of florpyrauxifen-benzyl (19.870 g a.e./L) for use as an herbicide in sugar beets.
F7B-39-30 is submitted to Southern and Central zones with France and Poland acting as zRMS respectively. Concerned Member States are Spain, Italy, Portugal, Greece, Croatia in Southern zone and Belgium, The Netherlands, Luxembourg, Hungary, Germany, Austria, Romania, Czech Republic, Romania, Slovakia in Central zone.

Florpyrauxifen-benzyl (trademark: Rinskor® active) is a New Active Substance (NAS), developed by Corteva Agrisciences, approved in accordance with Regulation (EC) No 1107/2009 on July 3rd, 2019. Details of the approval Regulation, Commission Review Report and EFSA R.O. are provided in the below table:

Active Substance	*Approval Regulation*	*SANCO/SANTE Review Report*	*EFSA Scientific Report*
Florpyrauxifen-benzyl (trademark: Rinskor® active)	Commission Implementing Regulation (EU) 2019/1138 of 3 July 2019	SANTE/10658/2019 rev2 of 21 May 2019	EFSA Journal 2018;16(8):5378. doi: 10.2903/j.efsa.2018.5378.

The Regulation (EU) 2019/1138 for Florpyrauxifen-benzyl (trademark: Rinskor® active) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation: "*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 21 March 2019, 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 protection of aquatic and terrestrial non-target plants. Conditions of use shall include risk mitigation measures such as buffer zones and/or drift reduction nozzles, where appropriate*."
These concerns have been addressed within the current submission, where not otherwise stated.

Florpyrauxifen-benzyl (trademark: Rinskor® active) is a foliar post-emergence herbicide effective to control the most import weeds present in rice paddies; it is not yet authorized for sugar beets. Florpyrauxifen-benzyl is a member of the arylpicolinate family of chemistry, a new structural class of synthetic auxin herbicides, Group O (according to HRAC MOA classification). F7B-39-30 is active at low use rates in post-emergence applications against broadleaf weeds in sugar-beet.

F7B-39-30 (trademark: Rinpode) is very similar to GF-3206 (trademark Loyant 25 Neo EC), with the addition of a food-grade dye, included in the composition at 0.0005% w/w. F7B-39-30 and GF-3206 are the same formulation type (emulsion concentrate) and contain equal amounts of active ingredient, antifoam, emulsifiers, solvents and adjuvant. The minimal difference in composition between F7B-39-30 and GF-3206 lead to toxicological and ecotoxicological properties that can be considered equivalent and in comparable performance on crop safety or efficacy. Based on comparability of both formulations, data generated with GF-3206 are used in support of the claim for F7B-39-30. GF-3206, which is authorized formulation since 2019 in all Southern Europe rice countries, is the representative formulation considered for the florpyrauxifen-benzyl (trademark: Rinskor® active) approval, so it was fully evaluated in the active substance European process.

Information on the detailed composition of F7B-39-30 or of the GF-3206 formulation used as read-across can be found in the CONFIDENTIAL dossier of this submission (draft Registration Report - Part C).

F7B-39-30 Rinpode critical and Country GAP within the Central zones is given in Part B, Section 0.

Based on the minimal difference in composition between F7B-39-30 and GF-3206, no change in the

toxicological property is anticipated for the non-target organisms. Ecotoxicological testing has been performed with this dye showing low acute toxicity to fish with LC_{50} > 47 mg/L and green algae, *Lemna* species and *Daphnia magna* with EC_{50}>100 mg/L (according to safety data sheet and ECHA inventory[1]).

[1] Registration Dossier - ECHA (europa.eu)

9.1 Critical GAP and overall conclusions

Table 9.2-1: Table of critical GAPs

GAP rev. 7, date: 14 Dec 2022

PPP (product name/code):	F7B-39-30	Formulation type:	EC [a, b]
Active substance:	FLORPYRAUXIFEN-BENZYL (*Rinskor® active*)	Conc. of as:	25 g as/L [c]
Safener:	n/a	Conc. of safener:	n/a [c]
Synergist:	n/a	Conc. of synergist:	n/a [c]
Applicant:	Corteva Agriscience	Professional use:	Yes
Zone(s):	Central[d]	Non professional use:	No
Verified by MS:	Yes/No		
Field of use:	Herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha[f]	**Conclusions**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	g product / ha a) max. rate per appl. b) max. total rate per crop/season	g ai/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	Central Zone: Poland, Belgium, The Netherlands, Luxemburg, Hungary, Germany, Austria, Czech Republic, Romania, Slovakia	Sugar beet: *Beta vulgaris* (BEAVA). Fodder beet (BEAVC)	F	*Chenopodium album (CHEAL) Aethusa cynapium (AETCY) Galium aparine (GALAP), Galisonga parviflora (GASPA) Abutilon teophrasti (ABUTH)* and other species	Overall, foliar spray	BBCH 10 to 19	a) 1 b) 1	N/A	a) 0.08 L pr/ha b) 0.08 L pr/ha	a) 2.0 b) 2.0	100-300	N/A	A maximum of 1 application at a dose range of 2.0 g ai/ha and per season.							
2	Central Zone: Poland, Belgium, The	Sugar beet:	F	*Chenopodium album (CHEAL)*	Overall, foliar spray	BBCH 10 to 19	a) 2 b) 2	5-7 days	a) 0.04 L pr/ha b) 0.08 L	a) 1.0 b) 2.0	100-300	N/A	A maximum of 2 applications at a dose of 1.0 gai/ha							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha[f]	**Conclusions**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	g product / ha a) max. rate per appl. b) max. total rate per crop/season	g ai/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
	Netherlands, Luxemburg, Hungary, Germany, Austria, Czech Republic, Romania, Slovakia	*Beta vulgaris* (BEAVA). Fodder beet (BEAVC)		*Aethusa cynapium (AETCY) Galium aparine (GALAP), Galisonga parviflora (GASPA) Abutilon teophrasti (ABUTH)* and other species					pr/ha				per application, with a total maximum dose of 2.0 g ai per ha and per season.								
3	Central Zone: Poland, Belgium, The Netherlands, Luxemburg, Hungary, Germany, Austria, Czech Republic, Romania, Slovakia	Sugar beet: *Beta vulgaris* (BEAVA). Fodder beet (BEAVC)	F	*Chenopodium album (CHEAL) Aethusa cynapium (AETCY) Galium aparine (GALAP), Galisonga parviflora (GASPA) Abutilon teophrasti (ABUTH)* and other species	Overall, foliar spray	BBCH 10 to 19	a) 3 b) 3	5-7 days	a) 0.026 L pr/ha b) 0.08 L pr/ha	a) 0.66 b) 2.0	100-300	N/A	A maximum of 3 applications at a dose of 0.66 g ai/ha per application, with a total maximum dose of 2.0 g ai per ha and per season.								
4	Central Zone: Poland, Belgium, The Netherlands, Luxemburg, Hungary, Germany, Austria, Czech Republic, Romania, Slovakia	Sugar beet: *Beta vulgaris* (BEAVA). Fodder beet (BEAVC)	F	*Chenopodium album (CHEAL) Aethusa cynapium (AETCY) Galium aparine (GALAP), Galisonga parviflora (GASPA) Abutilon teophrasti (ABUTH)* and other species	Overall, foliar spray	BBCH 10 to 19	a) 4 b) 4	5-7 days	a) 0.02 L pr/ha b) 0.08 L pr/ha	a) 0.5 b) 2.0	100-300	N/A	A maximum of 4 applications at a dose of 0.5 g ai/ha per application, with a total maximum dose of 2.0 g ai per ha and per season.								
5	Central Zone: Poland, Belgium, The Netherlands, Luxemburg, Hungary,	Sugar beet: *Beta vulgaris* (BEAVA). Fodder		*Chenopodium album (CHEAL) Aethusa cynapium (AETCY)*	Overall, foliar spray	BBCH 10 to 19	a) 1 - 4 b) 1 - 4	5-7 days	a) 0.02 – 0.08 L pr/ha b) 0.02 - 0.08 L pr/ha	a) 0.5 – 2.0 b) 0.5 – 2.0	100-300	N/A	A maximum of 4 applications at a dose of 0.5 – 2.0 g ai/ha per application, with a total maximum dose of								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha[(f)]	**Conclusions**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	g product / ha a) max. rate per appl. b) max. total rate per crop/season	g ai/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
	Germany, Austria, Czech Republic, Romania, Slovakia	beet (BEAVC)		*Galium aparine (GALAP), Galisonga parviflora (GASPA) Abutilon teophrasti (ABUTH)* and other species									2.0 g ai per ha and per season.							

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

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

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

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

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

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

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.

11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

13 PHI - minimum pre-harvest interval

14 Remarks may include: Extent of use/economic importance/restrictions

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

9.1.1 Overall conclusions

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 acceptable acute and long-term risk to birds is expected from the proposed uses of F7B-39-30 in sugar and fodder beet.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

Acceptable acute and long-term risks have been demonstrated for aquatic organisms following applications of F7B-39-30 in sugar and fodder beet. To prevent undesired effects, it is recommended to use the following mitigations measures:

Use in sugar and fodder beet (1 x 2 g/ha):

- 90% drift reducing nozzles or
- 5 m buffer zone and 50% drift reducing nozzles or
- 10 m buffer zone

Use in sugar and fodder beet (2 x 1 g/ha):

- 75% drift reducing nozzles or
- 5 m buffer zone

Use in sugar and fodder beet (3x 0.66 g/ha):

- 50% drift reducing nozzles or
- 5 m buffer zone

Use in sugar and fodder beet (4x 0.5 g/ha):

- 50% drift reducing nozzles or
- 5 m buffer zone

9.1.1.3 Effects on bees (KCP 10.3.1)

An acceptable risk to bees is expected from the proposed uses of F7B-39-30 in sugar and fodder beet, without the need of any risk mitigation.

9.1.1.4 An acceptable risk to bees is expected from the proposed uses of F7B-39-30 in sugar beet and fodder beet (BBCH 10-19), without the need of any risk mitigation.

Evaluator Comments:

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

The required study on oral and contact toxicity of the formulated product of Rinpode (F7B-39-30) to honey bees was conducted and considered to be valid.

The hazard quotients are below the trigger value, indicating that the formulation Rinpode (F7B-39-30) poses an acceptable acute risk to bees.

New studies for acute toxicity of bumble bees were submitted and accepted.

The specific requirements of the Regulation (EU) 546/2011 regarding effects on bee brood development and possible chronic effects on adults were included by the Applicant and accepted.

The EPPO 2010 (ECPA proposal of 9 June 2017) scheme proposes a trigger of 1 for assessment of the risk to honey bees. All TER values for chronic risk assessment for adult bees and bee larvae were above a trigger of 1, indicating that the proposed uses of Rinpode (F7B-39-30) poses an acceptable chronic risk to adult bees and bee larvae. However the risk assessment performed in accordance with EPPO 2010 (ECPA proposal of 9 June 2017) has not been agreed yet its relevance will be decided at the Member State level.

Moreover, the evaluator provided the risk assessment according to the new bee guidance "EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp.) and solitary bees", EFSA Journal 2013; 11(7):3295 The risk assessment performed in accordance with EFSA guidance (2013) was also submitted but as this guidance has not been agreed yet its relevance will be decided at the Member State level.

The screening step values ETR for florpyrauxifen-benzyl are less than the triggers for downward sprays according to EFSA/2013/3295, indicating that the risk to bees and bumble bees is acceptable for florpyrauxifen-benzyl following use of Rinpode (F7B-39-30) according to the proposed use pattern.

9.1.1.5 Effects on arthropods other than bees (KCP 10.3.2)

An acceptable risk to non-target arthropods is expected from the proposed uses of F7B-39-30 in sugar and fodder beet, without the need of any risk mitigation.An acceptable risk to non-target arthropods is expected from the proposed uses of F7B-39-30 in sugar and fodder beet, without the need of any risk mitigation.

9.1.1.6

9.1.1.7 Evaluator comments:

9.1.1.8

9.1.1.9 The submitted risk assessment based on the "Guidance Document on Terrestrial Ecotoxicology" (2002) was accepted.

The laboratory studies 2D and 3D for *Aphidius rhopalosiphi*, *Typhlodromus pyr* and *Chrysoperla carnea* are submitted and accepted for risk assessment.

In field risk
The hazard quotients are below the trigger value (HQ ≤ 2) for all species indicating that the formulation Rinpode (F7B-39-30) poses an acceptable risk to arthropods other than bees.

Off-field risk
The hazard quotients are below the trigger value (HQ ≤ 2) for all species indicating that the formulation Rinpode (F7B-39-30) poses an acceptable risk to arthropods other than bees.

Based on the results of the risk assessment it can be concluded that low risk for non-target arthropods is expected from the use of Rinpode (F7B-39-30) according to the proposed use pattern.

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

An acceptable risk to earthworms and soil macro-organisms is expected from the proposed uses of F7B-39-30 in sugar and fodder beet, without the need of any risk mitigation.

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

The risk assessment demonstrates that the use of F7B-39-30 on sugar and fodder beet is unlikely to result in an unacceptable risk to non-target terrestrial plants if it applied according to the intended GAP.

9.1.1.12 The risk assessment demonstrates that the use of F7B-39-30 on sugar and fodder beet is unlikely to result in an unacceptable risk to non-target terrestrial plants if it applied according to the intended GAP.

Evaluator comment:
The risk assessment for the formulation F7B-39-30 (Rinpode) was based on the worst endpoint for the representative formulated product GF-3206 (an emulsifiable concentrate (EC) containing 25 g/L florpyrauxifen-benzyl). The formulations can be considered equivalent.

The worst endpoints for the metabolite X11438848 was used for the risk assessment.
As indicated in the EFSA Conclusions (EFSA Journal 2018; 16(7):5378), a specific assessment of the risk posed by the metabolites X12300837, X11966341, X12131932, X12393505 and X12483137 to non-target plants is not necessary in light of the lower toxicity of these metabolites compared to the active substance. Therefore evaluator did not check the endpoints for other metabolites.

The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000) to calculate maximum off-field predicted environmental rates (PERoff-field).

The TER value for formulation is above the trigger of 1 (trigger of 1 was set at EU level).
The TER value for X11438848 is above the trigger of 5,

Conclusion:
The risk for the terrestrial plants following use of F7B-39-30 (Rinpode) could be considered as low.

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

No effects on other terrestrial organisms are anticipated if F7B-39-30 is applied according to the intended GAP.

9.1.2 Grouping of intended uses for risk assessment

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

Table 9.2-2: Critical use pattern of F7B-39-30

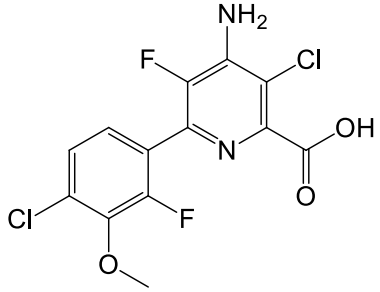
Grouping according to use pattern			
Group	**Intended uses**	**Relevant use parameters for grouping**	**Relevant parameter or value for sorting**
A	Application in sugar and fodder beet	GAP: 1 × 0.08 L product/ha (1 × 2 g a.s./ha) BBCH 10 - 19	Critical use for the risk to: • Birds and mammals • Aquatic organisms • Bees • Non-target arthopods • Non-target soil invetebrates and micro-organisms • Non-target plants
B		GAP: 2 × 0.04 L product/ha (2 × 1 g a.s./ha) BBCH 10 – 19, 5-7 day interval	Risk addressed via Use Group A
C		GAP: 3 × 0.026 L product/ha (3 × 0.66 g a.s./ha) BBCH 10 – 19, 5-7 day interval	
D		GAP: 4 × 0.02 L product/ha (4 × 0.5 g a.s./ha) BBCH 10 – 19, 5-7 day interval	

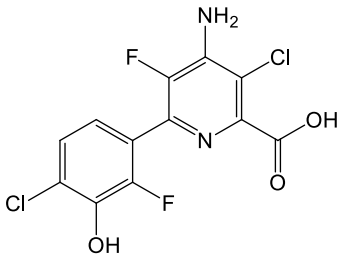
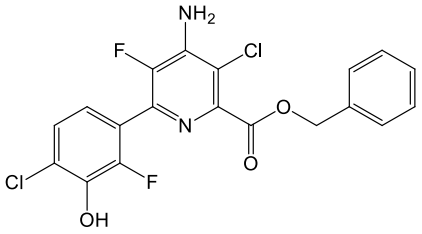
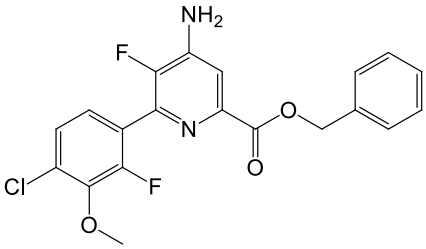
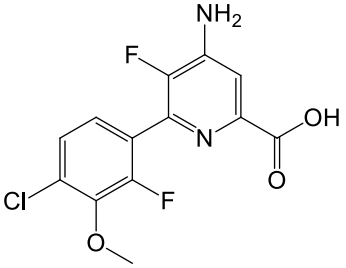
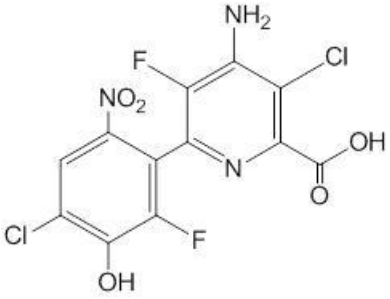
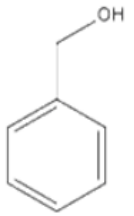
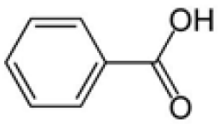
~~An acceptable acute and long-term risk to birds and mammals is expected from the proposed uses of F7B-39-30, without the need of any risk mitigation.~~

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 F7B-39-30 is indicated in the table.

Table 9.2-3 Metabolites of florpyrauxifen-benzyl

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
X11438848, XDE-848 acid		349.12	Water: 100% Sediment: 4% Terrestrial soil: 62% Flooded soil: 33%	Yes, aquatic, sediment and soil organisms

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
X11966341, XDE-848 hydroxy acid		335.09	Water: 58% Sediment: 35% Terrestrial soil: 8% Flooded soil: 64%	Yes, aquatic, sediment and soil organisms
X12300837, XDE-848 hydroxy BE, XDE-848 benzyl hydroxy		425.21	Water: 7% Sediment: 19% Terrestrial soil: 2.5% Flooded soil: 16%	Yes, sediment and soil organisms (may be formed in soil paddy when paddy is flooded)
X12131932, dechlorinated XDE-848 BE		404.8	Water: 30.8% Sediment: N/A Terrestrial soil: N/A Flooded soil: N/A	Yes, aquatic organisms
X12393505, dechlorinated XDE-848 acid		314.7	Water: 10.4% Sediment: N/A Terrestrial soil: N/A Flooded soil: N/A	Yes, aquatic organisms
X12483137, nitro hydroxyl acid		380.09	Water: N/A Sediment: N/A Terrestrial soil: 11.1% Flooded soil: N/A	Yes, aquatic and soil organisms (formed only under aerobic soil conditions)
X195023, benzyl alcohol		108.14	Water: 100% Sediment: N/A Terrestrial soil: N/A Flooded soil: N/A	Yes, aquatic organisms
X194973, benzoic acid		122.12	Water: 20% Sediment: 1% Terrestrial soil: N/A Flooded soil: N/A	Yes, aquatic organisms

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with florpyrauxifen-benzyl. Full details of these studies are provided in the respective EU DAR and related documents.
Results on the product are based on study from GF-3206 which has identical composition of F7B-39-30 (Rinpode) except for adding the blue dye at 0.0005% w/w. GF-3206 is the representative formulation fully evaluated in the active substance European approval process.
Effects on birds of GF-3206 were evaluated as part of the EU assessment of florpyrauxifen-benzyl.
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
Colinus virginianus	Florpyrauxifen-benzyl	Oral 1 d Acute	LD_{50} >2250 mg/kg bw	EFSA Conclusion
Colinus virginianus	GF-3206	Oral 1 d Acute	LD_{50} >2500 mg product/kg bw	EFSA Conclusion
Colinus virginianus	Florpyrauxifen-benzyl	Dietary Reproductive toxicity	NOEL = 87.2 mg/kg bw/d (highest test concentration)	EFSA Conclusion

EFSA Conclusion: EFSA Journal 2018; 16(7):5378

9.2.1.1 Justification for new endpoints

Not applicable.

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

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

The results of the acute and reproductive screening are summarised in the following tables.

Table 9.2-2: Screening risk assessment of the acute and long-term/reproductive risk for birds due to the use of F7B-39-30 in sugar and fodder beet (Use group A) – florpyrauxifen-benzyl

Intended use	Sugar beet				
Active substance	Florpyrauxifen-benzyl				
Application rate (g a.s./ha)	1 × 2				
Acute toxicity (mg/kg bw)	>2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator species for screening**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Sugar beet	Small omnivorous bird	158.8	1.0	0.318	> 7031
Reprod. toxicity (mg/kg bw/d)	87.2				
TER criterion	5				
Crop scenario Growth stage	**Indicator species for screening**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Sugar beet	Small omnivorous bird	64.8	1.0 × 0.53	0.069	1264

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

Table 9.2-3: Screening risk assessment of the acute risk for birds due to the use of F7B-39-30 in sugar and fodder beet (Use group A) – F7B-39-30

Intended use	Sugar beet				
Product	F7B-39-30				
Application rate (g product/ha)	1 × 74[1]				
Acute toxicity (mg/kg bw)	≥2500				
TER criterion	10				
Crop scenario Growth stage	**Indicator species for screening**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Sugar beet	Small omnivorous bird	158.8	1.0	11.8	212

[1] Based on a use rate of 0.08 L product/ha and a nominal formulation density of 0.925 kg/L.
SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

9.2.2.2 Higher-tier risk assessment

Since acceptable acute and long-term risks have been concluded for birds exposed to florpyrauxifen-benzyl or the product F7B-39-30 at the screening level, a higher-tier risk assessment is not required for the proposed uses of F7B-39-30

9.2.2.3 Drinking water exposure

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

Leaf scenario

The 'Leaf scenario' is relevant for birds taking water that is collected in leaf whorls after application and applies to leafy vegetables forming heads or with a morphology that facilitates collection of rain/irrigation water sufficiently to attract birds, i.e. for the before named crops at BBCH ≥ 41. Since none of the proposed uses falls into these categories, the leaf scenario does not apply to the use of F7B-39-30.

Puddle scenario

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

With a K(f)oc of 21159 mL/g, florpyrauxifen-benzyl belongs to the group of more sorptive substances.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A covers the risk for birds for all intended uses (see 9.1.2).

Effective application rate (g/ha)	=	2		
Acute toxicity (mg/kg bw)	=	2250	quotient =	0.0009
Reprod. toxicity (mg/kg bw/d)	=	87.2	quotient =	0.023

Since the ratio of the effective application rate and relevant endpoints do not exceed ~~500~~ 3000 for florpyrauxifen-benzyl no specific calculations of exposure and TER are necessary.

9.2.2.4 Effects of secondary poisoning

The log P_{OW} value of the florpyrauxifen-benzyl amounts to 5.46 (pH 7) (EFSA Journal 2018; 16(8):5378) and thus exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Assessment for the use in sugar and fodder beet (use group A) covers the risk for birds for all intended uses (see 9.1.2).

Table 9.2-4: Assessment of the risk for earthworm-eating birds due to exposure to florpyrauxifen-benzyl via bioaccumulation in earthworms (secondary poisoning) for the intended use in sugar and fodder beet (Use group A)

Parameter	Florpyrauxifen-benzyl	Comments
PEC_{soil} (initial) (mg/kg soil)	~~0.0022~~ 0.0021	$PEC_{soil,accu}$
log P_{OW} / P_{OW}	5.46 / 288403	EFSA Journal 2018; 16(8):5378
Koc	65038	Mean (n = 6), DAR CA-B.8
foc	0.02	Default
BCF_{worm}	~~2.7~~ 2.66	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times K_{ow}) / foc \times Koc$
PEC_{worm}	~~0.00585~~ 0.00559	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$

Parameter	Florpyrauxifen-benzyl	Comments
Daily dietary dose (mg/kg bw/d)	~~0.00615~~ 0.00587	DDD = PEC_{worm} × 1.05
NOEL (mg/kg bw/d)	87.2	
TER_{lt}	~~14152~~ 14859	

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

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

Table 9.2-5: Assessment of the risk for fish-eating birds due to exposure due to exposure to florpyrauxifen-benzyl via bioaccumulation in fish (secondary poisoning) for the intended use in sugar and fodder beet (Use group A).

Parameter	Florpyrauxifen-benzyl	Comments
PEC_{sw} (21d TWA) (mg/L)	0.000003	Highest PEC_{sw} across all uses (FOCUS, Step 2)
BCF_{fish}	356	EFSA Journal 2018; 16(8):5378
BMF	N/A	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.00107	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.00017	DDD = PEC_{fish} × 0.159
NOEL (mg/kg bw/d)	87.2	
TER_{lt}	513509	

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 acceptable acute and long-term risk to birds is expected from the proposed uses of F7B-39-30 in sugar and fodder beet.

Review comments:

The risk assessment to birds was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438).

The results of the 'screening phase' acute and long term dietary risk assessment - Toxicity Exposure Ratios (TER_A and TER_{LT}) were calculated taking into account the EU agreed endpoints for the most sensitive species for the active substance and using the EFSA Bird and Mammal risk assessment calculator for the higher predicted application rate than it is foreseen in GAP exceeding the trigger set by Commission regulation (EU) 546/2011 for acceptability of effects. Revealed that there is no potential of risk for birds resulting from acute and long-term exposure to active substance following use of Rinpode (F7B-39-30) in compliance with proposed GAP.

Drinking water

The ratio of the effective application rate to the relevant endpoints is below the value of 3000 for florpyrauxifen-benzyl, a quantitative risk assessment for the proposed use pattern of Rinpode (F7B-39-30) is not necessary.

Secondary poisoning

The TER_{LT} value are greater than the Annex VI trigger of 5 for the fish and earthworms eating birds, indicating that Rinpode (F7B-39-30) poses low long-term risk to these birds following application at the proposed rate in sugar and fodder beet.

No risk mitigation measures are required.

Conclusion

According to the performed risk assessment there is no potential of risk to birds resulting from exposure to active substance following use of Rinpode (F7B-39-30) in compliance with proposed GAP.

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

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with florpyrauxifen-benzyl. Full details of these studies are provided in the respective EU DAR and related documents.
Results on the product are based on study from GF-3206 which has identical composition of F7B-39-30 (Rinpode) except for adding the blue dye at 0.0005% w/w. GF-3206 is the representative formulation fully evaluated in the active substance European approval process.
Effects on mammals of GF-3206 were evaluated as part of the EU assessment of florpyrauxifen-benzyl.
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
Rat	Florpyrauxifen benzyl	Oral 1 d Acute	LD_{50} >5000 mg/kg bw	EFSA Conclusion
Rat	GF-3206	Oral 1 d Acute	LD_{50} >5000 mg product/kg bw	EFSA Conclusion
Rat	Florpyrauxifen benzyl	Dietary Reproductive toxicity Two-generation study	NOAEL = 300 mg/kg bw/d	EFSA Conclusion

EFSA Conclusion: EFSA Journal 2018; 16(7):5378

9.3.1.1 Justification for new endpoints

Not applicable.

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 Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).
To achieve a concise risk assessment, the risk envelope approach is applied. Assessment for the use in sugar and fodder beet (use group A) cover the risk for mammals for all intended uses (see 9.1.2).

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

The results of the acute and reproductive screening are summarised in the following tables.

Table 9.3-2: Screening risk assessment of the acute and long-term/reproductive risk for mammals due to the use of F7B-39-30 in sugar and fodder beet (Use group A) - florpyrauxifen-benzyl

Intended use	Sugar beet				
Active substance	Florpyrauxifen-benzyl				
Application rate (g a.s./ha)	1 × 2				
Acute toxicity (mg/kg bw)	> 5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator species for screening**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Sugar beet	Small herbivorous mammal	118.4	1.0	0.237	21097
Reprod. toxicity (mg/kg bw/d)	300				
TER criterion	5				
Crop scenario Growth stage	**Indicator species for screening**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Grassland	Small herbivorous mammal	48.3	1.0 × 0.53	0.051	5882

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

Table 9.3-3: Screening risk assessment of the acute and long-term/reproductive risk for mammals due to the use of F7B-39-30 in sugar and fodder beet (Use group A) – F7B-39-30

Intended use	Sugar beet				
Active substance	F7B-39-30				
Application rate (g a.e./ha)	1 × 74[1]				
Acute toxicity (mg/kg bw)	> 5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator species for screening**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Sugar beet	Small herbivorous mammal	118.4	1.0	8.762	571

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

9.3.2.2 Higher-tier risk assessment

Since acceptable acute and long-term risks have been concluded for mammals exposed to florpyrauxifen-benzyl or to the product GF-3206 at the screening level, a higher-tier risk assessment is not required for the proposed uses of F7B-39-30.

9.3.2.3 Drinking water exposure

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

Puddle scenario

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

With a K(f)oc of 21159 mL/g, florpyrauxifen-benzyl belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Assessment for the use in sugar and fodder beet (use group A) cover the risk for birds for all intended uses (see 9.1.2).

Effective application rate (g/ha)	=	2			
Acute toxicity (mg/kg bw)	=	5000	quotient =		0.0004
Reprod. toxicity (mg/kg bw/d)	=	300	quotient =		0.007

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceeds the critical value of 3000, a quantitative risk assessment (calculation of TER values) for florpyrauxifen-benzyl is not necessary.

9.3.2.4 Effects of secondary poisoning

The log P_{OW} value of the florpyrauxifen-benzyl amounts to 5.46 (pH 7) (EFSA Journal 2018; 16(8):5378) and thus exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Assessment for the use in sugar and fodder beet (use group A) covers the risk for birds from all other intended uses (see **Błąd! Nie można odnaleźć źródła odwołania.**).

Table 9.3-4: Assessment of the risk for earthworm-eating mammals due to exposure to florpyrauxifen-benzyl via bioaccumulation in earthworms (secondary poisoning) for the intended use in sugar and fodder beet (Use group A)

Parameter	Florpyrauxifen-benzyl	Comments
PEC_{soil} (initial) (mg/kg soil)	~~0.0022~~ 0.0021	$PEC_{soil,accu}$
log P_{OW} / P_{OW}	5.46 / 288403	EFSA Journal 2018; 16(8):5378
Koc	65038	Mean (n = 6), DAR CA-B.8
foc	0.02	Default
BCF_{worm}	~~2.7~~ 2.66	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times K_{ow}) / foc \times Koc$
PEC_{worm}	~~0.00585~~ 0.00559	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	~~0.00749~~ 0.00715	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	300	

Parameter	Florpyrauxifen-benzyl	Comments
TER_{lt}	~~40050~~ 41937	

Risk assessment for fish-eating mammals via secondary poisoning

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

To achieve a concise risk assessment, the risk envelope approach is applied. Assessment for the use in sugar and fodder beet (use group A) covers the risk for birds for all intended uses (see 9.1.2).

Table 9.3-5: Assessment of the risk for fish-eating mammals due to exposure to florpyrauxifen-benzyl via bioaccumulation in fish (secondary poisoning) for the intended use in sugar and fodder beet (Use group A)

Parameter	Florpyrauxifen-benzyl	Comments
PEC_{sw} (21d TWA) (mg/L)	0.000003	Highest PEC_{sw} across all uses (FOCUS, Step 2)
BCF_{fish}	356	EFSA Journal 2018; 16(8):5378
BMF	N/A	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.00107	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.00015	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	300	
TER_{lt}	1978161	

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 acceptable acute and long-term risk to mammals is expected from the proposed uses of F7B-39-30 in sugar beet, without the need of any risk mitigation.

Review comments:

The risk assessment to mammals was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438).

The results of the 'screening phase' acute and long term dietary risk assessment - Toxicity Exposure Ratios (TER_A and TER_{LT}) were calculated taking into account the EU agreed endpoints for the most

sensitive species for the active substance and using the EFSA Bird and Mammal risk assessment calculator for the higher predicted application rate than it is foreseen in GAP exceeding the trigger set by Commission regulation (EU) 546/2011 for acceptability of effects. Revealed that there is no potential of risk for wild mammals resulting from acute and long-term exposure to active substance following use of Rinpode (F7B-39-30) in compliance with proposed GAP.

Drinking water

The ratio of the effective application rate to the relevant endpoints is below the value of 3000 for florpyrauxifen-benzy, a quantitative risk assessment for the proposed use pattern of Rinpode (F7B-39-30) is not necessary.

Secondary poisoning

The TER_{LT} value are greater than the Annex VI trigger of 5 for the fish and earthworms eating mammals, indicating that Rinpode (F7B-39-30) poses low long-term risk to these mammals following application at the proposed rate in sugar and fodder beet.

No risk mitigation measures are required.

Conclusion

According to the performed risk assessment there is no potential of risk to wild mammals resulting from exposure to active substance following use of Rinpode (F7B-39-30) in compliance with proposed GAP.

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

According to the data requirements under regulation 1107/2009 (Commission Regulations (EU) 283/2013 and 284/2013), the risk to amphibians and reptiles shall be addressed. However, there is no EU guidance or validated regulatory protocol yet available, neither on the type of the necessary regulatory testing nor on how to conduct a risk assessment for amphibians and reptiles. Accordingly, specific toxicity tests for amphibian and reptile species are not requested and therefore no data on reptiles and terrestrial amphibians are available for GF-3206 and its actives.

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 florpyrauxifen-benzyl and its major metabolites. Full details of these studies are provided in the respective EU DAR and related documents.
Results on the product are based on studies from GF-3206 which has identical composition of F7B-39-30 (Rinpode) except for adding the blue dye at 0.0005% w/w. GF-3206 is the representative formulation fully evaluated in the active substance European approval process.
Effects on aquatic organisms of GF-3206 were evaluated as part of the EU assessment of florpyrauxifen-benzyl.
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
Fish				
Cyprinus carpio	Florpyrauxifen-benzyl	96 h, f	LC_{50} > 0.0414 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Oncorhynchus mykiss	Florpyrauxifen-benzyl	96 h, f	LC_{50} > 0.0490 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Pimephales promelas	Florpyrauxifen-benzyl	96 h, f	LC_{50} > 0.0518 mg/L mm	EFSA Journal 2018; 16(8):5378
Oncorhynchus mykiss	X11438848	96 h, ss	LC_{50} > 100 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Cyprinus carpio	X12131932	96 h, ss	LC_{50} > 1 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Cyprinus carpio	X12393505	96 h, ss	LC_{50} > 90 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Cyprinus carpio	X11966341	96 h, ss	LC_{50} > 120 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Cyprinus carpio	X12483137	96 h, ss	LC_{50} > 10 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Cyprinus carpio	X195023	96 h, f	LC_{50} > 0.0414 mg/L $_{mm}$ [1]	EFSA Journal 2018; 16(8):5378
Oncorhynchus mykiss	X194973	96 h, ss	LC_{50} > 120 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Pimephales promelas	Florpyrauxifen-benzyl	33 d (ELS), f	NOEC = 0.037 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Pimephales promelas	X11438848	33 d (ELS), f	NOEC = 29.8 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Pimephales promelas	X195023	33 d (ELS), f	NOEC = 0.037 mg/L $_{mm}$ [1]	EFSA Journal 2018; 16(8):5378
Aquatic invertebrates				
Gammarus pseudolimnaeus	Florpyrauxifen-benzyl	96 h, f	EC_{50} > 0.0419 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378

Species	Substance	Exposure System	Results	Reference
Daphnia magna	Florpyrauxifen-benzyl	48 h, ss	EC_{50} > 0.0626 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Daphnia magna	X11438848	48 h, s	EC_{50} > 91.8 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Daphnia magna	X12131932	48 h, ss	EC_{50} > 0.98 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Daphnia magna	X12393505	48 h, ss	EC_{50} > 100 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Daphnia magna	X11966341	48 h, ss	EC_{50} > 100 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Daphnia magna	X12483137	48 h, ss	EC_{50} > 10 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Gammarus pseudolimnaeus	X195023	96 h, f	EC_{50} > 0.0419 mg/L $_{mm}$ [1]	EFSA Journal 2018; 16(8):5378
Daphnia magna	X194973	48 h, ss	EC_{50} > 120 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Americamysis bahia	Florpyrauxifen-benzyl	28 d, f	NOEC = 0.0078 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Daphnia magna	X11438848	21 d, ss	NOEC = 25 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Americamysis bahia	X195023	28 d, f	NOEC = 0.0078 mg/L $_{mm}$ [1]	EFSA Journal 2018; 16(8):5378
Gammarus pseudolimnaeus	Florpyrauxifen-benzyl	96 h, f	EC_{50} > 0.0419 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Chironomus riparius	Florpyrauxifen-benzyl	48 h, ss	EC_{50} > 0.0558 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Daphnia magna	Florpyrauxifen-benzyl	21 d. ss	NOEC = 0.0378 mg/L im	EFSA Journal 2018; 16(8):5378
Chironomus riparius	Florpyrauxifen-benzyl	28 d, s (spiked water)	NOEC = 0.0785 mg/L $_{im}$	EFSA Journal 2018; 16(8):5378
Chironomus riparius	X12300837	28 d, s (spiked sediment)	NOEC = 1000 mg/kg sed $_{im}$	EFSA Journal 2018; 16(8):5378
Chironomus riparius	X11966341	28 d, s (spiked sediment)	NOEC = 160 mg/kg sed $_{mm}$	EFSA Journal 2018; 16(8):5378
Algae				
Pseudokirchneriella subcapitata	Florpyrauxifen benzyl	96 h, s	E_rC_{50} > 0.0337 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Navicula pelliculosa	Florpyrauxifen benzyl	96 h, s	E_rC_{50} > 0.0342 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Anabaena flos-aquae	Florpyrauxifen benzyl	96 h, s	E_rC_{50} > 0.0449 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Pseudokirchneriella subcapitata	X11438848	96 h, s	E_rC_{50} = 57 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Navicula pelliculosa	X12131932	96 h, s	E_rC_{50} > 0.36 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378

Species	Substance	Exposure System	Results	Reference
Navicula pelliculosa	X12393505	96 h, s	E_rC_{50} > 9.9 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Navicula pelliculosa	X11966341	96 h, s	E_rC_{50} > 5.3 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Navicula pelliculosa	X12483137	96 h, s	E_rC_{50} > 1.4 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Pseudokirchneriella subcapitata	X195023	96 h, s	E_rC_{50} > 0.0337 mg/L $_{mm}$ [1]	EFSA Journal 2018; 16(8):5378
Desmodesmus subspicatus	X194973	72 h, s	E_rC_{50} > 1000 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Aquatic macrophytes				
Lemna gibba	Florpyrauxifen-benzyl	7 d, ss	E_rC_{50} > 0.0461 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Myriophyllum spicatum	Florpyrauxifen-benzyl**	28 d, s	E_rC_{50} = 0.00012 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Myriophyllum spicatum	Florpyrauxifen-benzyl**	14 d, s	ErC_{50} = 0.000154 mg/L nom	EFSA Journal 2018; 16(8):5378
Ceratophyllum demersum	Florpyrauxifen-benzyl**	14 d, s	ErC_{50} = 0.00694 mg/L nom	EFSA Journal 2018; 16(8):5378
Cabomba caroliniana	Florpyrauxifen-benzyl**	21 d, s	ErC_{50} = 0.00367 mg/L nom	EFSA Journal 2018; 16(8):5378
Bidens beckii	Florpyrauxifen-benzyl**	14 d, s	ErC_{50} = 0.00036 mg/L nom	EFSA Journal 2018; 16(8):5378
Elodea canadensis	Florpyrauxifen-benzyl**	14 d, s	ErC_{50} = 0.0003 mg/L nom	EFSA Journal 2018; 16(8):5378
Hydrilla verticillata	Florpyrauxifen-benzyl**	14 d, s	ErC_{50} = 0.0017 mg/L nom	EFSA Journal 2018; 16(8):5378
Nymphoides cristata	Florpyrauxifen-benzyl**	14 d, s	ErC_{50} = 0.0059 mg/L nom	EFSA Journal 2018; 16(8):5378
Myriophyllum spicatum	X11438848	14 d, s	E_rC_{50} = 0.00035 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Myriophyllum spicatum	X11438848	14 d, s	E_rC_{50} = 0.00122 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Ceratophyllum demersum	X11438848	14 d, s	E_rC_{50} = 0.101 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Cabomba caroliniana	X11438848	14 d, s	E_rC_{50} = 0.151 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Bidens beckii	X11438848	14 d, s	E_rC_{50} = 0.0073 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Elodea canadensis	X11438848	14 d, s	E_rC_{50} = 0.0074 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378

Species	Substance	Exposure System	Results	Reference
Hydrilla verticillata	X11438848	14 d, s	E_rC_{50} = 0.0034 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Nymphoides cristata	X11438848	14 d, s	E_rC_{50} = 0.0266 mg/L $_{nom}$	EFSA Journal 2018; 16(8):5378
Myriophyllum spicatum	X12131932	14 d, s	E_rC_{50} = 0.0778 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Myriophyllum spicatum	X12393505	14 d, s	E_rC_{50} = 1.9 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Myriophyllum spicatum	X12300837	14 d, s	E_rC_{50} = 0.0123 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Myriophyllum spicatum	X11966341	14 d, s	E_rC_{50} = 0.0505 mg/L $_{mm}$	EFSA Journal 2018; 16(8):5378
Myriophyllum spicatum	X12483137	14 d, s	E_rC_{50} = 0.0505 mg/L $_{mm}$ [2]	EFSA Journal 2018; 16(8):5378
Myriophyllum spicatum	X195023	28 d, s	E_rC_{50} = 0.00012 mg/L $_{nom}$ [1]	EFSA Journal 2018; 16(8):5378

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

[1] Toxicity of the metabolite X195023 assumed to be equal to that of the parent on the base of comparison of publicly available data not validated by EFSA or the RMS

[2] Toxicity endpoints assumed to be the same of the metabolite X11966341 on the base of similarity of molecular structure and effects on other organisms

** study considered a higher tier test with refined exposure

zRMS comments:
The public data for aquatic toxicity of metabolite X195023 are available:
- ECHA website: https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/14748/6/2/2
- PubChem: https://pubchem.ncbi.nlm.nih.gov/compound/244#section=Ecotoxicity-Values
- OECD; SIDS Initial Assessment Report for SIAM 13. Report on Benzoates: Benzoic acid, Sodium benzoate, Potassium benzoate, Benzyl alcohol (CAS No: 65-85-0, 532-32-1, 582-25-2, 100-51-6) p.245 UNEP Publications (November 2001). https://hpvchemicals.oecd.org/UI/handler.axd?id=aa89d225-a2a7-4ed5-b8d6-c06b5e30b45b

A summary from the OECD SIDS report is presented below:
Environment From the data (fish, daphnia, algae, bacteria) it is obvious that neutralization of the pH greatly reduces (up to one order of magnitude) the acute toxicity of benzoic acid. This is also supported by the lower toxicity observed with sodium benzoate. Under environmental relevant conditions therefore the acute toxicity of benzoic acid, sodium benzoate and potassium benzoate for all four trophic levels is > 100 mg/l. Under environmental relevant conditions the acute toxicity of benzyl alcohol for fish, daphnia and bacteria is > 100 mg/l. For algae, an EC_{50} 3hrs of 95 mg/l is reported. Under environmental relevant conditions, benzoic acid and its salts have very low acute toxicity, whereas benzyl alcohol has low to moderate acute toxicity.

Taking into account publicly available data, the toxicity of the metabolite X195023 is not greater than toxicity of parent.

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – F7B-39-30

Species	Substance	Exposure System	Results	Reference
Cyprinus carpio	GF-3206	96 h, ss	LC_{50} > 120 mg/L $_{mm}$ (> 3.240 mg a.s./L)	EFSA Journal 2018; 16(8):5378
Daphnia magna	GF-3206	48 h, ss	EC_{50} > 49 mg/L $_{mm}$ (> 1.323 mg a.s./L)	EFSA Journal 2018; 16(8):5378
Pseudokirchneriella subcapitata	GF-3206	96 h, s	E_rC_{50} > 4.2 mg/L $_{mm}$ (> 0.113 mg a.s./L)	EFSA Journal 2018; 16(8):5378
Lemna gibba	GF-3206	7-s, ss	E_rC_{50} = 83 mg/L $_{mm}$ (2.241 mg a.s./L)	EFSA Journal 2018; 16(8):5378
Myriophyllum spicatum	GF-3206	14 d, s	E_rC_{50} = 0.000919 mg/L $_{nom}$ (0.0000248 mg a.s./L)	EFSA Journal 2018; 16(8):5378

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

9.5.1.1 Justification for new endpoints

Not applicable.

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 SW PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the tables below. Details of all PEC_{SW} derivation are provided

in Section 8 (Environmental fate), Chapter 8.9. Only FOCUS scenarios relevant for the Central Zone were considered in the assessment.

The following major metabolites of florpyrauxifen-benzyl have been considered in the aquatic risk assessment: X11438848, X12131932, X12393505, X12300837, X11966341, X12483137, X195023 and X194973. Studies with aquatic organisms relevant to the compartment where each metabolite is formed (**Błąd! Nie można odnaleźć źródła odwołania.**) and where it could be encountered have been performed.

Following the dilution and spraying of the formulated product, much of the formulation constituents are likely to be lost by volatilisation. Therefore, shortly after application of a formulated product, aquatic organisms are mainly exposed to the active substance present in the formulation. An evaluation of the risk posed by the intact formulation is therefore relevant only for the acute assessment. The long-term risk will be assessed considering data for the active substance in the formulation.

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

Florpyrauxifen-benzyl and relevant metabolites

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC <1) for florpyrauxifen-benzyl for each organism group based on FOCUS Step 1-3 calculations for the use of F7B-39-30 in sugar and fodder beet (Use group A)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic macrophytes
Test species		***Cyprinus carpio***	***Pimephales promelas***	***Gammarus pseudolimn***	***Americamysis bahia***	***Pseudokirchneriella***	***Chironomus riparius***	***Myriophyllum***
Endpoint (µg/L)		LC_{50} > 41.4	NOEC = 37	EC_{50} > 41.9	NOEC = 7.8	E_rC_{50} > 33.7	NOEC = 78.5	E_rC_{50} = 0.12
AF		100	10	100	10	10	10	10
RAC (µg/L)		> 0.414	3.7	> 0.419	0.78	> 3.37	7.85	0.012
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							
Step 1								
	0.041	< 0.099	0.011	< 0.098	0.053	< 0.012	0.005	**3.4**
Step 2								
N-Europe	0.018	-	-	-	-	-	-	**1.5**
S-Europe	0.018	-	-	-	-	-	-	**1.5**
Step 3								
D3 ditch	0.010	-	-	-	-	-	-	0.83
D4 pond	~~0.0004~~ 0.001	-	-	-	-	-	-	~~0.03~~ 0.083
D4 stream	0.008	-	-	-	-	-	-	0.67
D5 pond	~~0.0004~~ 0.001	-	-	-	-	-	-	~~0.03~~ 0.083
D5 stream	0.008	-	-	-	-	-	-	0.67
R1 pond	~~0.0004~~ 0.001	-	-	-	-	-	-	~~0.03~~ 0.083
R1 stream	0.007	-	-	-	-	-	-	0.58
R3 stream	0.010	-	-	-	-	-	-	0.83
R4 stream	0.007	-	-	-	-	-	-	0.58

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; - not relevant

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC <1) for X11438848 for each organism group based on FOCUS Step 1-3 calculations for the use of F7B-39-30 in sugar and fodder beet (Use group A)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophyte
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella***	***Myriophyllum spicatum***
Endpoint (µg/L)		LC_{50} > 100000	NOEC = 29800	EC_{50} > 91800	NOEC = 25000	E_rC_{50} > 57000	E_rC_{50} = 0.35
AF		100	10	100	10	10	10
RAC (µg/L)		> 1 000	2 980	> 918	2 500	> 5 700	0.03500

FOCUS Scenario	**$PEC_{sw, max}$ (µg/L)**						
Step 1							
	0.5282	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	**15**
Step 2							
N-Europe	0.083	-	-	-	-	-	**2.4**
S-Europe	0.162	-	-	-	-	-	**4.6**
Step 3							
D3 ditch	<0.001	-	-	-	-	-	<0.029
D4 pond	~~0.002~~ 0.001	-	-	-	-	-	0.029
D4 stream	0.002	-	-	-	-	-	0.057
D5 pond	<0.001	-	-	-	-	-	<0.029
D5 stream	0.001	-	-	-	-	-	0.029
R1 pond	0.001	-	-	-	-	-	0.029
R1 stream	0.010	-	-	-	-	-	0.29
R3 stream	0.015	-	-	-	-	-	0.43
R4 stream	0.010	-	-	-	-	-	0.29

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; - not relevant

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC <1) for X12131932 for each organism group based on FOCUS Step 1-2 calculations for the use of F7B-39-30 in sugar and fodder beet (Use group A)

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Cyprinus carpio***	***Daphnia magna***	***Navicula pelliculosa***	***Myriophyllum spicatum***
Endpoint (µg/L)		LC_{50} > 1000	EC_{50} > 980	E_rC_{50} > 360	E_rC_{50} = 77.8
AF		100	100	10	10
RAC (µg/L)		> 10	> 9.8	> 36	7.78
FOCUS Scenario	**$PEC_{sw, max}$ (µg/L)**				
Step 1					
	0.012	< 0.001	< 0.001	< 0.001	0.002
Step 2					
N-Europe	0.005	< 0.001	< 0.001	< 0.001	< 0.001
S-Europe	0.005	< 0.001	< 0.001	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC <1) for X12393505 for each organism group based on FOCUS Step 1-2 calculations for the use of F7B-39-30 in in sugar and fodder beet (Use group A)

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Cyprinus carpio***	***Daphnia magna***	***Navicula pelliculosa***	***Myriophyllum spicatum***
Endpoint (µg/L)		LC_{50} > 90000	EC_{50} > 100000	E_rC_{50} > 9900	E_rC_{50} = 1900
AF		100	100	10	10
RAC (µg/L)		> 900	> 1 000	> 990	190
FOCUS Scenario	**$PEC_{sw, max}$ (µg/L)**				
Step 1					
	0.047	< 0.001	< 0.001	< 0.001	< 0.001
Step 2					
N-Europe	0.008	< 0.001	< 0.001	< 0.001	< 0.001
S-Europe	0.015	< 0.001	< 0.001	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration;

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC <1) for X12300837 for each organism group based on FOCUS Step 1-2 calculations for the use of F7B-3930 in sugar and fodder beet (Use group A)

Group		**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Myriophyllum spicatum***		***Chironomus riparius***
Endpoint (µg/L)		E_rC_{50} = 12.3		NOEC = 1000000
AF		10		10
RAC (µg/L)		1.23		100 000
FOCUS Scenario	$PEC_{sw, max}$ (µg/L)		$PEC_{sed, max}$ (µg/kg)	
Step 1				
	0.036	0.029	0.8732	< 0.001
Step 2				
N-Europe	0.006	0.005	0.15	< 0.001
S-Europe	0.011	0.009	0.285	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration;

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC <1) for X11966341 for each organism group based on FOCUS Step 1-2 calculations for the use of F7B-3930 in sugar and fodder beet (Use group A)

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Cyprinus carpio***	***Daphnia magna***	***Navicula pelliculosa***	***Myriophyllum spicatum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} > 120000	EC_{50} > 100000	E_rC_{50} > 5300	E_rC_{50} = 50.5		NOEC = 160000
AF		100	100	10	10		10
RAC (µg/L)		> 1 200	> 1 000	> 530	5.05		16 000
FOCUS Scenario	**$PEC_{sw, max}$ (µg/L)**					**$PEC_{sed, max}$ (µg/kg)**	
Step 1							
	0.415	< 0.001	< 0.001	< 0.001	0.082	0.252	< 0.001
Step 2							
N-Europe	0.071	< 0.001	< 0.001	< 0.001	0.014	0.043	< 0.001
S-Europe	0.132	< 0.001	< 0.001	< 0.001	0.026	~~0.079~~ 0.080	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC <1) for X12483137 for each organism group based on FOCUS Step 1-2 calculations for the use of F7B-39-30 in sugar and fodder beet (Use group A)

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Cyprinus carpio***	***Daphnia magna***	***Navicula pelliculosa***	***Myriophyllum spicatum***
Endpoint (µg/L)		LC_{50} > 10000	EC_{50} > 10000	E_rC_{50} > 1400	E_rC_{50} = 50.5
AF		100	100	10	10
RAC (µg/L)		> 100	> 100	> 140	5.05
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**				
Step 1					
	0.063	< 0.001	< 0.001	< 0.001	0.012
Step 2					
N-Europe	0.010	< 0.001	< 0.001	< 0.001	0.002
S-Europe	0.020	< 0.001	< 0.001	< 0.001	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC <1) for X195023 for each organism group based on FOCUS Step 1-2 calculations for the use of F7B-39-30 in sugar and fodder beet (Use group A)

Group		**Fish acute**	**Fish prolonge**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophyte**
Test species		***Cyprinus***	***Pimephales***	***Gammarus pseudolimnae***	***Americamysis bahia***	***Pseudokirchneriella subcapitata***	***Myriophyllum spicatum***
Endpoint (µg/L)		LC_{50} > 41.4	NOEC = 37	EC_{50} > 41.9	NOEC = 7.8	E_rC_{50} > 33.7	E_rC_{50} = 0.12
AF		100	10	100	10	10	10
RAC (µg/L)		> 0.414	3.7	> 0.419	0.78	> 3.37	0.012
FOCUS Scenario	**$PEC_{sw, max}$ (µg/L)**						
Step 1							
	0.135	< 0.33	0.036	< 0.32	0.17	< 0.040	**11**
Step 2							
N-Europe	~~0.021~~ 0.024	~~< 0.051~~ < 0.058	0.006	~~< 0.050~~ < 0.057	~~0.027~~ 0.031	~~< 0.006~~ < 0.007	~~**1.8**~~ **2.0**
S-Europe	~~0.041~~ 0.044	~~< 0.099~~ < 0.106	0.011	~~< 0.098~~ < 0.105	~~0.053~~ 0.056	~~< 0.012~~ 0.013	~~**3.4**~~ **3.7**
Step 3 *	0.002	-	-	-	-	-	0.17

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; * Estimated PECsw, see explanation in the below text

Step 3 estimate for metabolite X195023

In the EFSA evaluation for florpyrauxifen-benzyl, an aquatic toxicity endpoint for the metabolite X195023, which is the common industrial chemical benzyl alcohol, was not available, so a worst-case RAC of 0.012 µg/L, based on the parent value, was assigned. From the step 1-2 calculations for this metabolite, some exceedances of this value were calculated. As a worst-case estimate of a step 3 determination, the maximum parent Step 3 value of 0.010 µg/L was converted by taking the maximum amount found in the photolysis study (81.5 molar percent), along with an molecular weight factor of 108.1/439.2. This yields a worst-case estimate of 0.010 * 0.815 * 108.1/439.2 = 0.002 µg/L, which is below the parent RAC. Since this is a worst-case estimate, the risk is acceptable.

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC <1) for X194973 for each organism group based on FOCUS Step 1-2 calculations for the use of F7B-39-30 in sugar and fodder beet (Use group A)

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Desmodesmus subspicatus***
Endpoint (µg/L)		LC_{50} > 120000	EC_{50} > 120000	E_rC_{50} > 1000000
AF		100	100	10
RAC (µg/L)		> 1 200	> 1 200	> 100 000
FOCUS Scenario	**$PEC_{sw, max}$ (µg/L)**			
Step 1				

	0.040	< 0.001	< 0.001	< 0.001
Step 2				
N-Europe	0.006	< 0.001	< 0.001	< 0.001
S-Europe	0.012	< 0.001	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration

Product F7B-39-30

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC <1) of F7B-39-30 for each organism group based on SWASH drift for its use in sugar and fodder beet (1x 2 g/ha)

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Cyprinus carpio***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum spicatum***
Endpoint (µg/L)		LC_{50} > 120000	EC_{50} > 49000	E_rC_{50} > 4200	E_rC_{50} = 0.919
AF		100	100	10	10
RAC (µg/L)		> 1 200	> 490	> 420	0.0919
FOCUS Scenario	**$PEC_{sw, max}$ (µg/L)**				
Default (1 m BF)	0.393	< 0.001	< 0.001	< 0.002	**4.3**
5 m BF	0.129	< 0.001	< 0.001	< 0.001	**1.4**
10 m BF	0.068	< 0.001	< 0.001	< 0.001	0.74
5 m BF + 50% DRN	0.064	< 0.001	< 0.001	< 0.001	0.70
90% DRN	0.039	< 0.001	< 0.001	< 0.001	0.42

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
BF: Buffer strip; DRN: Drift Reducing Nozzles

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC <1) of F7B-39-30 for each organism group based on SWASH drift for its use in sugar and fodder beet (2x 1 g/ha)

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Cyprinus carpio***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum spicatum***
Endpoint (µg/L)		LC_{50} > 120000	EC_{50} > 49000	E_rC_{50} > 4200	E_rC_{50} = 0.919
AF		100	100	10	10
RAC (µg/L)		> 1 200	> 490	> 420	0.0919
FOCUS Scenario	**$PEC_{sw, max}$ (µg/L)**				
Default (1 m BF)	0.197	< 0.001	< 0.001	< 0.001	**2.14**
5 m BF	0.064	< 0.001	< 0.001	< 0.001	0.70
75% DRN	0.049	< 0.001	< 0.001	< 0.001	0.53

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

BF: Buffer strip; DRN: Drift Reducing Nozzles

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC <1) of F7B-39-30 for each organism group based on SWASH drift for its use in sugar and fodder beet (3x 0.66 g/ha)

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Cyprinus carpio***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum spicatum***
Endpoint (µg/L)		LC_{50} > 120000	EC_{50} > 49000	E_rC_{50} > 4200	E_rC_{50} = 0.919
AF		100	100	10	10
RAC (µg/L)		> 1 200	> 490	> 420	0.0919
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**				
Default (1 m BF)	0.128	< 0.001	< 0.001	< 0.001	**1.39**
5 m BF	0.042	< 0.001	< 0.001	< 0.001	0.46
50% DRN	0.064	< 0.001	< 0.001	< 0.001	0.70

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
BF: Buffer strip; DRN: Drift Reducing Nozzles

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC <1) of F7B-39-30 for each organism group based on SWASH drift for its use in sugar and fodder beet (4x 0.5 g/ha)

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Cyprinus carpio***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum spicatum***
Endpoint (µg/L)		LC_{50} > 120000	EC_{50} > 49000	E_rC_{50} > 4200	E_rC_{50} = 0.919
AF		100	100	10	10
RAC (µg/L)		> 1 200	> 490	> 420	0.0919
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**				
Default (1 m BF)	0.098	< 0.001	< 0.001	< 0.001	**1.07**
5 m BF	0.032	< 0.001	< 0.001	< 0.001	0.35
50% DRN	0.049	< 0.001	< 0.001	< 0.001	0.53

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
BF: Buffer strip; DRN: Drift Reducing Nozzles

An acceptable risk to aquatic organisms from exposure to the intact F7B-39-30 formulation is anticipated if either of the following mitigations are implemented:

Use in sugar and fodder beet (~~2x 1~~ 1 x 2 g/ha):

- 90% drift reducing nozzles or
- 5 m buffer zone and 50% drift reducing nozzles or
- 10 m buffer zone

Use in sugar and fodder beet (~~1x 2~~ 2 x 1 g/ha):

- 75% drift reducing nozzles or
- 5 m buffer zone

Use in sugar and fodder beet (3x 0.66 g/ha):

- 50% drift reducing nozzles or
- 5 m buffer zone

Use in sugar and fodder beet (4x 0.5 g/ha):

- 50% drift reducing nozzles or
- 5 m buffer zone

9.5.3 Overall conclusions

Acceptable acute and long-term risks have been demonstrated for aquatic organisms following applications of F7B-39-30 in sugar and fodder beet. To prevent undesired effects, it is recommended to use the following mitigations measures:

Use in sugar and fodder beet (~~2x 1~~ 1 x 2 g/ha):

- 90% drift reducing nozzles or
- 5 m buffer zone and 50% drift reducing nozzles or
- 10 m buffer zone

Use in sugar and fodder beet (~~1x 2~~ 2 x 1 g/ha):

- 75% drift reducing nozzles or
- 5 m buffer zone

Use in sugar and fodder beet (3x 0.66 g/ha):

- 50% drift reducing nozzles or
- 5 m buffer zone

Use in sugar and fodder beet (4x 0.5 g/ha):

- 50% drift reducing nozzles or
- 5 m buffer zone

Evaluator comment:
The risk assessment for aquatic organisms was performed in accordance with the recommendation of Guidance Document on Aquatic Ecotoxicology, as provided by the Commission Services (SANCO/3268/2001 rev.4 (final), 17 October 2002).

Florpyrauxifen-benzyl and its metabolites
The first tier risk assessment for florpyrauxifen-benzyl and its metabolites was performed based on the EU agreed endpoints and FOCUS Step 1 to 3 PECsw values taking into account the worst application rate.
For florpyrauxifen-benzyl and metabolites the risk is acceptable. No mitigation measures are required.

F7B-39-30 (Rinpode)
The risk assessment for the formulation F7B-39-30 (Rinpode) was based on the endpoints for the representative formulated product GF-3206 (an emulsifiable concentrate (EC) containing 25 g/L florpyrauxifen-benzyl). The formulations can be considered equivalent.

The risk to aquatic organisms was accepted with appropriate risk mitigation measures:

For use in sugar and fodder beet (1 x 2 g/ha):

- 90% drift reducing nozzles or
- 5 m buffer zone and 50% drift reducing nozzles or
- 10 m buffer zone

For use in sugar and fodder beet (2 x 1 g/ha):
- 75% drift reducing nozzles or
- 5 m buffer zone

For use in sugar and fodder beet (3 x 0.66 g/ha):
- 50% drift reducing nozzles or
- 5 m buffer zone

For use in sugar and fodder beet (4 x 0.5 g/ha):
- 50% drift reducing nozzles or
- 5 m buffer zone

Conclusion
According to the performed risk assessment there is no potential of risk for aquatic organisms resulting from acute and long-term exposure to active substance following use of F7B-39-30 (Rinpode) in compliance with proposed GAP when:

- for use in sugar and fodder beet (1 x 2 g/ha):

  90% drift reducing nozzles or
  5 m buffer zone and 50% drift reducing nozzles or
  10 m buffer zone

- for use in sugar and fodder beet (2 x 1 g/ha):

  75% drift reducing nozzles or
  5 m buffer zone

- for use in sugar and fodder beet (3x 0.66 g/ha):

  50% drift reducing nozzles or
  5 m buffer zone

- for use in sugar and fodder beet (4x 0.5 g/ha):

  50% drift reducing nozzles or
  5 m buffer zone

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with florpyrauxifen-benzyl. 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).
Results on the product are based on studies from GF-3206 which has identical composition of F7B-39-30 (Rinpode) except for adding the blue dye at 0.0005% w/w. GF-3206 is the representative formulation fully

evaluated in the active substance European approval process.
Effects on bees of GF-3206 were evaluated as part of the EU assessment of florpyrauxifen-benzyl.
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Florpyrauxifen-benzyl	48 h, oral	LD_{50} > 105.4 µg/bee	EFSA Journal 2018; 16(8):5378
Apis mellifera	Florpyrauxifen-benzyl	48 h, contact	LD_{50} > 100 µg/bee	EFSA Journal 2018; 16(8):5378
Bombus terrestris	Florpyrauxifen-benzyl	48 h, oral	LD_{50} > 110.1 µg/bee	Chwiesko, 2017, 170055*
Bombus terrestris	Florpyrauxifen-benzyl	48 h, contact	LD_{50} > 100 µg/bee	Chwiesko, 2017, 170055*
Apis mellifera	GF-3206	48 h, oral	LD_{50} > 212.2 µg/bee (> 5.73 µg a.s./bee)	EFSA Journal 2018; 16(8):5378
Apis mellifera	GF-3206	48 h, contact	LD_{50} > 200 µg/bee (> 5.4 µg a.s./bee)	EFSA Journal 2018; 16(8):5378
Bombus terrestris	GF-3206	48 h, oral	LD_{50} > 673.5 µg/bee (> 18.1 µg a.s./bee)	Amsel, K. 2022 220817
Bombus terrestris	GF-3206	48 h, contact	LD_{50} > 1400 µg/bee (> 37.8 µg a.s./bee)	Amsel, K. 2022 220817
Apis mellifera	GF-3206	10 d, oral	LDD_{50} = 238 µg prod./bee/d (6.43 µg a.s./bee/d) NOEDD = 160 µg prod./bee/d (4.33 µg a.s./bee/d)	Vergé, E., 2017, 170080*
Apis mellifera	GF-3206	22 d (larvae, repeated dosing), oral	NOED= 178.5 µg prod./larva/developmental period (4.82 µg a.s./larva/ developmental period)	Vergé, E., 2018, 170081*
Apis mellifera	X11438848	7 d (larvae, single dosing), oral	LD_{50} > 30 µg/larva (>1000 mg/L diet)	EFSA Journal 2018; 16(8):5378

* Study accepted in previous zRR by other MSs

9.6.1.1 Justification for new endpoints

Studies assessing the acute contact and oral toxicity of florpyrauxifen-benzyl and the formulation GF-3206 to bumblebees, as well as the chronic toxicity to honey bees and the toxicity from repeated exposure of honey bee larvae were conducted and are submitted for evaluation.

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) referring to the Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(3)), Bulletin OEPP/EPPO Bulletin 40: 323-331, 2010; hereafter referred to as EPPO (2010) considering recommendations by ECPA (2017) (Proposal for a protective and workable regulatory European bee risk assessment scheme based on the EFSA bee guidance and other new data and available approaches, POS/17/LO/28028).

In addition, a risk assessment according to the "EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bee" (2013) is presented to address the data requirements of the Regulation (EU) No. 284/2013, chronic risk to adult bees and bee brood.

Based on the PRAPeR meeting 2015 (Outcome of the pesticides peer review meeting on recurring issues in ecotoxicology, EFSA Supporting publication 2015:EN-924) the risk assessment currently addresses only honeybees. However, in the case that studies or information on bumblebees are available, the information is presented.

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 F7B-39-30 in sugar and fodder beet

Intended use	Sugar beet and fodder beet (BBCH 10-19)		
Product	F7B-39-30		
Application rate (g prod./ha)*	1 × 74		
Test design	**LD_{50} (lab.) (µg prod./bee)**	**Max. single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>212.2	74	<0.35
Contact toxicity	>200		<0.37

*Product density is 0.925 g/mL

Risk assessment based on available chronic or repeated exposure studies

Chronic adult and larval honey bee studies have been conducted with the formulation GF-3206, according to the data requirements under 1107/2009. The endpoint from the study with GF-3206 has been assessed by applying the EPPO 2010 scheme with modifications by ECPA (2017), which provides a comparable level of protection to the EFSA approach and is based on the current scientific state of the art for bee pollinator risk assessment.

Worst-case data from Rortais et al., 2005[2] as proposed in the EPPO scheme have been used to estimate the consumption by **honey bee larvae**. Based on the data in this publication, a worker larva consumes 59.4 mg sugar in 5 days. Assuming a 30% sugar content of nectar, the resulting worst-case consumption for a worker larva is: 59.4/0.30 = *198 mg nectar in 5 days* (larval development).

[2] Rortais A, Arnold G, Halm M-P, Touffet-Briens F (2005) Modes of honey bees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. Apidologie 36: 71–83

In addition, a worker larva is considered to consume *2 mg pollen during its development phase* (EFSA 2013). Thus, considering the mean RUD values for nectar (i.e. 2.9 mg/kg) and pollen (i.e. 6.1 mg/kg) from foliar sprays as proposed in the modified EPPO 2010 approach by ECPA, based on a database of measured values (RUD, residues unit dose) from the EFSA 2013 (Appendix F), exposure can be estimated for the whole larval development period of 5 days. The final estimated exposure levels deriving from nectar and pollen consumption can be compared to the available larval NOEL values for GF-3206 and its active substances. The EPPO 2010 scheme proposes a trigger of 1 for assessment of the risk to honeybees. Results are presented in the following table.

Table 9.6-3: Assessment of the risk for bee larvae due to the use of F7B-3930 in sugar beet and fodder beet (BBCH 10-19)

Intended use **Active substance** **Application rate (kg total a.s./ha)**	Sugar beet and fodder beet (BBCH 10-19) Florpyrauxifen-benzyl 1 × 0.002			
NOEL (µg/bee/developmental period)	4.82			
Food item	**Consumption (kg/bee/developmental period)**	**RUD (µg/kg/kg/ha)**	**Dietary dose (µg/bee/developmental period)**	**TER criterion: TER ≥ 1**
Nectar	198×10^{-6}	2.9×10^{3}	0.0115	
Pollen	2×10^{-6}	6.1×10^{3}	0.000244	
		Total	0.0117	412
Product **Application rate (kg prod./ha)**	F7B-39-30 1 × 0.074			
NOEL (µg/bee/developmental period)	178.5			
Food item	**Consumption (kg/bee/developmental period)**	**RUD (µg/kg/kg/ha)**	**Dietary dose (µg/bee/developmental period)**	**TER criterion: TER ≥ 1**
Nectar	198×10^{-6}	2.9×10^{3}	0.0425	
Pollen	2×10^{-6}	6.1×10^{3}	0.0009	
		Total	0.0434	4113

TER values shown in bold breach the relevant trigger.

Intended use **Active substance** **Application rate (kg total a.s./ha)**	Sugar beet and fodder beet (BBCH 10-19) Florpyrauxifen-benzyl 1 × 0.002		
NOED (µg/bee/developmental period)	4.82		
Food item	**RUD (mg a.s./kg)**	**Dietary dose (µg/bee/developmental period)**	**TER criterion: TER ≥ 1**
Nectar	2.9	0.0011	
Pollen	6.1	0.00002	
Total		0.0001	4109

All the TER values above greatly exceed the EPPO trigger of 1, indicating that the proposed uses of F7B-39-30 in sugar and fodder beet (BBCH 10-19) pose an acceptable risk to bee larval development.

The risk assessment for chronic exposure of **adult honey bees** is based upon the method of EPPO 2010 risk assessment for systemic substances which is cited in the regulation as a current risk assessment scheme. It uses NOEDD values for the endpoint so avoids the issues associated with the generation of LDD_{50} values for substances of low toxicity, and calculates exposure in a similar way to EFSA 2013. The approach is also in line with other chronic risk assessments (e.g. birds and mammals) and derives a TER value. Worst-case data from Rortais et al., 2005 indicates a sugar need of 128 mg/bee/day for a bee feeding exclusively from nectar containing 30% sugar. This results in a worst-case consumption for an adult honey bee is: 128/0.30 = *427 mg nectar/day*. Considering the mean RUD value for nectar from foliar sprays (i.e. 2.9 mg/kg) in EFSA 2013 (Appendix F), the daily dietary exposure for adult honey bees can be estimated and it can be compared to the available chronic adult NOEDD values for GF-3206 and its active substances. The EPPO 2010 scheme proposes a trigger of 1 for assessment of the risk to honey bees. Results are presented in the following table.

Table 9.6-4: Assessment of the chronic risk for adult bees due to the use of F7B-39-30 in sugar beet and fodder beet (BBCH 10-19)

~~**Intended use**~~ ~~**Active substance**~~ ~~**Application rate (kg a.s./ha)**~~	~~Sugar and fodder beet (BBCH 10-19)~~ ~~Florpyrauxifen-benzyl~~ ~~1 × 0.002~~			
~~**NOEDD (µg/bee/day)**~~	~~6.43~~			
~~**Food item**~~	~~**Consumption (kg/bee/day)**~~	~~**RUD (µg/kg/kg/ha)**~~	~~**Dietary dose (µg/bee/day)**~~	~~**TER criterion: TER ≥ 1**~~
~~Nectar~~	~~427×10^{-6}~~	~~2.9×10^{3}~~	~~0.0248~~	~~259~~
~~**Product**~~ ~~**Application rate (kg prod./ha)**~~	~~F7B-39-30~~ ~~1 × 0.074~~			
~~**NOEDD (µg/bee/day)**~~	~~160~~			
~~**Food item**~~	~~**Consumption (kg/bee/day)**~~	~~**RUD (µg/kg/kg/ha)**~~	~~**Dietary dose (µg/bee/day)**~~	~~**TER criterion: TER ≥ 1**~~
~~Nectar~~	~~427×10^{-6}~~	~~2.9×10^{3}~~	~~0.0916~~	~~1747~~

TER values shown in bold breach the relevant trigger.

Intended use **Active substance** **Application rate (kg total a.s./ha)**	Sugar beet and fodder beet (BBCH 10-19) Florpyrauxifen-benzyl 1 × 0.002		
NOEDD (µg/bee/day)	4.33		
Food item	**RUD (mg a.s./kg)**	**Dietary dose (µg/bee/developmental period)**	**TER criterion: TER ≥ 1**
Nectar	2.9	0.0025	1750

All the TER values above greatly exceed the EPPO trigger of 1, indicating that the proposed uses of F7B-39-30 in sugar beet and fodder beet (BBCH 10-19) pose an acceptable chronic risk to adult bees.

Risk assessment according to the EFSA draft Guidance Document (2013)

Although the EFSA Draft Bee Guidance Document issued in 2013 has not been noted and is currently being revised, following the national approach for Belgium on the Data Requirements and Risk Assessment for Bees (version 2.2, 2018), a risk assessment according the EFSA Draft Bee Guidance document was conducted. As indicated in the Belgian guidance[3], the focus of the assessment based on the EFSA draft Guidance Document (2013) was the acute/chronic risks to honey bees as well as the acute risk to bumble bees only. Indeed no agreed test guidelines are available to address chronic toxicity to bumble bees and the acute and chronic toxicity to solitary bees and no agreed extrapolation factor exists to derive endpoints based on the existing studies on honey bees.

Endpoints of the formulation studies with GF-3206 were used to assess the risks. The EFSA Bee-Tool v3 was used for the following assessment.

The Screening Step was conducted considering a risk envelope using the highest application rate of 74 g GF-3206/ha in sugar beet and fodder beet (BBCH 10-19, downwards spray).

Table 9.6-5: Screening assessment of the acute contact risk to honey bees due to the use of F7B-39-30 in sugar beet and fodder beet (BBCH 10-19)

Intended use **Product** **Application rate (g prod./ha)**	Sugar beet and fodder beet (BBCH 10-19) (Spray DW) F7B-39-30 1 × 74	
Acute contact	LD_{50} > 200 µg/bee	
	Honey bee (contact)	
Screening category (acc. to EFSA 2013)	**HQ**	**Trigger**
Spray DW	0.37	42

HQ: Hazard quotients
Values shown in **bold** breach the relevant trigger.

[3] FPS Health, Food Chain Safety and Environment (2019). Data requirements and risk assessment for bees – national approach for Belgium. Version 2.3. 4 April 2019.

Table 9.6-6: Screening assessment of the acute and chronic oral risk to honey bees due to the use of F7B-39-30 in sugar beet and fodder beet (BBCH 10-19)

Intended use	Sugar beet and fodder beet (BBCH 10-19) (Spray DW)
Product	F7B-39-30
Application rate (g prod./ha)	1 × 74

	Honey bee (oral)	
Screening category (acc. to EFSA 2013)	**ETR**	**Trigger**
Acute	0.003	0.2
Chronic	0.002	0.03
Larvae	0.002	0.2

ETR: Exposure toxicity ratio
Values shown in **bold** breach the relevant trigger.

All the ETR (oral exposure) and HQ (contact exposure) calculated above indicate acceptable acute and chronic risks to honeybees following uses of F7B-39-30 in sugar beet and fodder beet (BBCH 10-19). Therefore, Tier 1 assessment is not required.

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

Not required.

9.6.3 Effects on bumble bees

Although the EFSA Draft Bee Guidance Document issued in 2013 has not been noted and is currently being revised, following the national approach for Belgium on the Data Requirements and Risk Assessment for Bees (version 2.2, 2018), a risk assessment according the EFSA Draft Bee Guidance document was conducted. As indicated in the Belgian guidance[4], the focus of the assessment based on the EFSA draft Guidance Document (2013) was the acute/chronic risks to honeybees as well as the acute risk to bumblebees only. Indeed no agreed test guidelines are available to address chronic toxicity to bumblebees and the acute and chronic toxicity to solitary bees and no agreed extrapolation factor exists to derive endpoints based on the existing studies on honeybees.

Endpoints of the formulation studies with GF-3206 were used to assess the risks. The EFSA Bee-Tool v3 was used for the following assessment.

The Screening Step was conducted considering a risk envelope using the highest application rate of 74 g GF-3206/ha sugar beet and fodder beet (BBCH 10-19, downwards spray).

[4] FPS Health, Food Chain Safety and Environment (2019). Data requirements and risk assessment for bees – national approach for Belgium. Version 2.3. 4 April 2019.

Table 9.6-7: Screening assessment of the acute contact risk to bumble bees due to the use of F7B-39-30 in sugar beet and fodder beet (BBCH 10-19)

Intended use	Sugar beet and fodder beet (BBCH 10-19) (Spray DW)	
Product	F7B-39-30	
Application rate (g prod./ha)	1 × 74	
Acute contact	LD_{50} > 1400 µg/bee	
	Honey bee (contact)	
Screening category (acc. to EFSA 2013)	**HQ**	**Trigger**
Spray DW	< 0.1	~~42~~ 7

HQ: Hazard quotients
Values shown in **bold** breach the relevant trigger.

Table 9.6-8: Screening assessment of the acute oral risk to bumble bees due to the use of F7B-39-30 in sugar beet and fodder beet (BBCH 10-19)

Intended use	Sugar beet and fodder beet (BBCH 10-19)	
Product	F7B-39-30	
Application rate (g prod./ha)	1 × 74	
Acute oral	LD_{50} > 673.5 µg/bee	
	Bumble bee (oral)	
Screening category (acc. to EFSA 2013)	**ETR**	**Trigger**
Spray DW	< 0.001	0.036

ETR: Exposure toxicity ratio
Values shown in **bold** breach the relevant trigger.

All the ETR (oral exposure) and HQ (contact exposure) calculated above indicate acceptable acute and chronic risks to bumble bees following uses of F7B-39-30 in sugar beet and fodder beet (BBCH 10-19). Therefore, Tier 1 assessment is not required.

9.6.4 Effects on solitary bees

No data on solitary bees is available for florpyrauxifen-benzyl and the formulation GF-3206.

9.6.5 Overall conclusions

An acceptable risk to bees is expected from the proposed uses of F7B-39-30 in sugar beet and fodder beet (BBCH 10-19), without the need of any risk mitigation.

Evaluator Comments:

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

The required study on oral and contact toxicity of the formulated product of Rinpode (F7B-39-30) to honey bees was conducted and considered to be valid.

The hazard quotients are below the trigger value, indicating that the formulation Rinpode (F7B-39-30) poses an acceptable acute risk to bees.

New studies for acute toxicity of bumble bees were submitted and accepted.

The specific requirements of the Regulation (EU) 546/2011 regarding effects on bee brood development and possible chronic effects on adults were included by the Applicant and accepted.

The EPPO 2010 (ECPA proposal of 9 June 2017) scheme proposes a trigger of 1 for assessment of the risk to honey bees. All TER values for chronic risk assessment for adult bees and bee larvae were above a trigger of 1, indicating that the proposed uses of Rinpode (F7B-39-30) poses an acceptable chronic risk to adult bees and bee larvae. However the risk assessment performed in accordance with EPPO 2010 (ECPA proposal of 9 June 2017) has not been agreed yet its relevance will be decided at the Member State level.

Moreover, the evaluator provided the risk assessment according to the new bee guidance "EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp.) and solitary bees", EFSA Journal 2013; 11(7):3295 The risk assessment performed in accordance with EFSA guidance (2013) was also submitted but as this guidance has not been agreed yet its relevance will be decided at the Member State level.

The screening step values ETR for florpyrauxifen-benzyl are less than the triggers for downward sprays according to EFSA/2013/3295, indicating that the risk to bees and bumble bees is acceptable for florpyrauxifen-benzyl following use of Rinpode (F7B-39-30) according to the proposed use pattern.

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 florpyrauxifen-benzyl, tested as the formulation GF-3206. GF-3206 is the representative formulation fully evaluated in the active substance European approval process.
Full details of these studies are provided in the respective EU DAR and related documents.
Results on the product are based on study from GF-3206 which has identical composition of F7B-39-30 (Rinpode) except for adding the blue dye at 0.0005% w/w.
Effects on non-target arthropods of GF-3206 were evaluated as part of the EU assessment of florpyrauxifen-benzyl.
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	GF-3206	Laboratory test glass plates (2D)	LR_{50} = 972 mL/ha ER_{50} > 1061 mL/ha	EFSA Journal 2018; 16(8):5378
Aphidius rhopalosiphi (adults)	GF-3206	Laboratory test glass plates (2D)	LR_{50} = 1347 mL/ha ER_{50} > 1500 mL/ha	EFSA Journal 2018; 16(8):5378
Typhlodromus pyri (protonymphs)	GF-3206	Extended laboratory test French bean leaf discs (2D)	LR_{50} > 6000 mL/ha ER_{50} > 6000 mL/ha	EFSA Journal 2018; 16(8):5378
Chrysoperla carnea (larvae)	GF-3206	Extended laboratory test French bean leaf discs (2D)	LR_{50} > 2200 mL/ha ER_{50} > 2200 mL/ha	EFSA Journal 2018; 16(8):5378

9.7.1.1 Justification for new endpoints

Not relevant.

9.7.2 Risk assessment

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

To achieve a concise risk assessment, the risk envelope approach is applied. Assessment for the use in sugar and fodder beet (use group A) covers the risk for arthropods others than bees for all intended uses (see **Błąd! Nie można odnaleźć źródła odwołania.**).

9.7.2.1 Risk assessment for in-field exposure

The results of the risk assessment for in-field exposure are summarised in the following table.

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of F7B-39-30 in sugar and fodder beet (Use group A)

Intended use	Sugar beet and fodder beet (BBCH 10-19)		
Product	F7B-39-30		
Application rate (mL/ha)	1 × 80		
MAF	1 (Appendix III, ESCORT 2, default MAF for leaf applications)		
Test species Tier I	**LR_{50} (lab.) (mL/ha)**	**$PER_{in-field}$ (mL/ha)**	**$HQ_{in-field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	972	80	0.08
Aphidius rhopalosiphi	1347		0.06
Test species Higher-tier	**Rate with ≤ 50% effect* (mL/ha)**	**$PER_{in-field}$ (mL/ha)**	**$PER_{in-field}$ below rate with ≤ 50% effect?**
Typhlodromus pyri	LR_{50} and ER_{50} > 6000	80	yes
Chrysoperla carnea	LR_{50} and ER_{50} > 2200		yes

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient.
Criteria values shown in bold breach the relevant trigger.
* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50% effect.

9.7.2.2 Risk assessment for off-field exposure

The results of the risk assessment for off-field exposure are summarised in the following table.

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of F7B-39-30 in sugar and fodder beet (Use group A)

Intended use	Sugar and fodder beet (BBCH 10-19)				
Product	F7B-39-30				
Application rate (mL/ha)	1 × 80				
MAF	1 (Appendix III, ESCORT 2, default MAF for leaf applications)				
vdf	5 (2D-study) and 10				
Test species Tier I	**LR_{50} (lab.) (mL/ha)**	**Drift rate [1]**	**$PER_{off-field}$ (mL/ha)**	**CF**	**$HQ_{off-field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	972	2.77% (1 m)	0.443 (0.2216)	10	0.005 (0.00228)
Aphidius rhopalosiphi	1347				0.003 (0.00165)
Test species Higher-tier	**Rate with ≤ 50% effect* (mL/ha)**	**Drift rate [1]**	**$PER_{off-field}$ (mL/ha)**	**CF**	**corr. $PER_{off-field}$ below rate with ≤ 50% effect?**
Typhlodromus pyri	LR_{50} and ER_{50}> 6000	2.77% (1 m)	0.443 (0.2216)	5	yes
Chrysoperla carnea	LR_{50} and ER_{50}> 2200				yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.
* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50% effect.
[1]: Appendix IV, ESCORT 2 for one application to field crops

9.7.2.3 Additional higher-tier risk assessment

Not required.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

An acceptable risk to non-target arthropods is expected from the proposed uses of F7B-39-30 in sugar and fodder beet, without the need of any risk mitigation.

Evaluator comments:

The submitted risk assessment based on the "Guidance Document on Terrestrial Ecotoxicology" (2002) was accepted.

The laboratory studies 2D and 3D for *Aphidius rhopalosiphi*, *Typhlodromus pyr* and *Chrysoperla carnea* are submitted and accepted for risk assessment.

In field risk
The hazard quotients are below the trigger value (HQ ≤ 2) for all species indicating that the formulation Rinpode (F7B-39-30) poses an acceptable risk to arthropods other than bees.

Off-field risk
The hazard quotients are below the trigger value (HQ ≤ 2) for all species indicating that the formulation Rinpode (F7B-39-30) poses an acceptable risk to arthropods other than bees.

Based on the results of the risk assessment it can be concluded that low risk for non-target arthropods is expected from the use of Rinpode (F7B-39-30) according to the proposed use pattern.

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 florpyrauxifen-benzyl and its major metabolites. Full details of these studies are provided in the respective EU DAR and related documents.
Results on the product are based on study from GF-3206 which has identical composition of F7B-39-30 (Rinpode) except for adding the blue dye at 0.0005% w/w. GF-3206 is the representative formulation fully evaluated in the active substance European approval process.
Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of GF-3206 were evaluated as part of the EU assessment of florpyrauxifen-benzyl. The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.
Additional studies with florpyrauxifen-benzyl and its metabolite have been conducted on earthworms, Folsomia and Hypoaspis. Although these data should be evaluated at EU level, it only became available recently. For completeness and transparency the studies are being submitted and all of them have been previously evaluated in another RR by other zRMS (in Central and Southern Zone).

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

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Florpyrauxifen-benzyl	Mixed into substrate 56 d, chronic 10% peat content	$NOEC_{corr}$ = 67.5 mg/kg dw* $EC_{10\ corr}$ = 45.7 mg/kg dw*	EFSA Journal 2018; 16(8):5378
~~*Folsomia candida*~~	~~Florpyrauxifen-benzyl~~	~~Mixed into substrate 28 d, chronic 5% peat content~~	~~NOEC ≥ 1000 mg/kg dw NOEC ≥ 500 mg/kg dw*~~	~~Straube, D., 2018 180818[a]~~
~~*Hypoaspis aculeifer*~~	~~Florpyrauxifen-benzyl~~	~~Mixed into substrate 14 d, chronic 5% peat content~~	~~NOEC ≥ 1000 mg/kg dw NOEC ≥ 500 mg/kg dw*~~	~~Straube, D., 2018 180820[a]~~
~~*Folsomia candida*~~	~~Florpyrauxifen-benzyl non-extractable residues (NER)~~	~~Mixed into substrate 28 d, chronic artificial soil with 5% peat content or natural soil~~	~~NOEC ≥ 0.800 mg/kg dw~~	~~Wagenhoff, E., 2017 160450[a]~~
Eisenia fetida	X11438848	Mixed into substrate 56 d, chronic 10% peat content	NOEC = 213 mg/kg dw	EFSA Journal 2018; 16(8):5378
Folsomia candida	X11438848	Mixed into substrate 28 d, chronic 5% peat content	NOEC = 25 mg/kg dw	EFSA Journal 2018; 16(8):5378
Hypoaspis aculeifer	X11438848	Mixed into substrate 14 d, chronic 5% peat content	NOEC = 25 mg/kg dw	EFSA Journal 2018; 16(8):5378
~~*Eisenia fetida*~~	~~X12300837~~	~~Mixed into substrate 56 d, chronic 10% peat content~~	~~NOEC ≥ 612 mg/kg dw~~	~~Wagenhoff, E., 2018 180822[a]~~
~~*Folsomia candida*~~	~~X12300837~~	~~Mixed into substrate 28 d, chronic 5% peat content~~	~~NOEC ≥ 1000 mg/kg dw~~	~~Wagenhoff, E., 2018 180819[a]~~
~~*Hypoaspis aculeifer*~~	~~X12300837~~	~~Mixed into substrate 14 d, chronic 5% peat content~~	~~NOEC ≥ 1000 mg/kg dw~~	~~Wagenhoff, E., 2018 180821[a]~~
Eisenia fetida	X11966341	Mixed into substrate 56 d, chronic 10% peat content	NOEC = 5 mg/kg dw	EFSA Journal 2018; 16(8):5378
Folsomia candida	X11966341	Mixed into substrate 28 d, chronic 5% peat content	NOEC = 10 mg/kg dw	EFSA Journal 2018; 16(8):5378
Hypoaspis aculeifer	X11966341	Mixed into substrate 14 d, chronic 5% peat content	NOEC = 10 mg/kg dw	EFSA Journal 2018; 16(8):5378
Eisenia fetida	X12483137	Mixed into substrate	NOEC = 5 mg/kg dw	EFSA Journal 2018;

Species	Substance	Exposure System	Results	Reference
		56 d, chronic 10% peat content		16(8):5378
Folsomia candida	X12483137	Mixed into substrate 28 d, chronic 5% peat content	NOEC = 3.1 mg/kg dw	EFSA Journal 2018; 16(8):5378
Hypoaspis aculeifer	X12483137	Mixed into substrate 14 d, chronic 5% peat content	NOEC = 10 mg/kg dw	EFSA Journal 2018; 16(8):5378

* Corrected value derived by dividing the endpoint by a factor of 2 for substances with a Log Pow >2. [a] Study previously evaluated and accepted in previous ZRR

Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) – F7B-39-30

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	GF-3206	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 300 mg/kg dw (8.10 mg a.s./kg dw) $NOEC_{corr}$ = 150 mg/kg dw* (4.05 mg a.s./kg dw)*	EFSA Journal 2018; 16(8):5378
Folsomia candida	GF-3206	Mixed into substrate 28 d, chronic 5 % peat content	NOEC = 300 mg/kg dw (8.10 mg a.s./kg dw) $NOEC_{corr}$ = 150 mg/kg dw* (4.05 mg a.s./kg dw)*	EFSA Journal 2018; 16(8):5378
Hypoaspis aculeifer	GF-3206	Mixed into substrate 14 d, chronic 5 % peat content	NOEC = 300 mg/kg dw (8.10 mg a.s./kg dw) $NOEC_{corr}$ = 150 mg/kg dw* (4.05 mg a.s./kg dw)*	EFSA Journal 2018; 16(8):5378

* Corrected value derived by dividing the endpoint by a factor of 2 for substances with a Log Kow > 2.

9.8.1.1 Justification for new endpoints

New studies were conducted to fulfil the data requirements for plant protection products in accordance with Regulation (EC) No 1107/2009. The endpoints are summarised in Tables 9.8.**Błąd! Nie można odnaleźć źródła odwołania.**

9.8.2 Risk assessment

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

9.8.2.1 First-tier risk assessment

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

(Environmental Fate), Chapter 8.7.2. Where applicable the PEC_{soil} accumulation value has been used in the risk assessment for a conservative approach.

To achieve a concise risk assessment, the risk envelope approach is applied. Assessment for the use in sugar and fodder beet (use group A) cover the risk for earthworms and other non-target soil organisms (meso- and macrofauna) for all intended uses (see 9.1.2).
Metabolite X12300837 is formed under anaerobic conditions e.g. flooded rice paddy, and therefore not relevant for the risk assessment when the product is applied to other crops.

Table 9.8-2: First-tier assessment of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of F7B-39-30 in sugar and fodder beet

Intended use	Sugar beet		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} [scenario] (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Florpyrauxifen-benzyl	45.7*	~~0.0022~~ 0.0021	~~20772~~ 21762
GF-3206	4.05* a.s.	~~0.0022~~ 0.0021	~~1841~~ 1929
X11438848	213	0.0011	193636
X11966341	5	0.0001	50000
X12483137	5	~~0.0004~~ 0.0003	12500
Chronic effects on other soil macro- and mesofauna ~~(worst case species)~~ *Folsomia candida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} [scenario] (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Florpyrauxifen-benzyl	~~500*~~ 4.05**	~~0.0022~~ 0.0021	~~227272~~ 1929
GF-3206	4.05* a.s.	~~0.0022~~ 0.0021	~~1841~~ 1929
X11438848	25	0.0011	22727
X11966341	10	0.0001	100000
X12483137	3.1	~~0.0004~~ 0.0003	7750
Chronic effects on other soil macro- and mesofauna *Hypoaspis aculeifer*			
Florpyrauxifen-benzyl	4.05**	0.0021	1929
GF-3206	4.05*	0.0021	1929
X11438848	25	0.0011	22727
X11966341	10	0.0001	100000
X12483137	10	0.0003	33333

TER values shown in bold fall below the relevant trigger.
* Corrected value derived by dividing the endpoint by a factor of 2 for substances with a Log P_{ow} >2.
** Based on the result of GF-3206 study expressed as mg a.s./kg dw

Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

An acceptable risk to earthworms and soil macro-organisms is expected from the proposed uses of F7B-39-30 in sugar and fodder beet, without the need of any risk mitigation.

Evaluator comment:
The applicant provided several studies with the active substance and the metabolite X12300837. In the evaluator's opinion these studies should be evaluated at EU-level. Additionally, they are not necessary to demonstrate acceptable risk due to the use of F7B-39-30.

PECsoil values were re-calculated in Part B Section 8 considering GAP of F7B-39-30 (Rinpode). The highest predicted environmental concentrations (PECsoil) of the active substance and its metabolites were taken into account for the risk assessment. The risk assessment for active substance and its metabolites was based on the EU agreed endpoints. The risk assessment for the formulation F7B-39-30 (Rinpode) was based on the endpoints for the representative formulated product GF-3206 (an emulsifiable concentrate (EC) containing 25 g/L florpyrauxifen-benzyl). The formulations can be considered equivalent.

All TER values for earthworms, *Folsomia candida* and *Hypoaspis aculeifer* are above the trigger value of 5 indicating acceptable risk.

Conclusion:
According to the performed risk assessment there is low chronic risk to earthworms and other non-target soil organisms resulting from long-term exposure to active substance following use of F7B-39-30 (Rinpode) in compliance with proposed GAP.

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 florpyrauxifen-benzyl and its major metabolites. Full details of these studies are provided in the respective EU DAR and related documents.
Results on the product are based on study from GF-3206 which has identical composition of F7B-39-30 (Rinpode) except for adding the blue dye at 0.0005% w/w. GF-3206 is the representative formulation fully evaluated in the active substance European approval process.
Effects on soil microorganisms of GF-3206 were evaluated as part of the EU assessment of florpyrauxifen-benzyl. The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Florpyrauxifen-benzyl	28 d, aerobic silty sand soil	Nitrate formation rate < 25% at 17 mg/kg soil dw	EFSA Journal 2018; 16(8):5378
N-mineralisation	X11438848	28 d, aerobic silty sand soil	Nitrate formation rate < 25% at 0.467 mg/kg soil dw	EFSA Journal 2018; 16(8):5378

Endpoint	Substance	Exposure System	Results	Reference
~~N-mineralisation~~	~~X12300837~~	~~28 d, aerobic medium loamy sand soil~~	~~Nitrate formation rate < 25% at 0.1 mg/kg soil dw~~	~~Stojanowitsch, 2018. 180859*~~
N-mineralisation	X11966341	28 d, aerobic loamy sand soil	Nitrate formation rate < 25% at 0.427 mg/kg soil dw	EFSA Journal 2018; 16(8):5378
N-mineralisation	X12483137	28 d, aerobic silty sand soil	Nitrate formation rate < 25% at 0.467 mg/kg soil dw	EFSA Journal 2018; 16(8):5378

EFSA Conclusion: EFSA Journal 2018; 16(7):5378; * Study evaluated and accepted in previous ZRR

Table 9.9-2: Endpoints and effect values relevant for the risk assessment for soil microorganisms – F7B-39-30

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	GF-3206	28 d, aerobic silty sand soil	Nitrate formation rate 74 mg/kg dw (2.0 mg a.s./kg soil dw) -14.98%	EFSA Journal 2018; 16(8):5378

9.9.1.1 Justification for new endpoints

A study assessing the toxicity of X12300837 to soil micro-organisms have been completed after the EU review. For completeness and transparency the study is submitted.

9.9.2 Risk assessment

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

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2. Where applicable the PEC_{soil} accumulation value has been used in the risk assessment for a conservative approach.

To achieve a concise risk assessment, the risk envelope approach is applied. Assessment for the use in sugar and fodder beet (use group A) cover the risk for soil micro-organisms for all intended uses (see 9.1.2).

Metabolite X12300837 is formed under anaerobic conditions e.g. flooded rice paddy, and therefore not relevant for the risk assessment when the product is applied to other crops.

Table 9.9-3: Assessment of the risk for effects on soil micro-organisms due to the use of F7B-39-30 in sugar and fodder beet

Intended use	Sugar and fodder beet		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25% (mg/kg dw)**	**PEC_{soil} [scenario] (mg/kg dw)**	**Risk acceptable?**

Florpyrauxifen-benzyl	17 (at 28 d)	~~0.0022~~ 0.0021	yes
GF-3206	2.0 (at 28 d) a.s.	~~0.0022~~ 0.0021	yes
X11438848	0.467 (at 28 d)	0.0011	yes
X11966341	0.427 (at 28 d)	0.0001	yes
X12483137	0.467 (at 28 d)	~~0.0004~~ 0.0003	yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25% (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Florpyrauxifen-benzyl	17 (at 28 d)	~~0.0022~~ 0.0021	yes
GF-3206	2.0 (at 28 d) a.s.	~~0.0022~~ 0.0021	yes
X11438848	0.467 (at 28 d)	0.0011	yes
X11966341	0.427 (at 28 d)	0.0001	yes
X12483137	0.467 (at 28 d)	~~0.0004~~ 0.0003	yes

9.9.3 Overall conclusions

An acceptable risk to soil micro-organisms is expected from the proposed uses of F7B-39-30 in sugar and fodder beet, without the need of any risk mitigation.

Evaluator comment:
The applicant provided study with the metabolite X12300837. In the evaluator's opinion this study should be evaluated at EU-level.

PECsoil values were calculated considering GAP of F7B-39-30 (Rinpode). The highest predicted environmental concentrations (PECsoil) of the active substance and its metabolites were taken into account for the risk assessment. The risk assessment for active substance and its metabolites was based on the EU agreed endpoints. The risk assessment for the formulation F7B-39-30 (Rinpode) was based on the endpoint for the representative formulated product GF-3206 (an emulsifiable concentrate (EC) containing 25 g/L florpyrauxifen-benzyl). The formulations can be considered equivalent.

Conclusion:
Since no effects (> 25%) were seen at application rates far higher than the values of PEC_{soil} for active substance and metabolites it can be concluded that application of F7B-39-30 (Rinpode), according to the GAP, will not cause any detrimental effect to soil micro-organisms

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 florpyrauxifen-benzyl. Full details of these studies are provided in the respective EU DAR and related documents.
Results on the product are based on study from GF-3206 which has identical composition of F7B-39-30

(Rinpode) except for adding the blue dye at 0.0005% w/w. GF-3206 is the representative formulation fully evaluated in the active substance European approval process.

Effects on non-target terrestrial plants of GF-3206 were evaluated as part of the EU assessment of florpyrauxifen-benzyl. The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

At the request of the zRMS, ER_{50} values based on visual phytotoxicity were derived. The ToxRatPro v. 3.3.0 statistical package was used in the derivation of these endpoints. ToxRat output reports for these calculations can be made available upon request.

The ER_{50} derived for the species for which visual phytotoxicity was observed in the formulation studies are summarised in the table below, along with their confidence limits and information on the statistical model used. In the vegetative vigour study for GF-3206 (study ID 140394[5]), no effects on visual phytotoxicity were reported for oat and ryegrass at any of the test concentrations. Similarly for maize, oat, ryegrass, cucumber, oilseed rape, soybean, sugar beet and sunflower in the seedling emergence study for GF-3206 (study ID 140396[6]), no visual phytotoxicity was observed at any of the concentrations tested. For all those species, ER_{50} values based on visual phytotoxicity were therefore estimated to be >60 g a.s./ha, the highest concentration evaluated in the studies. For brevity, these unbound ER_{50} values are omitted from the table below.

Derivation of visual phytotoxicity endpoints for the X11438848 metabolite was not considered necessary because this metabolite is less toxic to terrestrial plants than the parent compound florpyrauxifen-benzyl contained in the GF-3206 formulation, exposure of terrestrial plants to this metabolite is lower than for the parent (maximum occurrence in soil: 62%), and the visual phytotoxicity observations in the non-target plant studies for this metabolite (study IDs 140979[7] and 140778[8]) are not indicative of a remarkably higher toxicity than that observed for the shoot weight endpoints, e.g. visual injury effects around 50% at 1.5 g/ha for carrot and soybean in the Vegetative vigour study, which would results in similar EC_{50} of 1.2 g/ha value based on plant weight for carrot and soybean, with which the TER is 85 indicating a large margin of safety.

[5] Lee, B. 2015. GF-3206 (XDE-848 Benzyl, 25 a.s./L, EC): Effects on the Vegetative Vigor of Non-Target Terrestrial Plants (Tier II). Study ID 140394. ABC Laboratories, Inc., Columbia, Missouri 65202, USA.

[6] Bergfield, A. 2015. GF-3206 (XDE-848 Benzyl, 25 g a.s./L EC): Effects on the Seedling Emergence and Growth of Non-Target Terrestrial Plants (Tier II) DAS Report No. 140396. ABC Laboratories, Inc., Missouri 65202 USA.

[7] Bergfield, A. 2015. X11438848 (XDE-848 Acid): Effects on the Vegetative Vigor of Non-Target Terrestrial Plants (Tier II) DAS Report No. 140979. ABC Laboratories, Inc., Missouri 65202 USA.

[8] Lee, B. 2015. X11438848 (XDE-848 Acid): Effects on the Seedling Emergence and Growth of Non-Target Terrestrial Plants (Tier II). DAS Report No. 140778. ABC Laboratories, Inc., Missouri 65202 USA.

Table 9.10-1: Visual phytotoxicity ER_{50} values for the formulation GF-3206

Species	ER_{50} (g a.s./ha)	Confidence limits (g a.s./ha)	Model used	r^2	p-value
Vegetative vigour study for GF-3206 (Study ID 140394)					
Zea mays	38.3	29.5–49.6	Probit	0.945	≤0.001
Allium cepa	7.22	5.74-9.07	Probit	0.966	≤0.001
Daucus carota	0.18	0.14-0.24	Probit	0.940	≤0.001
Cucumis sativus	2.49	1.08-5.72	Probit	0.843	≤0.001
Brassica napus	41.5	31.8-54.2	Probit	0.959	≤0.001
Glycine max	0.45	0.34-0.61	Probit	0.946	≤0.001
Beta vulgaris	1.50	1.01-2.24	Probit	0.918	≤0.001
Helianthuus annuus	1.57	0.97-2.55	Probit	0.916	≤0.001
Seedling emergence study for GF-3206 (Study ID 140396)					
Allium cepa	22.3	15.9-31.3	Probit	0.935	0.002
Daucus carota	5.40	4.34-6.72	Probit	0.909	≤0.001

Based on the endpoints summarised in the table above, the visual phytotoxicity ER_{50} value for carrot, one of two most sensitive species in the vegetative vigour study (see table below), is slightly lower than the previously reported endpoints for this species. The phytotoxicity ER_{50} derived for the second most sensitive species in the vegetative vigour study, soybean, is slightly higher than previously reported endpoints. The visual phytotoxicity endpoints derived from the data of the seedling emergence study are equal to, or higher than, the corresponding ER_{50} based on weight that were originally reported in this study. The lowest newly derived phytotoxicity endpoints from both studies have been added to the table below for completeness.

Table 9.10-2: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
Daucus carota	GF-3206	21 d Seedling emergence	[1)] ER_{50} emergence: 23 g a.s./ha [2)] ER_{50} plant weight: 2.3 g a.s./ha [3)] ER_{50} plant height: 11 g a.s./ha [4)] ER_{50} phytotoxicity: 5.40 g a.s./ha	EFSA Journal 2018; 16(8):5378 and DAR
Daucus carota (w, p); *Glycine max* (h)	GF-3206	21 d Vegetative vigour	[1)] ER_{50} plant weight: 0.27 g a.s./ha [2)] ER_{50} plant height: 0.40 g a.s./ha [3)] ER_{50} phytotoxicity: 0.18 g a.s./ha HC_5 = 0.086 g a.s./ha	EFSA Journal 2018; 16(8):5378

Table 9.10-3: Endpoints for non-target terrestrial plants - florpyrauxifen-benzyl metabolites

Species	Substance	Exposure System	Results	Reference
Daucus carota (e, w, h); *Allium cepa* (e)	X11438848	21 d Seedling emergence	[1)] ER_{50} emergence: 30 g/ha [2)] ER_{50} plant weight: 1.4 g/ha [3)] ER_{50} plant height: 12 g/ha	EFSA Conclusion and DAR
D. carota; *G. max*; *H. annuus*; *C. sativus*; *G. hirsutum*	X12300837	21 d Seedling emergence	[1)] ER_{50} emergence: >100 g/ha [2)] ER_{50} plant weight: >100 g/ha [3)] ER_{50} plant height: >100 g/ha	EFSA Conclusion and DAR
D. carota; *G. max*; *H. annuus*; *C. sativus*; *G. hirsutum*	X11966341	21 d Seedling emergence	[1)] ER_{50} emergence: >100 g/ha [2)] ER_{50} plant weight: >100 g/ha [3)] ER_{50} plant height: >100 g/ha	EFSA Conclusion and DAR
D. carota; *G. max*; *H. annuus*; *C. sativus*; *G. hirsutum*	X12131932	21 d Seedling emergence	[1)] ER_{50} emergence: >64 g/ha [2)] ER_{50} plant weight: >64 g/ha [3)] ER_{50} plant height: >64 g/ha	EFSA Conclusion and DAR
D. carota; *G. max*; *H. annuus*; *C. sativus*; *G. hirsutum*	X12393505	21 d Seedling emergence	[1)] ER_{50} emergence: >54 g/ha [2)] ER_{50} plant weight: >54 g/ha [3)] ER_{50} plant height: >54 g/ha	EFSA Conclusion and DAR
D. carota; *G. max*; *H. annuus*; *C. sativus*; *G. hirsutum*	X12483137	21 d Seedling emergence	[1)] ER_{50} emergence: >100 g/ha [2)] ER_{50} plant weight: >100 g/ha [3)] ER_{50} plant height: >100 g/ha	EFSA Conclusion and DAR
Daucus carota (w); *Glycine max* (w, h)	X11438848	21 d Vegetative vigour	[1)] ER_{50} plant weight: 1.2 g/ha [2)] ER_{50} plant height: 1.9 g/ha	EFSA Conclusion and DAR
D. carota; *G. max*; *H. annuus*; *C. sativus*; *G. hirsutum*	X12300837	21 d Vegetative vigour	[1)] ER_{50} plant weight: >100 g/ha [2)] ER_{50} plant height: >100 g/ha	EFSA Conclusion and DAR
D. carota; *G. max*; *H. annuus*; *C. sativus*; *G. hirsutum*	X11966341	21 d Vegetative vigour	[1)] ER_{50} plant weight: >100 g/ha [2)] ER_{50} plant height: >100 g/ha	EFSA Conclusion and DAR
D. carota; *G. max*; *H. annuus*; *C. sativus*; *G. hirsutum*	X12131932	21 d Vegetative vigour	[1)] ER_{50} plant weight: >64 g/ha [2)] ER_{50} plant height: >64 g/ha	EFSA Conclusion and DAR
D. carota; *G. max*; *H. annuus*; *C. sativus*; *G. hirsutum*	X12393505	21 d Vegetative vigour	[1)] ER_{50} plant weight: >54 g/ha [2)] ER_{50} plant height: >54 g/ha	EFSA Conclusion and DAR
D. carota; *G. max*; *H. annuus*; *C. sativus*; *G. hirsutum*	X12483137	21 d Vegetative vigour	[1)] ER_{50} plant weight: >100 g/ha [2)] ER_{50} plant height: >100 g/ha	EFSA Conclusion and DAR

e: plant emergence, w: plant weight, h: plant height

9.10.1.1 Justification for new endpoints

~~Not applicable.~~

As discussed above, the zRMS requested the derivation of ER50 values based on visual phytotoxicity to be considered in the risk assessment. The newly derived endpoints for the formulation GF-3206 are summarised in Table 9.10-1.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant. Since florpyrauxifen-benzyl has herbicidal activity, the risk to terrestrial non-target plants has been evaluated below on the basis of dose-response data.

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

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. The lowest endpoint derived in the non-target plant studies for the formulated product has been considered in the initial deterministic risk assessment.

Table 9.10-2: Deterministic assessment of the risk for non-target plants due to the use of F7B-39-30 in sugar and fodder beet (Use group A)

Intended use	Sugar and fodder beet
Product	F7B-39-30
Application rate (g a.s./ha)	1 × 2
MAF	1.0

Test species	**ER_{50} (g a.s./ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5**
Daucus carota	0.18	2.77 (1 m)	0.056	**3.21**

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

The deterministic risk assessment for uses of the formulation F7B-39-30 in sugar and fodder beet indicates a potential risk to terrestrial plants. However, a sufficient number of endpoints (i.e. at least six) is available from the vegetative vigour (plant weight and visual phytotoxicity ER_{50} values) study for the formulation to use a probabilistic risk assessment approach for these datasets (Guidance Document on Terrestrial Ecotoxicology, SANCO/10329/2002). The HC_5 based on the plant weight data from the vegetative vigour study (i.e. 0.086 g a.s./ha) was derived and agreed upon during the Active Approval evaluation of florpyrauxifen-benzyl and it is reported in the EFSA conclusions (EFSA Journal 2018; 16(8):5378). Only the HC_5 based on the visual phytotoxicity ER_{50} values is therefore derived below.

Probabilistic methods that make use of species sensitivity distributions (SSD) may be used when at least 6-10 species have been tested and the SSD toxicity data fit a log-normal distribution. The SSD was built using ETX v. 2.3 developed by RIVM (Rijksinstituut voor Volksgezondheid en Milieu, The Netherlands). The data was tested for the Goodness of Fit prior to the analysis and resulted normally distributed according to the three tests available in the software (i.e. Kolmogorov Smirnov, Cramer Von Mises and Anderson Darling).

Table 9.10-3: Goodness of fit results

Test	Statistic	n	Significance level	Critical	Normal?
Vegetative vigour - Phytotoxicity					
Anderson-Darling	0.286	8	0.05	0.752	Accepted
Kolmogorov-Smirnov	0.494	8	0.05	0.895	Accepted
Cramer von Mises	0.0277	8	0.05	0.126	Accepted

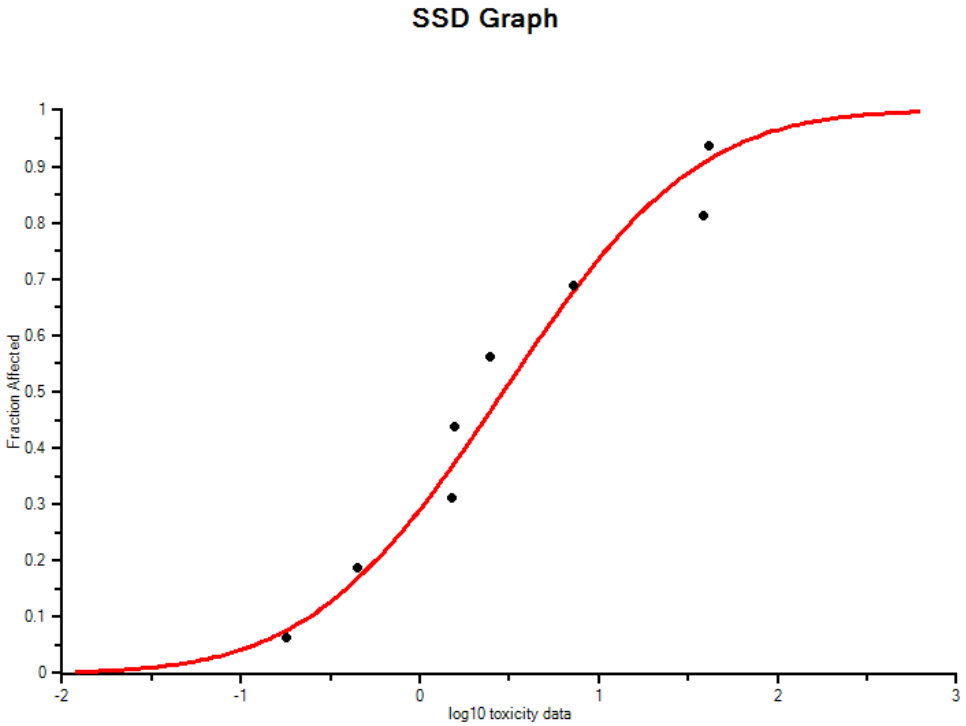
After the SSD was built, the HC_5 in the distribution was determined and it is summarised in the following

table. The graph of the SSD for this HC_5 is also shown below.

Table 9.10-4: Results of HC_5 determination based on the visual phytotoxicity data from the vegetative vigour study

Parameter	HC_5 estimate (g a.s./ha)		
	Lower	Median	Upper
Phytotoxicity	0.00587	0.103	0.453

Figure 9.10-1: Species Sensitivity Distribution for phytotoxicity ER_{50} from the vegetative vigour study for GF-3206



The HC_5 of 0.103 g a.s./ha derived based on the visual phytotoxicity endpoints from the vegetative vigour study for GF-3206 is higher than the HC_5 of 0.086 g a.s./ha derived from the same study, and reported in the EFSA conclusions for florpyrauxifen-benzyl, considering shoot weight. The latter endpoint is therefore considered in the following risk assessment for the formulated product.

~~For the risk assessment with the formulation the HC_5 of 0.086 g a.s./ha was used, which is based on the ER_{50} values determined for shoot weight~~.

As the florpyrauxifen-benzyl metabolite X11438848 has a maximum occurrence of 62% in soil it was also taken into account for risk assessment. The most sensitive endpoint for this florpyrauxifen-benzyl metabolite, i.e. the $ER_{50,\ plant\ weight}$ = 1.2 g/ha was taken into account for risk assessment. No further risk assessment is presented for the other metabolites as they are less harmful to non-target terrestrial plants and have lower maximum occurrences in soil (see Table 9.1-3).

Table 9.10-7: Probabilistic assessment of the risk for non-target plants due to the use of F7B-39-30 in sugar and fodder beet (Use group A)

Intended use	Sugar and fodder beet
Product	F7B-39-30
Application rate (g a.s./ha)	1 × 2
MAF	1.0

Test species	**HC_5 (g a.s./ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 1**
4 monocots + 6 dicots	0.086	2.77 (1 m)	0.056	1.54
4 monocots + 6 dicots	0.086	0.57 (5 m)	0.0114	7.54

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

Table 9.10-8: Assessment of the risk for non-target plants due to the use of F7B-39-30 in sugar and fodder beet (Use group A)

Intended use	Sugar and fodder beet
Metabolite	X11438848
Application rate (g/ha)	1 × 1.59 [1]
MAF	1.0

Test species	**ER_{50} (g/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Daucus carota	1.2	2.77 (1 m)	0.044	27

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1]: Calculated from the single application rate of 2 g a.s./ha, accounting for the molecular weights of florpyrauxifen-benzyl (i.e. 439.24) and X11438848 (i.e. 349.12).

As indicated in the EFSA Conclusions (EFSA Journal 2018; 16(7):5378), a specific assessment of the risk posed by the metabolites X12300837, X11966341, X12131932, X12393505 and X12483137 to non-target plants is not necessary in light of the lower toxicity of these metabolites compared to the active substance.

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

The risk assessment demonstrates that the use of F7B-39-30 on sugar and fodder beet is unlikely to result in an unacceptable risk to non-target terrestrial plants if it applied according to the intended GAP.

Evaluator comment:

The risk assessment for the formulation F7B-39-30 (Rinpode) was based on the worst endpoint for the representative formulated product GF-3206 (an emulsifiable concentrate (EC) containing 25 g/L florpyrauxifen-benzyl). The formulations can be considered equivalent.

The worst endpoints for the metabolite X11438848 was used for the risk assessment.
As indicated in the EFSA Conclusions (EFSA Journal 2018; 16(7):5378), a specific assessment of the risk posed by the metabolites X12300837, X11966341, X12131932, X12393505 and X12483137 to non-target plants is not necessary in light of the lower toxicity of these metabolites compared to the active substance. Therefore evaluator did not check the endpoints for other metabolites.

The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000) to calculate maximum off-field predicted environmental rates (PERoff-field).

The TER value for formulation is above the trigger of 1 (trigger of 1 was set at EU level).
The TER value for X11438848 is above the trigger of 5,

Conclusion:
The risk for the terrestrial plants following use of F7B-39-30 (Rinpode) could be considered as low.

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

No effects on other terrestrial organisms are anticipated if F7B-39-30 is applied according to the intended GAP.

9.12 Monitoring data (KCP 10.8)

Monitoring studies are not available for florpyrauxifen-benzyl and GF-3206 and are not considered necessary in light of the acceptable risk concluded for all non-target organisms from uses of F7B-39-30 in sugar and fodder beet at rates up to 1 × 2 g a.s./ha.

9.13 Classification and Labelling

Hazard class(es), categories	Aquatic Acute Cat. 1, Aquatic Chronic Cat.1	
Hazard pictograms or Code(s) for hazard pictogram(s)	 GHS 09	Triggered by H410
Signal word	Warning	Triggered by H410
Hazard statement(s)	H410 Very toxic to aquatic life with long lasting effects. H400 Very toxic to aquatic life	Triggered by study data.
Precautionary statement	P391 Collect spillage. P501 Dispose of contents/container in accordance with applicable regulations.	Recommended phrase. (H410) Recommended phrase. (H410)
Additional labelling phrases	EUH401 To avoid risks to human health and the environment, comply with the instructions for use.	All plant protection products subject to 1107/2009/EC shall also include this phrase.

Evaluator comments:
Evaluator agrees.

Based on the *Myriophyllum spicatum* E_rC_{50} equal to 0.919 µ/L and in accordance with the CLP Regulation the following classification for formulation is proposed:

Aquatic acute toxicity Category 1, H 400, Very toxic to aquatic life.

Based on the *Myriophyllum spicatum* NOEC equal to 0.0954 µg/L and in accordance with the CLP Regulation the following classification for formulation is proposed:

Aquatic chronic toxicity Category 1, H 410, Very toxic to aquatic life with long lasting effects.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 10.3.1.1.1/02	Amsel, K	2022	F7B-39-1 (GF-3206): Acute Contact and Oral Toxicity to the Bumblebee *Bombus terrestris* L. under Laboratory Conditions. BioChem agrar Labor für biologische und chemische Analytik GmbH, Germany. DAS Report No.: 220817 GLP/GEP (Y/N):Y Published (Y/N):N	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.1.1/01	[redacted]	2015	GF-3206: An Acute Oral Toxicity Study with the Northern Bobwhite Using a Sequential Testing Procedure [redacted] GLP/GEP (Y/N): Yes Published (Y/N): No	Y	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)

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
KCA 8.2.1/01	[redacted]	2015a	GF-3206: Acute Toxicity to the Common Carp, *Cyprinus carpio*, Determined Under Static-Renewal Test Conditions [redacted] GLP/GEP (Y/N): Yes Published (Y/N): No	Y	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCP 10.2.1/02	Lamichhane, K.	2015	GF 3206: Acute Toxicity to the Cladoceran, *Daphnia magna*, Determined Under Static Renewal Test Conditions DAS Report No.150488 ABC Laboratories, Inc. Columbia, Missouri, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCP 10.2.1/03	Aufderheide, J.	2015	GF-3206: Growth Inhibition Test with the Unicellular Green Alga, *Pseudokirchneriella subcapitata* DAS Report No.130425 ABC Laboratories, Inc. Columbia, Missouri, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCP 10.2.1/04	Mays, C.	2015	GF-3206: Growth Inhibition Test with the Freshwater Aquatic Plant, Duckweed, *Lemna gibba* DAS Report No.150487 ABC Laboratories, Inc. Columbia, Missouri, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCP 10.2.1/05	Gonsior, G.	2015	GF-3206: Growth Inhibition of *Myriophyllum spicatum* in a Water/Sediment System DAS Report No.150382 Eurofins Agroscience Services EcoChem GmbH, Niefern-Öschelbronn, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.1.1.1/01	Schmitzer, S.	2015	GF-3206: Acute contact and oral effects on honeybees (*Apis mellifera* L.) in the laboratory DAS Report No.150360 Ibacon GmbH, Rossdorf, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCA 8.3.1.1	Chwiesko, D.	2017	XDE-848 Benzyl Ester: Effects (Acute Contact and Oral) on Bumble bees (*Bombus terrestris* L.) in the Laboratory. DAS Report No. 170055 ibacon GmbH, Leverkusen, Germany GLP/GEP (Y/N):Y Published (Y/N):N	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCA 8.3.1.2	Vergé, E.	2017	GF-3206 - Assessment of Effects on the Adult Honey Bee, *Apis mellifera* L., in a 10 Day Chronic Feeding Test under Laboratory Conditions. DAS Report No. 170080 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Öschelbronn, Germany GLP/GEP (Y/N):Y Published (Y/N):N	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCA 8.3.1.3	Vergé, E.	2018	GF-3206 - Honey Bee (*Apis mellifera* L.) 22 Day Larval Toxicity Test (Repeated Exposure) DAS Report No. 170081 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Öschelbronn, Germany GLP/GEP (Y/N):Y Published (Y/N):N	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCA 9.3.2.1/01	Moll, M.	2015a	GF-3206: Effects on the Parasitoid *Aphidius rhopalosiphi* in the Laboratory (Tier I) - Dose Response Test DAS Report No. 130245 Institut für Biologische Analytik und Consulting IBACON GmbH, 64380 Rossdorf, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.2.1/02	Moll, M.	2015b	GF-3206: Effects on the Predatory Mite *Typhlodromus pyri* in the Laboratory (Tier 1) - Dose Response Test DAS Report No. 130246 Institut für Biologische Analytik und Consulting IBACON GmbH, 64380 Rossdorf, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCP 10.3.2.2/01	Vaughan, R.	2015	GF-3206: A rate-response extended laboratory study with the green lacewing *Chrysoperla carnea* (Neuroptera, Chrysopidae) DAS Report No.130247 Mambo-Tox Ltd., Southampton, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCP 10.3.2.2/02	Fallowfield, L.	2015	GF-3206: A rate-response extended laboratory bioassay of the effects of fresh residues on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae) DAS Report No.150327 Mambo-Tox Ltd., Southampton, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCP 8.4.1/02	Straube, D.	2015a	GF-3206: Effects on Reproduction and Growth of Earthworms *Eisenia fetida* in Artificial Soil DAS Report No.150331 ibacon GmbH, Rossdorf, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
~~KCA 8.4.2.1~~	~~Straube. D.~~	~~2018~~	~~Florpyrauxifen-benzyl: Effects on Reproduction of the Collembola *Folsomia candida* in Artificial Soil~~ ~~Study No. 180818[b]~~ ~~ibacon GmbH~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)~~

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
~~KCA 8.4.2.1~~	~~Straube. D.~~	~~2018~~	~~Florpyrauxifen-benzyl: Effects on Reproduction of the Predatory Mite *Hypoaspis aculeifer* in Artificial Soil with 5% Peat~~ ~~Study No. 180820[b]~~ ~~ibacon GmbH~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)~~
~~KCA 8.4.2.1~~	~~Wagenhoff, E.~~	~~2017~~	~~XDE-848 BE: Effects on the Reproductive Output of the Springtail *Folsomia candida* Willem (Collembola, Isotomidae) in different soils when the concentration of non-extractable residues is higher than 70%~~ ~~Study No. 160450[b]~~ ~~Eurofins Agroscience Services Ecotox GmbH~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)~~
~~KCA 8.4.2.1~~	~~Wagenhoff, E.~~	~~2018~~	~~X12300837: Effects on the Reproduction of the Springtail *Folsomia candida* Willem (Collembola, Isotomidae) in Artificial Soil~~ ~~Study No. 180819[b]~~ ~~Eurofins Agroscience Services Ecotox GmbH~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)~~
~~KCA 8.4.2.1~~	~~Wagenhoff, E.~~	~~2018~~	~~X12300837: Effects on the Reproduction of the Predatory Mite *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae) in Artificial Soil~~ ~~Study No. 180821[b]~~ ~~Eurofins Agroscience Services Ecotox GmbH~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)~~
~~KCA 8.4.1~~	~~Wagenhoff, E.~~	~~2018~~	~~X12300837: Effects on Reproduction of the Earthworm *Eisenia fetida* (Annellida, Lumbricidae) in Artificial Soil with 10% Peat~~ ~~Study No. 180822[b]~~ ~~Eurofins Agroscience Services Ecotox GmbH~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)~~

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4.2.1/01	Straube, D.	2015b	GF-3206: Effects on Reproduction of the Predatory Mite *Hypoaspis aculeifer* in Artificial Soil with 5% Peat DAS Report No.150330 ibacon GmbH, Rossdorf Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCP 10.4.2.1/02	Straube, D.	2015c	GF-3206: Effects on Reproduction of the Collembola *Folsomia candida* in Artificial Soil with 5% Peat DAS Report No.150329 ibacon GmbH, Rossdorf, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCP 10.5/01	Hammesfahr, U.	2015b	GF-3206: Effects on the Activity of the Soil Microflora in the Laboratory DAS Report No.150326 ibacon GmbH, Rossdorf, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCP 10.6.2/01	Lee, B.	2015b	GF-3206 (XDE-848 Benzyl, 25 g a.s./L, EC): Effects on the Vegetative Vigor of Non-Target Terrestrial Plants (Tier II) DAS Report No. 140394 ABC Laboratories, Inc., Columbia, Missouri 65202, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCP 10.6.2/02	Bergfield, A.	2015b	GF-3206 (XDE-848 Benzyl, 25 g a.s./L EC): Effects on the Seedling Emergence and Growth of Non-Target Terrestrial Plants (Tier II) DAS Report No. 140396 ABC Laboratories, Inc. 7200 E. ABC Lane Columbia, Missouri 65202 USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.4.2.1	Straube. D.	2018	Florpyrauxifen-benzyl: Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil with 5% Peat Study No. 180820b ibacon GmbH GLP Unpublished	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCA 8.4.2.1	Wagenhoff, E	2017	XDE-848 BE: Effects on the Reproductive Output of the Springtail Folsomia candida Willem (Collembola, Isotomidae) in different soils when the concentration of non-extractable residues is higher than 70% Study No. 160450b Eurofins Agroscience Services Ecotox GmbH GLP Unpublished	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCA 8.4.2.1	Wagenhoff, E.	2018	X12300837: Effects on the Reproduction of the Springtail Folsomia candida Willem (Collembola, Isotomidae) in Artificial Soil Study No. 180819b Eurofins Agroscience Services Ecotox GmbH GLP Unpublished	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont

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
					Crop Protection, and Dow AgroSciences)
KCA 8.4.2.1	Wagenhoff, E.	2018	X12300837: Effects on the Reproduction of the Predatory Mite Hypoaspis aculeifer Canestrini (Acari: Laelapidae) in Artificial Soil Study No. 180821b Eurofins Agroscience Services Ecotox GmbH GLP Unpublished	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCA 8.4.1	Wagenhoff, E.	2018	X12300837: Effects on Reproduction of the Earthworm Eisenia fetida (Annellida, Lumbricidae) in Artificial Soil with 10% Peat Study No. 180822b Eurofins Agroscience Services Ecotox GmbH GLP Unpublished	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection, and Dow AgroSciences)
KCP 10.4.2.1/01	Straube, D.	2015b	GF-3206: Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil with 5% Peat DAS Report No.150330 ibacon GmbH, Rossdorf Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience (bringing together the global heritage businesses of Pioneer, DuPont Crop Protection,

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
					and Dow AgroSciences)

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

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

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

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

No new study available.

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

No new study available.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

No new study available.

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

No new study available.

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

There is no EU guidance or validated regulatory protocol yet available on the type of the necessary regulatory testing for reptiles and amphibians.

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

No new study available.

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

Additional long-term and chronic toxicity studies on aquatic organisms conducted with the formulated product GF-3206 are not necessary since the acute toxicity of the formulated product to these organisms is not greater than expected, based on the toxicity of its active substance.

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

No new study available for honeybees. The acute contact toxicity of GF-3206 to bumblebees has been assessed in the same study in which the acute oral toxicity was assessed.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

The acute contact toxicity of GF-3206 to bumblebees has been assessed in the same study in which the acute oral toxicity was assessed.

A 2.3.1.1.3 F7B-39-1 (GF-3206): Acute Contact and Oral Toxicity to the Bumblebee *Bombus terrestris* L. under Laboratory Conditions

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information

Reference:	KCP 10.3.1.1.1/2
Report	F7B-39-1 (GF-3206): Acute Contact and Oral Toxicity to the Bumblebee Bombus terrestris L. under Laboratory Conditions; Amsel, K., 2022, Lab Study No. 22 48 BBA 0031; Sponsor Study No. 220817
Guideline(s):	OECD 247 (2017) and OECD 256 (2017)
Deviations:	No
GLP:	Yes
Acceptability:	Acceptable
Duplication (if vertebrate study)	Not applicable

Materials and methods

Test item(s)

Test item:	F7B-39-1 (GF-3206)
Purity:	2.7 wt% florpyrauxifen-benzyl
Description:	Liquid emulsifiable concentrate
Lot/batch no.:	D085I3ME02 TSN402339

Test system

Organism (Species):	Bumble bee (*Bombus terrestris*)	
Study type:	48-hour acute contact and oral toxicity test	
Study design:	Assessment of survival and sublethal effects. 60 (control) and 60 (test item) replicates per treatment for contact test; 30 (control) and 30 (test item) replicates per treatment for oral test. 1 individual per replicate.	
Age of test organism at initiation:	Adult worker bumble bees	
Test concentrations:	Contact: 0 (control), 1400.0 µg F7B-39-1 (GF-3206)/bumble bee. Oral (nominal): 0 (control), 800.0, 480.0, 288.0, 172.8 and 103.7 µg F7B-39-1 (GF-3206)/bumble bee. Oral (actual consumed): 0 (control), 673.5, 437.0, 273.7, 167.4 and 101.1 µg F7B-39-1 (GF-3206)/bumble bee.	
Information on bumble bee colony (health, etc.):	The bumblebees used in the test were from healthy and queen-right colonies, obtained from a commercial bumblebee breeding company (Biobest Belgium N.V., Ilse Velden 18, 2260 Westerlo, Belgium). The bumblebees were maintained in a clean cylindrical, latticed plastic cage.	
Feeding method:	Feeding with 50 % (w/v) aqueous sucrose solution was done *ad libitum* during acclimatisation and the test period (except starvation and feeding of application solutions in oral toxicity test).	
Environmental conditions:	Temperature:	Contact: 25.1 to 25.2°C Oral: 25.1 to 25.2°C
	Relative Humidity:	Contact: 60 to 63% Oral: 60 to 63%
	Photoperiod:	24 h darkness (except room light during treatment and observations)
Reference substance:	Dimethoate	

Dates of work: 01 September 2022 – 03 September 2022

Methodology

Contact In a 48 hours test, adults of Bombus terrestris were exposed to one dose rate of F7B-39-1 (GF-3206) in an appropriate carrier (0.5% (v/v) TritonX) placed on the dorsal bumblebee thorax. In total, 3 treatment groups were set up: 2 control groups, 1 dose rate of the test item and 1 dose rate of the reference item with 60 replicates per dose (30 replicates for reference item) and one bumblebee per replicate. Assessments of bumblebee mortality and behavioural effects were done after 4, 24 and 48 hours.

Oral: In a 48 hours test, adults of *Bombus terrestris* L. were exposed to five dose rates of F7B-39-1 (GF-3206) in treated food (50% (w/v) sucrose solution). In total, 3 treatment groups were set up: 1 control group, 5 dose rates of the test item and 1 dose rate of the reference item with 30 replicates per dose for the controls, test item as well as the reference item. Each replicate consists of 1 bumblebee. Assessments of bumblebee mortality and behavioural effects were done after 4, 24 and 48 hours.

For verification of the exposure concentration, the treatment solutions were analysed for concentrations of Florpyrauxifen-benzyl, active ingredient in GF-3206. The determination was conducted by an in-house developed method using reversed phase - high performance liquid chromatography (RP-HPLC) with tandem mass spectrometric (MS/MS) detection.

No statistical analysis was necessary since no control and test item mortality occurred during the contact and oral toxicity test.

Results and discussions

Analysis of the contact treatment solution yielded recoveries of 94.4% for florpyrauxifen-benzyl. Analysis of the oral treatment solution yielded recoveries of 86.5% to 102% for florpyrauxifen-benzyl. The results were evaluated based on nominal concentrations.

Contact test: No mortality or behavioural effects occurred in the control or the test item group within 48 hours.

Oral test: No mortality or behavioural effects occurred in the control or the test item group within 48 hours.

Study Validity

To demonstrate the validity of the study, the following conditions were fulfilled:

OECD Criteria	Required	Observed
Mean control mortality at the end of the test (Contact test)	≤10%	0.0%
Mean control mortality at the end of the test (Oral test)	≤10%	0.0%
Response to the reference toxicant (Contact test): Mean control mortality at the end of the test	≥50%	100%
Response to the reference toxicant (Oral test): Mean control mortality at the end of the test	≥50%	100%

Table A 2.3.1.1.1.2-1: Analytical verification of treatment solution (Contact test)

Treatment µg F7B-39-1 (GF-3206)/bumble bee	% of nominal
	Florpyrauxifen-benzyl
Control	<LOD
1400	94.4

LOQ = 4530 mg/L of florpyrauxifen-benzyl, LOD = 1009 mg/L of florpyrauxifen-benzyl

Table A 2.3.1.1.1.2-2: Analytical verification of treatment solution (Oral test)

Treatment µg F7B-39-1 (GF-3206)/bumble bee	Actual dose consumed µg F7B-39-1 (GF-3206)/bumble bee	% of nominal
		Florpyrauxifen-benzyl
Control		<LOD
800.0	673.5	101
480.0	437.0	101
288.0	273.7	102
172.8	167.4	86.5
103.7	101.1	102

LOQ = 27.8 mg/kg of florpyrauxifen-benzyl, LOD = 6.55 mg/kg of florpyrauxifen-benzyl

Table A 2.3.1.1.1.2-3: Mortality (Contact test)

Treatment µg F7B-39-1 (GF-3206)/ bumble bee	Cumulative mortality			
	24-hour		48-hour	
	Mean No. dead	Mean %	Mean No. dead	Mean %
Control	0	0.0	0	0.0
TritonX control	0	0.0	0	0.0
1400.0	0	0.0	0	0.0

Table A 2.3.1.1.1.2-4: Mortality (Oral test)

Treatment µg F7B-39-1 (GF-3206)/bumble bee	Actual dose consumed µg F7B-39-1 (GF-3206)/bumble bee	Cumulative mortality			
		24-hour		48-hour	
		No. dead	Mean %	No. dead	Mean %
Control		0	0.0	0	0.0
800.0	673.5	0	0.0	0	0.0
480.0	437.0	0	0.0	0	0.0
288.0	273.7	0	0.0	0	0.0
172.8	167.4	0	0.0	0	0.0
103.7	101.1	0	0.0	0	0.0

Table A 2.3.1.1.1.2-5: Sublethal effects (Contact test)

Treatment µg F7B-39-1 (GF-3206)/bumble bee	Cumulative sublethal effects			
	24-hour		48-hour	
	Effects (n)	%	Effects (n)	%
Control	AN	0	AN	0
Surfactant control	AN	0	AN	0
1400.0	AN	0	AN	0

AN: All appeared normal

Table A 2.3.1.1.1.2-6: Sublethal effects (Oral test)

Treatment µg F7B-39-1 (GF-3206)/bumble bee	Actual dose consumed µg F7B-39-1 (GF-3206)/bumble bee	Cumulative sublethal effects			
		24-hour		48-hour	
		Effects (n)	%	Effects (n)	%
Control		AN	0	AN	0
800.0	673.5	AN	0	AN	0
480.0	437.0	AN	0	AN	0
288.0	273.7	AN	0	AN	0
172.8	167.4	AN	0	AN	0
103.7	101.1	AN	0	AN	0

AN: All appeared normal

Table A 2.3.1.1.1.2-7: Effects of F7B-39-1 (GF-3206) on the bumble bee, *Bombus terrestris*

Endpoint type		Endpoint value µg F7B-39-1 (GF-3206)/bumble bee	95% confidence limits µg F7B-39-1 (GF-3206)/bumble bee
24-h contact	LD_{50}	> 1400.0	N/A
	NOED	1400.0	N/A
48-h contact	LD_{50}	> 1400.0	N/A

Endpoint type		Endpoint value µg F7B-39-1 (GF-3206)/bumble bee	95% confidence limits µg F7B-39-1 (GF-3206)/bumble bee
	NOED	1400.0	N/A
24-h oral	LD_{50}	> 673.5	N/A
	NOED	673.5	N/A
48-h oral	LD_{50}	> 673.5	N/A
	NOED	673.5	N/A

N/A: Not applicable, ND: not determined

Conclusion

The acute contact and oral toxicity of F7B-39-1 (GF-3206) was tested on bumblebees under laboratory conditions for a period of 48 hours.

For the contact test, the 24-hour and 48-hour LD_{50} values were > 1400.0 µg F7B-39-1 (GF-3206)/bumble bee and the 24-hour and 48-hour NOED values were 1400.0 µg F7B-39-1 (GF-3206)/bumble bee.

For the oral test, based on actual dose consumed, the 24-hour and 48-hour LD_{50} values were > 673.5 µg F7B-39-1 (GF-3206)/bumble bee and the 24-hour and 48-hour NOED values were 673.5 µg F7B-39-1 (GF-3206)/bumble bee.

Common name	Species	Test item	Time-scale	Endpoint	Toxicity value	Units of test item
Bumble bee	*Bombus terrestris*	F7B-39-1 (GF-3206)	48-hr - contact	LD_{50}	> 1400.0	µg/bumble bee
Bumble bee	*Bombus terrestris*	F7B-39-1 (GF-3206)	48-hr - oral	LD_{50}	> 673.5	µg/bumble bee

A 2.3.1.1.4 XDE-848 Benzyl Ester: Effects (Acute Contact and Oral) on Bumble bees (Bombus *terrestris* L.) in the Laboratory

Comments of zRMS:	Study was already evaluated and accepted by IT: OECD methods to rely on, are currently available, please consider OECD 246 and 247 as reference guidelines. Nonetheless study is acceptable, comparable methods have been considered. Contact: LD50:=24 and 48 hr) >100 µg a.s./bumble bee Oral: LD50=(24 and 48 hr) >110.1 µg a.s./bumble bee

Reference:	KCA 8.3.1.1
Report	XDE-848 Benzyl Ester: Effects (Acute Contact and Oral) on Bumble bees (*Bombus terrestris* L.) in the Laboratory, Chwiesko, D., 2017, Lab Study No. 119721105, DAS Report No. 170055
Guideline(s):	No, methods used comparable to guidelines OECD 213 and 214 with

	modifications and adaptions as described in Ring test bumble bee acute oral toxicity (ICPPR non-*Apis* group, 2015 and 2016)
Deviations:	No
GLP:	Yes
Acceptability:	Acceptable
Duplication (if vertebrate study)	Not applicable

Materials and methods

Test Item(s)

Test item:	XDE-848 benzyl ester (i.e. florpyrauxifen-benzyl)
Purity:	94.6% w/w
Description:	White solid
Lot/batch no.:	ENBK-135600-003 (TSN306037)

Test System

Organism (*Species*):	Bumble bee (*Bombus terrestris*)	
Study type:	Acute contact and oral laboratory study	
Study design:	Limit test; acute oral and contact toxicity test; duration 48 hours (contact and oral test); 50 replicates for test item, water control and solvent control and 30 replicates for reference item treatment group with 1 individual per replicate unit (contact and oral test); for the oral test individual bumble bees which did not take up at least 80% of the mean food uptake per treatment group were excluded from the evaluation; assessment of mortality after 4, 24 and 48 hours.	
Test concentrations:	Contact dose level: Oral nominal dose level: Oral measured dose level:	100 µg a.s./bumble bee 100 µg a.s./bumble bee 110.1 µg a.s./bumble bee
Information on bumble bee colony (health, etc.):	The bumble bees used in the test were from three healthy and queen-right colonies, obtained from a commercial bumble bee breeding company (Koppert B.V., Veilingweg 14, 2651 BE Berkel en Rodenrijs, Netherlands). The bumble bees were maintained in a clean cylindrical, latticed plastic cage.	
Feeding method:	50% w/v sucrose solution *ad libitum*; was given before and directly after treatment using syringes; replacements of the food was not necessary during the experimental time of the contact and oral test (48 h).	
Environmental conditions:	Temperature: Relative Humidity: Photoperiod:	Acclimatisation: 24 – 25°C Exposure: 24 – 25°C Acclimatisation: 40 – 63% Exposure: 40 – 64% 24 h darkness (except handling procedures, including treatment and observations)
Reference substance:	Contact dose level: Oral nominal dose level: Oral measured dose level:	10 µg dimethoate/bumble bee 4 µg dimethoate/bumble bee 5.0 µg dimethoate/bumble bee

Methodology

The studies comprised 4 treatment groups, one dose rate of the test item, water control, solvent control with 50 replicates and reference item with 30 replicates each containing 1 bumble bee. Under laboratory conditions the bumble bees were exposed to the test item by contact and oral application. In the oral test from 50 bumble bees per treatment group (test item, water control and solvent control) and 30 bumble bees for the reference item treatment group only those were taken into consideration for the evaluation which achieved at least 80% of the mean food uptake per treatment group. Mortality and sub-lethal effects were assessed at 4, 24, and 48 hours after treatment (contact and oral test).

Results and discussions

In the *contact test* the bumble bees were exposed to 100 µg a.s./bumble bee. At the end of the contact toxicity test (48 hours after application) 100 µg a.s./bumble bee led to no mortality. No mortality occurred also in the water control group (tap water containing 0.1% v/v Triton X-100). In the solvent control group (acetone) 2.0% mortality occurred.

No test item induced behavioural effects were observed at any time during the contact test.

In a contact-exposure laboratory test with the bumble bee *Bombus terrestris* L, the 24-h and 48-h NOED for XDE-848 Benzyl Ester was ≥100 µg a.s./bumble bee. As the test item treatment group did not show mortality above 50.0%, no statistical evaluation on the LD_{50} was carried out. The contact LD_{50} is considered as >100 µg a.s./bumble bee.

In the *oral test* the bumble bees were exposed to 110.1 µg a.s./bumble bee. For the oral test individual bumble bees which did not take up at least 80% of the mean food uptake per treatment group were excluded from the evaluation. At test end (48 hours after application) the actual oral dose of 110.1 µg a.s./bumble bee resulted in no mortality. No mortality occurred also in the water control group (50% w/v sucrose solution) and in the solvent control treatment group (50% w/v sucrose solution containing 5% w/w acetone and 1% v/v Tween 80). No test item induced behavioural effects were observed at any time during the oral test.

In an oral-exposure laboratory test with the bumble bee *Bombus terrestris* L., the 24-h and 48-h NOED for XDE-848 Benzyl Ester was ≥110.1 µg a.s./bumble bee. As the test item treatment group did not show mortality above 50.0%, no statistical evaluation on the LD_{50} was carried out. The oral LD_{50} is considered as >110.1 µg a.s./bumble bee.

Table A 2.3.1.1.1.1-1: Toxicity of XDE-848 Benzyl Ester to bumble bees in contact and oral toxicity test

Contact		Oral	
Application rate	48-hr Mortality (% mean)	Application rate [a]	48-hr Mortality (% mean)
XDE-848 benzyl ester: 100 µg a.s./bumble bee	0.0	Test Item: 110.1 µg a.s./bumble bee	0.0
Water Control: (tap water containing 0.1% v/v Triton X-100)	0.0	Water Control: (50% w/v sucrose solution)	0.0
Solvent Control: (acetone)	2.0	Solvent Control: (50% w/v sucrose solution containing 5% w/w acetone and 1% v/v Tween 80)	0.0
Reference Item: 10 µg dimethoate/bumble bee	93.3	Reference Item: 5.0 µg dimethoate/bumble bee	100.0
NOED: (24 and 48 hr) ≥100 µg a.s./bumble bee		NOED: (24 and 48 hr) ≥110.1 µg a.s./bumble bee	
LD_{50}: (24 and 48 hr) >100 µg a.s./bumble bee		LD_{50}: (24 and 48 hr) >110.1 µg a.s./bumble bee	

[a]: Based on consumed doses

Table A 2.3.1.1.1.1-2: Mortality and behavioural abnormalities of the bumble bees in the contact toxicity test

Treatment group	after 4 hours		after 24 hours		after 48 hours	
	Mortality	Beh. abnor.	Mortality	Beh. abnor.	Mortality	Beh. abnor.
	mean %	mean %	mean %	mean %	mean %	mean %
XDE-848 benzyl ester: 100 µg a.s./bumble bee	0.0	0.0	0.0	0.0	0.0	0.0
Water Control: (tap water containing 0.1% v/v Triton X-100)	0.0	0.0	0.0	0.0	0.0	0.0
Solvent Control: (acetone)	0.0	0.0	2.0	0.0	2.0	0.0
Reference Item: 10 µg dimethoate/bumble bee	3.3	34.5	86.7	100.0	93.3	100.0

Mortality mean: mean of 50 individuals per test item and controls, mean of 30 individuals for reference item
Behavioural abnormalities: mean of living individuals per treatment group

Table A 2.3.1.1.1.1-3: Mortality and behavioural abnormalities of the bumble bees in the oral toxicity test

Treatment group	after 4 hours		after 24 hours		after 48 hours	
	Mortality	Beh. abnor.	Mortality	Beh. abnor.	Mortality	Beh. abnor.
	mean %	mean %	mean %	mean %	mean %	mean %
XDE-848 benzyl ester: 110.1 µg a.s./bumble bee	0.0	0.0	0.0	0.0	0.0	0.0
Water Control: (50% w/v sucrose solution)	0.0	0.0	0.0	0.0	0.0	0.0
Solvent Control: (50% w/v sucrose solution containing 5% w/w acetone and 1% v/v Tween 80)	0.0	0.0	0.0	0.0	0.0	0.0
Reference Item: 5.0 µg dimethoate/bumble bee	28.0	88.9	100.0	-	100.0	-

Mortality mean: mean of 40 - 49 individuals per test item and controls, mean of 25 individuals for reference item
Behavioural abnormalities: mean of living individuals per treatment group
Considering only those bumble bees which achieved at least 80% of the mean food uptake per treatment group

Conclusion

Under laboratory conditions 50 worker bumble bees (*Bombus terrestris* L.) per treatment group were exposed to 100 µg a.s. per bumble bee by contact application and led to 0.0% mortality. In the solvent control group (acetone) 2.0% mortality occurred. No mortality occurred in the water control group (tap water containing 0.1% v/v Triton X-100). The contact LD_{50} for XDE-848 benzyl ester (i.e. florpyrauxifen-benzyl) is considered as >100 µg/bumble bee (24 and 48 h). The contact NOED (24 and 48 h) was calculated to be ≥100 µg/bumble bee.

For the oral test 40 bumble bees which achieved at least 80% of the mean food uptake of the test item treatment group were considering for the evaluation, this corresponded to the actual oral dose of 110.1 µg a.s./bumble bee (recommendations from ICPPR 2016) and resulted in 0.0% mortality. No mortality occurred in the water control (50% w/v sucrose solution) and in the solvent control group (50% w/v sucrose solution containing 5%

w/w acetone and 1% v/v Tween 80). The oral LD_{50} for XDE-848 benzyl ester (i.e. florpyrauxifen-benzyl) is considered as >110.1 µg a.s./bumble bee (24 and 48 h). The oral NOED (24 and 48 h) was calculated to be ≥110.1 µg a.s./bumble bee.
Mortality and sub-lethal effects were assessed at 4, 24, and 48 hours after treatment. No test item induced behavioural effects were observed at any time during the contact and oral test. The contact and oral test is considered valid as the control mortality in each case was <10% and the reference item mortality was ≥50%.

Common name	Species	Test item	Time-scale	Endpoint	Toxicity value	Units of test item
Bumble bee	*Bombus terrestris*	Florpyrauxifen-benzyl	48-hr - contact	LD_{50}	>100	µg/bumble bee
Bumble bee	*Bombus terrestris*	Florpyrauxifen-benzyl	48-hr - oral	LD_{50}	>110.1	µg/bumble bee

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	Study was already evaluated and accepted by IT: OECD methods to rely on, is currently available, please consider OECD 245 as reference guidelines. Nonetheless study is acceptable, considering OECD 245 all validity cciteria are met. 10 day LDD_{50} = 6.43 µg a.s./bee/day (5.95 – 6.95) 10 day LC_{50} =456 mg a.s./kg food (405 – 515)

Reference:	KCA 8.3.1.2
Report	GF-3206 - Assessment of Effects on the Adult Honey Bee, *Apis mellifera* L., in a 10 Day Chronic Feeding Test under Laboratory Conditions, Vergé, E., 2017, Lab Study No. S17-00195, DAS Report No. 170080
Guideline(s):	No, methods used comply with OECD guideline proposal (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Acceptable
Duplication (if vertebrate study)	Not applicable

Materials and methods

Test Item(s)

Test item:	GF-3206
Purity:	2.7% w/w florpyrauxifen-benzyl (i.e. 25 g/L)
Description:	Amber liquid

Lot/batch no.:	ENBK-163805-001 (TSN311359)

Test System

Organism (*Species*):	Honey bee (*Apis mellifera*)
Study type:	Chronic oral
Study design:	Dose-response test; duration 10 days; minimum 3 replicates, each consisting of 10 bees in one cage per test concentration; assessment of mortality, food consumption and behavioural effects daily.
Test concentrations:	0 (control), 62.5, 125, 250, 500 and 1000 mg a.s./kg diet, equivalent to daily dietary dosages of 1.69, 2.68, 4.33, 6.84 and 10.4 µg a.s./bee
Information on bee colony (health, etc.):	The bees used in the test were from a single, disease-free colony. The hive had not been treated for *Varroa* mites or for disease in the last 4 weeks. The bees were maintained in a clean holding cage at a temperature of approximately 35°C and 50 to 70% humidity.
Amount of treated diet consumed:	Consumption of the treated diets ranged from 27.1 to 10.4 mg of diet. Calculated daily dosages ranged from 1.69 to 10.4 µg a.s./bee.
Feeding method:	During holding/acclimation and after administration of the test dosages, bees were provided ad libitum a 500 g/L (w/v) sucrose solution in water. The bees for the definitive test were housed in cages containing pre-weighed feeders (syringes) containing approximately 400 mg of the appropriate control or treated solutions. All control and treatment feeders were exchanged daily with freshly prepared diet. Consumption of the feeding solutions was monitored by weighing the syringe before and after feeding, correcting for evaporation.
Environmental conditions:	Temperature: 32.3 – 33.1°C Relative Humidity: 51.0 – 66.3% Photoperiod: 24 h darkness (except handling procedures, including treatment and observations)
Reference substance:	0.9 mg dimethoate/kg diet
Solvent substance (if applicable):	0.1% Xanthan and 1% Tween 80

Methodology

Honey bees were exposed to a 50% (w/v) aqueous sucrose solution containing five concentrations of GF-3206 by continuous and *ad libitum* feeding over a period of 10 days. The control group was fed with pure 50% (w/v) aqueous sucrose solution. All feeding solutions contained 0.1% Xanthan and 1% Tween 80. Mortality and behavioural abnormalities were assessed daily during the 10 day exposure period. The chronic effects of GF-3206 were evaluated by comparing the results of the test item group to those of the control group. Additionally 4 test units without bees but with full food syringes containing pure 50% (w/v) aqueous sucrose solution containing 0.1% Xanthan and 1% Tween 80 were placed in the climatic chamber for the evaluation of the evaporation.

Results and discussions

In the control group, after 10 days of continuous feeding, no mortality occurred. After 10 days, the mortality was statistically significantly different with 62.5 and 100% at the concentrations of 500 and 1000 mg a.s./kg food, respectively.
The overall mean daily consumption of feeding solution over the entire test period was 27.1 mg/bee/day in the control group and 29.3 mg/bee/day in the solvent control group. At the concentrations of 62.5, 125, 250, 500 and 1000 mg a.s./kg food the overall mean daily consumption of feeding solution was 27.1, 21.5, 17.3, 13.7

and 10.4 mg/bee/day, respectively. The food consumption was statistically significantly different compared to the control group in the four highest test item groups.
At the end of the 10 day test period, the accumulated uptake of the test item at the concentrations of 62.5, 125, 250, 500 and 1000 mg a.s./kg food was 16.9, 26.9, 43.3, 68.4 and 70.2 µg a.s./bee/day, respectively. The corresponding daily mean uptake was 1.69, 2.68, 4.33, 6.84 and 10.4 µg a.s./bee, respectively.

Table A 2.3.1.2.1-1: Toxicity of GF-3206 to honey bees in the chronic oral toxicity test

Treatment		Mortality (%)									
Nominal (mg a.s./kg diet)	Measured daily mean (µg a.s./bee)	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
Control (0)	Control (0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
62.5	16.92	0.0	0.0	0.0	2.5	2.5	2.5	2.5	2.5	2.5	2.5
125	26.86	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	2.5
250	43.32	0.0	0.0	0.0	0.0	0.0	0.0	5.0	5.0	5.0	5.0
500	68.42	2.5	5.0	10.0	20.0	25.0	30.0	30.0	35.0	57.5	62.5
1000	70.19	2.5	27.5	40.0	60.0	72.5	92.5	100	100	100	100
Reference item		0.0	0.0	0.0	7.5	22.5	47.5	72.5	95.0	97.5	100
10 day LDD_{10}		4.49 µg a.s./bee/day (3.52 – 5.05)									
10 day LDD_{50}		6.43 µg a.s./bee/day (5.95 – 6.95)									
10 day NOEDD		4.33 µg a.s./bee/day									
10 day LC_{10}		265 mg a.s./kg food (180 – 317)									
10 day LC_{50}		456 mg a.s./kg food (405 – 515)									
10 day NOEC		250 mg a.s./kg food									

Table A 2.3.1.2.1-2: Effect of GF-3206 to diet consumption in honey bees in the chronic oral toxicity test

Treatment		Diet consumption (mg/day)									
Nominal (mg a.s./kg diet)	Measured daily mean (µg a.s./bee)	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
Control (0)	Control (0)	27.4	34.5	35.2	38.9	34.6	25.1	23.3	19.7	29.8	24.9
62.5	16.92	24.3	21.4	31.9	27.1	34.6	26.8	22.1	27.6	26.0	28.8
125	26.86	20.2	25.8	27.2	27.6	25.7	18.0	12.5	22.5	16.0	19.3
250	43.32	12.2	15.2	20.6	18.1	20.9	19.2	11.7	16.4	19.2	19.8
500	68.42	13.3	16.4	20.4	14.4	18.3	15.4	3.9	15.2	12.5	7.2
1000	70.19	9.4	14.3	12.8	14.5	11.3	7.9	0.0	-	-	-
Reference item		20.1	27.8	16.6	19.5	14.6	10.6	13.4	18.7	43.7	5.7
10 day NOEC		62.5 mg a.s./kg food									

(diet consumption)	

-: All bees were dead

Table A 2.3.1.2.1-3: Effect of GF-3206 on weight of surviving bees in honey bees in the chronic oral toxicity test

Treatment		Mean weight surviving bees (mg)			
Nominal (mg a.s./kg diet)	Measured daily mean (µg a.s./bee)	Replicate 1	Replicate 2	Replicate 3	Replicate 4
Control (0)	Control (0)	104.2	99.0	94.2	89.7
62.5	16.92	98.1	95.5	110.4	99.0
125	26.86	93.8	85.7	93.1	96.5
250	43.32	92.2	88.5	88.9	81.8
500	68.42	85.0	86.2	-	74.2
10 day NOEC (weight surviving bees)		62.5 mg a.s./kg food			

-: All bees were dead

Table A 2.3.1.2.1-4: Sublethal effects of GF-3206 to honey bees in the chronic oral toxicity test

Treatment		Behavioural abnormalities									
Nominal (mg a.s./kg diet)	Measured daily mean (µg a.s./bee)	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
Control (0)	Control (0)	1ap	0	0	0	0	0	1ap	0	0	0
62.5	16.92	0	0	1a, 2ap,1m	1a, 1ap		0	0	0	0	0
125	26.86	2ap	0	0	0	0	2ap	0	1a, 1h	0	1a
250	43.32	0	1a, 4ap	0	2ap	0	2ap	2ap	5a	1ap	0
500	68.42	2ap, 1m	3ap, 1m	1a, 4ap, 1m	3a, 2ap	4a	2ap	1a	1a, 1ap, 1m	1m	0
1000	70.19	3ap, 6m	1a, 2ap	2a, 5m	3a, 2m	1a, 1m	3a	-	-	-	-
Reference item		1a	3a	2a	2a	2a	6a	7a	2a	1a	-

a: affected; ap: apathy/lethargy; h: hyperactive; m: moribund
-: All bees were dead

Conclusion

It can be concluded that the continuous *ad libitum* feeding of honey bees in the laboratory over a period of 10 consecutive days with the test item GF-3206 at the treatment levels of 62.5, 125, 250, 500 and 1000 mg a.s./kg food (2315, 4630, 9259, 18519 and 37037 mg GF-3206/kg food) caused adverse effects regarding mortality, behavioural abnormalities and food consumption. No adverse effects regarding weight of surviving bees could be observed.

The LC_{10} and LDD_{10} after 10 days of continuous exposure were determined to be 265 mg a.s./kg food (9815 mg GF-3206/kg food) and 4.49 µg a.s./bee/day (166 µg GF-3206/bee/day), respectively.
The LC_{50} and LDD_{50} after 10 days of continuous exposure were determined to be 456 mg a.s./kg food (16889 mg GF-3206/kg food) and 6.43 µg a.s./bee/day (238 µg GF-3206/bee/day), respectively.
The NOEC for mortality after 10 days of continuous exposure was determined to be 250 mg a.s./kg food (9259 mg GF-3206/kg food). The corresponding NOEDD, based on the actual consumption of the respective feeding solutions, was determined to be 4.33 µg a.s./bee/day (160 µg GF-3206/bee/day).
The NOEC based on overall mean consumption of feeding solution after 10 days of continuous exposure was determined to be 62.5 mg a.s./kg food (2315 mg GF-3206/kg food).
The LOEC based on weight of surviving bees after 10 days of continuous exposure could not be statistically determined. Therefore the NOEC was considered to be ≥500 mg a.s./kg food (18519 mg GF-3206/kg food).

Common name	Species	Test item	Time-scale	Endpoint	Toxicity value	Units of test item
Honey bee	*Apis mellifera*	Florpyrauxifen-benzyl (tested as GF-3206)	10 days	LDD_{50}	6.43	µg a.s./bee/d

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

Comments of zRMS:	Study was already evaluated and accepted by IT: Please consider OECD DRAFT GD "Honey Bee (Apis mellifera) Larval Toxicity Test, Repeated Exposure, February 2014, as reference guidelines. Nonetheless study is acceptable. 22 days NOED = 4.82 µg a.s./larva/dev. period

Reference:	KCA 8.3.1.3
Report	GF-3206 - Honey Bee (*Apis mellifera* L.) 22 Day Larval Toxicity Test (Repeated Exposure), Vergé, E., 2018, Lab Study No. S17-00210, DAS Report No. 170081
Guideline(s):	No, methods used comply with OECD guidance document 239 (2016)
Deviations:	For the toxic reference item group only mortality was assessed. No emergence boxes were used as of day 15 to enable the assignment of each emerged bee to the respective replicate as the well plate containing the test organisms was covered with its lid. These deviations are not deemed to have an adverse impact on the study and the interpretation of its results.
GLP:	Yes
Acceptability:	Acceptable
Duplication (if vertebrate study)	Not applicable

Materials and methods

Test Item(s)

Test item:	GF-3206
Purity:	2.7% w/w florpyrauxifen-benzyl (i.e. 25 g/L)
Description:	Amber liquid
Lot/batch no.:	ENBK-163805-001 (TSN311359)

Test System

Organism (*Species*):	Honey bee (*Apis mellifera*)
Study type:	Chronic larval – repeated exposure
Study design:	Dose-response test; duration 22 days; 3 or more replicates, each starting with at least 12 synchronised first instar larvae per test concentration; assessment of mortality and behavioural effects daily after administration of the test item on days 3, 4, 5, and 6 and on days 7, 8, 15 and 22. Visual assessment of uneaten food on day 8 prior to transfer of plate into pupal desiccator. Monitoring of pupal development and adult emergence (eclosion) until day 22. Weighing of emerged bees on day 22.
Test concentrations:	0 (control), 0 (solvent control), 15.6, 31.3, 62.5, 125 and 250 mg a.s./kg diet, equivalent to 0 (control), 0 (solvent control), 2.40, 4.82, 9.63, 19.3 and 38.5 µg a.s./larva per developmental period
Information on bee colony (health, etc.):	The larvae used in the test were from three disease-free colonies (one per replicate). The hive had not been treated for *Varroa* mites or for disease for at least 4 weeks prior to study initiation.
Analytical verification:	Florpyrauxifen-benzyl and florpyrauxifen acid were analysed in the stock solution, the test item solutions and solvent control solution as well as in the test item treated larval diet and the diet of the control group and solvent control group by liquid chromatography and mass spectrometric detection (HPLC-MS/MS). Additional verification of the homogeneity (top and bottom sampling of treated diet) and stability (sampling at 24 ± 1 hours after preparation) of the test item in the larval diet. The analytical verification of florpyrauxifen-benzyl and florpyrauxifen acid resulted in recoveries of 85 to 113% (solutions) and 82 to 98% (diet) of the nominal values for florpyrauxifen-benzyl ester, as well as 0.0117 to 0.104% (solutions) and <LOD (diet) of the nominal values for florpyrauxifen-benzyl acid. Thus, the concentration of the test item in the larval diet was confirmed. The concentrations of florpyrauxifen-benzyl in the homogeneity samples taken from the top and bottom of the treated diet of the highest and lowest test item group were equivalent to recoveries of 88 to 95%. No florpyrauxifen acid could be detected in the homogeneity samples taken from the top and bottom of the treated diet of the highest and lowest test item group. The measured recovery rate of florpyrauxifen-benzyl and florpyrauxifen acid in the aged larval diet was 92 and 0.138%, respectively. Therefore, the stability of the test item in the larval diet was proven for this period.
Feeding method:	Three different diets (A, B and C) were administered depending on the developmental stage of the larvae. The diets were based on 50% fresh royal jelly and 50% aqueous solution containing variable amounts of yeast extract, glucose and fructose in the three diets. The feeding solutions were prepared as needed. Diets A and B (20 µL/larvae, each) were administered on days 1 and 3, respectively. Diet C was administered once on days 4 to 6 in increasing volumes

	of 30 to 50 µL/larvae. The test item was administered on days 3, 4, 5 and 6 homogeneously dispersed in 20 to 50 µL/larvae of diet B or C depending upon the day of incubation.	
Environmental conditions:	Temperature:	32.9 – 35.1°C
	Relative Humidity:	70.2 – 100.0% (days 1 to 8) 58.7 – 85.4% (days 8 to 15) 36.8 – 75.4% (days 15 to 22)
	Photoperiod:	24 h darkness (except handling procedures, including grafting, feeding and observations)
Reference substance:	1. 48.0 mg dimethoate/kg diet, or 7.39 µg dimethoate/larva per developmental period 2. 0.320 mg fenoxycarb/kg diet, or 0.0493 µg fenoxycarb/larva per developmental period	

Methodology

On day 1 synchronised honey bee larvae (first instar, L1) were taken from the combs of 3 hives and were individually transferred into well-plates, where they were fed a standardised amount of artificial diet. From day 3 until day 6 GF-3206 was administered daily to the larvae in the diet in a range of increasing concentrations, which remained constant during the application period. The presence of uneaten food was qualitatively recorded on day 8. Cumulative mortalities during the larval phase were assessed daily from day 4 until day 8. Cumulative mortalities during the pupation phase were assessed on day 15 and on day 22. The adult emergence rate was assessed on day 22. Additionally, the weight of emerged bees was assessed on day 22. Other observations and any other adverse effects were recorded in comparison to the solvent control group.

Results and discussions

On day 8 the cumulative mortality was 6.3% in the control, 14.6% in the solvent control, 95.8% in the dimethoate reference item group and 6.3% in the fenoxycarb reference item group. On day 22, the adult emergence rate in the control and solvent control group was 75.0 and 70.8%, respectively. The adult emergence rate in the fenoxycarb reference item group was 2.1%.
Compared to the control group, the adult emergence rate on day 22 was statistically significantly different in the test item group dosed at 62.5 mg a.s./kg diet (Cochran-Armitage test with Rao-Scott adjustment, one sided greater, $\alpha = 0.05$). Therefore, the NOEC for adult emergence on day 22 was determined as 31.3 mg a.s./kg diet, equivalent to a NOED of 4.82 µg a.s./larva per developmental period.

Table A 2.3.1.3.1-1: Toxicity of GF-3206 to honey bee larvae in a chronic exposure toxicity test

Nominal treatment		Mortality (%) [corrected mortality (%)]		Emergence (%)
mg a.s./kg diet	µg a.s./larva/ dev. period	Day 8	Day 15	Day 22
Control (0)	Control (0)	6.3 [N/A]	25.0. [N/A]	75.0
Solvent control (0)	Solvent control (0)	14.6 [N/A]	27.1 [N/A]	70.8
15.6	2.40	2.1 [-4.5]	18.8 [-8.3]	81.3
31.3	4.82	4.2 [-2.2]	25.0 [0.0]	72.9
62.5	9.63	14.6* [8.9]	47.9 [30.5]	52.1*
125	19.3	39.6* [35.5]	66.7* [55.6]	29.2*
250	38.5	100* [100]	100* [100]	0.0*
Reference item 1 (7.39 µg		95.8 [95.5]	--	--

dimethoate/larva/dev. period)			
Reference item 2 (0.0493 µg fenoxycarb/larva/dev. period)	6.3 [-9.7]	18.8 [-11.4]	2.1
22 day NOED (nominal)	4.82 µg a.s./larva/developmental period (equivalent to 31.3 mg a.s./kg diet)		

N/A: not applicable; --: All bees were dead
*: Significantly different from the control

Table A 2.3.1.3.1-2: Uneaten food, developmental and behavioural effects in the chronic exposure larval toxicity test for GF-3206

Nominal treatment		Uneaten food observed on day 8	Behavioural effects (day)	Developmental effects (day)
mg a.s./kg diet	µg a.s./larva/ dev. period			
Control (0)	Control (0)	No	None	None
Solvent control (0)	Solvent control (0)	Yes	None	None
15.6	2.40	No	None	None
31.3	4.82	Yes	None	None
62.5	9.63	Yes	None	None
125	19.3	Yes	None	None
250	38.5	N/A	None	None
Reference item 1 (7.39 µg dimethoate/larva/dev. period)		Yes	None	None
Reference item 2 (0.0493 µg fenoxycarb/larva/dev. period)		Yes	None	None

N/A: not applicable

Conclusion

In a repeated exposure larval toxicity test with GF-3206 and a duration of 22 days, the NOEC for adult emergence was determined as 31.3 mg a.s./kg diet, equivalent to a NOED of 4.82 µg a.s./larva per developmental period.
The study was deemed valid since all validity criteria were met

Common name	Species	Test item	Time-scale	Endpoint	Toxicity value	Units of test item
Honey bee	*Apis mellifera*	Florpyrauxifen-benzyl (tested as GF-3206)	22 days	NOED	4.82	µg a.s./larva/dev. period

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

The toxicity of florpyrauxifen-benzyl and the formulated product GF-3206 have been adequately characterised in lower tier studies. In addition an acceptable risk assessment was concluded for the proposed uses of F7B-39-30. No additional study is therefore considered necessary.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

The toxicity of florpyrauxifen-benzyl and the formulated product GF-3206 have been adequately characterised in lower tier studies. In addition an acceptable risk assessment was concluded for the proposed uses of F7B-39-30. No additional study is therefore considered necessary.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

The toxicity of florpyrauxifen-benzyl and the formulated product GF-3206 have been adequately characterised in lower tier studies. In addition an acceptable risk assessment was concluded for the proposed uses of F7B-39-30. No additional study is therefore considered necessary.

A 2.3.1 KCP 10.3.2 Effects on non-target arthropods other than bees

A 2.3.1.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

No new study available.

A 2.3.1.2 KCP 10.3.2.2 Extended laboratory testing, aged residues studies with non-target arthropods

No new study available.

A 2.3.1.3 KCP 10.3.2.3 Semi-field studies with non-target arthropods

The toxicity of florpyrauxifen-benzyl and the formulated product GF-3206 have been adequately characterised in lower tier studies. In addition an acceptable risk assessment was concluded for the proposed uses of F7B-39-30. No additional study is therefore considered necessary.

A 2.3.1.4 KCP 10.3.2.4 Field studies with non-target arthropods

The toxicity of florpyrauxifen-benzyl and the formulated product GF-3206 have been adequately characterised in lower tier studies. In addition an acceptable risk assessment was concluded for the proposed uses of F7B-39-30. No additional study is therefore considered necessary.

A 2.3.1.5 KCP 10.3.2.5 Other routes of exposure for non-target arthropods

All the relevant routes of exposure of non-target arthropods to florpyrauxifen-benzyl have been evaluated.

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

A 2.4.1 KCP 10.4.1 Earthworms

No new study available.

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

No new study available.

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

The toxicity of florpyrauxifen-benzyl and the formulated product GF-3206 have been adequately characterised in lower tier studies. In addition an acceptable risk assessment was concluded for the proposed uses of F7B-39-30. No additional study is therefore considered necessary.

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

A 2.4.2.1 KCP 10.4.2.1 Species level testing

No new study available.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

The toxicity of florpyrauxifen-benzyl and the formulated product GF-3206 have been adequately characterised in lower tier studies. In addition an acceptable risk assessment was concluded for the proposed uses of F7B-39-30. No additional study is therefore considered necessary.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

No new study available.

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

A 2.6.1 KCP 10.6.1 Summary of screening data

Since florpyrauxifen-benzyl has herbicidal activity, screening data is not relevant for this active substance.

A 2.6.2 KCP 10.6.2 Testing on non-target plants

No new study available.

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

The toxicity of florpyrauxifen-benzyl and the formulated product GF-3206 have been adequately characterised in lower tier studies. In addition adequate risk mitigations were identified to conclude an acceptable risk to non-target plants for the proposed uses of F7B-39-30. No additional study is therefore considered necessary.

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

No new study available.

A 2.8 KCP 10.8 Monitoring data

Monitoring studies are not available for florpyrauxifen-benzyl and are not considered necessary in light of the acceptable risk concluded for all non-target organisms from uses of F7B-39-30.