

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: K-300SL-RR

Product name(s): Faworyt 300 SL

Chemical active substance:

clopyralid, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT – Art 43

(Renewal of authorisation)

Applicant: CIECH Sarzyna S.A.

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPS

[illegible]

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Minor uses according to Article 51 (interzonal uses)																				

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

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

Explanation for column 15 – 21 “Conclusion”

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

Remarks table:

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

9.1.1 Overall conclusions

zRMS comment:

This report was prepared following renewal of the active substance clopyralid. As a result all authorisations of plant protection products containing clopyralid have to be renewed in order to comply with the new list of endpoints EFSA Journal 2018;16(7):5389.

This document is based on the information provided by Applicant and reflects the Applicant's opinion. Clarifications and conclusions of the zRMS are presented in the commenting boxes.

Amendments/corrections by zRMS are marked in blue.

The zRMS has focused the review on the elements which are crucial for the risk assessment and decision-making; hence, minor errors of no importance for the overall conclusion, or the specific phrasing of the text may not have been commented upon. Not agreed or not relevant information is struck through and shaded for transparency.

9.1.1.1 No metabolites of MCPA were observed or identified Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

The risk assessment 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).

The risk assessment performed for birds and mammals indicate acceptable acute and long-term risk to birds and mammals exposed to clopyralid following application of Faworyt 300 SL acc. to intended GAP.

Regarding effects on other terrestrial vertebrate wildlife (reptiles and amphibians), no data/information available.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

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 risk for aquatic organisms from exposure to clopyralid applied as Faworyt 300 SL in winter wheat, rape and sugar beet is indicated to be acceptable based on Tier 1 data and FOCUS Step 1 calculations. No mitigation is required.

9.1.1.3 Effects on bees (KCP 10.3.1)

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 (SAN-

CO/10329/2002 rev.2 (final), October 17, 2002).

Effects on bees of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid. Faworyt 300 SL was tested in acute (oral and contact exposure) and chronic studies (oral exposure of adults and larvae). Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of this part of Section.

The acute risk assessments for the active substance as well as for the formulated product Faworyt 300 SL with Hazard Quotients well below the trigger for acceptability of effects indicate an acceptable risk for bees exposed in accordance with the intended uses in winter wheat, winter rape and sugar beet.

In addition, the chronic study for adult bees and chronic study for larvae were submitted according to EU Reg. 284/2009 and should be considered further at MSs level.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

The evaluation of the risk for non-target arthropods was principally 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.

Effects on non-target arthropods other than bees of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid. Faworyt 300 SL was tested on *Aphidius rhopalosiphii* (Tier 1 data and 2 data), *Typhlodromus pyri* (Tier 1) and *Chrysoperla carnea* (Tier 2 data). Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of this part of Section.

The in-field and off-field risk from exposure to clopyralid applied as Faworyt 300 SL for the in-tended uses in winter wheat, winter rape and sugar beet is indicated to be acceptable for non-target arthropods other than bees based on Tier 2 data without the need for risk mitigation measures.

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

The risk assessment was conducted according to the Guidance Document on Terrestrial Ecotoxicology (2002).

The risk from exposure to clopyralid applied as Faworyt 300 SL for all intended uses (risk envelope: 1 x 120 g a.s./ha for wheat within BBCH stage of 21-29) is indicated to be acceptable for the soil meso-/macrofauna and soil microflora.

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

The risk assessment was based on the “Guidance Document on Terrestrial Ecotoxicology” (SANCO/10329/2002 rev.2 final, 2002).

For all intended used of Faworyt 300 SL the risk for non-target plants in the off-crop area is indicated to be acceptable when either 50% drift reduction or a 5 m unsprayed buffer strip zone is applied to non-crop land.

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

No further relevant data available and considered necessary.

9.1.2 Grouping of intended uses for risk assessment

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

Table 9.1-2: Critical use pattern of Faworyt 300 SL grouped according to criterion

Grouping according to criterion			
Group	Intended uses	relevant use parameters for grouping	relevant parameter or value for sorting
1	Winter wheat, BBCH 21-29	-highest PEC soil for clopyralid and Faworyt 300 SL	- risk assessment for soil organisms
2	Winter wheat, BBCH 21-29 Winter rape, BBCH 10-50	- the highest exposure scenario	- risk assessment for bees, arthropods other than bees
3	Winter wheat, BBCH 21-29	-highest PEC _{sw} for clopyralid and Faworyt 300 SL	- risk assessment for aquatic organisms

9.1.3 Consideration of metabolites

No metabolites of clopyralid were observed or identified.

9.2 No metabolites of MCPA were observed or identified Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with clopyralid and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid. 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
Mallard duck	clopyralid	Acute	LD ₅₀ = 1465 mg/kg bw/day	EFSA Journal 2018;16(7):5389
Mallard duck	clopyralid	Long-term	NOEC = 118 mg/kg bw/day	EFSA Journal 2018;16(7):5389

9.2.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

9.2.2 Risk assessment for spray applications

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

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

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

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of Faworyt 300SL in all intended uses

Intended use		Cereals/ Oilseed rape				
Active substance/product		clopyralid				
Application rate (g/ha)		1 × 120 (cereals, oilseed rape) 1 x 90 (sugar beet)				
Acute toxicity (mg/kg bw)		1465				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Cereals/ Oilseed rape	Small omnivorous bird	158.8	1	19.1	76.7	
Sugar beet				14.3	102.4	
Reprod. toxicity (mg/kg bw/d)		118				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _t	
Cereals/ Oilseed rape	Small omnivorous bird	64.8	1 x 0.53	4.1	28.8	
Sugar beet				3.1	38.1	

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

zRMS comment:

The risk assessment at screening step is considered acceptable. 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).

Safe use of clopyralid for birds were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively. Based on the intended use on for Faworyt 300 SL no unacceptable risk for birds is expected from acute or long-term exposure.

9.2.2.2 Higher-tier risk assessment

No higher-tier risk assessment required

9.2.2.3 Drinking water exposure

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

Leaf scenario

Since Faworyt 300 SL is not a product for spray applications / not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

C_{spray-sol}: concentration in spray solution; PEC_{leaf-whorl}: concentration in pools in leaf whorls; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

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 1.41, clopyralid belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals and oilseed rape also covers the risk for birds from all other intended uses in groups sugar beet (see 9.1.2).

Effective application rate (g/ha) =	120			
Acute toxicity (mg/kg bw) =	1465	quotient	=	0.08
Reprod. toxicity (mg/kg bw/d) =	118	quotient	=	1.02

zRMS comment:

We agree that since the ratio of the total annual application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the relevant critical value for at least one use scenario, a quantitative risk assessment (calculation of TER values) is not necessary.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of clopyralid amounts to -2.63 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

zRMS comment:

The risk assessment for earthworm-eating birds via secondary poisoning is not required as active substance has $\log P_{ow} < 3$.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

zRMS comment:

The risk assessment for fish-eating birds via secondary poisoning is not required as active substance has $\log P_{ow} < 3$.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.2.4 Overall conclusions

There is no potential risk for birds resulting from acute exposure or long-term exposure to active substance following use of Faworyt 300 SL in compliance with GAP.

zRMS comment:

The acute and chronic risks of Faworyt 300 SL to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active substances, and maximum residues occurring on food items.

For active substance all TER values exceed the relevant triggers indicating that Faworyt 300 SL does not pose an unacceptable risk to birds following applications according to recommended use pattern. Evaluation of exposing to mammals through the drinking water demonstrated the acceptable risk.

The risk to earthworm - and fish-eating animals from secondary poisoning is low.

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 clopyralid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid.

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

Species	Substance	Exposure System	Results	Reference
Rat	clopyralid	Acute	LD ₅₀ > 5000 mg/kg bw/day	EFSA Journal 2018;16(7):5389
Rat	clopyralid	Long-term	NOAEL = 50 mg/kg bw/day	EFSA Journal 2018;16(7):5389

9.3.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.3.2 Risk assessment for spray applications

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

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

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

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Faworyt 300 SL in all intended uses.

Intended use		Cereals/ oilseed rape			
Active substance/product		clopyralid			
Application rate (g/ha)		1 × 120 (cereals, oilseed rape) 1 x 90 (sugar beet)			
Acute toxicity (mg/kg bw)		> 5000			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
cereals, oilseed rape	Small herbivorous mammals	118.4	1	14.2	> 352.1

sugar beet				10.7	467.3
Reprod. toxicity (mg/kg bw/d)	50				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
cereals, oilseed rape	Small herbivorous mammals	48.3	1 x 0.53	3.1	16.1
sugar beet				2.3	21.7

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

zRMS comment:

The risk assessment at screening step is considered acceptable. 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).

Safe use of clopyralid for mammals were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively.

Based on the intended use on for Faworyt 300 SL no unacceptable risk for mammals is expected from acute or long-term exposure.

9.3.2.2 Higher-tier risk assessment

No higher-tier risk assessment required

9.3.2.3 Drinking water exposure

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

Puddle scenario

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

With a $K(f)_{oc}$ of 1.41, clopyralid belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals and oilseed rape also covers the risk for birds from all other intended uses in groups sugar beet (see 9.1.2).

Effective application rate (g/ha) =	120		
Acute toxicity (mg/kg bw) =	>5000	quotient	= 0.02
Reprod. toxicity (mg/kg bw/d) =	50	quotient	= 2.4

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of clopyralid amounts to -2.63 and thus does not 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

Not required.

zRMS comment:

The risk assessment for earthworm - eating mammals via secondary poisoning is not required as active substance has $\log P_{ow} < 3$.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

zRMS comment:

The risk assessment for fish - eating mammals via secondary poisoning is not required as active substance has $\log P_{ow} < 3$.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.3.4 Overall conclusions

There is no potential risk for mammals resulting from acute exposure or long-term exposure to active substance following use of Faworyt 300 SL in compliance with GAP.

zRMS comment:

The acute and chronic risks of Faworyt 300 SL to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active substance, and maximum residues occurring on food items. For active substance all TER values exceed the relevant triggers indicating that Faworyt 300 SL does not pose an unacceptable risk to mammals following applications according to recommended use pattern. Evaluation of exposing to mammals through the drinking water demonstrated the acceptable risk. The risk to earthworm - and fish-eating animals from secondary poisoning is low.

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

No additional new data is submitted. Refer to the EU review of the active substance.

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 Clopyralid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid.

New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	Clopyralid	96 h	LC ₅₀ = 99.9 mg a.s./L _{mm}	EFSA Journal 2018;16(7):5389
<i>Pimephales promelas</i>	Clopyralid	NOEC	NOEC = 10.8 mg a.s./L _{mm}	EFSA Journal 2018;16(7):5389
<i>Daphnia magna</i>	Clopyralid	48 h	EC ₅₀ > 99.0 mg a.s./L _{mm}	EFSA Journal 2018;16(7):5389
<i>Daphnia magna</i>	Clopyralid	21 d	NOEC = 17 mg a.s./L _{mm}	EFSA Journal 2018;16(7):5389
<i>Daphnia magna</i>	Clopyralid	21 d	NOEC = 23.5 mg a.s./L _{mm}	EFSA Journal 2018;16(7):5389
<i>Chironomus riparius</i>	Clopyralid	28 d, s	NOEC = 50 mg a.s./L _{nom}	EFSA Journal 2018;16(7):5389
<i>Selenastrum capricornutum</i>	Clopyralid	72 h, s	E _b C ₅₀ = 30.9 mg a.s./L _{mm} E _r C ₅₀ =30 mg a.s./L	EFSA Journal 2018;16(7):5389
<i>Navicula pelliculosa</i>	Clopyralid	72 h	ErC ₅₀ = 31.3 mg a.s./L _{mm}	EFSA Journal 2018;16(7):5389
<i>Navicula pelliculosa</i>	Clopyralid	72 h	ErC ₅₀ = 31.5 mg a.s./L _{mm}	EFSA Journal 2018;16(7):5389
<i>Lemna gibba</i>	Clopyralid	14 d	EC ₅₀ = 89 mg a.s./L _{mm}	EFSA Journal 2018;16(7):5389

Species	Substance	Exposure System	Results	Reference
<i>Myriophyllum spicatum</i>	Clopyralid	14 d	ErC ₅₀ > 3.0 mg a.s./L _{mm}	EFSA Journal 2018;16(7):5389
Higher-tier studies (micro- or mesocosm studies)				
-				

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

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Faworyt 300 SL

Species	Substance	Exposure System	Results	Reference
<i>Rainbow trouts</i>	Chlopyralid 300 SL (Faworyt 300 SL)	96 h, s	LC ₅₀ > 1000 mg/L _{nom}	P. Fochtman, 2001 a*; Stuy code: W/10/01;
<i>Daphnia magna</i>	Chlopyralid 300 SL (Faworyt 300 SL)	48 h, s	EC ₅₀ > 1000 mg/L _{nom}	P. Fochtman, 2001 b*; Stuy code: W/10/01;
<i>Scenedesmus subspicatus</i>	Chlopyralid 300 SL (Faworyt 300 SL)	72 h, s	IC ₅₀ = 65.2 mg/L _{nom} IC ₅₀ = 16.73 mg as/L _{nom} NOEC = 10 mg/L**	P. Fochtman, 2001 c*; Stuy code: W/10/01
<i>Navicula pelliculosa</i>	Faworyt 300 SL	72 h, s	ErC ₅₀ > 100 mg/L _{nom} ErC ₅₀ > 26.07 mg a.s./L _{nom} EyC ₅₀ = 61.298 mg/L _{nom} EyC ₅₀ = 15.98 mg a.s. /L _{nom} NOEC = 12.50 mg/L _{nom}	Freshwater alga growth inhibition test; A. Woźniak; 2019; study code: 0016/0057/E
<i>Daphnia magna</i>	Faworyt 300 SL	21 d, s	NOEC ≥ 100.0 mg/L _{nom} NOEC > 26.07 mg a.s./L _{nom}	Faworyt 300 SL Reproduction test of <i>Daphnia magna</i> according to guideline OECD 211; A. Woźniak; 2019; study code: 0016/0058/E
<i>Myriophyllum spicatum</i>	Faworyt 300 SL	14 d,s	ErC₅₀ = 10.038 mg/L_{mm} ErC ₅₀ = 2.68 mg a.s./L _{mm} (average specific growth rate for dry weight) NOEC = 9.53 mg /L	Faworyt 300 SL Water-sediment <i>Myriophyllum spicatum</i> toxicity test according to OECD 239; A. Kamińska; 2019; study code: 0016/0061/E

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

*The studies previously evaluated for PL registration of the product Faworyt 300 SL.

** estimated by zRMS

9.5.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.5.2 Risk assessment

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

The relevant global maximum FOCUS Step 1 and 2 for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below. Assessments are provided for the worst case max PEC_{sw} resulted from Faworyt 300SL use in winter cereals.

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for clopyralid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Faworyt 300 SL in winter cereals (worst case of maxPEC_{sw}).

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Algae	Sed. dwell. prolonged	Aquatic plants	Faworyt 300 SL
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Selenastrum capricornutum</i>	<i>Selenastrum capricornutum</i>	<i>Chironomus riparius</i>	<i>M. Spicatum</i>	<i>M. Spicatum</i> Formulation endpoint to the most sensitive organism
End-point (µg/L)		LC ₅₀	NOEC	EC ₅₀	NOEC	E ₅₀ C ₅₀	E ₅₀ C ₅₀	NOEC	ErC ₅₀	ErC ₅₀
AF		99900	10800	99000	17000	30900	30000	50000	3000	2680
RAC (µg/L)		100	10	100	10	10	10	10	10	10
		999	1080	990	1700	3090	3000	5000	300	268
FOCUS Scenario	PEC _{gl-max} (µg/L)									
Step 1										
	41.029	0.04	0.04	0.04	0.02	0.01	0.013	0.01	0.14	0.15
Step 2										
N-Europe	5.4101	-	-	-	-	-	-	-	-	-

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

For the intended uses of clopyralid applied as Faworyt 300 SL in winter wheat, rape and sugar beet the calculated PEC/RAC ratio for clopyralid did indicate an acceptable risk for all aquatic organisms at FOCUS Step 1. No further calculations are required.

zRMS comment:

The evaluation of the risk for aquatic 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” (EFSA Journal 2013;11(7):3290).

The ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PEC_{SED}) and regulatory acceptable concentrations (RAC) for a.s.- clopyralid and for product Faworyt 300 SL based on the worst case for aquatic organisms were <1 indicating acceptable risk to aquatic organism.

9.5.3 Overall conclusions

The risk for aquatic organisms from exposure to clopyralid applied as Faworyt 300 SL in winter wheat, rape and sugar beet is indicated to be acceptable based on Tier 1 data and FOCUS Step 1 calculations. No mitigation is required.

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 clopyralid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of Faworyt 300 SL were not evaluated as part of the EU assessment of active substance clopyralid. New data submitted with this application are listed in **Błąd! Nie można odnaleźć źródła odwołania.** and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	clopyralid	Oral	LD ₅₀ > 100 µg a.s /bee	EFSA Conclusion 2018;16(7):5389,
<i>Apis mellifera</i>	clopyralid	Contact	LD ₅₀ > 98.1 µg/bee	EFSA Conclusion 2018;16(7):5389,
<i>Apis mellifera</i>	clopyralid	Chronic oral	LDD ₅₀ > 71.2 µg a.i/bee/day	EFSA Conclusion 2018;16(7):5389,
<i>Apis mellifera</i>	clopyralid	Larval toxicity	LD ₁₀ = 12.5 µg a.i/bee/day	EFSA Conclusion 2018;16(7):5389,
<i>Apis mellifera</i>	Chlopyralid 300 SL (Faworyt 300 SL)	Oral	LD ₅₀ > 100 µg/bee	Irzyk M., 2001, OSŻ-09/01*

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	Chlopyralid 300 SL (Faworyt 300 SL)	Contact	LD ₅₀ > 200 µg/bee	Irzyk M., 2001, OSŻ-09/01*
<i>Apis mellifera</i>	Faworyt 300 SL	Chronic 10days	NOEDD ≥2500 mg product/kg of food LDD ₅₀ >2500 mg product/kg of food	Orzechowska U., 2019, 0016/0015/E
<i>Apis mellifera</i>	Faworyt 300 SL	Larval toxicity test, repeated exposure, 22 days	22-day LC ₅₀ : 3.209 mg product/kg food 22-day NOEC: 0.42 mg product/kg food 22-day NOEDD: 0.065 µg product/bee	Orzechowska U., 2019, 0016/0056/E
Higher-tier studies (tunnel test, field studies)				
Not relevant				

*The studies previously evaluated for PL registration of the product.

9.6.1.1 Justification for new endpoints

No new endpoints – formulation studies for acute oral and contact exposure have been submitted and assessed during first registration of the product Faworyt 300 SL in 2013.

New formulation studies have been submitted for chronic exposure to adult bees, and larval development to fulfilled new specific requirements of the Regulation (EU) 284/2013.

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 (SAN-CO/10329/2002 rev.2 (final), October 17, 2002).

The risk assessment was provided and positively assessed during first registration of the product Faworyt 300 SL in 2013, but Applicant decided to submit it again.

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 Faworyt 300 SL in winter wheat, winter rape and sugar beet

Intended use	winter wheat, winter rape and sugar beet		
Active substance	clopyralid		
Application rate (g a.s/ha)	1 × 120		
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g a.s/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	>100	120	< 1.2

Contact toxicity	>98.1		< 1.22
Product	Faworyt 300 SL		
Application rate (g/ha)	1 ×462.4*		
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g a.s/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	>100	462.4	< 4.624
Contact toxicity	>200		< 2.312

* Application rate of = 0.4 L product ha⁻¹ x (relative density 1.156) = 462.4 g product/ha

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

zRMS comment:

The risk assessment was provided and assessed during first registration of the product Faworyt 300 SL in 2013. According to recommendation given in “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

Based on the acute risk assessment with the consideration SANCO/10329/2002 rev.2 (final), October 17, 2002), HQ values for adult bees from exposure of Faworyt 300 SL are < 50, indicating un acceptable risk to adult bees. The HQ values are lower than the trigger of 50, indicating low risk to bees from following application of Faworyt 300 SL. In addition, the chronic studies for bees were submitted by the applicant. The risk assessment based on these studies should be considered when GD for Bees, 2013 is implemented at EU level. **Final decision should be taken into account at MSs level.**

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

Not relevant.

9.6.3 Effects on bumble bees

No data/information available.

9.6.4 Effects on solitary bees

No data/information available.

9.6.5 Overall conclusions

The acute risk assessments for the active substances as well as for the formulated product Faworyt 300 SL with Hazard Quotients well below the trigger for acceptability of effects indicate an acceptable risk for bees exposed in accordance with the intended uses in winter wheat, winter rape and sugar beet. Therefore, a low risk to bees is expected from the application of Faworyt 300 SL according to the proposed GAP. Toxicity endpoints for chronic adults bees and chronic effects of on larvae and worker honeybees are available. Therefore, the new specific requirements of the Regulation (EU) 284/2013 with regard to effects on bee brood development and possible chronic effects on adults are administrative fulfilled.

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 clopyralid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
Clopyralid and related formulated products from EU review				
<i>Typhlodromus pyri</i>	EF-1136 (100 g/l Clopyralid)	Laboratory test glass plates	LR ₅₀ > 200 g a.s /ha	(EFSA Scientific Report (2005) 50, 1–65)
<i>Aphidius rhopalosiphi</i>	EF-1136 (100 g/l Clopyralid)	Laboratory test glass plates	LR ₅₀ > 200 g a.s /ha	(EFSA Scientific Report (2005) 50, 1–65)
<i>Typhlodromus pyri</i>	GF-1374	Extended study	LR ₅₀ = 2000 ml/ha	(EFSA Scientific Report (2005) 50, 1–65)
<i>Aphidius rhopalosiphi</i>	GF-1374	Extended study	LR ₅₀ = 2000 ml/ha	(EFSA Scientific Report (2005) 50, 1–65)
<i>Chrysoperla carnea</i>	EF-1136	Laboratory test glass plates	LR ₅₀ > 200 g a.s /ha	(EFSA Scientific Report (2005) 50, 1–65)
<i>Chrysoperla carnea</i>	GF-1374	Extended study	LR ₅₀ = 2000 ml/ha	(EFSA Scientific Report (2005) 50, 1–65)
<i>Poecilus cupreus</i>	EF-1136	Laboratory test	LR ₅₀ > 200 g a.s /ha	(EFSA Scientific Report (2005) 50, 1–65)
Faworyt 300 SL				
<i>Typhlodromus pyri</i>	Formulation: Faworyt 300 SL	Laboratory test glass plates (2D)	LR ₅₀ / ER ₅₀ > 400 ml product/ha (121 g a.s/ha)	Moll M., 2019, Study No. 140601063
<i>Aphidius rhopalosiphi</i>	Formulation: Faworyt 300 SL	Laboratory test glass plates (2D)	LR ₅₀ / ER ₅₀ > 400 ml product/ha (121 g a.s/ha)	Moll M., 2019, Study No. 140601001
<i>Aphidius rhopalosiphi</i>	Formulation: Faworyt 300 SL	Extended study, barley plants	LR ₅₀ / ER ₅₀ > 400 ml product/ha (121 g a.s/ha)	Moll M., 2019, Study No. 140601002
<i>Chrysoperla carnea</i>	Formulation: Faworyt 300 SL	Extended study, blackberry leaves	LR ₅₀ / ER ₅₀ > 400 ml product/ha (121 g a.s/ha)	Moll M., 2019, Study No. 140601047

Species	Substance	Exposure System	Results	Reference
			a.s/ha)	
Field or semi-field tests				
Not relevant				

9.7.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

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 determine the risk envelope, the table below was set up where the exposure of non-target arthropods for in- and off-field is compared for the different use patterns and crops of Faworyt 300 SL

Use No.	Crop	Crop type acc. to BBA drift tables	Application rate [L product/ha]	MAF	PER _{in-field} [L product/ha]	Drift percentile [%]	Drift rate [L product/ha]
1	Winter rape	Field crops	1 x 0.4	1	0.4	2.77	0.011
2	Winter wheat	Field crops	1 x 0.4	1	0.4	2.77	0.011
3	Sugar beet	Vegetables, Ornamentals, Small fruits	1 x 0.3	1	0.3	2.77	0.008

In conclusion, the worst-case in-field and off-field exposure of 0.4 and 0.011 L product/ha, respectively, is to be expected from 1 x 0.4 L product/ha in winter rape and winter wheat which is therefore the case that is presented for the in-field and off-field risk assessments below.

9.7.2.1 Risk assessment for in-field exposure

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of Faworyt 300 SL in different crops

Intended use		Winter wheat, winter rape, sugar beet	
Product		Faworyt 300 SL	
Application rate (g/ha)		1 × 0.4	
MAF		1	
Test species	LR₅₀ (lab.)/ER₅₀ (L product/ha)	PER_{in-field} (L product/ha)	HQ_{in-field} criterion: HQ ≤ 2
Tier I			
<i>Typhlodromus pyri</i>	> 0.4	0.4	< 1
<i>Aphidius rhopalosiphi</i>	> 0.4		< 1

Test species Tier II (Extended lab testing)	ER ₅₀ [L product/ha]	PER _{in-field} (L product/ha)	PER _{in-field} below rate with ≤ 50 % effect?
<i>Aphidius rhopalosiphi</i>	> 0.4	0.4	Yes; (< 1)
<i>Chrysoperla carnea</i>	> 0.4		Yes; (< 1)

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

* If an LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Accordingly, under consideration of extended laboratory tests, the risk for *Chrysoperla carnea* and *Aphidius rhopalosiphi* exposed to the risk envelope PER_{in-field} of Faworyt 300 SL is indicated to be acceptable for the intended uses in winter wheat, winter rape and sugar beet.

zRMS comment:

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. The calculations of the risk assessment for in – field for two indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi* based on laboratory studies were accepted by zRMS as HQ values were below 2 for these species. In addition, based on the results from extended laboratory tests for *Chrysoperla carnea* and *Aphidius rhopalosiphi* the PER_{in-field} of Faworyt 300 SL is considered to be acceptable as PER_{in-field} was below rate with ≤50 % effect.

Finally , the risk in - field for NTA is considered acceptable.

9.7.2.2 Risk assessment for off-field exposure

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Faworyt 300 SL in different crops

Intended use	Winter wheat, winter rape, sugar beet					
Active substance/product	Faworyt 300 SL					
Application rate (g/ha)	1 × 0.4					
MAF	1					
vdf	10 (2D) and 5 (2D)**, n.a. (3D)***					
Test species Tier I	LR ₅₀ /ER ₅₀ (L product /ha)	Drift percentile [%]	Drift rate (L product/ha)	PER _{off-field} (L product /ha)	CF	HQ _{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	> 0.4	2.77	0.011	0.0011 0.0022*	10	< 0.0277 <0.0554*
<i>Aphidius rhopalosiphi</i>	> 0.4					< 0.0277 <0.0554*

Test species Tier II (Extended lab test-ing)	ER ₅₀ [L product/ha]	Drift percentile [%]	Drift rate (L product/ha)	PER _{off-field} (L prod- uct/ha)	CF	corr. PER _{off-field} below rate with ≤ 50 % effect?
<i>Aphidius rhopalosiphi</i>	> 0.4	2.77	0.011	0.0011 0.011*	5	Yes; < 0.014 0.138*
<i>Chrysoperla carnea</i>	> 0.4					Yes; < 0.014 0.138*

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 LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

**According to Working document on Risk Assessment of Plant Protection Products in the Central Zone (CZSC, May 2021) VDF of 5 should be used for all the tiers of the assessment as an interim solution until the revision of the current risk assessment scheme.

*** not applicable

Accordingly, also for the off-field scenario an acceptable risk is indicated for *T. pyri* and *A. rhopalosiphi* as well as for the additional species *Chrysoperla carnea* exposed to Faworyt 300 SL for the intended uses in winter wheat, winter rape and sugar beet.

zRMS comment:

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. The calculations of the risk assessment for off – field for two indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi* based on laboratory studies were verified by zRMS. After that HQ values were still below 2 for these species indicated acceptable risk. In addition, based on the results from extended laboratory tests for *Chrysoperla carnea* and *Aphidius rhopalosiphi* the PER_{in-field} of Faworyt 300 SL the risk off -field for these species is considered acceptable as PER_{off-field} was below rate with ≤50 % effect. Finally, the risk off-field for NTA is considered acceptable.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

Not relevant.

9.7.3 Overall conclusions

The in-field and off-field risk from exposure to clopyralid applied as Faworyt 300 SL for the intended uses in winter wheat, winter rape and sugar beet (risk envelope: 1 x 0.4 L product/ha) is indicated to be acceptable for non-target arthropods other than bees based also on Tier 2 data without the need for risk mitigation measures.

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

9.8.1 Toxicity data

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

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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
<i>Eisenia fetida</i>	clopyralid	Overspray 28 d, chronic 10% OM	NOEC = 1.97 mg ai/kg dw	EFSA Conclusion 2018;16(7):5389
<i>Folsomia candida</i>	Reference product GF-1374	Mixed into substrate 28 d, chronic 5 % peat content	NOEC = 50 mg product/kg dw	EFSA Conclusion 2018;16(7):5389
<i>Hypoaspis aculeifer</i>	Reference product GF-1374	Mixed into substrate 14 d, chronic 5 % peat content	NOEC = 100 mg product/kg dw	EFSA Conclusion 2018;16(7):5389
<i>Eisenia fetida</i>	Faworyt 300 SL	Mixed into substrate 56 d, chronic 10 % peat content	LC _{50, mortality} > 250 mg product/kg dw NOEC, mortality = 138.89 mg product/kg dw EC _{10, reproduction} = 8.134 mg product /kg dw EC _{20, reproduction} = 71.686 mg product/kg dw EC _{50, reproduction} > 250 mg product/kg dw NOEC, reproduction = 23.73 mg/kg dw	Woźniak A., 2019 Study code: 0016/0054/E
<i>Folsomia candida</i>	Faworyt 300 SL	Mixed into substrate 28 d, chronic 5 % peat content	LC _{50, mortality} > 1000 mg product/kg dw NOEC, mortality ≥ 1000 mg product/kg dw EC _{50, reproduction} >> 1000 mg product/kg dw NOEC, reproduction ≥ 1000 mg product/kg	Straube D., 2019 Study No.: 140601016

Species	Substance	Exposure System	Results	Reference
			dw	
<i>Hypoaspis aculeifer</i>	Faworyt 300 SL	Mixed into substrate 14 d, chronic 5 % peat content	LC _{50, mortality} > 1000 mg product/kg dw NOEC, mortality ≥ 1000 mg product/kg dw EC _{10, reproduction} > 1000 mg product/kg dw EC _{20, reproduction} > 1000 mg product/kg dw EC _{50, reproduction} >> 1000 mg product/kg dw NOEC, reproduction ≥ 1000 mg product/kg dw	Straube D., 2019 Study No.: 140601089
Field studies				
n.a.				
Litter bag test				
n.a.				

9.8.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.8.2 Risk assessment

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

9.8.2.1 First-tier risk assessment

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 (wheat) also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses in groups 2-3 (oilseed rape and sugar beet) (see 9.1.2).

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of Faworyt 300 SL in winter wheat (use group 1)

Intended use	Winter wheat		
Chronic effects on earthworms			
Product/active substance	NOEC/EC _x (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
clpyralid	1.97	0.1280	15
Faworyt 300 SL	8.134	0.4966	16
Chronic effects on other soil macro- and mesofauna			
Product/active substance	NOEC/EC _x (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
Folsomia candida			
clpyralid	n.a.	n.a.	n.a.
Reference product GF 1374	50	0.4966	101
Faworyt 300 SL	1000	0.4966	2014
Hypoaspis aculiefer			
clpyralid	n.a.	n.a.	n.a.
Reference product GF 1374	100	0.4966	201
Faworyt 300 SL	1000	0.4966	2014

TER values shown in bold fall below the relevant trigger.

zRMS comment:

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate). The TER_{LT} values for active substance and for product are above trigger value of 5, indicating an acceptable risk for earthworm and soil macro-organism for proposed use of the product Faworyt 300 SL.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

The risk from exposure to clpyralid applied as Faworyt 300 SL for all intended uses is indicated to be acceptable for the soil meso- and macrofauna.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with active substance and the reference product. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of Faworyt 300 SL were not evaluated as part of the EU assessment of clocpyralid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	clocpyralid	56 d, aerobic	No negative effect > 25% at 56 d at 209 mg a.s./kg dws	EFSA Conclusion 2018;16(7):5389
N-mineralisation	Reference product GF 1374	28 d, aerobic	No negative effect > 25% at 28 d at 13.9 mg product/kg dws	EFSA Conclusion 2018;16(7):5389
N-mineralisation	Faworyt 300 SL	28 d, aerobic	No negative effect > 25% at 28 d at 3.7152 mg product/kg dws	Woźniak A., 2021 Study code: 0016/0138/E

9.9.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.9.2 Risk assessment

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

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 (wheat) also covers the risk for the soil microorganisms from all other intended uses in groups 2 and 3 (oilseed rape and sugar beet) (see 9.1.2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of Faworyt 300 SL in winter wheat (use group 1)

Intended use	Winter wheat		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?

clopyralid	209	0.1280	No
Reference product GF-1374	13.9	0.4966	No
Faworyt 300 SL	3.7152	0.4966	No

zRMS comments:

The risk assessment for soil micro-organism after exposure of ppp Faworyt 300 SL has been accepted by the zRMS-PL. The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PECs for the maximum application rate of Faworyt 300 SL. The results indicate no adverse effect on nitrogen transformation even at soil concentrations well higher than the ones expected following application of **Faworyt 300 SL**.

9.9.3 Overall conclusions

The risk from exposure to clopyralid applied as Faworyt 300 SL for all intended uses is indicated to be acceptable for the soil microflora.

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 clopyralid and the representative formulation, GF-1374. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
<i>Glycine max</i> _d	Clopyralid	21 d Seedling emergence	ER ₅₀ shoot weight = 21.47 g a.s/ha	EFSA Conclusion 2018;16(7):5389
<i>Lactuca sativa</i> _d	Reference product GF-1374	21 d Seedling emergence	ER ₅₀ shoot weight = 0.46 L product/ha	EFSA Conclusion 2018;16(7):5389

Species	Substance	Exposure System	Results	Reference
Cucumber <i>d</i> Carrot <i>d</i> Broccoli <i>d</i> Mung bean <i>d</i> Oat <i>m</i> Corn <i>m</i>	Faworyt 300 SL	21 d Seedling emergence	¹⁾ ER ₅₀ emergence and survival > 0.4 L product/ha (all tested species) ²⁾ ER₅₀ plant fresh weight = 0.031 L product/ha (Mung bean) ³⁾ ER ₅₀ plant dry weight = 0.080 L product/ha (carrot) ⁴⁾ ER ₅₀ plant height > 0.4 L product/ha (all tested species) ⁵⁾ ER ₅₀ phytotoxicity = 0.385 L product/ha (carrot)	Kamińska A., 2019 with amendment by Woźniak A., 2021 Study code: 0016/0059/E
<i>Lactuca sativa d</i>	Clopyralid	21 d Vegetative vigour	ER ₅₀ shoot weight = 33.78 g ai/ha	EFSA Conclusion 2018;16(7):5389
Cucumber <i>d</i> Carrot <i>d</i> Broccoli <i>d</i> Mung bean <i>d</i> Oat <i>m</i> Corn <i>m</i>	Faworyt 300 SL	21 d Vegetative vigour	¹⁾ ER ₅₀ survival > 0.4 L product/ha (all tested species) ²⁾ ER ₅₀ plant fresh weight = 0.211 L product/ha (carrot) ³⁾ ER ₅₀ plant dry weight = 0.151 L product/ha (Mung bean) ³⁾ ER ₅₀ plant height > 0.4 L product/ha (all species) ⁴⁾ ER ₅₀ phytotoxicity = 0.170 L product/ha (carrot)	Kamińska A., 2019 with amendment by Woźniak A., 2021 Study code: 0016/0060/E

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

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

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

Table 9.10-2: Assessment of the risk for non-target plants due to the use of Faworyt 300 SL in wheat, oilseed rape and sugar beet (use group 1-3)

Intended use		Wheat and oilseed rape		
Active substance/product		clopyralid/Faworyt 300 SL		
Application rate		1 × 0.4 L product/ha (1× 120 g ai/ha)		
MAF		n.a.		
Test species	ER₅₀	Drift rate	PER_{off-field}	TER criterion: TER ≥ 5
<i>Glycine max</i> _d	ER ₅₀ shoot weight = 21.47 g a.s/ha	2.77%	3.324 g a.s/ha	6.46
<i>Lactuca sativa</i> _d	ER ₅₀ shoot weight = 0.46 L product/ha	2.77%	0.01108 L product/ha	41.5
Cucumber _d Carrot _d Broccoli _d Mung bean _d Oat _m Corn _m	ER ₅₀ plant fresh weight = 0.031 L product/ha	2.77%	0.01108 L product/ha	2.80
Intended use		Sugar beet		
Active substance/product		clopyralid/Faworyt 300 SL		
Application rate		1 × 0.3 L product/ha (1× 90 g ai/ha)		
MAF		n.a.		
Test species	ER₅₀	Drift rate	PER_{off-field}	TER criterion: TER ≥ 5
<i>Glycine max</i> _d	ER ₅₀ shoot weight = 21.47 g a.s/ha	2.77%	2.493 g a.s/ha	8.61
<i>Lactuca sativa</i> _d	ER ₅₀ shoot weight = 0.46 L product/ha	2.77%	0.00831 L product/ha	55.35

Cucumber _d Carrot _d Broccoli _d Mung bean _d Oat _m Corn _m	ER ₅₀ plant fresh weight = 0.031 L product/ha	2.77%	0.00831 L product/ha	3.73
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MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comment:

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SAN-CO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. The deterministic risk based on the ER₅₀ of 0.031 L/ha value from seedling emergence test and PER_{off-field}, indicated needs for further refinement.

The risk mitigation measures are proposed at **Point 9.10.2.4**.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

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

Table 9.10-3: Risk assessment for non-target terrestrial plants due to the use of Faworyt 300 SL in wheat, oilseed rape and sugar beet (use group 1-3) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Wheat and oilseed rape			
Active substance/product		clopyralid/Faworyt 300 SL			
Application rate		1 × 0.4 L product/ha (1× 120 g ai/ha)			
MAF		n.a.			
Buffer strip (m)	Drift rate (%)	PER_{off-field} (L product/ha)	PER_{off-field} 50 % drift red. (L product/ha)	PER_{off-field} 75 % drift red. (L product/ha)	PER_{off-field} 90 % drift red. (L product/ha)
1	2.77	0.01108	0.00554	-	-
5	0.57	0.00228	-	-	-
10	0.29	-	-	-	-
Toxicity value		TER			
ER ₅₀ = 0.031 (L product/ha)		criterion: TER ≥ 5			
1		2.80	5.75	-	-

5	13.59	-	-	-	-
10	-	-	-	-	-
Intended use		Sugar beet			
Active substance/product		clopyralid/Faworyt 300 SL			
Application rate		1 × 0.3 L product/ha (1× 90 g ai/ha)			
MAF		n.a.			
Buffer strip (m)	Drift rate (%)	PER_{off-field} (L product/ha)	PER_{off-field} 50 % drift red. (L product/ha)	PER_{off-field} 75 % drift red. (L product/ha)	PER_{off-field} 90 % drift red. (L product/ha)
1	2.77	0.00831	0.004155	-	-
5	0.57	0.00171	-	-	-
10	0.29	-	-	-	-
Toxicity value		TER			
ER ₅₀ = 0.031 (L product/ha)		criterion: TER ≥ 5			
1		3.73	7.46	-	-
5		18.12	-	-	-
10		-	-	-	-

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

zRMS comment:

In order to reduce the off-field exposure, risk mitigation measures is implemented based on the lowest ER₅₀=0.031 L product/ha and PER_{off-field} for max. application rate = 0.3 Lproduct /ha.

TER_{LT} for all use patterns of Faworyt 300 SL are above the trigger of 5 when the either 50% drift reduction or a 5 m unsprayed buffer zone is applied to non-crop land.

9.10.3 Overall conclusions

The table above shows that the TER for all use patterns of Faworyt 300 SL are above the trigger of 5 even when the either 50% drift reduction or a 5 m buffer strip is applied.

Overall, the risk for non-target plants for Faworyt 300 SL is acceptable.

zRMS comment:

TER_{LT} for all use patterns of Faworyt 300 SL are above the trigger of 5 when the either 50% drift reduction or a 5 m unsprayed buffer zone is applied to non-crop land.

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

Not relevant.

9.12 Monitoring data (KCP 10.8)

No monitoring data are available and to be considered.

9.13 Classification and Labelling

According to REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 formulation Faworyt 300 SL should not be classified and labeled as hazardous to the aquatic environment. I was assumed based on available acute and chronic toxicity data for formulation and on information contained in table 4.1.0 of Regulation (EC) No 1272/2008.

CLASSIFICATION	
Hazard class(es), categories:	None
LABELLING	
Hazard pictograms:	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	None

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 10.2.1/01	Fochtman P.	2001	Ocena toksycznego działania preparatu Chlopypiralid 300 SL na organizmy wodne Instytut Przemysłu Organicznego Oddział w Pszczynie W/10/01 GLP	N	CIECH Sarżyna S.A.
KCP 10.2.1/02	Woźniak A.	2019	Freshwater alga growth inhibition according to OECD 201 Sorbolab Research Labolatory LLC 0016/0057/E GLP Unpublished	N	CIECH Sarżyna S.A.
KCP 10.2.1/02	Kamińska A.	2019	Water-sediment <i>Myriophyllum spicatum</i> toxicity test according to OECD 239 Sorbolab Research Labolatory LLC 0016/0061/E GLP Unpublished	N	CIECH Sarżyna S.A.
KCP 10.2.2	Woźniak A.	2019	Reproduction test of <i>Daphnia magna</i> according to guideline OECD 211 Sorbolab Research Labolatory LLC 0016/0058/E GLP Unpublished	N	CIECH Sarżyna S.A.

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 10.3.1.1/01	Irzyk M.	2001	Ocena toksycznego działania preparatu Chlorypyralid 300 SL dla pszczoły miodnej (<i>Apis mellifera L.</i>) Instytut Przemysłu Organicznego Oddział w Pszczynie OSŻ-09/01, OSD-10/01 GLP	N	CIECH Sarżyna S.A.
KCP 10.3.1.2/01	Orzechowska U.	2019	Honey Bee, Chronic Oral Toxicity Test according to OECD 245 Sorbolab Research Laboratory LLC 0016/0015/E GLP Unpublished	N	CIECH Sarżyna S.A.
KCP 10.3.1.3/01	Orzechowska U.	2019	Chronic Toxicity Test for Bee Larvae Sorbolab Research Laboratory LLC 0016/0056/E GLP Unpublished	N	CIECH Sarżyna S.A.
KCP 10.3.2.1/01	Moll M.	2019	Faworyt 300 SL: Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> in the Laboratory - Dose Response Test – Ibacon GmbH Study No. 140601001 GLP Unpublished	N	CIECH Sarżyna S.A.
KCP 10.3.2.1/02	Moll M.	2019	Faworyt 300 SL: Effects on the Predatory Mite <i>Typhlodromus pyri</i> in the Laboratory - Dose Response Test- Ibacon GmbH Study No. 140601063 GLP Unpublished	N	CIECH Sarżyna S.A.
KCP 10.3.2.2/01	Moll M.	2019	Faworyt 300 SL: Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> , Extended Laboratory Study - Dose Response Test – Ibacon GmbH Study No. 140601002	N	CIECH Sarżyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 10.3.2.2/02	Moll M.	2019	Faworyt 300 SL: Effects on the Lacewing <i>Chrysoperla carnea</i> , Extended Laboratory Study - Dose Response Test - Ibacon GmbH Study No. 140601047 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.4.1.1	Woźniak A.	2019	Earthworm reproduction test according to OECD 222 SORBOLAB Research Laboratory LLC Study code: 0016/0054/E GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.4.2.1_01	Straube D.	2019	Faworyt 300 SL: Collembola <i>Folsomia candida</i> in Artificial Soil Ibacon GmbH Study No. 140601016 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.4.2.1_02	Straube D.	2019	Faworyt 300 SL: Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil Ibacon GmbH Study No. 140601089 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.5	Woźniak A.	2021	Study of impact of test item Faworyt 300 SL on soil microorganisms - nitrogen transformation test according to guideline OECD 216 SORBOLAB Research Laboratory LLC Study code: 0016/0138/E GLP Unpublished	N	CIECH Sarzyna S.A.

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 10.6_01	Kamińska A.	2019	Seedling emergence and seedling growth test according to OECD 208 SORBOLAB Research Laboratory LLC Study code: 0016/0059/E GLP Unpublished	N	CIECH Sarzyna S.A.
10.6_01a	Woźniak A.	2021	Annex No. 1 to the Final report: Seedling emergence and seedling growth test according to guideline OECD 208 SORBOLAB Research Laboratory LLC Study code: 0016/0059/E GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.6_02	Kamińska A.	2019	Vegetative Vigour Test according to OECD 227 SORBOLAB Research Laboratory LLC Study code: 0016/0060/E GLP Unpublished	N	CIECH Sarzyna S.A.
10.6_02a	Woźniak A.	2021	Annex No. 1 to the Final report: Vegetative Vigour Test according to OECD 227 SORBOLAB Research Laboratory LLC Study code: 0016/0060/E GLP Unpublished	N	CIECH Sarzyna S.A.

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

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

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

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

Appendix 2 Detailed evaluation of the new studies

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
A 2.1.1.2	KCP 10.1.1.2	Higher tier data on birds
A 2.1.2	KCP 10.1.2	Effects on terrestrial vertebrates other than birds
A 2.1.2.1	KCP 10.1.2.1	Acute oral toxicity to mammals
A 2.1.2.2	KCP 10.1.2.2	Higher tier data on mammals
A 2.1.3	KCP 10.1.3	Effects on other terrestrial vertebrate wildlife (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

Study 1

Comments of zRMS	<p>Result of the study evaluated by the zRMS – PL during the first authorisation process for Faworyt 300 SL. (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments). No new study for fish was submitted.</p> <p>Agreed endpoints:</p> <p>96 h LC₅₀ >1000 mg product/L</p> <p>Results based on nominal concentration.</p>
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Reference:	KCP 10.2.1
Report	Chlopyralid 300 SL, Ocena toksycznego działania preparatu na ryby, P. Fochtman, 2001a, STUDY CODE: W/10/01
Guideline(s):	Yes. According to the OECD Guideline No. 203
Deviations:	No

GLP: Yes

Acceptability: Yes

Material and Methods:

Chlopyralid 300 SL (batch No. 01/2001) is a brown liquid containing clopyralid as the active substance (nominal concentration: 300 g/L, measured concentration: 305.8 g/L). Test was carried out in 10 L glass tanks in static manner. Test material was used in the form of water solutions at five concentrations: 100, 180, 320, 560 and 1000 mg/L. Seven rainbow trouts (*Oncorhynchus mykiss*) and eight common carps (*Cyprinus carpio*) were used for each concentration and control groups. The test duration was 96 hrs.

Table : Acute toxicity of Chlopyralid 300 SL to fish

Concentration [mg/L]	No of fish used*	Mortality	
		[No]	[%]
Control	7/8	0	0
100	7/8	0	0
180	7/8	0	0
320	7/8	0	0
560	7/8	0	0
1000	7/8	0	0

* Number of trouts/number of carps

Findings:

- No deaths were observed during the study.

Conclusion/endpoint:

Under the experimental conditions, the LC₅₀ (96hrs) of Chlopyralid 300 SL is higher than 1000 mg/L for rainbow trout and common carp.

Result of the study presented above was already evaluated and accepted by the zRMS (Poland) during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments).

Study 2

Comments of zRMS:	<p>Result of the study was evaluated by the zRMS –PL during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments). No new study was submitted.</p> <p>Agreed endpoint:</p> <p>48 h EC₅₀ >1000 mg product/L for Daphnia.</p> <p>Results based on nominal concentration.</p>
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Reference:	KCP 10.2.1
Report	Chlopyralid 300 SL, Ocena toksycznego działania preparatu na rozwielitce, P. Fochtman, 2001b, STUDY CODE: W/10/01
Guideline(s):	Yes. According to the OECD Guideline No. 202
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Material and Methods:

Chlopyralid 300 SL (batch No. 01/2001) is a brown liquid containing clopyralid as the active substance (nominal concentration: 300 g/L, measured concentration: 305.8 g/L). Test was carried out in 1 L glass containers in static manner. Test material was used at seven concentrations: 15.6, 31.2, 62.5, 125, 250, 500 and 1000 mg/L. Each concentration and control were done in four replications. Twenty young *Daphnia magna* (less than 24hrs old) were used in each concentration and in control. The test duration was 48 hrs.

Table: Acute toxicity of Chlopyralid 300 SL to Daphnia

Concentration [mg/L]	No of Daphnias used	Dead and immobilized Daphnias after 48hrs		
		No	Observed %	Corrected %
Control	20	0	0	-
15.6	20	0	0	-
31.2	20	0	0	-
62.5	20	0	0	-
125	20	1	5	-
250	20	0	0	-
500	20	1	5	-
1000	20	0	0	-

Findings:

- One dead Daphnia was found in concentration of 125 and 500 mg/L after 48hrs.

Conclusion/endpoint:

Under the experimental conditions, the EC₅₀ (48hrs) of Chlopyralid 300 SL is higher than 1000 mg/L for Daphnia.

Result of the study presented above was already evaluated and accepted by the zRMS (Poland) during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments).

Study 3

Comments of zRMS:	Result of the study was evaluated and accepted by the zRMS –PL during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments). No new study was submitted for this species.
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	Agreed endpoints: 72 h EC ₅₀ = 65.2 mg product/L for algae (<i>Scenedesmus subspicatus</i>) Results based on nominal concentration.
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Reference: KCP 10.2.1

Report Chlopyralid 300 SL, Ocena toksycznego działania preparatu na glony, P. Fochtman, 2001c, STUDY CODE: W/10/01

Guideline(s): Yes. According to the OECD Guideline No. 201

Deviations: No

GLP: Yes

Acceptability: Yes

Material and Methods:

Chlopyralid 300 SL (batch No. 01/2001) is a brown liquid containing clopyralid as the active substance (nominal concentration: 300 g/L, measured concentration: 305.8 g/L). Test was carried out in 200 mL Erlenmayer flasks in static manner. Test material was used at six concentrations: 1.0, 3.2, 10, 32, 100 and 3200 mg/L. Each concentration was done in three replications and control in six one. The series of concentrations of test material was made on the basis of medium and inoculated with algae (*Scenedesmus subspicatus*) to reach the initial concentration of 1×10^4 cells per mL. The test duration was 72 hrs.

Table: Toxicity of Chlopyralid 300 SL to algae

Concentration [mg/L]	N (x 10 ⁶ /mL)	N/N ₀ of test material compared to N/N ₀ of control	
		N/N ₀ in % to the control	% of decrease N/N ₀ to the control
Control	1.490	100	-
1.0	1.629	109.3	0
3.2	1.638	109.9	0
10	1.588	106.6	0
32	1.175	78.9	21.1
100	0.458	30.7	69.3
320	0.038	2.6	97.4

N – cell concentration after 72 hrs

N₀ – initial cell concentration

Findings:

- Growth inhibition of algae was observed in concentration of 32 mg/L and in higher ones.

Conclusion/endpoint:

Under the experimental conditions, the IC₅₀ (72hrs) of Chlopyralid 300 SL is equal to 65.2 mg/L for algae.

Result of the study presented above was already evaluated and accepted by the zRMS (Poland) during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from

08.11.2013 r. with further amendments).

Study 4

Comments of zRMS:	<p>The study is considered acceptable . All validity criteria were met.</p> <ul style="list-style-type: none">- Biomass in control during 72 hours of test increased exponentially 82 times (requirements according to OECD 201: ≥16)- The coefficient of variation the average specific growth rate for all repetitions of the control culture over the entire time of the test was 5.0% (requirements according to OECD 201:<7%. For other less frequently tested species, the value should not exceed 10%.- The average coefficient of variance for a specific growth rate day after day (0-24 h, 24-48 h, 48-72 h) for the control culture was 12.1% (requirements according to OECD 201: <35%). <p>Agreed endpoints: (Navicula pelliculosa)</p> <table><tr><th>Parameter</th><th>Yield</th><th>Average specific growth rate</th><th>Sectional average specific growth rate</th></tr><tr><td>EC₁₀ - 72 h [mg/L]</td><td>5.334 (1.024 – 27.798)*</td><td>35.588 (18.725 – 67.640)*</td><td>n.d. (n.d. – n.d.)*</td></tr><tr><td>EC₂₀ - 72 h [mg/L]</td><td>12.333 (1.758 – 64.762)*</td><td>84.566 (35.210 – 183.089)*</td><td>n.d. (n.d. – n.d.)*</td></tr><tr><td>EC₅₀ - 72 h [mg/L]</td><td>61.298 (5.927 – 556.372)*</td><td>n.d.** (n.d. – n.d.)*</td><td>n.d. (n.d. – n.d.)*</td></tr><tr><td>LOEC - 72 h [mg/L]</td><td>25.00</td><td>25.00</td><td>>100.00</td></tr><tr><td>NOEC - 72 h [mg/L]</td><td>12.50</td><td>12.50</td><td>≥100.00</td></tr></table> <p>EC₁₀ effective concentration of test item for 10% reduction EC₂₀ effective concentration of test item for 20% reduction EC₅₀ effective concentration of test item for 50% reduction LOEC lowest observe effective concentration cause statistically significant differences in comparison to the control NOEC highest non observe effective concentration cause no statistically significant differences in comparison to the control) the lower and upper 95% confidence limits are given in brackets) based on the analysis of the results, this value was determined as >100 mg/L n.d. not determined due to mathematical reasons</p>	Parameter	Yield	Average specific growth rate	Sectional average specific growth rate	EC ₁₀ - 72 h [mg/L]	5.334 (1.024 – 27.798)*	35.588 (18.725 – 67.640)*	n.d. (n.d. – n.d.)*	EC ₂₀ - 72 h [mg/L]	12.333 (1.758 – 64.762)*	84.566 (35.210 – 183.089)*	n.d. (n.d. – n.d.)*	EC ₅₀ - 72 h [mg/L]	61.298 (5.927 – 556.372)*	n.d.** (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	LOEC - 72 h [mg/L]	25.00	25.00	>100.00	NOEC - 72 h [mg/L]	12.50	12.50	≥100.00
Parameter	Yield	Average specific growth rate	Sectional average specific growth rate																						
EC ₁₀ - 72 h [mg/L]	5.334 (1.024 – 27.798)*	35.588 (18.725 – 67.640)*	n.d. (n.d. – n.d.)*																						
EC ₂₀ - 72 h [mg/L]	12.333 (1.758 – 64.762)*	84.566 (35.210 – 183.089)*	n.d. (n.d. – n.d.)*																						
EC ₅₀ - 72 h [mg/L]	61.298 (5.927 – 556.372)*	n.d.** (n.d. – n.d.)*	n.d. (n.d. – n.d.)*																						
LOEC - 72 h [mg/L]	25.00	25.00	>100.00																						
NOEC - 72 h [mg/L]	12.50	12.50	≥100.00																						

Results based on nominal concentration.

Reference: KCP 10.2.1

Report Faworyt 300 SL, Freshwater alga growth inhibition Test, Agnieszka Woźniak, 2019, STUDY CODE: 0016/0057/E, SORBOLAB Research Laboratory, Poland

Guideline(s): Yes. According to the OECD Guideline No. 201

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

A. MATERIALS

1. Test material

Description	clear liquid, yellow in color with a characteristic weak odor
Lot/Batch #	201805002
Content of active substance	Clopyralid: 302.7 g/L
Density:	1.161 g/mL
Expiry date	15.05.2021

2. Test organism

Species	diatom <i>Navicula pelliculosa</i>
Source	Culture Collection of Algae and Protozoa, SAMS Research Services Ltd., Scottish Marine Institute, UK.
Culturing	At 21-24 ± 2 °C under constant illumination in f/2+Simedium.
Acclimation period	Culturing was done under test conditions.
Test units	250 mL glass erlenmeyers, containing ~ 100 mL test solution

3. Environmental conditions

Test water	f/2+Si medium containing the following constituents:
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No.	Chemical compound	Concentration in stock solution [mg/dm ³]	Concentration in solution [mg/L]
1.	Sea salt	*	33600
Basic solution 1			
1.	Na ₂ EDTA·2H ₂ O	4820	4.82
2.	FeCl ₃ ·6H ₂ O	3150	3.15
3.	CuSO ₄ ·5H ₂ O	10	0.01
4.	ZnSO ₄ ·7H ₂ O	22	0.022
5.	CoCl ₂ ·6H ₂ O	10	0.01
6.	MnCl ₂ ·4H ₂ O	180	0.18
7.	Na ₂ MoO ₄ ·2H ₂ O	6	0.006
Basic solution 2			
1.	Na ₂ SiO ₃ ·9H ₂ O	30000	30
Basic solution 3			
1.	NaNO ₃	75000	75
Basic solution 4			
1.	NaH ₂ PO ₄ ·2H ₂ O	5650	5.65
Solution of vitamins			
1.	Thiamine hydrochloride (vit. B ₁)	100	0.1
2.	Cyanocobalamin (vit. B ₁₂)	0,5	0.0005
3.	Biotin (vit. H)	0,5	0.0005

* Sea salt, Tropic marin

Water temperature	Nominal: 24 ± 2 °C; actual: 23.1 – 22.4°C
pH	Nominal: increase should be ≤ 1.5 units during test; actual: 7.99 – 8.09 at test start and 7.96 – 8.28 at test end
Lighting	The average light intensity was in the range: 4300-4400 Lux

B. STUDY DESIGNS AND METHODS

1. Experimental conditions

Test design

The freshwater algae *Navicula pelliculosa* was exposed in a 72 hours test to test item at five concentrations each with three replicates and six replicates of a test water control. The recorded effect was inhibition of algae growth based on measurements of the number of algae cells.

Inoculum at test start

Each vessel contained a total of 10 000 cells/mL.

Concentrations tested

Product was tested at nominal concentrations of 6.25; 12.5; 25; 50 L; 100 mg/L.. Test definitive test concentrations were chosen based on range finding test results. A control group with untreated test medium was used. The reference item was tested in a separate study

Treatment/Application

A stock solution was prepared by weighing 250 mg of the test item and filling it up to 25 mL test medium. The test solutions were prepared by dilution of the respective amount of the stock solution with test medium.

Analytics

The actual content of test item measured as clopyralid was determined in one replicate of each test item concentration and the control at test start and test end using HPLC with photodiode array detector (PDA). The method was validated according to SANCO/3029/99 rev.4

2. Sampling and measurements

The algae measurements were taken every day for each repetition of the concentration and control tested. In addition, microscopic observations were performed on the day of the end of the experiment to verify the abnormal appearance of the cells at any concentration.

The light intensity and media temperature were measured each day in every concentration. The pH values were measured at exposure initiation and at exposure termination. The morphological observations of algae cellswere performed after 3 days of exposure.

3. Calculation of toxicity

The average specific growth rates and yield of *Navicula pelliculoza* diatoms were determined based on measurements of the number of algae cells.

4. Statistics

The statistical evaluations were done with ToxRat Professional. No further information is given in the report.

Results and discussions

A. ANALYTICAL RESULTS

Analysis of the concentrations of the tested item was carried out for the control and concentration of the tested item at the beginning of the test (0 h) and after its completion (72 h). Determination was performed by high-performance liquid chromatography with diode UV detection. The identification of active substances in the tested material was made by comparing the UV spectra and the retention times of the refer-

ence substance and the sample of the item being tested . Analytically measured concentrations of Faworyt 300 SL measured as clopyralid were within the range of 80 – 120% of nominal.

Table. Results of analytical determinations

Date	Description of the sample by the Laboratory of Physical Chemistry	Description of the sample by the Laboratory of Ecotoxicology	Determined concentration of the test item [mg/L]	The concentration of the test item after dilution [mg/L]	Average concentration of the test item [mg/L]
05.04.2019	0016_0057_E K-T=0h 01	K-T= 0h	0.00000	0.00000	0.00
	0016_0057_E K-T=0h 02		0.00000	0.00000	
	0016_0057_E C1-T=0h 01	C1-T=0h	0.98708	98.70800	99.03
	0016_0057_E C1-T=0h 02		0.99355	99.35500	
	0016_0057_E C2-T=0h 01	C2-T=0h	0.48378	48.37800	47.78
	0016_0057_E C2-T=0h 02		0.47179	47.17900	
	0016_0057_E C3-T=0h 01	C3-T=0h	0.21952	21.95200	22.38
	0016_0057_E C3-T=0h 02		0.22806	22.80600	
	0016_0057_E C4-T=0h 01	C4-T=0h	1.24765	12.47650	12.48
	0016_0057_E C4-T=0h 02		1.24920	12.49200	
	0016_0057_E C5-T=0h 01	C5-T=0h	0.63862	6.38620	6.30
	0016_0057_E C5-T=0h 02		0.62178	6.21780	
	0016_0057_E K-T=72h 01	K-T= 72h	0.00000	0.00000	0.00
	0016_0057_E K-T=72h 02		0.00000	0.00000	
	0016_0057_E C1-T=72h 01	C1-T=72h	0.98424	98.42400	98.15
	0016_0057_E C1-T=72h 02		0.97880	97.88000	
	0016_0057_E C2-T=72h 01	C2-T=72h	0.48655	48.65500	48.28
	0016_0057_E C2-T=72h 02		0.47904	47.90400	
	0016_0057_E C3-T=72h 01	C3-T=72h	0.20777	20.77700	20.55
	0016_0057_E C3-T=72h 02		0.20321	20.32100	
	0016_0057_E C4-T=72h 01	C4-T=72h	1.26148	12.61480	12.55
	0016_0057_E C4-T=72h 02		1.24891	12.48910	
	0016_0057_E C5-T=72h 01	C5-T=72h	0.60554	6.05540	6.10
	0016_0057_E C5-T=72h 02		0.61389	6.13890	

B. BIOLOGICAL RESULTS

During the test, algae measurements were taken every day for each repetition of the concentration and control tested in the Segdewick-Rafter chambers. In addition, microscopic observations were performed on the day of the end of the experiment to verify the abnormal appearance of the cells at any concentration. The results are shown in table below.

Concentration [mg/L]	Observations
Control	normal cell morphology
6.25	normal cell morphology
12.5	normal cell morphology
25.0	normal cell morphology
50.0	normal cell morphology
100.0	normal cell morphology

C. VALIDITY CRITERIA

The test met all the validity criteria in accordance with the OECD Guideline 201:

- yield in control during 72 hours of test increased exponentially 82 times (requirements according to OECD 201: ≥ 16)
- the coefficient of variance for the average specific growth rate for all repetitions of the control culture over the entire time of the test was 5.0% (requirements according to OECD 201:
- the average coefficient of variance for a specific growth rate day after day (0-24 h, 24-48 h, 48-72 h) for the control culture was 12.1% (requirements according to OECD 201: $< 35\%$).

Conclusion

The test item in the course of the present test showed a toxic effect on yield and average specific growth rate of *Navicula pelliculosa* diatoms in the concentration range from 25 mg/L to 100 mg/L. The EC50 value for yield is 61.298 mg/L, and for the average specific growth rate, based on the inhibition results was defined as > 100 mg/L.

The final results are presented in table below.

Parameter	Yield	Average specific growth rate	Sectional average specific growth rate
EC ₁₀ - 72 h [mg/L]	5.334 (1.024 – 27.798)*	35.588 (18.725 – 67.640)*	n.d. (n.d. – n.d.)*
EC ₂₀ - 72 h [mg/L]	12.333 (1.758 – 64.762)*	84.566 (35.210 – 183.089)*	n.d. (n.d. – n.d.)*
EC ₅₀ - 72 h [mg/L]	61.298 (5.927 – 556.372)*	n.d.** (n.d. – n.d.)*	n.d. (n.d. – n.d.)*
LOEC - 72 h [mg/L]	25.00	25.00	> 100.00
NOEC - 72 h [mg/L]	12.50	12.50	≥ 100.00

EC₁₀ effective concentration of test item for 10% reduction

EC₂₀ effective concentration of test item for 20% reduction

EC₅₀ effective concentration of test item for 50% reduction

LOEC lowest observe effective concentration cause statistically significant differences in comparison to the control

NOEC highest non observe effective concentration cause no statistically significant differences in comparison to the control

*) the lower and upper 95% confidence limits are given in brackets

**) based on the analysis of the results, this value was determined as > 100 mg/L

n.d. not determined due to mathematical reasons

Study 5

Comments of zRMS:	<p>The study is considered as acceptable . All validity criteria were met.</p> <ul style="list-style-type: none"> - Mortality of parental individuals in the control at the end of experiment was 0% (requirement $< 20\%$) - The mean number of living offspring in control per parent animal surviving at the end of the test was 63 (requirement ≥ 60 offspring) - The number of parent organisms killed in a random and unidentified manner in the control and in the concentrations of the tested material it was 0% (requirements max. 20 %)
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Agreed endpoints:					
Parameter	EC ₁₀ [mg/L]	EC ₂₀ [mg/L]	EC ₅₀ [mg/L]	LOEC [mg/L]	NOEC [mg/L]
Cumulative offspring number per survival parent (21 days)	0.000 (n.d. – n.d.)*	0.007 (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	>100.0	≥100.0
Immobility	n.d. (n.d. – n.d.)*	26.660 (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	>100.0	≥100.0
Length of parental specimens	116.490 (52.870 – 256.666)*	n.d. (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	50.0	25.0
Age of first reproduction	0.000 (0.000 – 0.000)*	0.000 (0.000 – 0.000)*	0.000 (0.000 – 0.000)*	100.0	50.0
Development rate	44.116 (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	100.0	50.0
Intrinsic rate	21.725 (5.460 – 86.435)*	184.622 (21.936 – 1396.329)*	n.d. (n.d. – n.d.)*	12.5	6.25
EC ₁₀ effective test item concentration for 10% reduction EC ₂₀ effective test item concentration for 20% reduction EC ₅₀ effective test item concentration for 50% reduction LOEC lowest observe effective concentration cause statistically significant differences in comparison to the control NOEC highest non observe effective concentration cause no statistically significant differences in comparison to the control *) the lower and upper 95% confidence limits are given in brackets n.d. not determined due to mathematical reasons					

Reference: KCP 10.2.1

Report Faworyt 300 SL Reproduction test of *Daphnia magna* according to guideline OECD 211, Agnieszka Woźniak, 2019, STUDY CODE: 0016/0058/E, SORBOLAB Research Laboratory, Poland

Guideline(s): Yes. According to the OECD Guideline No. 211

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

A. MATERIALS

1. Test material

Description	clear liquid, yellow in color with a characteristic weak odor
Lot/Batch #	201805002
Content of active substance	Clopyralid: 302.7 g/L
Density:	1.161 g/mL
Expiry date	15.05.2021

2. Test organism

Species	<i>Daphnia magna</i>
Source	Culture Collection of the SORBOLAB Research Laboratory.
Culturing	At 20 ± 2 °C under constant illumination in M7 medium.
Acclimation period	Culturing was done under test conditions.
Test units	100 mL glass beakers, each containing one individual parent

3. Environmental conditions

Test water

M7 medium containing the following constituents:

Substance	Concentration [mg/L]
$\text{CaCl}_2 \cdot 2 \text{H}_2\text{O}$	293800
NaHCO_3	64800
$\text{MgSO}_4 \cdot 7 \text{H}_2\text{O}$	246600
$\text{Na}_2\text{SiO}_3 \cdot 5 \text{H}_2\text{O}$	50 000
KCl	58 000
NaNO_3	2740
KH_2PO_4	1430
K_2HPO_4	1840
Thiamine hydrochloride	750
Cyanocobalamine (B_{12})	10
Biotine	7.5
H_3BO_3	57 190
$\text{MnCl}_2 \cdot 4\text{H}_2\text{O}$	7210
$\text{LiCl} \cdot \text{H}_2\text{O}$	6120
RbCl	1420
$\text{SrCl}_2 \cdot 6\text{H}_2\text{O}$	3040
NaBr	320
$\text{Na}_2\text{MoO}_4 \cdot 2\text{H}_2\text{O}$	1260
$\text{CuCl}_2 \cdot 2\text{H}_2\text{O}$	335
ZnCl_2	260
$\text{CoCl}_2 \cdot 6\text{H}_2\text{O}$	200
KI	65
$\text{Na}_2\text{SeO}_3 \cdot 5\text{H}_2\text{O}$	43.8
NH_4VO_3	11.5
$\text{Na}_2\text{EDTA} \cdot 2\text{H}_2\text{O}$	5000
$\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$	1991

Water temperature

Average temperature 20.729°C (minimal temperature 19.30°C, maximal temperature 22.40°C)

pH

The pH value in the experimental vessels was maintained at 6.9-8.0 at the start 7.5-7.8 at the end and did not fluctuate by more than 1.5 units during the experiment (OECD 211 requirements: pH 6-9)

Lighting

Photoperiod 16 h day/8 h night with a light intensity 1000-1100 lux

B. STUDY DESIGNS AND METHODS

1. Experimental conditions

Test design

Daphnia magna were exposed in a 21days test to test item at five concentrations each with ten replicates and ten replicates of a test water control. One daphnia was introduced into each dish, the test vessels were randomly. The experiment was carried out using the semi-static method. During the experiment, the concentration solutions of the test material were changed every 72 hours.

During the experiment, the following parameters were observed and recorded:

- number of immobilized individuals in each experimental vessel after 24 and 48 hours from the beginning of the experiment
- symptoms of intoxication: changes in the appearance and behavior of animals

Concentrations tested

Product was tested at nominal concentrations of 6.25; 12.5; 25; 50 L; 100 mg/L.. Test definitive test concentrations were chosen based on range finding test results. A control group with untreated test medium was used. The reference item was tested in a separate study

Treatment/Application

A stock solution was prepared by weighing 100 mg of the test item and filling it up to 100 mL test medium. The test solutions were prepared by dilution of the respective amount of the stock solution with test medium.

Analytics

The actual content of test item measured as clopyralid was determined in one replicate of each test item concentration and the control at test start and test end using HPLC with photodiode array detector (PDA). The method was validated according to SANCO/3029/99 rev.4

2. Sampling and measurements

Test was conducted in semi-static system; test item solution were renewal every 72 hours (on the basis of results of stability test). The main objective of the study was to determine the effect of the test item on daphnia reproduction, furthermore, mortality of adults, adult length, age of first offspring production, development rate and intrinsic rate. The end points of the experiment are EC_x, NOEC and LOEC values.

3. Calculation of toxicity

The end points of the experiment are EC_x, NOEC and LOEC values.

4. Statistics

Based on the obtained data, a statistical analysis was carried out in accordance with the OECD 211 using the ToxRat Professional statistical program.

Results and discussions

A. ANALYTICAL RESULTS

Analysis of the concentrations determination was performed by high-performance liquid chromatography with diode UV detection. The identification of active substances in the tested material was made by comparing the UV spectra and the retention times of the reference substance and the sample of the item being tested. Analytically measured concentrations of Faworyt 300 SL measured as clopyralid were within the range of 80 – 120% of nominal.

Date	Labeling of the sample by Laboratory of Physicochemical and Analytical	Labeling of the sample by Laboratory of Ecotoxicology	Determined concentration of the tested item [mg/L]	The concentration of the test item after dilution [mg/L]	The average concentration of the tested item [mg/L]
29.03.2019 day 0	352_2019 01	control day 0	0.00000	0.00000	0.00
	352_2019 02		0.00000	0.00000	
	353_2019 01	6.25 mg/L day 0	0.55255	5.52550	5.53
	353_2019 02		0.55255	5.52550	
	354_2019 01	100 mg/L day 0	0.99289	99.28900	98.32
	354_2019 02		0.97360	97.36000	
02.04.2019 day 4	364_2019 01	control day 4 new	0.00000	0.00000	0.00
	364_2019 02		0.00000	0.00000	
	365_2019 01	6.25 mg/L day 4 new	0.55783	5.57830	5.54
	365_2019 02		0.55101	5.51010	
	366_2019 01	100 mg/L day 4 new	0.97070	97.07000	95.65
	366_2019 02		0.94229	94.22900	
	367_2019 01	control day 4 old	0.00000	0.00000	0.00
	367_2019 02		0.00000	0.00000	
	368_2019 01	6.25 mg/L day 4 old	0.57782	5.77820	5.73
	368_2019 02		0.56746	5.67460	
	369_2019 01	100 mg/L day 4 old	1.09218	109.21800	110.74
	369_2019 02		1.12271	112.27100	
04.04.2019 day 6	388_2019 01	control day 6 new	0.00000	0.00000	0.00
	388_2019 02		0.00000	0.00000	
	389_2019 01	6.25 mg/L day 6 new	0.57199	5.71990	5.71
	389_2019 02		0.57078	5.70780	
	390_2019 01	100 mg/L day 6 new	0.92167	92.16700	92.13
	390_2019 02		0.92097	92.09700	
	391_2019 01	control day 6 old	0.00000	0.00000	0.00
	391_2019 02		0.00000	0.00000	
	392_2019 01	6.25 mg/L day 6 old	0.56660	5.66600	5.71
	392_2019 02		0.57527	5.75270	
	393_2019 01	100 mg/L day 6 old	0.99855	99.85500	99.78
	393_2019 02		0.99703	99.70300	
09.04.2019 day 11	409_2019 01	control day 11 new	0.00000	0.00000	0.00
	409_2019 02		0.00000	0.00000	
	410_2019 01	6.25 mg/L day 11 new	0.55375	5.53750	5.53
	410_2019 02		0.55183	5.51830	
	411_2019 01	100 mg/L day 11 new	0.92168	92.16800	96.71
	411_2019 02		1.01250	101.25000	
	412_2019 01	control day 11 old	0.00000	0.00000	0.00
	412_2019 01	control day 11 old	0.00000	0.00000	0.00
	412_2019 02		0.00000	0.00000	
	413_2019 01	6.25 mg/L day 11 old	0.64512	6.45120	6.19
	413_2019 02		0.59355	5.93550	
	414_2019 01	100 mg/L day 11 old	1.03332	103.33200	103.06
	414_2019 02		1.02788	102.78800	

B. BIOLOGICAL RESULTS

During the experiment the following observations were performed:

- The number of offspring in each test vessel each day of the experiment (offspring were removed at once, during the observation), the number of dead offspring and abandoned eggs, as well as time of the first offspring were recorder.
- Immobility (mortality) of parental individuals each day of experiment - caused by the action of the material being tested or by an accidental cause.

- Length of the adult animals at the end of the experiment The results of the length of adults animals are presented in Table 25.
- Age of first reproduction The results of age of first reproduction are presented in Table 26.
- Development rate The results of development rate are presented in Table 27.
- Intrinsic rate (for adults remaining alive until the 21st day of the experiment). The results of intrinsic rate are presented in Table 28.
- It was observed also an unusual behavior of daphnia, symptoms of intoxication, i.e. production of ephippia, abandonment of winter eggs (during the study no symptoms of intoxication were observed)

The average number offspring in relation to surviving specimen

Concentration [mg/L]	The average number of offspring per survived parent on day 21 of the experiment [pcs.]	Reduction in comparison to control [%]	Statistical significance ^{*)}
Control	63.0	n/a	n/a
6.25	59.1	6.17	-
12.5	60.8	3.57	-
25.0	58.4	7.26	-
50.0	58.8	6.7	-
100.0	59.6	5.44	-

n/a not applicable

- not statistically significant

*) values calculated by ToxRat Professional using Dunett's test t-test at the significance level $p \leq 0.05$

Immobility of parental specimens

Concentration [mg/L]	Number of introduced parental individual [pcs.]	Repetition, in which mortality of parental individual was found	Day of experiment in which mortality of parental individual was found	The number of survived parental individual at the end of the experiment [pcs.]	Immobility of parental individual [%]	Statistical significance ^{*)}
Control	10	nd.	nd.	10	0	n/a
6.25	10	5	19	9	10	-
12.5	10	7, 9	21	8	20	-
25.0	10	1, 9, 10	13, 18, 19,	7	30	-
50.0	10	3	19	9	10	-
100.0	10	3, 8, 10	10, 13	7	30	-

n/a not applicable

- not statistically significant

*) values calculated by ToxRat Professional using the Fisher's exact binomial test with Bonferroni correction at the significance level $p > 0.05$

The obtained results indicate that the tested material does not affect the total number of offspring daphnia per parent surviving and immobilization of parental individuals in the range of tested concentrations. The test item affects the length of adults in the concentration range from 50 mg/L and the age of production of the first offspring and development rate at a concentration of 100 mg/L. In addition, the tested material affects the intrinsic rate of daphnia in the range of concentrations from 12.5 mg/L. The final results of the experiment are presented in table below.

Final Results

Parameter	EC ₁₀ [mg/L]	EC ₂₀ [mg/L]	EC ₅₀ [mg/L]	LOEC [mg/L]	NOEC [mg/L]
Cumulative offspring number per survival parent (21 days)	0.000 (n.d. – n.d.)*	0.007 (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	>100.0	≥100.0
Immobility	n.d. (n.d. – n.d.)*	26.660 (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	>100.0	≥100.0
Length of parental specimens	116.490 (52.870 – 256.666)*	n.d. (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	50.0	25.0
Age of first reproduction	0.000 (0.000 – 0.000)*	0.000 (0.000 – 0.000)*	0.000 (0.000 – 0.000)*	100.0	50.0
Development rate	44.116 (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	100.0	50.0
Intrinsic rate	21.725 (5.460 – 86.435)*	184.622 (21.936 – 1396.329)*	n.d. (n.d. – n.d.)*	12.5	6.25

EC₁₀ effective test item concentration for 10% reduction

EC₂₀ effective test item concentration for 20% reduction

EC₅₀ effective test item concentration for 50% reduction

LOEC lowest observe effective concentration cause statistically significant differences in comparison to the control

NOEC highest non observe effective concentration cause no statistically significant differences in comparison to the control

*) the lower and upper 95% confidence limits are given in brackets

n.d. not determined due to mathematical reasons

C. VALIDITY CRITERIA

The test met all the validity criteria in accordance with the OECD Guideline 211:

- mortality of parental individuals in the control at the end of experiment was 0% (requirement <20%)
- the mean number of living offspring in control per parent animal surviving at the end of the test was 63 (requirement ≥60 offspring)
- the number of parent organisms killed in a random and unidentified manner in the control and in the concentrations of the tested material it was 0% (requirements max. 20 %)

Conclusion

There was no statistically significant impact of the tested material on the number of young daphnia per introduced parental survivor within 21 days and immobilization (mortality) among adults in the range of concentrations adopted in the study in relation to control. The material tested affects the length of adults with controls for concentrations of 50 mg/L and 100 mg/L. A statistically significant difference was found for age of the first offspring production and development rate at a concentration of 100 mg/L compared to the control. In addition, the tested material affects the intrinsic rate of daphnia in a concentration of 12.5 mg/L, 25 mg/L, 50 mg/L and 100 mg/L in comparison to the control

Study 6

Comments of zRMS:

The study is considered as acceptable . All validity criteria were met.

- The fresh weight factor for control plants was 2.2 (requirements according to OECD 239: minimum 2)
- The total shoot length factor for control plants was 2.3 (requirements according to OECD 239: minimum 2)
- The coefficient of variations for yield based on fresh weight was 31.1% (requirements according to OECD 239: ≤35%)

Agreed endpoints:

The results of the definitive test calculated by ToxRat Professional					
Rated value	EC ₁₀ [mg/L]	EC ₂₀ [mg/L]	EC ₅₀ [mg/L]	NOEC [mg/L]	LOEC [mg/L]
Yield for fresh weight	13.385 (7.101 - 25.231)*	15.002 (7.907 - 28.334)*	18.659 (7.592 - 43.742)*	9.530	17.150
Average specific growth rate for fresh weight	16.150 (0.000 - n.d.)*	16.684 (0.000 - n.d.)*	17.755 (n.d. - n.d.)*	9.530	17.150
Yield for dry weight	8.094 (3.127 - 20.950)*	9.008 (3.444 - 23.552)*	11.053 (2.774 - 41.008)*	9.530	17.150
Average specific growth rate for dry weight	9.110 (0.000 - n.d.)*	9.419 (n.d. - n.d.)*	10.038 (n.d. - n.d.)*	9.530	17.150
Yield for total shoot length after 14 days	21.953 (10.052 - 47.940)*	26.739 (12.655 - 56.444)*	38.994 (15.677 - 95.802)*	30.860	55.560
Average specific growth rate for total shoot length after 14 days	21.233 (7.770 - 57.966)*	28.707 (10.965 - 75.269)*	51.159 (15.689 - 163.034)*	30.860	55.560

EC₁₀

concentration of test item causing symptoms of intoxication in 10% of the population

EC₂₀

concentration of test item causing symptoms of intoxication in 20% of the population

EC₅₀

concentration of test item causing symptoms of intoxication in 50% of the population

NOEC

highest non observe effective concentration cause no statistically significant differences in comparison to the control

LOEC

lowest observe effective concentration cause statistically significant differences in comparison to the control

*)

the lower and upper 95% confidence limits are given in brackets

n.d.

not determined due to mathematical reasons

Reference: KCP 10.2.1

Report Faworyt 300 SL Water-sediment *Myriophyllum spicatum* toxicity test according to OECD 239, Aleksandra Kamińska, 2019, STUDY CODE: 0016/0061/E, SORBOLAB Research Laboratory, Poland

Guideline(s): Yes. According to the OECD Guideline No. 239

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

A. MATERIALS

1. Test material

Description	clear liquid, yellow in color with a characteristic weak odor
Lot/Batch #	201805002

Content of active substance Clopyralid: 302.7 g/L
Density: 1.161 g/mL
Expiry date 15.05.2021

2. Test organism

Species spiked water-milfoil *Myriophyllum spicatum*
Source Culture grown in the SORBOLAB Research Laboratory.
Culturing At 20 ± 2 °C under constant illumination in Smart & Barko medium.
Acclimation period Culturing was done under test conditions.
Test units Plastic pots with sediment were placed in bakers in which three shoot apices were planted and the baker was filled with Smart&Barko medium

3. Environmental conditions

Test water Smart & Barko medium containing the following constituents:

Substance	Concentration [mg/L]
CaCl ₂ · 2 H ₂ O	91.7
MgSO ₄ · 7 H ₂ O	69.0
NaHCO ₃	58.4
KHCO ₃	15.4
pH	7.9

Water temperature 21.583°C, minimal temperature 19.60°C, maximal temperature 23.30°C
pH The pH value in the experimental vessels was maintained at 7.81-7.98 at the start, 7.89-8.02 at the end and did not fluctuate by more than 1.5 units during the experiment (OECD 211 requirements: pH 6-9)
Lighting Photoperiod 16 h day/8 h night with a light intensity 10700-115700 lux

B. STUDY DESIGNS AND METHODS

1. Experimental conditions

Test design

Test design B: one pot per one test vessel with tree shoots

All concentrations of the test item were prepared in four replicates and control in six. Plastic pots with sediment were placed in bakers in which three shoot apices were planted and the baker was filled with Smart&Barko medium. Rooting phase lasted 13 days. Exposition phase to tested item lasted 14 days. The test was carried out in 2 L glass bakers filled with 1.7 L of Smart&Barko medium

The aim of the study was to determine the effect of the test item Faworyt 300 SL on growth of spiked water-milfoil *Myriophyllum spicatum*, expressed as increase in yield (EyCx) and average specific growth rate (ErCx) for fresh and dry weight and total shoot length after 14 days. End points of the study are ECx values for tested parameters. Also statistically were determined NOEC and LOEC values

Concentrations tested

Product was tested at nominal concentrations of 9.53 mg/L; 17.15 mg/L; 30.86 mg/L; 55.56 mg/L; 100 mg/L in four repetitions mg/L.. Test definitive test concentrations were chosen based on range finding test results. A control group with untreated test medium was used. The reference item was tested in a separate study

Treatment/Application

A stock solution was prepared by weighing 2 000 mg of the test item and filling it up to 1000 mL test medium. The test solutions were prepared by dilution of the respective amount of the stock solution with test medium.

Analytics

The actual content of test item measured as clopyralid was determined in one replicate of each test item concentration and the control at test start and test end using HPLC with photodiode array detector (PDA). The method was validated according to SANCO/3029/99 rev.4

2. Sampling and measurements

Test was conducted in semi-static system; test item solution were renewal every 72 hours (on the basis of results of stability test). The main objective of the study was to determine the effect of the test item on daphnia reproduction, furthermore, mortality of adults, adult length, age of first offspring production, development rate and intrinsic rate. The end points of the experiment are ECx, NOEC and LOEC values.

3. Calculation of toxicity

The end points of the experiment are ECx, NOEC and LOEC values.

4. Statistics

Based on the obtained data, a statistical analysis was carried out in accordance with the OECD 211 using the ToxRat Professional statistical program.

Results and discussions

A. ANALYTICAL RESULTS

Analysis of the concentrations determination was performed by high-performance liquid chromatography with diode UV detection. The identification of active substances in the tested material was made by comparing the UV spectra and the retention times of the reference substance and the sample of the item being tested . Analytically measured concentrations of Faworyt 300 SL measured as clopyralid were within the range of 80 – 120% of nominal.

Results of analytical determinations

Date	Sample ID in Physicochemistry and Analytics Laboratory	Sample ID in Ecotoxicology Laboratory	Determined concentration of test item [mg/L]	Concentration of test item in solution after correction of dilution [mg/L]	Average concentration of test item in solution [mg/L]
23.04.2019	449_2019 01	control	0.00000	0.00000	0.00
	449_2019 02		0.00000	0.00000	
	450_2019 01	9.53 mg/L	0.88474	8.84740	8.88
	450_2019 02		0.89071	8.90710	
	451_2019 01	17.15 mg/L	0.76734	15.34680	15.57
	451_2019 02		0.78949	15.78980	
	452_2019 01	30.86 mg/L	0.26560	26.56000	26.62
	452_2019 02		0.26680	26.68000	
	453_2019 01	55.56 mg/L	0.50484	50.48400	50.91
	453_2019 02		0.51333	51.33300	
	454_2019 01	100 mg/L	0.93190	93.19000	92.92
	454_2019 02		0.92651	92.65100	
07.05.2019	497_2019 01	control	0.00000	0.00000	0.00
	497_2019 02		0.00000	0.00000	
	498_2019 01	9.53 mg/L	0.87697	8.76970	8.76
	498_2019 02		0.87439	8.74390	
	499_2019 01	17.15 mg/L	0.74912	14.98240	15.33
	499_2019 02		0.78379	15.67580	
	500_2019 01	30.86 mg/L	0.23391	23.39100	23.79
	500_2019 02		0.24196	24.19600	
	501_2019 01	55.56 mg/L	0.50233	50.23300	49.53
	501_2019 02		0.48817	48.81700	
	502_2019 01	100 mg/L	0.89209	89.20900	89.10
	502_2019 02		0.88996	88.99600	

B. RESULTS

The aim of the conducted study was to determine a toxicological impact of the test item on spiked water-milfoil (*Myriophyllum spicatum*) in yield (EyCx) and average specific growth rate (ErCx) for fresh and dry weight and total shoot length at tested concentrations. Statistically NOEC and LOEC values for all parameters were calculated. The obtained EC10, EC20, EC50 and NOEC and LOEC values after 14 days from the application of the tested item, testify to the ecotoxic effect of the tested material in concentrations of 17.15 mg/L, 30.86 mg/L, 55.56 mg/L, 100 mg/L for yield of fresh and dry weight, average specific growth rate for fresh and dry weight and for 55.56 mg/L, 100 mg/L concentrations for yield of the total shoot length and the average specific growth rate for total shoot length

C. VALIDITY CRITERIA

The validity criteria in accordance with OECD Guideline 239 were met:

- the fresh weight factor for control plants was 2.2 (requirements according to OECD 239: minimum 2)

– the total shoot length factor for control plants was 2.3 (requirements according to OECD 239:
minimum 2

– the coefficient of variations for yield based on fresh weight was 31.1% (requirements according to OECD 239: $\leq 35\%$)

Conclusion

The results of the definitive test calculated by ToxRat Professional					
Rated value	EC ₁₀ [mg/L]	EC ₂₀ [mg/L]	EC ₅₀ [mg/L]	NOEC [mg/L]	LOEC [mg/L]
Yield for fresh weight	13.385 (7.101 - 25.231)*	15.002 (7.907 - 28.334)*	18.659 (7.592 - 43.742)*	9.530	17.150
Average specific growth rate for fresh weight	16.150 (0.000 - n.d.)*	16.684 (0.000 - n.d.)*	17.755 (n.d. - n.d.)*	9.530	17.150
Yield for dry weight	8.094 (3.127 - 20.950)*	9.008 (3.444 - 23.552)*	11.053 (2.774 - 41.008)*	9.530	17.150
Average specific growth rate for dry weight	9.110 (0.000 - n.d.)*	9.419 (n.d. - n.d.)*	10.038 (n.d. - n.d.)*	9.530	17.150
Yield for total shoot length after 14 days	21.953 (10.052 - 47.940)*	26.739 (12.655 - 56.444)*	38.994 (15.677 - 95.802)*	30.860	55.560
Average specific growth rate for total shoot length after 14 days	21.233 (7.770 - 57.966)*	28.707 (10.965 - 75.269)*	51.159 (15.689 - 163.034)*	30.860	55.560

EC₁₀ concentration of test item causing symptoms of intoxication in 10% of the population

EC₂₀ concentration of test item causing symptoms of intoxication in 20% of the population

EC₅₀ concentration of test item causing symptoms of intoxication in 50% of the population

NOEC highest non observe effective concentration cause no statistically significant differences in comparison to the control

LOEC lowest observe effective concentration cause statistically significant differences in comparison to the control

*) the lower and upper 95% confidence limits are given in brackets

n.d. not determined due to mathematical reasons

A 2.2.1 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.2 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

Comments of zRMS:	<p>Result of the study was evaluated by the zRMS – PL during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments).</p> <p>Agreed endpoints:</p> <p>48 h LD₅₀ >100 µg product/bee (oral and contact)</p>
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Reference:	KCP 10.3.1.1/01
Report:	Ocena toksycznego działania preparatu Chlopyralid 300 SL dla pszczoły miodnej (<i>Apis mellifera</i> L.), Irzyk M., 2001, OSŻ-09/01
Guideline(s):	OECD 213 and 214 (1998)
Deviations:	None
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Material and Methods:

Chlopyralid 300 SL (batch No. 01/2001) is a brown liquid containing clopyralid as the active substance (nominal concentration: 300 g/L, measured concentration: 305.8 g/L). Test material was given to honey bees (*Apis mellifera*) individually with help of micropipette after dispensing in 50% water solution of sugar. Every insect was fed on 10µL of that syrup. Test material was used in four concentrations: 12.5, 25, 50 and 100 µg/bee. Every dose and control group was performed in 3 replicates with 10 honey-bees in every replicate, 30 insects in total. The test duration was 96 hrs.

Table 10.4.2.1-1: Acute oral toxicity of Chlopyralid 300 SL to bees

Dose [µg/bee]	Mortality after													
	4 h		24 h		LD ₅₀ [µg/bee]	48 h		LD ₅₀ [µg/bee]	72 h		LD ₅₀ [µg/bee]	96 h		LD ₅₀ [µg/bee]
	[no]	[%]	[no]	[%]		[no]	[%]		[no]	[%]		[no]	[%]	
0.0 (Control)	0	0	0	0	>100	0	0	>100	1	3.33	>100	2	6.67	>100
12.5	0	0	0	0		0	0		1	3.33		2	6.67	
25.0	0	0	0	0		0	0		1	3.33		1	3.33	
50.0	0	0	0	0		0	0		1	3.33		2	6.67	
100.0	0	0	0	0		1	3.33		1	3.33		3	10.00	

Findings:

- Very low mortality was observed during the study.
- No abnormal symptoms in behaviour of honey-bees were noticed.

Conclusion/endpoint:

Under the experimental conditions, the oral LD₅₀ (48hrs) of Chlopyralid 300 SL is higher than 100 µg/bee for honey bees

Result of the study presented above was already evaluated and accepted by the zRMS (Poland)

during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments).

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Reference is made to Point KCP 10.3.1.1

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	<p>The study is considered as acceptable . All validity criteria were met.</p> <ul style="list-style-type: none">- Bee mortality in control after 10 days was 2% (acceptable $\leq 15\%$)- Bee mortality in the reference test after 10 days was 53.3% <p>Agreed endpoints: Due to performing the definitive test for highest concentration (limit test), concentration causing mortality of 50% of the population in the experiment (LC50 value) and a dose of food causing mortality of 50% of the population after 10 days (LDD₅₀ as well as NOEC and NOEDD values were not determined. Therefore, zRMS estimated the following values:</p> <p>LC₅₀ >2500 mg/kg of food LDD₅₀ >2500 mg/kg of food NOEC >2500 mg/kg of food NOEDD >2500 mg/kg of food</p>
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Reference:	KCP 10.3.1.2/01
Report:	Honey Bee, Chronic Oral Toxicity Test according to OECD 245, Orzechowska U., 2019, 0016/0052/E
Guideline(s):	OECD 245 (2017)
Deviations:	None
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and Methods

Test item

Name:	Faworyt 300 SL
Test material description:	clear liquid, yellow-colored of characteristic faint scent
Batch No.	201805002
Name of active ingredient	chlopyralid
Content of active ingredient	302.7 g/L (purity min. 95% w/w)
CAS of active ingredient	1702-17-6
Production date	16.05.2018
Expiry date	15.05.2021

Tested species

The study was carried out on honeybee *Apis mellifera* L. coming from a registered breeding. Quarantine of bees was not carried out, because in the month before the start of test insects were not treated with chemical compounds, including antibiotics or anti-mite agents.

The study used young honeybees (2-day-old) of similar age derived from healthy, well-maintained breeding. The physiological condition of the bees was tested during the test with a reference substance (dimethoate).

The bees were placed in the test room under the conditions of the experiment one day before the experiment.

Method of test item preparation

The weight of the test item was dissolved in a 50% aqueous sucrose solution. Next a series of dilutions of the test solutions were prepared from the resulting stock solution. The stock solution and test solutions were stored in a closed container in the dark at $6\pm 2^{\circ}\text{C}$. The test solutions were prepared every four days from the stock solution.

Range-finding test

The test consisted of feeding the bees a 50% sugar solution containing the test item for 10 days. In the range finding test, was used: control fed with a 50% sugar solution and the following concentrations of the test item: 2.5 mg/kg; 25 mg/kg; 250 mg/kg and 2500 mg/kg of food. Feeders were exchanged daily, every 24 ± 2 hours.

Each concentration and control consisted of three replicates. Ten bees were introduced into each cage measuring 20x20x20 cm. The study lasted 10 days.

During the experiment, no statistically significant mortality of bees was observed in comparison to the control. The signs of intoxication were recorded in few concentrations, but no significant signs were observed. The analysis was carried out in statistical analysis program ToxRat Professional and determined the values NOEC and LOEC ≥ 2500 mg/kg of food.

Reference test

Experiment with the reference substance (dimethoate) was conducted in parallel with the definitive test. The aim of the study was to determine the sensitivity of the honeybee (*Apis mellifera* L.) used for research. One concentration of reference substance was used: 0.75 mg/kg of food and control. The test was performed in triplicate for concentration and control, 10 bees each in each replicate.

Definitive test

Based on the results of the range finding test, the definitive test was performed using one concentration of the test item: 2500 mg/kg of food and control (50% sucrose solution). Concentration and control were prepared in five repeats. To each cage of 20x20x20 cm dimension 10 bees were introduced. The test consisted of feeding the bees for 10 days with 50% sucrose solution containing the test item. Feeders were exchanged daily, every 24 ± 2 hours. Food was prepared each four days.

Average temperature during the definitive test was 34.14°C (minimal temperature 32.6°C . maximal temperature 36.1°C) and average relative humidity 66.199% (minimal humidity 45.1%. maximal humidity 72.6%). The study was conducted in darkness.

Conclusion

In the definitive test, no statistically significant bee mortality was observed in bee mortality after 10 days of the test. The test item is not apitoxic in concentration 2500 mg/kg of food.

Due to the fact of conducting the definitive as limit test, the concentration causing 50% mortality of the population in the experiment (LC50 value) and dose of food causing 50% mortality of the population after 10 days (LDD50 value), as well as NOEC and NOEDD were not determined. No signs of the intoxication were recorded in any repeat of the tested dose.

Mortality of bees at the end of test			
Concentration of the test item [mg/kg of food]	Number of dead bees	Mortality [%]	Statistical significance comparing to the control *
Control	1	2	no application
2500	4	8	-

* + statistically significant, - no statistical significance

For statistical calculations was used Fisher's test in ToxRat Professional software

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

Comments of zRMS:

The study is considered as acceptable . All validity criteria were met.

- Cumulative larval mortality in control in days 3-8 was 2.8% (required: $\leq 15\%$)
- The adults emergence rate in control on day 22 was 88.9% (required: $\geq 70\%$)
- Cumulative larval mortality in reference test on day-8 was 52.8% (required: $\geq 50\%$)

Agreed endpoints:

Parametr	Concentration [mg/kg of food]	Parametr	Dose [µg/larva]
LC ₁₀	na. (na.-na.)*	LD ₁₀	na. (na.-na.)*
LC ₂₀	0.168 (na.-na.)*	LD ₂₀	0.026 (na.-na.)*
LC ₅₀	3.209 (na.-na.)*	LD ₅₀	0.487 (na.-na.)*
NOEC	0.42	NOED	0.065

*

upper and lower confidence limits (95%)

na.

not applicable

Reference: KCP 10.3.1.3/01

Report: Chronic Toxicity Test for Bee Larvae, U.Orzechowska, 2019, 0016/0056/E

Guideline(s): OECD Guidance document 239 (2016)

Deviations: None

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): -

Materials and methods:

Test item

Name: Faworyt 300 SL

Test material description	clear liquid, yellow-colored of characteristic faint scent
Original package appearance	HDPE container
Batch No.	201805002
Name of active ingredient	chlopyralid
Content of active ingredient	302.7 g/L (purity min. 95% w/w)
CAS of active ingredient	1702-17-6
Production date	16.05.2018
Expiry date	15.05.2021

Test species

The study was carried out on honeybee *Apis mellifera* L. coming from a registered breeding. Quarantine of bees was not carried out, because in the month before the start of test insects were not treated with chemical compounds, including antibiotics or anti-mite agents.

The study used 1-day larvae of honey bee originated from 3 different, healthy, well-maintained breeding. The physiological condition of the bees was tested during the test with a reference substance (dimethoate), chosen on the base of range-finding test.

3 days before the beginning of the test (D-3), in each family, queen bee was isolated using one-frame isolator. After max. 30 hours (D-2), queens were released from the isolator (after confirming the presence of freshly laid eggs). The frame containing the eggs remains in the isolator, placed next to the frame containing brood, for 3 days, until the hatching (D1). For the study are chosen larvae, which has not yet formed C-shape or the ones laying on the top of royal jelly. The larvae were carefully placed in the same position at the bottom of queen-cell cup filled with diet A. Larvae are collected in excess to provide minimal amount of larvae (12 larvae from each colony) required for the beginning of test item exposition at day 3.

Method of test item preparation

The weight of the test item was dissolved in a deionized water. Then final solutions of test item were prepared by adding given volume of stock solution to following portions of food (larval diets). Fresh diets were prepared daily.

Methods of preparation of food

Larval diets were adjusted depending on the developmental stage (all solutions were prepared in weight percentage):

- Food A: 50% fresh royal jelly + 50% aqueous solution containing 2% yeast extract/ 12% glucose/ 12% fructose
- Food B: 50% fresh royal jelly + 50% aqueous solution containing 3% yeast extract / 15% glucose / 15% fructose
- Food C: 50% fresh royal jelly + 50% aqueous solution containing 4% yeast extract / 18% glucose / 18% fructose.

Following the above, prepared food should have density around 1.1 mg/ μ L (20 μ L of food corresponds to 22 mg of food).

Before administration, food was warmed to 35°C. It was provided using automatic pipette, with caution to avoid touching a larva or drowning it in food liquid.

From the emergence phase (day 15-22) as food was used:

- 50% aqueous solution of sucrose
- pine speck

Range-finding test

During the range-finding test, test item was added to the food during 4-day exposition. The observations of mortality and behavioral changes were recorded daily during 22 days of the test. Basing on the range-finding test, number and range of concentrations for definitive test were determined.

Additionally, the repeats were made with use of two reference items – dimethoate and fenoxycarb, to determine proper substance for reference test, carried out parallel to the definitive test.

Range-finding test was performed for four concentrations of test item and control. Following concentrations of test item were used: 0.65 mg/kg; 6.5 mg/kg; 65 mg/kg and 650 mg/kg of food, which correspond to dose: 0.1 μ g/larva; 1 μ g/larva; 10 μ g/larva and 100 μ g/larva. Each concentration

and control were prepared in one repetition, 36 larvae per repeat (12 larvae from 3 colonies). During range-finding test statistically significant larval mortality was observed in all tested doses. Mortality and signs of intoxication for following developmental stages were equally significant. The NOEC value was determined for the following developmental stages. Based on the results, it was decided to perform definitive test using doses with spacing factor equal 2.5; starting from the dose in 6.5 mg/kg of food.

Analysis of preliminary results was conducted using program for statistical analysis ToxRat Professional
Reference test

Experiment with the reference substance (dimethoate) was conducted in parallel with the definitive test. The aim of the study was to determine the sensitivity of the honeybee larvae (*Apis mellifera* L.) used for research. The concentration causing mortality of 50% of the larval population in the experiment after 8 first days was determined.

Definitive test

During the definitive test, test item was administrated in food during 4-day exposition. The observations of mortality and behavioral changes were recorded daily during 22 days of the test. Parallel to definitive test, reference test was performed using dimethoate as reference item. In the definitive test, were used following concentration: 0.17 mg/kg; 0.42 mg/kg; 1.04 mg/kg; 2.6 mg/kg and 6.5 mg/kg of food. Each concentration and control were prepared in one repetition, 36 larvae per repeat (12 larvae from 3 colonies).

Conclusion

In course of the experiment, the test item have shown apitoxic effect in mortality of following developmental stages of bees after 22 days of the test.

At the end of the study, the concentration and the dose causing 50% mortality of the population in the test (LC₅₀ and LD₅₀ values), along with NOEC, NOED and other EC_x/ED_x.

Parametr	Concentration [mg/kg of food]	Parametr	Dose [µg/larva]
LC ₁₀	na. (na.-na.)*	LD ₁₀	na. (na.-na.)*
LC ₂₀	0.168 (na.-na.)*	LD ₂₀	0.026 (na.-na.)*
LC ₅₀	3.209 (na.-na.)*	LD ₅₀	0.487 (na.-na.)*
NOEC	0.42	NOED	0.065

* upper and lower confidence limits (95%)
na. not applicable

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

No additional data submitted.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

No additional data submitted.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

No additional data submitted.

A 2.3.2 KCP 10.3.2 Effects on arthropod other than bees

A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing

A 2.3.2.1.1 Study 1: Toxicity to *Aphidius rhopalospihi*

Comments of zRMS:

The study is considered as acceptable . All validity criteria were met.

Control Mortality: 0.0 % (should not exceed 13%)
Reference Item Mortality: 100.0 % corrected mortality (should result in at least 50% corrected mortality)
Control Reproduction Rate: 41.0 mummies per female (mean value) (should be ≥ 5 female)
There was no parasitoid producing zero values (there should be no more than 2 parasitoids producing zero values)

Agreed endpoints:

	Rate ¹⁾ [mL/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction ⁴⁾ [mummies/female]	Effect on reproduction ⁵⁾ [%]
Control	0	0.0	--	41.0	--
Faworyt 300 SL	4.94	2.5 n.s.	2.5	45.6 n.s.	-11.3
Faworyt 300 SL	14.8	5.0 n.s.	5.0	30.8 *	24.8
Faworyt 300 SL	44.4	0.0 n.s.	0.0	32.6 *	20.5
Faworyt 300 SL	133	0.0 n.s.	0.0	29.4 *	28.3
Faworyt 300 SL	400	10.0 n.s.	10.0	22.0 *	46.3

Endpoints

LR₅₀: > 400 mL product/ha (equivalent to 121 g a.s./ha)
ER₅₀: > 400 mL product/ha (equivalent to 121 g a.s./ha)

1) Application rate in 200 L water/ha
2) Mortality: after 48 hours of exposure to spray residues on glass plates, (Bonferroni-Holm Fisher's Exact Test, $\alpha = 0.05$; n.s. = not significant)
3) Corrected mortality according to Abbott and improvements by Schneider-Orelli
4) Reproduction: mean number of parasitised aphids/female, (Williams t-test, $\alpha = 0.05$; n.s. = not significant, * = significant)
5) Calculated on the exact raw data; negative values indicate better performance compared to the control

Reference: KCP 10.3.2.1/01

Report: Faworyt 300 SL: Effects on the Parasitoid *Aphidius rhopalosiphi* in the Laboratory - Dose Response Test, Moll M., 2019, 140601001

Guideline(s): IOBC (Mead-Briggs et al., 2000 and 2010)

Deviations: None

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) -

Material and methods:

Test Item:	Faworyt 300 SL; batch no.: 201805002; content of a.s.: 302.7 g/L Chlopyralid.
Test Species:	Parasitoid (<i>Aphidius rhopalosiphi</i>), adults not older than 48 hours; source: Katz Biotech AG, Baruth, Germany.
Test Design:	This study encompassed 7 treatment groups (5 dose rates of the test item, control, reference item) with 4 replicates each containing 10 adult parasitoids. The parasitoids were exposed to dried residues on treated glass plates. Survival of the parasitoids was assessed after 2, 24 and 48 hours. At 48 hours, for treatment groups where the corrected mortality was < 50 % the reproductive capacity was assessed by confining females individually over untreated barley plants infested with the host cereal aphids, <i>Rhopalosiphum padi</i> . The females were removed after 24 hours and the aphid-infested plants left for a further 11 - 12 days before the numbers of aphid mummies that had developed were assessed.
Endpoints:	Mortality of exposed parasitoids; LR50: lethal rate producing 50 % mortality after 48 h of exposure. Additionally reproductive capacity for female survivors.
Reference Item:	Perfekthion (nominal: 400 g dimethoate/L).
Test Rates:	Control, 4.94, 14.8, 44.4, 133 and 400 mL product/ha (equivalent to 1.50, 4.48, 13.4, 40.3 and 121 g a.s./ha) and reference item. The reference item was applied at an application rate of 0.3 mL Perfekthion/ha. All treatments were applied in 200 L water/ha. The spraying dilutions were sprayed onto glass plates via laboratory spraying equipment, which were then air dried.
Test Conditions:	Temperature: 19 - 21 °C; relative humidity: 69 - 72 % (acclimatisation and exposure period), 77 - 84 % (post-exposure period, within the test units); photoperiod: 16 h light : 8 h dark; light intensity: 1140 - 2060 lux (acclimatisation, exposure and parasitisation period), 8560 - 15110 lux (post-parasitisation period)

Findings:

	Rate ¹⁾ [mL/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction ⁴⁾ [mummies/female]	Effect on reproduction ⁵⁾ [%]
Control	0	0.0	--	41.0	--
Faworyt 300 SL	4.94	2.5 n.s.	2.5	45.6 n.s.	-11.3
Faworyt 300 SL	14.8	5.0 n.s.	5.0	30.8 *	24.8
Faworyt 300 SL	44.4	0.0 n.s.	0.0	32.6 *	20.5
Faworyt 300 SL	133	0.0 n.s.	0.0	29.4 *	28.3
Faworyt 300 SL	400	10.0 n.s.	10.0	22.0 *	46.3
Endpoints					
LR ₅₀ : > 400 mL product/ha (equivalent to 121 g a.s./ha)					
ER ₅₀ : > 400 mL product/ha (equivalent to 121 g a.s./ha)					

1) Application rate in 200 L water/ha

2) Mortality: after 48 hours of exposure to spray residues on glass plates,
(Bonferroni-Holm Fisher's Exact Test, $\alpha = 0.05$; n.s. = not significant)

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

4) Reproduction: mean number of parasitised aphids/female,
(Williams t-test, $\alpha = 0.05$; n.s. = not significant, * = significant)

5) Calculated on the exact raw data; negative values indicate better performance compared to the control

Conclusion:

Under worst case laboratory conditions the LR50 of Faworyt 300 SL is estimated to be greater than 400mL product/ha (equivalent to 121 g a.s./ha) in 200 L water/ha.

Reproduction of *Aphidius rhopalosiphi* was assessed in the control and at all test item dose rates. There was no statistically significant effect on reproduction at 4.94 mL product/ha (equivalent to 1.50 g a.s./ha). At 14.8, 44.4, 133 and 400 mL product/ha (equivalent to 4.48, 13.4, 40.3 and 121 g a.s./ha) reproduction was statistically significantly affected, but the effect on reproduction was below the trigger value of 50 % (20.5 - 46.3 %). Therefore it can be summarised that there was no effect on reproduction up to and including 400 mL product/ha (equivalent to 121 g a.s./ha). The ER₅₀ is estimated to be greater than 400 mL product/ha (equivalent to 121 g a.s./ha) in 200 L water/ha.

A 2.3.2.1.2 Study 2: Toxicity to *Typhlodromus pyri*

Comments of zRMS:	<p>The study is considered as acceptable . All validity criteria were met.</p> <ul style="list-style-type: none"> - Control mortality: 18.3% (should not exceed 20%) on day 7 - Reference item mortality: 100% corrected mortality (should results in at least 50% corrected mortality on day 7 after exposure) - Control Reproduction: 8.4 eggs per female (No. of eggs per female should be ≥ 4 eggs for the second week) <p>Agreed endpoints:</p> <table border="1"> <thead> <tr> <th></th><th>Rate ¹⁾ [mL/ha]</th><th>Mortality ²⁾ [%]</th><th>Mortality corr. ³⁾ [%]</th><th>Reproduction ⁴⁾ [eggs/female]</th><th>Effect on reproduction ⁵⁾ [%]</th></tr> </thead> <tbody> <tr> <td>Control</td><td>0</td><td>18.3</td><td>--</td><td>8.4</td><td>--</td></tr> <tr> <td>Faworyt 300 SL</td><td>4.94</td><td>18.3 n.s.</td><td>0.0</td><td>8.1 n.s.</td><td>4.3</td></tr> <tr> <td>Faworyt 300 SL</td><td>14.8</td><td>3.3 n.s.</td><td>-18.4</td><td>7.3 n.s.</td><td>12.9</td></tr> <tr> <td>Faworyt 300 SL</td><td>44.4</td><td>10.0 n.s.</td><td>-10.2</td><td>8.5 n.s.</td><td>-1.1</td></tr> <tr> <td>Faworyt 300 SL</td><td>133</td><td>23.3 n.s.</td><td>6.1</td><td>9.6 n.s.</td><td>-13.5</td></tr> <tr> <td>Faworyt 300 SL</td><td>400</td><td>25.0 n.s.</td><td>8.2</td><td>6.7 n.s.</td><td>20.2</td></tr> </tbody> </table> <p style="text-align: center;">Endpoints</p> <p style="text-align: center;">LR₅₀: > 400 mL product/ha (equivalent to 121 g a.s./ha) ER₅₀: > 400 mL product/ha (equivalent to 121 g a.s./ha)</p> <p>1) Application rate in 200 L water/ha 2) Mortality: after 7 days of exposure to spray residues on glass plates (Bonferroni-Holm Fisher's Exact Test, α = 0.05; n.s. = not significant) 3) Corrected mortality according to Abbott and improvements by Schneider-Orelli; negative values indicate better survivorship compared to control 4) Reproduction: mean number of eggs/female, (Dunnett's t-test, α = 0.05; n.s. = not significant) 5) Calculated on the exact raw data; negative values indicate better performance compared to the control</p>						Rate ¹⁾ [mL/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction ⁴⁾ [eggs/female]	Effect on reproduction ⁵⁾ [%]	Control	0	18.3	--	8.4	--	Faworyt 300 SL	4.94	18.3 n.s.	0.0	8.1 n.s.	4.3	Faworyt 300 SL	14.8	3.3 n.s.	-18.4	7.3 n.s.	12.9	Faworyt 300 SL	44.4	10.0 n.s.	-10.2	8.5 n.s.	-1.1	Faworyt 300 SL	133	23.3 n.s.	6.1	9.6 n.s.	-13.5	Faworyt 300 SL	400	25.0 n.s.	8.2	6.7 n.s.	20.2
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Faworyt 300 SL	400	25.0 n.s.	8.2	6.7 n.s.	20.2																																										

Reference:	KCP 10.3.2.1/02
Report	Faworyt 300 SL: Effects on the Predatory Mite <i>Typhlodromus pyri</i> in the Laboratory - Dose Response Test -
Guideline(s):	IOBC (Blümel et al., 2000), Moll M., 2019, 140601063
Deviations:	None
GLP:	Yes

Acceptability: Yes

Duplication
(if vertebrate study) -

Material and Methods:

Test Item: Faworyt 300 SL; batch no.: 201805002; content of a.s.: 302.7 g/L Chlopyralid.

Test Species: Predatory Mite (*Typhlodromus pyri*), protonymphs not older than 24 hours old; source: Katz Biotech AG, Baruth, Germany.

Test Design: This study comprised 7 treatment groups (5 dose rates of the test item, control, reference item) with 3 replicates each containing 20 mites. The mites were exposed to dried residues on treated glass plates. Survival of the mites was assessed after 3 and 7 days. For the reproduction assessment surviving mites from the control and from all test item groups where the corrected mortality was < 50 % were sexed and the number of eggs per female was recorded at 3 assessment days within one week.

Endpoints: Mortality after 7 days of exposure; LR50: lethal rate producing 50 % mortality after exposure over 7 days, additionally reproduction capacity for survived mites.

Reference Item: Perfekthion (nominal: 400 g dimethoate/L).

Test Rates: Control, 4.94, 14.8, 44.4, 133 and 400 mL product/ha (equivalent to 1.50, 4.48, 13.4, 40.3 and 121 g a.s./ha) and reference item. The reference item was applied at an application rate of 8.0 mL Perfekthion/ha. All treatments were applied in 200 L water/ha. The spraying dilutions were sprayed onto glass plates via laboratory spraying equipment, which were then air dried.

Test Conditions: Temperature: 24 - 25 °C; relative humidity: 71 - 76 %; photoperiod: 16 h light : 8 h dark; light intensity: 330 - 520 lux

Findings:

	Rate ¹⁾ [mL/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction ⁴⁾ [eggs/female]	Effect on reproduction ⁵⁾ [%]
Control	0	18.3	--	8.4	--
Faworyt 300 SL	4.94	18.3 n.s.	0.0	8.1 n.s.	4.3
Faworyt 300 SL	14.8	3.3 n.s.	-18.4	7.3 n.s.	12.9
Faworyt 300 SL	44.4	10.0 n.s.	-10.2	8.5 n.s.	-1.1
Faworyt 300 SL	133	23.3 n.s.	6.1	9.6 n.s.	-13.5
Faworyt 300 SL	400	25.0 n.s.	8.2	6.7 n.s.	20.2
Endpoints					
LR ₅₀ : > 400 mL product/ha (equivalent to 121 g a.s./ha) ER ₅₀ : > 400 mL product/ha (equivalent to 121 g a.s./ha)					

1) Application rate in 200 L water/ha

2) Mortality: after 7 days of exposure to spray residues on glass plates
(Bonferroni-Holm Fisher's Exact Test, $\alpha = 0.05$; n.s. = not significant)

3) Corrected mortality according to Abbott and improvements by Schneider-Orelli; negative values indicate better survivorship compared to control

4) Reproduction: mean number of eggs/female,
(Dunnett's t-test, $\alpha = 0.05$; n.s. = not significant)

5) Calculated on the exact raw data; negative values indicate better performance compared to the control

Conclusion:

Under worst case laboratory conditions the LR₅₀ of Faworyt 300 SL is estimated to be greater than 400 mL product/ha (equivalent to 121 g a.s./ha) in 200 L water/ha.

Reproduction of *Typhlodromus pyri* was assessed in the control and all dose rates. The ER₅₀ is estimated to be greater than 400 mL product/ha (equivalent to 121 g a.s./ha) in 200 L water/ha.

A 2.3.2.2 KCP 10.3.2.2 Extended laboratory testing

A 2.3.2.2.1 Study 1 *Aphidius rhopalosiphi*

Comments of zRMS:

The study is considered as acceptable. All validity criteria were met.

- Control mortality: 0% (should not exceed 10%)
- Reference item mortality: 100% corrected mortality (should results in at least 50% corrected mortality)
- Control Reproduction rate : 57.7 mummies per female (≥ 5 mummies per female)
- No parasitoids produced zero values (there should be no more than 2 parasoidis producing zero values)

Agreed endpoints:

	Rate ¹⁾ [mL/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction ⁴⁾ [mummies/female]	Effect on reproduction ⁵⁾ [%]
Control	-	0.0	--	57.7	--
Faworyt 300 SL	4.94	0.0 n.s.	0.0	53.4 n.s.	7.5
Faworyt 300 SL	14.8	0.0 n.s.	0.0	54.2 n.s.	6.1
Faworyt 300 SL	44.4	3.3 n.s.	3.3	54.5 n.s.	5.7
Faworyt 300 SL	133	0.0 n.s.	0.0	51.5 n.s.	10.8
Faworyt 300 SL	400	0.0 n.s.	0.0	53.0 n.s.	8.2
Endpoints					
LR ₅₀ : > 400 mL product/ha (equivalent to 121 g a.s./ha)					
ER ₅₀ : > 400 mL product/ha (equivalent to 121 g a.s./ha)					

1) Application rate in 400 L water/ha

2) Mortality: after 48 hours of exposure to spray residues on plant surfaces (Bonferroni-Holm Fisher's Exact Test, $\alpha = 0.05$; n.s. = not significant)

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

4) Reproduction: mean number of parasitised aphids/female (Bonferroni-Holm U-test, $\alpha = 0.05$; n.s. = not significant)

5) Calculated on the exact raw data

Reference:	KCP 10.3.2.2/01
Report:	Faworyt 300 SL: Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> , Extended Laboratory Study - Dose Response Test -, Moll M, 2019, 140601002
Guideline(s):	Mead-Briggs et al. 2010
Deviations:	None
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Material and Methods:

Test Item:	Faworyt 300 SL; batch no.: 201805002; content of a.s.: 302.7 g/L Chlopyralid.
Test Species:	Parasitoid (<i>Aphidius rhopalosiphi</i>), adults not older than 48 hours; source: Katz Biotech AG, Baruth, Germany.
Test Design:	This study encompassed 7 treatment groups (5 dose rates of the test item, control, reference item) with 6 replicates each containing 5 female parasitoids. The parasitoids were exposed to dried residues on treated plant surfaces (barley plants). Survival of the parasitoids was assessed after 2, 24 and 48 hours. At 48 hours, for treatment groups with < 50 % corrected mortality survived females were removed and their reproductive capacity was assessed by confining them individually over untreated barley plants infested with the host cereal aphids, <i>Rhopalosiphum padi</i> . The adult parasitoids were removed after 24 hours and the aphid-infested plants left for further 10 days before the numbers of aphid mummies that had developed

were assessed.

Endpoints: Mortality of exposed parasitoids; additionally, reproductive capacity for female survivors was assessed.

Reference Item: Perfekthion (nominal: 400 g dimethoate/L).

Test Rates: Control, 4.94, 14.8, 44.4, 133 and 400 mL product/ha and reference item. The reference item was applied at an application rate of 10.0 mL Perfekthion/ha. All treatments were applied in 400 L water/ha. The spraying dilutions were sprayed onto barley plants via laboratory spraying equipment, which were then air dried.

Test Conditions: Temperature: 18 - 21 °C; relative humidity: 64 - 71 % (acclimatisation and exposure period), 71 - 80 % (post-exposure period, within the test units); photoperiod: 16 h light : 8 h dark; light intensity: 660 - 880 lux (acclimatisation and exposure period), 1030 - 1340 lux (parasitisation period), 11640 - 13240 lux (post-parasitisation period).

Findings:

	Rate ¹⁾ [mL/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction ⁴⁾ [mummies/female]	Effect on reproduction ⁵⁾ [%]
Control	-	0.0	--	57.7	--
Faworyt 300 SL	4.94	0.0 n.s.	0.0	53.4 n.s.	7.5
Faworyt 300 SL	14.8	0.0 n.s.	0.0	54.2 n.s.	6.1
Faworyt 300 SL	44.4	3.3 n.s.	3.3	54.5 n.s.	5.7
Faworyt 300 SL	133	0.0 n.s.	0.0	51.5 n.s.	10.8
Faworyt 300 SL	400	0.0 n.s.	0.0	53.0 n.s.	8.2
Endpoints					
LR ₅₀ : > 400 mL product/ha (equivalent to 121 g a.s./ha) ER ₅₀ : > 400 mL product/ha (equivalent to 121 g a.s./ha)					

1) Application rate in 400 L water/ha

2) Mortality: after 48 hours of exposure to spray residues on plant surfaces
(Bonferroni-Holm Fisher's Exact Test, $\alpha = 0.05$; n.s. = not significant)

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

4) Reproduction: mean number of parasitised aphids/female
(Bonferroni-Holm U-test, $\alpha = 0.05$; n.s. = not significant)

5) Calculated on the exact raw data

Conclusion:

Under extended laboratory conditions the LR₅₀ of Faworyt 300 is estimated to be greater than 400 mL product/ha (equivalent to 121 g a.s./ha) in 400 L water/ha. For mortality effects the NOER is equal or greater than 400 mL product/ha (equivalent to 121 g a.s./ha) and LOER is greater than 400 mL product/ha (equivalent to 121 g a.s./ha).

No repellent effect of the test item was observed compared to the control. The settling rate of the parasitoids on the plants was > 30 % at all dose rates.

The reproductive capacity of *A. rhopalosiphii* was tested at all dose rates. There was no effect on reproduction up to and including 400 mL product/ha compared to the control. ER₅₀ is estimated to be greater than 400 mL product/ha (equivalent to 121 g a.s./ha). For reproduction effects the NOER is equal or greater than 400 mL product/ha (equivalent to 121 g a.s./ha) and LOER is greater than 400 mL product/ha (equivalent to 121 g a.s./ha).

A 2.3.2.2.2 Study 2: Toxicity to *Chrysoperla carnea*

Comments of zRMS:

The study is considered as acceptable . All validity criteria were met.

- Control mortality: 2.5% . Pre-imaginal mortality should not exceed 20 %
- Reference Item Mortality: 84.6% Pre-imaginal mortality should result in at least 50 % (preferably < 100 %) corrected mortality
- Fecundity in the Control Group: 18.2 eggs per female (≥ 15 mean number of eggs per female per day)
- Fertility in the Control Group: 97.6 larval hatching rate ≥ 70 % (mean larval hatching rate)

Agreed endpoints:

	Rate ¹⁾ [mL/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction [eggs/female/day]	Larval hatching rate [%]
Control	--	2.5	--	18.2	97.6
Faworyt 300 SL	4.94	12.5 n.s.	10.3	19.6	96.8
Faworyt 300 SL	14.8	10.0 n.s.	7.7	17.4	97.2
Faworyt 300 SL	44.4	5.0 n.s.	2.6	19.3	96.7
Faworyt 300 SL	133	15.0 n.s.	12.8	17.1	95.0
Faworyt 300 SL	400	0.0 n.s.	-2.6	17.2	95.3
Endpoints					
LR ₅₀ : > 400 mL product/ha (equivalent to 121 g a.s./ha)					
ER ₅₀ : > 400 mL product/ha (equivalent to 121 g a.s./ha)					

1) Application rate in 200 L deionised water/ha

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

3) Corrected pre-imaginal mortality according to Abbott and improvements by Schneider-Orelli; negative value indicates better survivorship compared to control

Reference:	KCP 10.3.2.2/02
Report:	Faworyt 300 SL: Effects on the Lacewing <i>Chrysoperla carnea</i> , Extended Laboratory Study - Dose Response Test -, Moll M., 2019, 140601047
Guideline(s):	Vogt et al. 2000
Deviations:	None
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Material and Methods:

Test Item:	Faworyt 300 SL; batch-no.: 201805002; content of a.s.: 302.7 g/L Chlopyralid.
Test Species:	Lacewing (<i>Chrysoperla carnea</i>), 2 - 3 day old larvae; source: Katz Bio-tech AG, Baruth, Germany.
Test Design:	This study encompassed 7 treatment groups (5 dose rates of the test item, control, reference item) with 40 replicates each containing 1 larva. The larvae were exposed to dried residues on treated leaf surfaces (blackberry leaves). Exposure lasted until pupae were transferred to the reproduction units for development of adults. Mortality checks were carried out regu-

larly until hatching of adult lacewings. In addition, for the control and the test item treatment groups where the corrected mortality was < 50 %, the reproduction performance, i.e. egg deposition and larval hatching rate, was determined (2 checks/week, 24 hours period each check).

Endpoints: Larval and pupal mortality. Additionally, reproductive capacity of female survivors.

Reference Item: Perfekthion (nominal: 400 g dimethoate/L).

Test Rates: Control, 4.94, 14.8, 44.4, 133 and 400 mL product/ha and reference item. The reference item was applied at an application rate of 170 mL Perfekthion/ha. All treatments were applied in 200 L water/ha. The spraying dilutions were sprayed onto leaves via laboratory spraying equipment, which were then air dried.

Test Conditions: Temperature: 22 - 28 °C; relative humidity: 60 - 87 %; photoperiod: 16 h light : 8 h dark; light intensity: 1020 - 1380 lux.

Finding:

	Rate ¹⁾ [mL/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction [eggs/female/day]	Larval hatching rate [%]
Control	--	2.5	--	18.2	97.6
Faworyt 300 SL	4.94	12.5 n.s.	10.3	19.6	96.8
Faworyt 300 SL	14.8	10.0 n.s.	7.7	17.4	97.2
Faworyt 300 SL	44.4	5.0 n.s.	2.6	19.3	96.7
Faworyt 300 SL	133	15.0 n.s.	12.8	17.1	95.0
Faworyt 300 SL	400	0.0 n.s.	-2.6	17.2	95.3
Endpoints					
LR ₅₀ : > 400 mL product/ha (equivalent to 121 g a.s./ha)					
ER ₅₀ : > 400 mL product/ha (equivalent to 121 g a.s./ha)					

1) Application rate in 200 L deionised water/ha

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

3) Corrected pre-imaginal mortality according to Abbott and improvements by Schneider-Orelli; negative value indicates better survivorship compared to control

Conclusion

Under extended laboratory conditions the LR₅₀ of Faworyt 300 SL is estimated to be greater than 400 mL product/ha (equivalent to 121 g a.s./ha) in 200 L water/ha. The NOER for mortality effects is equal or greater than 400 mL product/ha and the LOER is greater than 400 mL product/ha.

The reproductive capacity of *C. carnea* was tested at all dose rates. Reproduction was > 15 eggs per female per day and the mean hatching rate was > 70 % at all dose rates. This indicates that there was no negative effect of the test item on reproductive performance of *C. carnea* up to and including 400 mL product/ha. The ER₅₀ is estimated to be greater than 400 mL product/ha (equivalent to 121 g a.s./ha) in 200 L water/ha.

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

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

A 2.4.1.2 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:	<p>The study is considered as acceptable . All validity criteria were met.</p> <ul style="list-style-type: none"> - Each replicate produced 108.5 juveniles (mean) at the end of the experiment (criterion: ≥ 30 juveniles by the end of the experiment), - The coefficient of variation of reproduction was 10.9 % (criterion: $\leq 30\%$), - Adult mortality over the initial 4 weeks of the experiment was 0% (criterion: $\leq 10\%$). - <p>Agreed endpoints:</p> <p>Table 1. Final results – definitive test</p> <table border="1"> <thead> <tr> <th>Parameter</th><th>EC₁₀ [mg/kg dry weight of soil]</th><th>EC₂₀ [mg/kg dry weight of soil]</th><th>EC₅₀ [mg/kg dry weight of soil]</th><th>LOEC [mg/kg dry weight of soil]</th><th>NOEC [mg/kg dry weight of soil]</th></tr> </thead> <tbody> <tr> <td>Offspring number</td><td>8.134 (0.636 – 114.363)*</td><td>71.686 (11.794 – 435.728)*</td><td>n.d. (n.d.- n.d.)*</td><td>42.71</td><td>23.73</td></tr> <tr> <td>Weight</td><td>33.026 (3.226 – 338.076)*</td><td>235.225 (11.982- 4156.078)*</td><td>n.d. (n.d.- n.d.)*</td><td>42.71</td><td>23.73</td></tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Parameter</th><th>LC₁₀ [mg/kg dry weight of soil]</th><th>LC₂₀ [mg/kg dry weight of soil]</th><th>LC₅₀ [mg/kg dry weight of soil]</th><th>LOEC [mg/kg dry weight of soil]</th><th>NOEC [mg/kg dry weight of soil]</th></tr> </thead> <tbody> <tr> <td>Survival</td><td>n.d. (n.d.-n.d.)*</td><td>n.d. (n.d.-n.d.)*</td><td>n.d. (n.d.-n.d.)*</td><td>250</td><td>138.89</td></tr> </tbody> </table>					Parameter	EC ₁₀ [mg/kg dry weight of soil]	EC ₂₀ [mg/kg dry weight of soil]	EC ₅₀ [mg/kg dry weight of soil]	LOEC [mg/kg dry weight of soil]	NOEC [mg/kg dry weight of soil]	Offspring number	8.134 (0.636 – 114.363)*	71.686 (11.794 – 435.728)*	n.d. (n.d.- n.d.)*	42.71	23.73	Weight	33.026 (3.226 – 338.076)*	235.225 (11.982- 4156.078)*	n.d. (n.d.- n.d.)*	42.71	23.73	Parameter	LC ₁₀ [mg/kg dry weight of soil]	LC ₂₀ [mg/kg dry weight of soil]	LC ₅₀ [mg/kg dry weight of soil]	LOEC [mg/kg dry weight of soil]	NOEC [mg/kg dry weight of soil]	Survival	n.d. (n.d.-n.d.)*	n.d. (n.d.-n.d.)*	n.d. (n.d.-n.d.)*	250	138.89
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Survival	n.d. (n.d.-n.d.)*	n.d. (n.d.-n.d.)*	n.d. (n.d.-n.d.)*	250	138.89																														

Reference:	KCP 10.4.1.1
Report	Earthworm reproduction test according to OECD 222, Agnieszka Woźniak, 2019 Study code 0016/0054/E, SORBOLAB Research Laboratory LLC, Poland
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 222
Deviations:	None.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

1. Test material: Faworyt 300 SL
Batch number: 201805002
Concentration of chlopyralid 302.7 g/L
1. Test organism: The test species was *Eisenia fetida*. Adult specimens (2-12 months old, being not more than 4 weeks apart in age), with a fully developed clitellum were used. The initial weight of the individuals was in the range from 300 to 600 mg.
2. Test design:

test duration: 56 days

number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate
3. Concentrations of the test item: control, 4.06; 7.32; 13.18; 23.73; 42.71; 76.87; 138.89; 250.0 mg/kg of dry artificial soil.
4. Composition of artificial soil: 10% sphagnum, 20% kaolin clay, 70% sand.

The aim of the study was to evaluate the effect of the test item Faworyt 300 SL on the *Eisenia fetida* earthworms reproduction according to OECD 222. During the test, the impact of the material being tested on the number of offspring, weight and survival of the parental individuals was determined and compared to the control group.

Test conditions

Temperature	20±2°C
Photoperiod	Under controlled light-dark cycles (16h: 8h) with illumination 400-800 lux
pH of soil	6.5
Water content of soil	within required: 40-60%

Results and discussions

In the course of the test and on the basis of performed statistical calculations, it has been shown that the tested item effect on the reproduction expressed in the offspring number of earthworms. Additionally survival and weight of the tested species were assessed. The appropriate endpoints derived based on the study results are presented in table below.

Table 1. Final results – definitive test

Parameter	EC ₁₀ [mg/kg dry weight of soil]	EC ₂₀ [mg/kg dry weight of soil]	EC ₅₀ [mg/kg dry weight of soil]	LOEC [mg/kg dry weight of soil]	NOEC [mg/kg dry weight of soil]
Offspring number	8.134 (0.636 – 114.363)*	71.686 (11.794 – 435.728)*	n.d. (n.d.- n.d.)*	42.71	23.73
Weight	33.026 (3.226 – 338.076)*	235.225 (11.982- 4156.078)*	n.d. (n.d.- n.d.)*	42.71	23.73
Parameter	LC ₁₀ [mg/kg dry weight of soil]	LC ₂₀ [mg/kg dry weight of soil]	LC ₅₀ [mg/kg dry weight of soil]	LOEC [mg/kg dry weight of soil]	NOEC [mg/kg dry weight of soil]
Survival	n.d. (n.d.-n.d.)*	n.d. (n.d.-n.d.)*	n.d. (n.d.-n.d.)*	250	138.89

Faworyt 300 SL had effect on reproduction of earthworms. The concentration of the test material (immediately below LOEC) that has no statistically significant effect on reproduction (NOEC) is 23.73 mg/kg of dry weight artificial soil. The lowest test concentration of the test material that has a statistically significant effect on reproduction (LOEC) is 42.71 mg/kg of dry weight artificial soil. The appropriate endpoints, which express 10, 20 and 50% effect on reproduction in compare to the control are 8.134, 71.686 and > 250 mg/kg of dry weight artificial soil, respectively.

Validity criteria:

The results are considered valid because the following OECD 207 criteria were satisfied in the controls:

- each replicate produced 108.5 juveniles (mean) at the end of the experiment (criterion: ≥ 30 juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 10.9 % (criterion: $\leq 30\%$),
- adult mortality over the initial 4 weeks of the experiment was 0% (criterion: $\leq 10\%$).

Conclusion:

In the course of this experiment and the statistical calculations performed, it was shown that test material affects reproduction expressed in the number of young earthworms under the end of the study with the lowest endpoint EC_{10} of 8.134 mg/kg dws.

A 2.4.1.3 KCP 10.4.1.2 Earthworms - field studies

Not needed.

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

Comments of zRMS: The study is considered as acceptable . All validity criteria were met.

- Mean adult mortality: 5% (criterion: $\leq 20\%$)
- Mean number of juveniles per vessel at the end of the test: 585-845 (criterion: ≥ 100 juveniles at the end of the test)
- The coefficient of variation calculated for the number of juveniles:14.1% (criterion: $\leq 30\%$)

Agreed endpoints:

Table 1. Effect of Faworyt 300 SL on Collembola (*Folsomia candida*) in a 28-day reproduction study

Faworyt 300 SL [mg/kg soil dry weight]	Control	16.3	29.4	52.9	95.3	171.5	308.6	555.6	1000
Mortality (day 28) [%]	5	8	15	13	8	25	20	13	13
Significance ¹⁾	-	n.s.	n.s.	n.s.	n.s.	* ⁴⁾	n.s.	n.s.	n.s.
No. of juveniles (day 28)	717	732	711	686	714	735	676	787	577
Reproduction in [%] of control (day 28)	-	102	99.2	95.6	99.6	103	94.3	110	80.4
Statistical significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Endpoints [mg/kg soil dry weight]									
NOEC (mortality)	≥ 1000								
LOEC (mortality)	> 1000								
LC ₅₀ ³⁾	> 1000								
NOEC (reproduction)	≥ 1000								
LOEC (reproduction)	> 1000								
EC ₅₀ ³⁾	> 1000								

n.s. = not significantly different compared to the control

* = significantly different compared to the control

¹⁾ Fisher's Exact Test, $\alpha = 0.05$, one-sided greater

²⁾ Dunnett's t-test, $\alpha = 0.05$, one-sided smaller

³⁾ estimated value

⁴⁾ the statistical significance of the test concentration of 171.5 mg/kg soil can be assumed to be not test item related due to the fact that mortality in all other test concentrations, including the higher ones up to and including 1000 mg test item/kg soil, was not statistically significant.

- not applicable

Reference:	KCP 10.4.2.1/01
Report	Faworyt 300 SL: Effects on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil, Daniela Straube, 2019, Study No. 140601016, Ibacon GmbH
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 232
Deviations:	No deviations.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

1. Test material: Faworyt 300 SL
Batch number: 201805002
Concentration of Chlopyralid: 302.7 g/L

2. Test organism:

9-11 days old collembolans, *Folsomia candida* originated from healthy and well-maintained own culture at the laboratory

3. Test design:

- range finding test – tested concentrations: 1.0; 10; 100; 500 and 1000 mg test item/kg dry weight in two replicates and control in two replicates; 10 Collembola in each replicate
- definitive test – tested concentrations: 16.3, 29.4, 52.9, 95.3, 171.5, 308.6, 555.6 and 1000 mg test item/kg dry weight of soil in four replicates and control in eight replicates

Time of exposure:

- range finding test – 28 days;
- definitive test – 28 days

4. Composition of artificial soil: 5% peat, 20% kaolin clay, 74.8% quartz sand (0.2% calcium carbonate (CaCO₃) was added to adjust pH to 6.0 ± 0.5)

The aim of the study was to determine the effect of the test item Faworyt 300 SL on the number of offspring and survival of the parent collembolans under laboratory conditions in an artificial soil substrate. Collembolans were exposed to test item incorporated into an artificial soil substrate, for a period of 28 days. The test item suspension was mixed into the artificial soil. For the control artificial soil was mixed with deionized water alone.

Glass containers (volume: 100 mL; diameter: 5 cm), closed tightly to avoid water evaporation, filled with 30 g ± 1.0 g artificial soil fresh weight were used in the study. The height of the soil layer in the containers was 2 to 2.5 cm.

Test conditions:

Temperature	18 – 22 °C
Photoperiod	16 hour photoperiod at 400-800 lux
pH of soil	5.6-5.8
Water content of soil	within recommended 40-60%

Results and discussion:

Mortality in the test item treated groups was not observed to be statistically significantly different in compare to the control. The only exception was the test concentration of 171.5 mg test item/kg soil where a mortality of 25% was observed, and was statistically significantly different compared to the control. Reproduction of the Collembolan exposed to Faworyt 300 SL was not statistically significantly different in compare to the control up to and including the highest test concentration of 1000 mg/kg soil. No behavioral abnormalities were observed in any of the treatment groups. The results are shown in table below.

Table 1. Effect of Faworyt 300 SL on Collembola (*Folsomia candida*) in a 28-day reproduction study

Faworyt 300 SL [mg/kg soil dry weight]	Control	16.3	29.4	52.9	95.3	171.5	308.6	555.6	1000
Mortality (day 28) [%]	5	8	15	13	8	25	20	13	13
Significance ¹⁾	-	n.s.	n.s.	n.s.	n.s.	* ⁴⁾	n.s.	n.s.	n.s.
No. of juveniles (day 28)	717	732	711	686	714	735	676	787	577
Reproduction in [%] of control (day 28)	-	102	99.2	95.6	99.6	103	94.3	110	80.4
Statistical significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Endpoints [mg/kg soil dry weight]									
NOEC (mortality)	≥1000								
LOEC (mortality)	>1000								
LC ₅₀ ³⁾	>1000								
NOEC (reproduction)	≥1000								
LOEC (reproduction)	>1000								
EC ₅₀ ³⁾	>1000								

n.s. = not significantly different compared to the control

* = significantly different compared to the control

¹⁾ Fisher's Exact Test, $\alpha = 0.05$, one-sided greater

²⁾ Dunnett's t-test, $\alpha = 0.05$, one-sided smaller

³⁾ estimated value

⁴⁾ the statistical significance of the test concentration of 171.5 mg/kg soil can be assumed to be not test item related due to the fact that mortality in all other test concentrations, including the higher ones up to and including 1000 mg test item/kg soil, was not statistically significant.

- not applicable

Validity criteria:

The results are considered valid because the following criteria of OECD 232 were satisfied in the controls:

- mean adult mortality: 5% (criterion: $\leq 20\%$),
- the mean number of juveniles per vessel at the end of the test: 585-845 criterion: ≥ 100 juveniles

- at the end of the test),
- the coefficient of variation calculated for the number of juveniles: 14.1% (criterion: $\leq 30\%$).

Conclusion:

The No Observed Effect Concentration (NOEC) for mortality was determined to be ≥ 1000 mg test item/kg soil. The Lowest Observed Effect Concentration (LOEC) is estimated to be >1000 mg test item/kg soil.

The NOEC and LOEC for reproduction was determined to be ≥ 1000 mg test item/kg soil. As the obtained results did not follow a concentration-response relationship ECx values (e.g. EC10, EC20) could not be determined mathematically. The LC50 and EC50 are estimated to be >1000 mg test item/kg soil.

Comments of zRMS:

The study is considered as acceptable . All validity criteria were met.

- Mean adult mortality: 3% (criterion: $\leq 20\%$);
- Mean number of juveniles per vessel at the end of the test: 139-181 (criterion: ≥ 50 juveniles at the end of the test);
- The coefficient of variation for the number of juveniles: 8.1% (criterion: $\leq 30\%$).

Agreed endpoints:

Table 1. Effect of Faworyt 300 SL on the Predatory Mite *Hypoaspis aculeifer* in a 14-day reproduction study

Faworyt 300 SL [mg/kg soil dry weight]	Control	16.3	29.4	52.9	95.3	171.5	308.6	555.6	1000
Mortality (day 14) [%]	3	10	0	5	3	5	5	5	10
Statistical significance ¹⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
No. of juveniles (day 14)	160	149	148	146	159	157	155	152	155
Reproduction in [%] of control (day 14)	-	93	92	92	99	98	97	95	97
Statistical significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Endpoints [mg/kg soil dry weight]									
NOEC (mortality)	≥ 1000								
LOEC (mortality)	> 1000								
LC ₅₀ ³⁾	> 1000								
NOEC (reproduction)	≥ 1000								
LOEC (reproduction)	> 1000								
EC ₅₀ ³⁾	> 1000								

n.s. = not significantly different compared to the control
²⁾ Dunnett's t-test, $\alpha = 0.05$, one-sided smaller
¹⁾ Fisher's Exact Test, $\alpha = 0.05$, one-sided greater
³⁾ estimated value - not applicable

Reference:	KCP 10.4.2.1/02
Report	Faworyt 300 SL: Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil. Daniela Straube, 2019, Study No. 140601089, Ibacon GmbH
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 226
Deviations:	No deviations.
GLP:	Yes

Acceptability: Yes

Duplication -
(if vertebrate study)

Materials and methods

1. Test material: Faworyt 300 SL
Batch number: 201805002
Concentration of chlopyralid 302.7g/L
2. Test organism: Predatory mite *Hypoaspis aculeifer*, adult females, approximately 14 days after reaching the adult stage (35 days after placing adult females in clean rearing vessels), cultured by Ibacon
3. Test design:
 - range finding test – tested concentrations 1,0; 10; 100; 500 and 1000 mg test item/kg dry weight in two replicates, control in two replicates, 10 adult females for replicate
 - definitive test: tested concentrations: 16.3, 29.4, 52.9, 95.3, 171.5, 308.6, 555.6 and 1000 mg test item/kg dry weight of soil in four replicates and controls in eight replicates, 10 adult females for replicate

Time of exposure: 14 days
4. Composition of artificial soil: 5% peat, 20% kaolin clay, 74.8% quartz sand (0.2% calcium carbonate (CaCO₃) was added to adjust pH to 6.0 ± 0.5)

The aims of the study were to assess the impact of Faworyt 300 SL on reproduction of the predatory mite, *Hypoaspis aculeifer* and to determine the EC_x, LOEC and NOEC. The test substance solution was mixed into the artificial soil. For the control artificial soil was mixed with deionized water alone.

Glass containers (volume: 100 mL; diameter: 5 cm), tight screw top closure to avoid water evaporation, filled with approximately 20 g ± 1.0 g artificial soil dry weight. The height of the soil layer in the containers was 1.5 to 2 cm.

Test conditions:

Temperature	18 – 22 °C
Photoperiod	16 hour photoperiod at 400-800 lux
pH of soil	5.6-5.8
Water content of soil	within recommended 40-60%

Results and discussion:

A mortality of up to 10% was observed in the test item treated groups, which was not statistically significantly different compared to the control.

Reproduction of the predatory mites exposed to Faworyt 300 SL was not statistically significantly different compared to the control up to and including the highest test concentration of 1000 mg/kg soil.

No behavioral abnormalities were observed in any of the treatment groups. The results are shown in a table below.

Table 1. Effect of Faworyt 300 SL on the Predatory Mite *Hypoaspis aculeifer* in a 14-day reproduction study

Faworyt 300 SL [mg/kg soil dry weight]	Control	16.3	29.4	52.9	95.3	171.5	308.6	555.6	1000
Mortality (day 14) [%]	3	10	0	5	3	5	5	5	10
Statistical significance ¹⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
No. of juveniles (day 14)	160	149	148	146	159	157	155	152	155
Reproduction in [%] of control (day 14)	-	93	92	92	99	98	97	95	97
Statistical significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Endpoints [mg/kg soil dry weight]									
NOEC (mortality)	≥1000								
LOEC (mortality)	>1000								
LC ₅₀ ³⁾	>1000								
NOEC (reproduction)	≥1000								
LOEC (reproduction)	>1000								
EC ₅₀ ³⁾	>1000								

n.s. = not significantly different compared to the control

²⁾ Dunnett's t-test, $\alpha = 0.05$, one-sided smaller

¹⁾ Fisher's Exact Test, $\alpha = 0.05$, one-sided greater

³⁾ estimated value - not applicable

Test item Faworyt 300 SL did not have any impact on reproduction process and survival of *Hypoaspis aculeifer* in the concentrations scope used in the study. ECx values and LOEC and NOEC were beyond the scope of maximal concentration tested.

Validity criteria:

The results are considered valid because the following criteria of OECD 226 were satisfied in the control:

- mean adult mortality: 3% (criterion: ≤ 20%);
- the mean number of juveniles per vessel at the end of the test: 139-181 (criterion: ≥ 50 juveniles at the end of the test);
- the coefficient of variation for the number of juveniles: 8.1% (criterion: ≤ 30%).

Conclusion:

Faworyt 300 SL caused no statistically significant effects on mortality and reproduction of *Hypoaspis aculeifer* up to and including the concentration of 1000 mg test item/kg soil.

Therefore, the NOEC and LOEC value was determined to be ≥ 1000 mg test item/kg soil. The LC₅₀ was estimated to be >1000 mg test item/kg soil. The EC₁₀, EC₂₀ and EC₅₀ values were not determined by statistical analysis since there was no adequate concentration response. The EC₁₀, EC₂₀ and EC₅₀ were estimated to be >1000 mg test item/kg soil.

KCP 10.4.2.2 Higher tier testing

Not needed.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	<p>The study is considered as acceptable . All validity criteria were met.</p> <ul style="list-style-type: none"> - The variation between replicate control samples should not be greater than $\pm 15\%$ <p>In present study the % of variation were as follows:</p> <ul style="list-style-type: none"> • Day 0: 3.08% • Day 7: 1.13% • Day 14: 1.79% • Day 28: 0.72% <p>Agreed endpoint: After 28 days of experiment, a statistically insignificant influence of the tested material on the nitrate production rates at 0.743 and 3.7152 mg /kg of dry weight of soil, respectively, was found in comparison to the control in the tested concentrations. The tested material does not show long-term effects on nitrogen transformation in soil.</p>
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Reference:	KCP 10.5
Report	Study of impact of test item Faworyt 300 SL on soil microorganisms – nitrogen transformation test according to guideline OECD 216, Agnieszka Woźniak, 2021 Study code 0016/0138/E, SORBOLAB Research Laboratory LLC, Poland
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 216
Deviations	None
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

1. Test material: Faworyt 300 SL
Batch number: 01/2020
Concentration of clopyralid 310 g/L
2. Soil: Was bought in Fraunhofer Institute for Molecular Biology and Applied Ecology in Germany. The soil was obtained from agricultural areas not ploughed for the last six months, which were not treated with plant protection products for five years before being used for testing, nor fertilized with any fertilizer for at least six months. Soil samples were taken from a depth of 0-20 cm and transported to the laboratory in dark containers, which guaranteed that the initial parameters were maintained.

3. Test design:

Test duration: 28 days. On the 28th day, differences between the rates of nitrate formation in treated and untreated soils samples were smaller than 25%, therefore measurements were not continued.

Two parts of soil were spiked with test material solutions and mixed. The third part of soil was mixed with distilled water without test material (control).

4. The study was carried out in two concentrations of the test item:

C1 = 0.743 mg/kg dw and C2 = 3.7152 mg/kg dw

In addition, control (without test item addition) was used in the test. Each concentration and control was prepared in three replicates.

A study of the test item Faworyt 300 SL effects on the activity of soil microorganisms responsible for nitrogen transformations occurring in aerobic soils in accordance to the guideline OECD 216.

The study consisted of comparing the rate of nitrate production in the soil exposed to the test item with the rate of nitrate production in the control soil.

Test conditions:

Conditions of the test were as recommended by OECD TG 216 (2000). The test was conducted in darkened plastic containers made of chemically inert material, with perforated covers. Soil samples of 500 grams took up $\frac{1}{4}$ of the test vessel to prevent the development of anaerobic conditions. The soil was modified by the addition of powdered lucerne meal in an amount of 5 g/kg of soil dry matter, as recommended by the OECD 216 guidance.

Once a week the water content in the soil (in control and test concentrations) was checked, after which the appropriate quantity of deionized water was added.

The following soil characteristic and environmental conditions were achieved during the test:

Soil characteristic and environmental conditions during the study:

pH of soil	6.32
Water content of soil	40±5%% of WHC
Sand content in the soil	69.8%

Organic carbon content in the soil	0.95%
Microbial biomass	1.83% of total organic carbon content
Temperature	19.7-20.0°C
Photoperiod	24 hours darkness

Results and discussion:

Faworyt 300 SL at the concentration of 1PEC and 5PEC (0.743 and 3.7152 mg /kg of dry weight of soil, respectively) did not have a statistically significant effect on the production rate of nitrates after 28 days of the experiment.

At this sampling period deviation from the control was < 25% for both concentrations of the test item. In addition, influence of both tested concentrations of the material on the nitrate production rate in compare to the control was statistically insignificant.

Calculated using the ToxRat Professional statistical program							
Time of observation	Control	1PEC ^{*)}			5PEC ^{**)}		
	Average rate of nitrate production [mg of nitrate/kg dry weight of soil/day]	Average rate of nitrate production [mg of nitrate/kg dry weight of soil/day]	Stimulation in relation to control [%]	Statistical significance ^{***)}	Average rate of nitrate production [mg of nitrate/kg dry weight of soil/day]	Stimulation in relation to control [%]	Statistical significance ^{***)}
after 7 days	8.537	6.726	21.210	+	6.319	25.978	+
after 14 days	16.670	16.527	0.856	-	16.134	3.211	+
after 28 days	11.417	11.698	2.461	-	11.655	2.082	-

^{*)} (Predicted Environmental Concentration): maximum predicted effective concentration in soil (0.743 mg of test item/kg dry weight of soil)

^{**)} (Predicted Environmental Concentration): 5 times the maximum expected effective concentration in soil (3.7152 mg of test item/ kg dry weight of soil)

^{***)} significance calculated by ToxRat Professional using the Student's t test at the significance level of $p \leq 0.05$

- statistically insignificant

+ statistically significant

Validity criteria:

The study satisfied the OECD 216 validity criterion that the variation between replicate control samples should not be greater than $\pm 15\%$.

- Day 0: 3.08%
- Day 7: 1.13%
- Day 14: 1.79%
- Day 28: 0.72%

Conclusions:

After 28 days of experiment, a statistically insignificant influence of the tested material on the nitrate production rate was found in comparison to the control in the tested concentrations. The tested material does not show long-term effects on nitrogen transformation in soil.

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

Not relevant.

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:

The study is considered as acceptable . All validity criteria were met.

- Seedling emergence in the control was at least 70%
- In none of the control replications of any plants species there were any signs of intoxications visible
- Mean survival of plants in control was 100% for every species (required at least 90%)
- Environmental conditions and soil were identical for all used in the experiment plants species

Agreed endpoints:

Dicotylenos						
Parameter		Fresh weight	Dry weight	Shoot length	Emergence	Survival
Mung Beans <i>Phaseolus aureus</i>	ER ₁₀ / LR ₁₀ [L/ha]	n.d. (n.d. – n.d.)*	0.016 (0.005 – 0.047)*	0.482 (n.d. – n.d.)*	0.277 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	ER ₂₅ / LR ₂₅ [L/ha]	0.003 (n.d. – 0.035)*	0.047 (0.023 – 0.095)*	1.428 (n.d. – n.d.)*	0.971 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	ER ₅₀ / LR ₅₀ [L/ha]	0.031 (0.020 – 0.438)*	0.158 (0.071 – 0.363)*	4.781 (n.d. – n.d.)*	3.910 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	LOER [L/ha]	≤ 0.038	≤ 0.038	> 0.4	> 0.4	> 0.4**
	NOER [L/ha]	< 0.038	< 0.038	≥ 0.4	≥ 0.4	> 0.4**
Cucumber <i>Cucumis sativus</i>	ER ₁₀ / LR ₁₀ [L/ha]	0.001 (n.d. – n.d.)*	0.379 (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	ER ₂₅ / LR ₂₅ [L/ha]	> 0.4** (n.d. – n.d.)*	0.400 (0.291 – 0.550)*	n.d. (n.d. – n.d.)*	11.627 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	ER ₅₀ / LR ₅₀ [L/ha]	> 0.4** (n.d. – n.d.)*	0.400 (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	LOER [L/ha]	> 0.4	0.400	> 0.4	> 0.4	> 0.4
	NOER [L/ha]	≥ 0.4	0.220	≥ 0.4	≥ 0.4	≥ 0.4
Broccoli <i>Brassica oleracea L. var. Italica Plenck</i>	ER ₁₀ / LR ₁₀ [L/ha]	n.d. (n.d. – n.d.)*	0.044 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*	0.227 (0.091 – 0.645)*	> 0.4** (n.d. – n.d.)*
	ER ₂₅ / LR ₂₅ [L/ha]	0.017 (n.d. – n.d.)*	0.564 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*	0.506 (0.283 – 37.343)*	> 0.4** (n.d. – n.d.)*
	ER ₅₀ / LR ₅₀ [L/ha]	> 0.4** (n.d. – n.d.)*	0.9535 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*	1.230 (0.509 – n.d.)*	> 0.4** (n.d. – n.d.)*
	LOER [L/ha]	> 0.4	> 0.4	> 0.4	> 0.4	> 0.4**
	NOER [L/ha]	≥ 0.4	≥ 0.4	≥ 0.4	≥ 0.4	> 0.4**
Carrot <i>Daucus carota</i>	ER ₁₀ / LR ₁₀ [L/ha]	n.d. (n.d. – 54.432)*	0.007 (0.001 – 0.073)*	0.074 (0.014 – 0.386)*	> 0.4** (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	ER ₂₅ / LR ₂₅ [L/ha]	0.005 (n.d. – 26.078)*	0.022 (0.005 – 0.105)*	0.195 (0.080 – 0.476)*	> 0.4** (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	ER ₅₀ / LR ₅₀ [L/ha]	0.075 (n.d. – n.d.)*	0.080 (0.016 – 0.445)*	0.570 (0.160 – 1.910)*	> 0.4** (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	LOER [L/ha]	≤ 0.038	≤ 0.038	0.220	> 0.4	> 0.4**
	NOER [L/ha]	< 0.038	< 0.038	0.120	≥ 0.4	> 0.4**

The lowest ER₅₀=0.031 L/ha , fresh weight (Mung Bean)

Monocotyledons - limit test						
Parameter		Fresh weight	Dry weight	Shoot length	Emergence	Survival
Oat <i>Avena sativa</i>	Reduction [%]	-13.91	1.98	-3.09		
	Statistical significance	statistically insignificant	statistically insignificant	statistically insignificant	statistically insignificant	statistically insignificant
Corn <i>Zea mays</i>	Reduction [%]	-2.01	-1.44	0.01		
	Statistical significance	statistically insignificant	statistically insignificant	statistically insignificant	statistically insignificant	statistically insignificant

ER_x dose of the material that exhibits intoxication effects in x% of population

LR_x dose of the material that exhibits intoxication causes mortality in x% of population

NOER highest non observe effective concentration cause no statistically significant differences in comparison to the control

LOER lowest observe effective concentration cause statistically significant differences in comparison to the control

n.d. impossible to calculate due to mathematical reasons

*) the lower and upper 95% confidence intervals

**) based on the analysis of the results, this value was defined as > 0.4 L/ha

Phytotoxicity effects									
Species	Control	Average phytotoxicity [%]					ER ₁₀ [L/ha]	ER ₂₅ [L/ha]	ER ₅₀ [L/ha]
		0.038 [L/ha]	0.069 [L/ha]	0.12 [L/ha]	0.22 [L/ha]	0.4 [L/ha]			
Mung Beans <i>Phaseolus aureus</i>	0.0	0.0	0.0	5.0	15.0	30.0	0.189 (0.006-0.342)*	0.331 (0.188 – 10.989)*	0.617 (0.341 – n.d.)*
Cucumber <i>Cucumis sativus</i>	0.0	0.0	0.0	0.0	0.0	30.0	0.365 (n.d. – n.d.)*	0.393 (n.d. – n.d.)*	0.426 (n.d. – n.d.)*
Broccoli <i>Brassica oleracea L. var. italica Plenck</i>	0.0	0.0	0.0	0.0	0.0	0.0	n.d.**	n.d.**	n.d.**
Carrot <i>Daucus carota</i>	0.0	0.0	0.0	0.0	20.0	50.0	0.192 (0.048 – 0.263)*	0.267 (0.149 – 0.397)*	0.385 (0.282 – 1.171)*
Oat <i>Avena sativa</i>						0.0	n.d.**	n.d.**	n.d.**
Corn <i>Zea mays</i>						0.0	n.d.**	n.d.**	n.d.**

ER_x dose of test item causing symptoms of intoxication in x% of the population
 n.d. impossible to determine for mathematical reasons
 *) the lower and upper and 95% confidence intervals
 **) based on the analysis of the results, the value was determined as > 0.4 L/ha

The lowest endpoint ER₅₀=0.385 L/ha (carrot), Phytotoxicity effects

Reference:	KCP 10.6.2/01
Report	Seedling emergence and seedling growth test according to OECD 208, Aleksandra Kamińska, 2019, Study code 0016/0059/E, Sorbolab Research Laboratory, Poland Annex No. 1 to the Final report: Seedling emergence and growth test according to OECD 208, Agnieszka Woźniak 2021, Sorbolab Research Laboratory Poland
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 208 “Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test”
Deviations:	OECD 208 guideline recommends CO ₂ concentration at the level of 350±50 ppm during the course of the study. In the test this parameter was exceeded. However, literature data show, that in year 2017 average CO ₂ concentration in the atmosphere exceeded 400 ppm. This deviation had no effect on the course of the study and obtained results.
GLP:	Yes
Acceptability:	Yes

Materials and methods

- Test material: Faworyt 300 SL
Batch number: 201805002
Concentration of clopyralid 302.7 g/L
- Test organism: Six plant species were tested, four dicotyledonous and two monocotyledonous: *Phaseolus aureus*, *Cucumis dativus*, *Brassica oleracea L. var. italica Plenck*, *Raphanus sativus*, *Dacus carota*, *Avena sativa*, *Zea mays*.
- Test design:

Definitive test with dicotyledonous species was performed using five doses of the test item. In the test doses: 0.4 L/ha; 0.22 L/ha; 0.12 L/ha; 0.069 L/ha 0.039 L/ha and control were used.
In case monocotyledonous species only the limit test was performed with the dosage of 0.4 L/ha.

All tested doses were chosen based on the results of range finding test.

Soil used in the study

Artificial soil was used in the study containing 20% kaolin clay and approx. 80% quartz sand

The basic indigents were calcined in temperature of $105\pm 5^{\circ}\text{C}$ and then mixed together in an appropriate amounts. Dry soil was sieved by a sieve of 2 mm mesh. Before the start of the test, artificial soil was moisten with deionized water, to not let it became too wet. After placing soil in the pots, the deionized water (with addition of fertilizer) was poured into stands. During the experiment regular watering was carried out, to prevent drying of the upper parts of the soil. The pH of the soil was 6.0 and contained 0.1% total dissolved solids as a measure of salinity.

Environmental conditions

Temperature	19.6- 27.3°C
Air relative humidity:	average relative air humidity 63.47%
Lightning	light cycle (16 h day / 8 h night); average light intensity 25900 lux
CO2 concentration:	average CO ₂ concentration 382.47 ppm

Results and discussions:

Based on the conducted test, observations and results obtained, it is stated that the test item - exhibits ecotoxic effects on mung beans and carrot (fresh weight), carrot, mung beans, cucumber (dry weight) and also on carrot and cucumber (shoot length). It does not cause cytotoxic effects in the case of broccoli, oat and corn.

ER₅₀ values for individual parameters were determined, such as: shoot length, dry and fresh weight, seedling emergence and survival.

Dicotylenos						
Parameter		Fresh weight	Dry weight	Shoot length	Emergence	Survival
Mung Beans <i>Phaseolus aureus</i>	ER ₁₀ / LR ₁₀ [L/ha]	n.d. (n.d. – n.d.)*	0.016 (0.005 – 0.047)*	0.482 (n.d. – n.d.)*	0.277 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	ER ₂₅ / LR ₂₅ [L/ha]	0.003 (n.d. – 0.035)*	0.047 (0.023 – 0.095)*	1.428 (n.d. – n.d.)*	0.971 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	ER ₅₀ / LR ₅₀ [L/ha]	0.031 (0.020 – 0.438)*	0.158 (0.071 – 0.363)*	4.781 (n.d. – n.d.)*	3.910 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	LOER [L/ha]	≤ 0.038	≤ 0.038	> 0.4	> 0.4	> 0.4**
	NOER [L/ha]	< 0.038	< 0.038	≥ 0.4	≥ 0.4	> 0.4**

Cucumber <i>Cucumis sativus</i>	ER ₁₀ / LR ₁₀ [L/ha]	0.001 (n.d. – n.d.)*	0.379 (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	ER ₂₅ / LR ₂₅ [L/ha]	> 0.4** (n.d. – n.d.)*	0.400 (0.291 – 0.550)*	n.d. (n.d. – n.d.)*	11.627 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	ER ₅₀ / LR ₅₀ [L/ha]	> 0.4** (n.d. – n.d.)*	0.400 (n.d. – n.d.)*	n.d. (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	LOER [L/ha]	> 0.4	0.400	> 0.4	> 0.4	> 0.4
	NOER [L/ha]	≥ 0.4	0.220	≥ 0.4	≥ 0.4	≥ 0.4
Broccoli <i>Brassica oleracea L. var. italica Plenck</i>	ER ₁₀ / LR ₁₀ [L/ha]	n.d. (n.d. – n.d.)*	0.044 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*	0.227 (0.091 – 0.645)*	> 0.4** (n.d. – n.d.)*
	ER ₂₅ / LR ₂₅ [L/ha]	0.017 (n.d. – n.d.)*	0.564 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*	0.506 (0.283 – 37.343)*	> 0.4** (n.d. – n.d.)*
	ER ₅₀ / LR ₅₀ [L/ha]	> 0.4** (n.d. – n.d.)*	0.9535 (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*	1.230 (0.509 – n.d.)*	> 0.4** (n.d. – n.d.)*
	LOER [L/ha]	> 0.4	> 0.4	> 0.4	> 0.4	> 0.4**
	NOER [L/ha]	≥ 0.4	≥ 0.4	≥ 0.4	≥ 0.4	> 0.4**
Carrot <i>Daucus carota</i>	ER ₁₀ / LR ₁₀ [L/ha]	n.d. (n.d. – 54.432)*	0.007 (0.001 – 0.073)*	0.074 (0.014 – 0.386)*	> 0.4** (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	ER ₂₅ / LR ₂₅ [L/ha]	0.005 (n.d. – 26.078)*	0.022 (0.005 – 0.105)*	0.195 (0.080 – 0.476)*	> 0.4** (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	ER ₅₀ / LR ₅₀ [L/ha]	0.075 (n.d. – n.d.)*	0.080 (0.016 – 0.445)*	0.570 (0.160 – 1.910)*	> 0.4** (n.d. – n.d.)*	> 0.4** (n.d. – n.d.)*
	LOER [L/ha]	≤ 0.038	≤ 0.038	0.220	> 0.4	> 0.4**
	NOER [L/ha]	< 0.038	< 0.038	0.120	≥ 0.4	> 0.4**

Monocotyledons - limit test						
Parameter		Fresh weight	Dry weight	Shoot length	Emergence	Survival
Oat <i>Avena sativa</i>	Reduction [%]	-13.91	1.98	-3.09		
	Statistical significance	statistically insignificant	statistically insignificant	statistically insignificant	statistically insignificant	statistically insignificant
Corn <i>Zea mays</i>	Reduction [%]	-2.01	-1.44	0.01		
	Statistical significance	statistically insignificant	statistically insignificant	statistically insignificant	statistically insignificant	statistically insignificant

ER_x dose of the material that exhibits intoxication effects in x% of population

LR_x dose of the material that exhibits intoxication causes mortality in x% of population

NOER highest non observe effective concentration cause no statistically significant differences in comparison to the control

LOER lowest observe effective concentration cause statistically significant differences in comparison to the control

n.d. impossible to calculate due to mathematical reasons

*) the lower and upper 95% confidence intervals

**) based on the analysis of the results, this value was defined as > 0.4 L/ha

Additionally, ER₅₀ for phytotoxicity effects were also determined.

Parameter Species	Average phytotoxicity [%]						ER ₁₀ [L/ha]	ER ₂₅ [L/ha]	ER ₅₀ [L/ha]
	Control	0.038 [L/ha]	0.069 [L/ha]	0.12 [L/ha]	0.22 [L/ha]	0.4 [L/ha]			
Mung Beans <i>Phaseolus aureus</i>	0.0	0.0	0.0	5.0	15.0	30.0	0.189 (0.008-0.342)*	0.331 (0.188 – 10.989)*	0.617 (0.341 – n.d.)*
Cucumber <i>Cucumis sativus</i>	0.0	0.0	0.0	0.0	0.0	30.0	0.365 (n.d. – n.d.)*	0.393 (n.d. – n.d.)*	0.426 (n.d. – n.d.)*
Broccoli <i>Brassica oleracea L. var. italica Plenck</i>	0.0	0.0	0.0	0.0	0.0	0.0	n.d.**	n.d.**	n.d.**
Carrot <i>Daucus carota</i>	0.0	0.0	0.0	0.0	20.0	50.0	0.192 (0.048 – 0.263)*	0.267 (0.149 – 0.397)*	0.385 (0.282 – 1.171)*
Oat <i>Avena sativa</i>							0.0	n.d.**	n.d.**
Corn <i>Zea mays</i>							0.0	n.d.**	n.d.**

ER_x dose of test item causing symptoms of intoxication in x% of the population

n.d. impossible to determine for mathematical reasons

*) the lower and upper and 95% confidence intervals

**) based on the analysis of the results, the value was determined as > 0.4 L/ha

Validity of the test:

- Seedling emergence in the control was at least 70%
- In none of the control replications of any plants species there were any signs of intoxications visible
- Mean survival of plants in control was 100% for every species (required at least 90%)
- Environmental conditions and soil were identical for all used in the experiment plants species

Conclusions:

The lowest ER₅₀ was 0.031 L of test item/ha for Mung bean fresh weight.

Comments of zRMS:	<p>The study is considered as acceptable . All validity criteria were met.</p> <p>Seedling emergence in control was at least 70%:</p> <ul style="list-style-type: none"> - bean mung <i>Phaseolus aureus</i> – 100% - cucumber <i>Cucumis sativus</i> – 100% - carrot <i>Daucus carota</i> – 100% - broccoli <i>Brassica oleracea L. var. italica Plenck</i> – 100% - oats <i>Avena sativa</i> – 100% (Table 23) - corn <i>Zea mays</i> – 100% (Table 24) <p>2. In none of the control replications of any plants species there were any signs of intoxications visible (i.e. chlorosis, necrosis, wilting, leaf/stalk deformation) for every species.</p> <p>3. Mean survival of plants in control was 100% (required at least 90%) for every species</p> <p>4. Environmental conditions and soil were identical for all used in the experiment plants species.</p>
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Agreed endpoints:

Dicotyledons					
Species	Parameter	Fresh weight	Dry weight	Shoot's length	Survival
Mung Bean <i>Phaseolus aureus</i>	ER ₁₀ /LR ₁₀ [L/ha]	0.054 (0.028 – 0.101)*	0.019 (0.010 – 0.039)*	0.276 (0.215 – 0.353)*	n.d.** (n.d. – n.d.)*
	ER ₂₅ /LR ₂₅ [L/ha]	0.113 (0.076 – 0.169)*	0.051 (0.032 – 0.081)*	0.406 (0.360 – 0.458)*	n.d.** (n.d. – n.d.)*
	ER ₅₀ /LR ₅₀ [L/ha]	0.260 (0.165 – 0.418)*	0.151 (0.091 – 0.259)*	0.625 (0.473 – 0.816)*	n.d.** (n.d. – n.d.)*
	LOER [L/ha]	≤0.038	≤0.038	0.4	>0.4
	NOER [L/ha]	<0.038	<0.038	0.22	≥0.4
Dicotyledons					
Species	Parameter	Fresh weight	Dry weight	Shoot's length	Survival
Cucumber <i>Cucumis sativus</i>	ER ₁₀ /LR ₁₀ [L/ha]	n.d.** (n.d. – n.d.)*	0.582 (n.d. – n.d.)*	0.197 (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	ER ₂₅ /LR ₂₅ [L/ha]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – ∞)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	ER ₅₀ /LR ₅₀ [L/ha]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	LOER [L/ha]	>0.4	>0.4	>0.4	n.d.**
	NOER [L/ha]	≥0.4	≥0.4	≥0.4	n.d.**
Carrot <i>Daucus carota</i>	ER ₁₀ /LR ₁₀ [L/ha]	0.035 (0.009 – 0.131)*	0.016 (0.004 – 0.062)*	0.287 (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	ER ₂₅ /LR ₂₅ [L/ha]	0.082 (0.035 – 0.192)*	0.047 (0.019 – 0.113)*	0.541 (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	ER ₅₀ /LR ₅₀ [L/ha]	0.211 (0.084 – 0.549)*	0.155 (0.060 – 0.421)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	LOER [L/ha]	0.120	≤0.038	>0.4	n.d.**
	NOER [L/ha]	0.069	<0.038	≥0.4	n.d.**

Dicotyledons					
Species	Parameter	Fresh weight	Dry weight	Shoot's length	Survival
Broccoli <i>Brassica oleracea</i> L. <i>va. italica</i> <i>Plenck</i>	ER ₁₀ /LR ₁₀ [L/ha]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	ER ₂₅ /LR ₂₅ [L/ha]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	ER ₅₀ /LR ₅₀ [L/ha]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	LOER [L/ha]	>0.4	>0.4	>0.4	n.d.**
	NOER [L/ha]	≥0.4	≥0.4	≥0.4	n.d.**
Monocots - limit test					
Species	Parameter	Fresh weight	Dry weight	Shoot's length	Survival
Oats <i>Avena sativa</i>	Reduction [%]	- 2.0	- 3.9	- 0.6	
	Statistical significance	statistically insignificant	statistically insignificant	statistically insignificant	statistically insignificant
Corn <i>Zea mays</i>	Reduction [%]	2.7	12.7	- 0.5	
	Statistical significance	statistically insignificant	statistically insignificant	statistically insignificant	statistically insignificant

ER_x dose of the material that exhibits intoxication effects in x% of population
 LR_x dose of the material that exhibits intoxication causes mortality in x% of population
 NOER highest non observe effective concentration cause no statistically significant differences in comparison to the control
 LOER lowest observe effective concentration cause statistically significant differences in comparison to the control
 n.d. impossible to calculate due to mathematical reasons
 *) the lower and upper 95% confidence intervals
 **) based on the analysis of the results, this value was defined as > 0.4 L/ha

The ER₅₀ (lowest endpoint) = 0.151 L/ha (Mung Bean)

Phytotoxicity effects									
Parameter		Average phytotoxicity [%]					ER ₁₀ [L/ha]	ER ₂₅ [L/ha]	ER ₅₀ [L/ha]
Species	Control	0.038 [L/ha]	0.069 [L/ha]	0.12 [L/ha]	0.22 [L/ha]	0.4 [L/ha]			
Mung Beans <i>Phaseolus aureus</i>	0.0	0.0	0.0	10.0	20.0	100.0	0.150 (0.078 – 0.192)*	0.188 (0.122 – 0.233)*	0.240 (0.186 – 0.314)*
Cucumber <i>Cucumis sativus</i>	0.0	5.0	10.0	15.0	20.0	35.0	0.076 (n.d. – n.d.)*	0.251 (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
Broccoli <i>Brassica oleracea L.</i> var. <i>italica</i> <i>Plenck</i>	0.0	0.0	0.0	0.0	0.0	0.0	n.d.**	n.d.**	n.d.**
Carrot <i>Daucus carota</i>	0.0	10.0	20.0	30.0	50.0	90.0	0.048 (0.012 – 0.078)*	0.087 (0.040 – 0.129)*	0.170 (0.113 – 0.296)*
Oat <i>Avena sativa</i>						0.0	n.d.**	n.d.**	n.d.**
Corn <i>Zea mays</i>						0.0	n.d.**	n.d.**	n.d.**
ER _x dose of test item causing symptoms of intoxication in x% of the population									
n.d. impossible to determine for mathematical reasons									
*) the lower and upper 95% confidence intervals									
**) based on the analysis of the results, the value was determined as > 0.4 L/ha									
The lowest endpoint: 0.17 l/ha (carrot), Phytotoxicity effects									

Reference:	KCP 10.6.2/02
Report	Vegetative Vigour Test according to OECD 227, Aleksandra Kamińska, 2019, Study code 0016/0060/E, Sorbolab Research Laboratory, Poland Annex No. 1 to the Final report: Vegetative Vigour Test according to OECD 227, Agnieszka Woźniak 2021, Sorbolab Research Laboratory Poland
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 227 “Terrestrial Plant Test: Vegetative Vigour Test”.
Deviations:	OECD 227 guideline recommends CO ₂ concentration at the level 350±50 ppm during the course of the experiment. In the test this parameter was exceeded. However literature data show , that in year 2017 average CO ₂ level in atmosphere exceeded 400 ppm. This deviation had no effect on the course of the study and obtained results.
GLP:	Yes
Acceptability:	Yes

Materials and methods:

- Test material: Faworyt 300 SL
Batch number: 201805002
Concentration of clopyralid 302.7 g/L

3. Test organism: Six plant species were tested, four dicotyledonous and two monocotyledonous: *Phaseolus aureus*, *Cucumis dativus*, *Brassica oleracea* L. var. *italica* Plenck, *Raphanus sativus*, *Dacus carota*, *Avena sativa*, *Zea mays*.

3. Test design:

Definitive test with dicotyledonous species was performed using five doses of the test item. In the test doses: 0.4 L/ha; 0.22 L/ha; 0.12 L/ha; 0.069 L/ha 0.038 L/ha and control were used.

In case monocotyledonous species only the limit test was performed with the dosage of 0.4 L/ha.

All tested doses were chosen based on the results of range finding test.

Soil used in the study

Artificial soil was used in the study containing 20% kaolin clay and approx. 80% quartz sand.

The basic indigents were calcined in temperature of $105\pm 5^{\circ}\text{C}$ and then mixed together in an appropriate amounts. Dry soil was sieved by a sieve of 2 mm mesh. Before the start of the test, artificial soil was moisten with deionized water, to not let it became too wet. After placing soil in the pots, the deionized water (with addition of fertilizer) was poured into stands. During the experiment regular watering was carried out, to prevent drying of the upper parts of the soil. The pH of the soil was 6.0 and contained 0.1% total dissolved solids as a measure of salinity.

Environmental conditions

Temperature	19.4- 27.5°C
Air relative humidity:	average relative air humidity 77%
Lightning	light cycle (16 h day / 8 h night); average light intensity 26654.59 lux
CO2 concentration:	average CO ₂ concentration 379.1 ppm

Results and discussions:

Based on the performed experiment, executed observations and obtained results, it is stated that the tested item exhibits ecotoxic effects on mung bean and carrot in relation to fresh and dry weigh. Statistical difference compared to control were determined at highest tested dose on mung bean.

Strong stimulation of momentum (exuberance) was observed in all cucumber doses tested. In the study, no statistically significant differences were found for plant mortality in the doses tested.

It does not cause ecotoxic effects on oats, corn and broccoli.

The final results of the study were determined using the ToxRat Professional statistical software.

In the presented study the LR10/ER10, LR25/ER25, LR/ER50, LOER and NOER value was determined for the individual parameters: fresh weight, dry weight, shoot length and survival.

Dicotyledons					
Species	Parameter	Fresh weight	Dry weight	Shoot's length	Survival
Mung Bean <i>Phaseolus aureus</i>	ER ₁₀ /LR ₁₀ [L/ha]	0.054 (0.028 – 0.101)*	0.019 (0.010 – 0.039)*	0.276 (0.215 – 0.353)*	n.d.** (n.d. – n.d.)*
	ER ₂₅ /LR ₂₅ [L/ha]	0.113 (0.076 – 0.169)*	0.051 (0.032 – 0.081)*	0.406 (0.360 – 0.458)*	n.d.** (n.d. – n.d.)*
	ER ₅₀ /LR ₅₀ [L/ha]	0.260 (0.165 – 0.418)*	0.151 (0.091 – 0.259)*	0.625 (0.473 – 0.816)*	n.d.** (n.d. – n.d.)*
	LOER [L/ha]	≤0.038	≤0.038	0.4	>0.4
	NOER [L/ha]	<0.038	<0.038	0.22	≥0.4
Dicotyledons					
Species	Parameter	Fresh weight	Dry weight	Shoot's length	Survival
Cucumber <i>Cucumis sativus</i>	ER ₁₀ /LR ₁₀ [L/ha]	n.d.** (n.d. – n.d.)*	0.582 (n.d. – n.d.)*	0.197 (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	ER ₂₅ /LR ₂₅ [L/ha]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – ∞)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	ER ₅₀ /LR ₅₀ [L/ha]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	LOER [L/ha]	>0.4	>0.4	>0.4	n.d.**
	NOER [L/ha]	≥0.4	≥0.4	≥0.4	n.d.**
Carrot <i>Daucus carota</i>	ER ₁₀ /LR ₁₀ [L/ha]	0.035 (0.009 – 0.131)*	0.016 (0.004 – 0.062)*	0.287 (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	ER ₂₅ /LR ₂₅ [L/ha]	0.082 (0.035 – 0.192)*	0.047 (0.019 – 0.113)*	0.541 (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	ER ₅₀ /LR ₅₀ [L/ha]	0.211 (0.084 – 0.549)*	0.155 (0.060 – 0.421)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	LOER [L/ha]	0.120	≤0.038	>0.4	n.d.**
	NOER [L/ha]	0.069	<0.038	≥0.4	n.d.**

Dicotyledons					
Species	Parameter	Fresh weight	Dry weight	Shoot's length	Survival
Broccoli <i>Brassica oleracea</i> L. var. <i>italica</i> Plenck	ER ₁₀ /LR ₁₀ [L/ha]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	ER ₂₅ /LR ₂₅ [L/ha]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	ER ₅₀ /LR ₅₀ [L/ha]	nd.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
	LOER [L/ha]	>0.4	>0.4	>0.4	n.d.**
	NOER [L/ha]	≥0.4	≥0.4	≥0.4	n.d.**
Monocots - limit test					
Species	Parameter	Fresh weight	Dry weight	Shoot's length	Survival
Oats <i>Avena sativa</i>	Reduction [%]	- 2.0	- 3.9	- 0.6	
	Statistical significance	statistically insignificant	statistically insignificant	statistically insignificant	statistically insignificant
Corn <i>Zea mays</i>	Reduction [%]	2.7	12.7	- 0.5	
	Statistical significance	statistically insignificant	statistically insignificant	statistically insignificant	statistically insignificant

ER_x dose of the material that exhibits intoxication effects in x% of population

LR_x dose of the material that exhibits intoxication causes mortality in x% of population

NOER highest non observe effective concentration cause no statistically significant differences in comparison to the control

LOER lowest observe effective concentration cause statistically significant differences in comparison to the control

n.d. impossible to calculate due to mathematical reasons

*) the lower and upper 95% confidence intervals

**) based on the analysis of the results, this value was defined as > 0.4 L/ha

Additionally, ER₅₀ for phytotoxicity effects were also determined.

Parameter Species	Average phytotoxicity [%]						ER ₁₀ [L/ha]	ER ₂₅ [L/ha]	ER ₅₀ [L/ha]
	Control	0.038 [L/ha]	0.069 [L/ha]	0.12 [L/ha]	0.22 [L/ha]	0.4 [L/ha]			
Mung Beans <i>Phaseolus aureus</i>	0.0	0.0	0.0	10.0	20.0	100.0	0.150 (0.078 – 0.192)*	0.188 (0.122 – 0.233)*	0.240 (0.186 – 0.314)*
Cucumber <i>Cucumis sativus</i>	0.0	5.0	10.0	15.0	20.0	35.0	0.076 (n.d. – n.d.)*	0.251 (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
Broccoli <i>Brassica oleracea</i> L. var. <i>italica</i> Plenck	0.0	0.0	0.0	0.0	0.0	0.0	n.d.**	n.d.**	n.d.**
Carrot <i>Daucus carota</i>	0.0	10.0	20.0	30.0	50.0	90.0	0.048 (0.012 – 0.078)*	0.087 (0.040 – 0.129)*	0.170 (0.113 – 0.296)*
Oat <i>Avena sativa</i>						0.0	n.d.**	n.d.**	n.d.**
Corn <i>Zea mays</i>						0.0	n.d.**	n.d.**	n.d.**

ER_x dose of test item causing symptoms of intoxication in x% of the population

n.d. impossible to determine for mathematical reasons

*) the lower and upper 95% confidence intervals

**) based on the analysis of the results, the value was determined as > 0.4 L/ha

Validity criteria:

All OECD 227 validity criteria were met:

1. Seedling emergence in control was at least 70%:
 - bean mung *Phaseolus aureus* – 100%
 - cucumber *Cucumis dativus* – 100%
 - carrot *Daucus carota* – 100%
 - broccoli *Brassica oleracea L. var. italica Plenck* – 100%
 - oats *Avena sativa* – 100% (Table 23)
 - corn *Zea mays* – 100% (Table 24)
2. In none of the control replications of any plants species there were any signs of intoxications visible (i.e. chlorosis, necrosis, wilting, leaf/stalk deformation) for every species.
3. Mean survival of plants in control was 100% (required at least 90%) for every species
4. Environmental conditions and soil were identical for all used in the experiment plants species.

Conclusions:

The lowest ER₅₀ was 0.151 L of test item/ha for Mung bean dry weight.

A 2.6.3	KCP 10.6.3	Extended laboratory studies on non-target plants
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Not needed.

A 2.7	KCP 10.7	Effects on other terrestrial organisms (flora and fauna)
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None.

A 2.8	KCP 10.8	Monitoring data
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None.