FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: CHR/H/IMA 40 SL

Product name(s):

Mazzam 40 SL

Zemax 40 SL

Chemical active substance(s):

Imazamox, 40 g/L

Central Zone

Zonal Rapporteur Member State: Poland

Co-Rapporteur Member State: Hungary, Romania, Slovakia

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 09.2022

MS Finalisation date: 09/12/2024

Version history

When	What
October 2022	Submission to the Polish Ministry of Agriculture and Rural Development
January 2023	Submission to the evaluation unit
November 2023	Applicant update
April 2024	zRMS finalised evaluation
July 2024	Final version prepared by zRMS after Commenting period
December 2024	zRMS update

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use -No. *	Mem-ber state(s)	Crop and/or situation (crop destina-tion / purpose of crop)	F, Fn, Fpn G, Gn, Gp n or I **	Pests or Group of pests con-trolled (additionally: developmen-tal stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Re-marks: e.g. g safener/ synergist per ha	**Conclusion**						
					Meth-od / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica-tions (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x			Birds	Mammals	Aquatic organ-	Bees	Non-target arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	pea	F	Mono and dicots weeds	Spray	BBCH 12-16	1	N/A	a) 0,9	b) 0,036	200-400	N/A								
2	HU, RO, SK	Soy	F	Mono and dicots weeds	Spray	Early postemer-gence BBCH 12-16	1	N/A	a) 1,0 - 1,2	b) 0,040 - 0,048	200-300	N/A								
3																				
4																				
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
Minor uses according to Article 51 (zonal uses)																				
5	PL, HU, RO,	Beans	F	Mono and dicots weeds	Spray	Spring BBCH 10-16, weeds BBCH 10-13	a) 1	N/A	c) 0,6 – 0,9	d) 0,024 - 0,036	200-400		*only for dry seeds							

	SK													use						
6	PL, HU, RO, SK	Broad bean	F	Mono and dicots weeds	Spray	Spring BBCH 10-16, weeds BBCH 10-13	b) 1	N/A	e) 0,6 - 0,9	f) 0,024 - 0,036	200-400		*only for dry seeds use							
7	PL, HU, RO, SK	Lentils	F	M8ono and dicots weeds	Spray	Spring BBCH 10-16, weeds BBCH 10-13	c) 1	N/A	g) 0,6 - 0,9	h) 0,024 - 0,036	200-400		*only for dry seeds use							
8	PL, HU, RO, SK	Lupine	F	Mono and dicots weeds	Spray	Spring BBCH 10-16, weeds BBCH 10-13	d) 1	N/A	i) 0,6 - 0,9	j) 0,024 - 0,036	200-400		*only for dry seeds use							
9	PL, HU, RO, SK	Linseeds	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	k) 0,6 - 0,9	l) 0,024 - 0,036	200-400		*only for seeds use							
10	PL, HU, RO, SK	Spring oilseed rape	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	m) 0,6 - 0,9	n) 0,024 - 0,036	200-400		*only for seeds use							
11	PL, HU, RO, SK	Breadseed poppy	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	o) 0,6 - 0,9	p) 0,024 - 0,036	200-400		*only for seeds use							
12	PL, HU, RO, SK	Sesame	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	q) 0,6 - 0,9	r) 0,024 - 0,036	200-400		*only for seeds use							
13	PL, HU, RO, SK	Mustard	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	s) 0,6 - 0,9	t) 0,024 - 0,036	200-400		*only for seeds use							
14	PL, HU, RO, SK	Sunflower	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	u) 0,6 - 0,9	v) 0,024 - 0,036	200-400		*only for seeds use							

15	PL, HU, RO, SK	Soy	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	w) 0,6 - 0,9	x) 0,024 - 0,036	200-400		*only for seeds use						
16	PL, HU, RO, SK	Safflower	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	y) 0,6 - 0,9	z) 0,024 - 0,036	200-400		*only for seeds use						
17	PL, HU, RO, SK	Borage	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	aa) 0,6 - 0,9	bb) 0,024 - 0,036	200-400		*only for seeds use						
18	PL, HU, RO, SK	Pumpkin	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	cc) 0,6 - 0,9	dd) 0,024 - 0,036	200-400		*only for seeds use						
19	PL, HU, RO, SK	Hemp	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	ee) 0,6 - 0,9	ff) 0,024 - 0,036	200-400		*only for seeds use						
20	PL, HU, RO, SK	Castor beans	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	gg) 0,6 - 0,9	hh) 0,024 - 0,036	200-400		*only for seeds use						
21	PL, HU, RO, SK	Cotton	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	ii) 0,6 - 0,9	jj) 0,024 - 0,036	200-400		*only for seeds use						
22	PL, HU, RO, SK	Tobacco *Nicotiana tabacum* (NIOTA)	F	Mono and dicots weeds	Spray	Spring BBCH 10-89	1	N/A	kk) 0,38-0,9	ll) 0,015 - 0,036	200-300								
23	PL, HU, RO, SK	Coniferous / deciduous forest nurseries, Ornamental	F	Mono and dicots weeds	Spray	Spring BBCH 10-89, the risk of infection, warning	1	N/A	mm) 0,38-0,9	nn) 0,015 - 0,036	200-300								

		shrubs																			
24	PL, HU, RO, SK	*Salix vimi-nalis* (SAXVI) Wicker (1SAXG)	F	Mono and dicots weeds	Spray	BBCH 10-89, the risk of infection, warning	1	N/A	oo) 0,38-0,9	pp) 0,015 - 0,036	200-300										
25	PL, HU, RO, SK	*Ornamen-tal*	F	Mono and dicots weeds	Spray	BBCH 10-89, the risk of infection, warning	1	N/A	qq) 0,38-0,9	ww) 0,015 - 0,036	200-300										
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

Review Comments:

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

9. Ecotoxicology (KCP 10)

Review Comments:

This application was submitted by Innvigo Sp. z o.o. for approval of the formulation CHR/H/IMA 40 SL / Mazzam, Zemax containing 40 g/L of imazamox, for use as a herbicide in main crops: pea and soy and in following minor crops: pulses, oilseeds, sunflower, borage, pumpkin, hemp, cotton, tobacco, coniferous / deciduous forest nurseries, ornamental shrubs and ornamentals and wicker.

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

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

9.1.1 Overall conclusions

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

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

CHR/H/IMA 40 SL poses no unacceptable acute and long-term risk to birds used according to the label and pose no unacceptable acute and long risk for mammals.

There were also no negative effects regarding to drinking water exposure and of secondary poisoning, according to the intended uses of CHR/H/IMA 40 SL.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

CHR/H/IMA 40 SL poses no unacceptable risk to aquatic organisms according to the label with appropriate 20 meter vegetative buffer zone without applying of drift reduction techniques.

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

9.1.1.3 Effects on bees (KCP 10.3.1)

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

CHR/H/IMA 40 SL poses no unacceptable risk to bees according to the label.

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

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

CHR/H/IMA 40 SL poses no unacceptable risk to arthropods other than bees according to the label.

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

CHR/H/IMA 40 SL poses no unacceptable risk to non-target soil meso- and macrofauna according to the label.

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

CHR/H/IMA 40 SL poses no unacceptable risk to non-target terrestrial plants according to the label with appropriate buffer zone and drift reducing techniques.
Based on the predicted rates of CHR/H/IMA 40 SL in off-field areas, the TER values describing the risk for non-target plants following exposure to CHR/H/IMA 40 SL according to the GAP of the formulation CHR/H/IMA 40 SL achieve the acceptability criteria TER ≥ 5, with applying:

- When using in oilseeds, pulses, cotton, tobacco, coniferous / deciduous forest nurseries, ornamental shrubs, ornamentals, salix, wicker all at h < 50 cm and ornamentals <50 cm
  - 5 m without use of drift reducing nozzles
  - 1 m and use of 75 % drift reducing nozzles
- When using in coniferous / deciduous forest nurseries, ornamental shrubs, ornamentals, salix, wicker all at h > 50 cm and ornamentals >50 cm:
  - 15 m buffer zone
  - 10 m and use of 50 % drift reducing nozzles
  - 5 m and use of 75 % drift reducing nozzles
  - 3 m and use of 90 % drift reducing nozzles

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

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

Not relevant

9.1.2 Grouping of intended uses for risk assessment

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

Table 9.1-1: Critical use pattern of CHR/H/IMA 40 SL grouped according to criterion

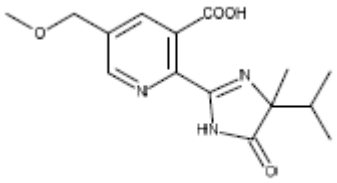
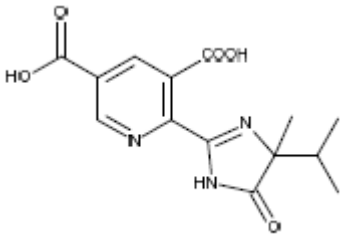
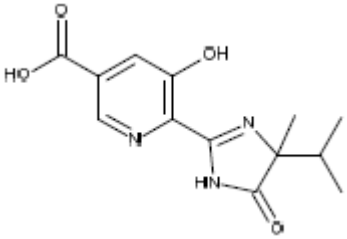
Grouping according to crop i			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
Pulses	BBCH 10-19, 48 g as/ha	Crop, application rate, number of applications, timing	Crop, application rate, number of applications, timing
Oilseeds	BBCH 10-19, 48 g as/ha	Crop, application rate, number of applications, timing	Crop, application rate, number of applications, timing
Cotton	BBCH 10-19, 48 g as/ha	Crop, application rate, number of applications, timing	Crop, application rate, number of applications, timing
Tobacco	BBCH 10-19, 48 g as/ha	Crop, application rate, number of applications, timing	Crop, application rate, number of applications, timing
Coniferous / decidu-ous forest nurseries, Ornamentals	BBCH 10-89, 48 g as/ha	Crop, application rate, number of applications, timing	Crop, application rate, number of applications, timing

Grouping according to crop i			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
Sunflower	BBCH 10-18, 36 g as /ha	Crop, application rate, number of applications, timing	Crop, application rate, number of applications, timing
Fruiting vegetabless, pumpkin	BBCH 10-18, 36 g as /ha	Crop, application rate, number of applications, timing	Crop, application rate, number of applications, timing

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of CHR/H/IMA 40 SL is indicated in the table.

Table 9.1-2 Metabolites of imazamox

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
Parent – imazamox (CL 299263)		305.3 g/mol	100%	Yes
CL 312622		305.3 g/mol	Soil: 43.6% Groundwater: 82.9% Surface water/Sediment: 13.6%	Yes
CL 354825		277.3 g/mol	Soil: 55.2% Groundwater: 77.8% Surface water/Sediment: 5.7%	Yes

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

However, the provision of further data on the CHR/H/IMA40 SL is not considered essential, because
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results [mg/kg bw/day]	Reference
Colinus virginianus	Imazamox	Acute	LD_{50} >1846*	EFSA Journal 2016;14(4):4432
Anas platyrhynchos	Imazamox	Acute	LD_{50} > 1950	EFSA Journal 2016;14(4):4432
Colinus virginianus	Imazamox	Short-term	LD_{50} diet > 2502	EFSA Journal 2016;14(4):4432
Anas platyrhynchos	Imazamox	Short-term	LD_{50} diet > 1934	EFSA Journal 2016;14(4):4432
Colinus virginianus	Imazamox	Long-term	LD50/10 > 348.52	EFSA Journal 2016;14(4):4432
Colinus virginianus	Imazamox	Long-term	NOEC = 2000 ppm NOAEL = 209.4	EFSA Journal 2016;14(4):4432
Anas platyrhynchos	Imazamox	Long-term	NOEC = 2000 ppm NOAEL = 236.5	EFSA Journal 2016;14(4):4432
* The extrapolated value of 3485.2 mg a.s./kg b.w (EFSA Journal 2016;14(4):4432).				

9.2.1.1 Justification for new endpoints

No new endpoints were established – it is not required.

9.2.2 Risk assessment for spray applications

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

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

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

Table 9.2-2: Screening ~~First-tier~~ assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/H/IMA 40 SL in oilseeds, pulses, ~~cotton,~~ tobacco (surrogate crop maize) ~~and ornamentals,~~ fruiting vegetables (pumpkin)

Intended use	Oilseed rape / pulses / sunflower / fruiting vegetables				
Active substance/product	Imazamox				
Application rate (g/ha)	1 × 48 g/L				
Acute toxicity (mg/kg bw)	**3485.2**				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**

Screening step	Small omnivorous bird	158.8	1.0	7.62	457.37 ~~253.7~~
Reprod. toxicity (mg/kg bw/d)					
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small omnivorous bird	64.8	1.0 x 0.53	1.65	117.3

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

Table 9.2-3: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/H/IMA 40 SL in cotton

Intended use	**Cotton**				
Active substance/product	Imazamox				
Application rate (g/ha)	1 × 48 g/L				
Acute toxicity (mg/kg bw)	**3485.2**				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	160.3	1.0	7.7	452.62
Reprod. toxicity (mg/kg bw/d)	**209.4**				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small omnivorous bird	65.4	1.0 x 0.53	1.66	126.14

Table 9.2-4: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/H/IMA 40 SL in Coniferous / decidu-ous forest nurse-ries, Ornamental shrubs, wicker

Intended use	**Orchards and ornamentals/nursery**				
Active substance/product	Imazamox				
Application rate (g/ha)	1 × 48 g/L				
Acute toxicity (mg/kg bw)	**3485.2**				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small insectivorous bird	46.8	1.0	2.25	1548.98

Reprod. toxicity (mg/kg bw/d)	**209.4**				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small insectivorous bird	18.2	1.0 x 0.53	0.46	455.22

9.2.2.2 Higher-tier risk assessment

Not required – all of TER values exceed triggered value 5.

9.2.2.3 Drinking water exposure

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

Leaf scenario

Since CHR/H/IMA 40 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.

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 13.4, imazamox 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 also covers the risk for birds from all other intended uses in pulses, rape cotton, maize, , ornamentals, and sunflower (BBCH 10-19) (see 9.1.2).~~

Effective application rate (g/ha)	=	48			
Acute toxicity (mg/kg bw)	=	**3485.2** ~~1934~~	quotient	=	0.0138 ~~0.0248~~
Reprod. toxicity (mg/kg bw/d)	=	209.4	quotient	=	0.2292

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of imazamox amounts to -2.9 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.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.2.4 Overall conclusions

In conclusion, the acute, ~~short term~~ and long term risk to birds from the proposed uses of imazamox was found acceptable.
~~With regards to the risk to earthworm eating birds an acceptable risk was not identified for the active substance.~~

Review comments:

The acute and long-term risk assessment for birds performed by the Applicant is agreed by the zRMS. It was performed in line with recommendations of the EFSA (2009) with assumption of EU agreed end-points. However screening assessment for two missing additional groups: Orchards and ornamentals/nursery and cotton needed to be has been added by the zRMS.

No formulation study was required.

Selection of the endpoint used for acute risk assessment:
For Acute risk assessment not correct endpoint from dietary short study of LD_{50} > 1934 mg/kg bw was used. Since it is even not the lowest endpoint which is 1846 mg/kg bw, this approach has not been accepted. This value used by the Applicant is lower than available acute extrapolated value of 3485.2 mg a.s./kg b.w (EFSA Journal 2016;14(4):4432) however for transparency and correctness of the assessment the value used in EFSA conclusion for imazamox would be used in risk assessment.

There were also no negative effects regarding to drinking water exposure and effect of secondary poisoning.
Since the log P_{ow} for Imazamox amounts to -0.3 at pH 4, -2.9 at pH 7 and -3.0 at pH 9 (EFSA Journal 2016;14(4):4432) and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

TER_A and TER_{LT} in the acute and long-term risk assessment indicated acceptable risk assessment for imazamox at screening step after application of CHR/H/IMA 40 SL according to critical GAP.

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

9.3.1 Toxicity data

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

Effects on mammals of CHR/H/IMA 40 SL were not evaluated as part of the EU assessment of imazamox. New data submitted with this application are listed in Appendix 1 and summarised in Section 6 (Mammalian Toxicology) of this report.

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

Species	Substance	Exposure System	Results [mg/kg bw/day]	Reference
Rat - Mouse	Imazamox	Acute	LD_{50} > 5000 mg/kg bw	EFSA Journal 2016;14(4):4432
Rabbit	Imazamox	Long term [for screening step]	NOAEL [developmental study] = 300 mg/kg bw/d	EFSA Journal 2016;14(4):4432

9.3.1.1 Justification for new endpoints

No new endpoints were established because it is not relevant.

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).
To achieve a concise risk assessment, the risk envelope approach is applied. ~~Here, the assessment for the use groups cotton, legume forage, maize, oilseed rape, ornamentals, pulses and sunflower (BBCH 10-19) also covers the risk for mammals from all other intended uses in these groups (see 9.1.2).~~

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

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

Table 9.3-2: Screening ~~First tier~~ assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/H/IMA in cotton, fruiting vegetables (pumpkin) ~~oilseeds,~~ maize (as surrogate for tobacco), pulses, , ornamentals/nurseries

Intended use					
Active substance/product	imazamox				
Application rate (g/ha)	1 × 48 g/ha				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	136.4	1.0	6.55	763.7
Reprod. toxicity (mg/kg bw/d)	300				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small herbivorous mammal	72.3	1.0	3.47	163.1

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.

Table 9.3-4: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/H/IMA in oilseed rape and sunflower

Intended use	oilseed rape and sunflower				
Active substance/product	imazamox				
Application rate (g/ha)	1 × 48 g/ha				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1.0	5.68	880.28
Reprod. toxicity (mg/kg bw/d)	300				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small herbivorous mammal	48.3	1.0 x 0.53	1.23	243.90

9.3.2.2 Higher-tier risk assessment

Not required – all of TER values exceed triggered value 5.

9.3.2.3 Drinking water exposure

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

Puddle scenario

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

With a K(f)oc of 13.4, imazamox 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 groups cotton, legume forage, maize, oilseed rape, ornamentals, pulses and sunflower (BBCH 10-19) also covers the risk for mammals from all other intended uses (see 9.1.2).

Effective application rate (g/ha)	=48		
Acute toxicity (mg/kg bw)	=5000	quotient	= 0.0096
Reprod. toxicity (mg/kg bw/d)	=300	quotient	= 0.16

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of imazamox amounts to -2.9 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 mammals via secondary poisoning

Not required.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.3.4 Overall conclusions

In conclusion, the acute, short term risk and long term to mammals from the proposed uses of imazamox was found acceptable.
~~With regards to the risk to earthworm-eating mammals an acceptable risk was not identified for the active substance.~~

Review comments:

The acute and long-term risk assessment for mammals performed by the Applicant is agreed by the zRMS. It was performed in line with recommendations of the EFSA (2009) with assumption of EU agreed endpoints. However screening assessment for two missing additional groups: oilseed and sunflower has been added by the zRMS.
No formulation study was required.
TER_A and TER_{LT} in the acute and long-term risk assessment indicated acceptable risk assessment already at screening step.
There were also no negative effects regarding to drinking water exposure and effect of secondary poisoning.
Since the log P_{ow} for Imazamox amounts to -0.3 at pH 4, -2.9 at pH 7 and -3.0 at pH 9 (EFSA Journal 2016;14(4):4432) and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

TER_A and TER_{LT} in the acute and long-term risk assessment indicated acceptable risk assessment for imazamox at screening step after application of CHR/H/IMA 40 SL according to critical GAP.

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

Effects on other terrestrial vertebrates were not assessed - it is not required.

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

Effects on aquatic organisms of CHR/H/IMA 40 SL were not evaluated as part of the EU assessment of imazamox. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
Fish				
Cyprinodon variegatus	imazamox	Acute 96 hr (flow-through)	Mortality, LC50 > 97 mg a.s./L (nom)	EFSA Journal 2016;14(4):4432

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	imazamox	Acute 96 hr (flow-through)	Mortality, LC50 > 122 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432
Lepomis macrochirus	imazamox	Acute 96 hr (flow-through)	Mortality, LC50 > 119 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432
Cyprinodon variegatus	imazamox	Chronic 35 d (flow-through)	ELS NOEC (length) 1.22 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432
Oncorhynchus mykiss	imazamox	Chronic 96 d (flow-through)	ELS NOEC 11.8 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432
		Chronic 28 d (flow-through)	NOEC (juvenile fish) 122 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432
Aquatic invertebrates				
Daphnia magna	imazamox	48 h (static)	Immobility, EC50 > 100 mg a.s./L (nom)	EFSA Journal 2016;14(4):4432
		48 h (flow-through)	Immobility, EC50 > 122 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432
Mysidopsis bahia	imazamox	96 h (flow-through)	Immobility, EC50 > 100 mg a.s./L	EFSA Journal 2016;14(4):4432
Daphnia magna	imazamox	21 d (flow-through)	Overall NOEC 137 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432
Algae				
Pseudokirchneriella subcapitata	imazamox	72 h (static)	Growth rate: ErC50 29.1 mg a.s./L (nom) ErC10 5.1 mg a.s./L (nom) Yield: EyC50 7.5 mg a.s./L (nom) EyrC10 1.2 mg a.s./L (nom)	EFSA Journal 2016;14(4):4432
Anabaena flos-aquae	imazamox	120 h (static)	EC50 > 0.038 mg a.s./L (mm) NOEC 0.038 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432
Skeletonoma costatum	imazamox	120 h (static)	EC50 > 0.039 mg a.s./L (mm) NOEC 0.039 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432
Navicula pelliculosa	imazamox	120 h (static)	EC50 > 0.037 mg a.s./L (mm) NOEC 0.037 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432

Species	Substance	Exposure System	Results	Reference
Selenastrum capricornutum	imazamox	120 h (static)	EC50 > 0.037 mg a.s./L (mm) NOEC 0.037 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432
Higher plants				
Lemna gibba	imazamox	7d, static	Fronds biomass, EC50 0.011 mg a.s./L (mm) Frond density, EC50 0.014 mg a.s./L (mm) NOEC 0.0045 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432
Lemna gibba	imazamox	14 d, static	Fronds number: ErC50 0.021 mg a.s./L (mm) EyC50 0.011 mg a.s./L (mm) ErC10 0.0067 mg a.s./L (mm) Dry weight: ErC50 0.050 mg a.s./L (mm) EyC50 0.015 mg a.s./L (mm) ErC10 0.044 mg a.s./L (mm)	EFSA Journal 2016;14(4):4432
Lemna gibba	imazamox	7 d (static in presence of sediment)	Fronds number: ErC50 0.022 mg a.s./L(nom) EyC50 0.0099 mg a.s./L(nom) ErC10 0.0054 mg a.s./L(nom) Dry weight: ErC50 0.060 mg a.s./L(nom) EyC50 0.010 mg	EFSA Journal 2016;14(4):4432

Species	Substance	Exposure System	Results	Reference
			a.s./L(nom) ErC10 0.0045 mg a.s./L(nom)	
Myriophyllum aquaticum	imazamox	7 d (static in presence of sediment)	Dry wet/shoot length: ErC50 > 100 mg a.s./L(nom) EyC50 > 100 mg a.s./L(nom) NOErC 100 mg a.s./L(nom) Wet weight: ErC50 > 100 mg a.s./L(nom) EyC50 54.0 mg a.s./L(nom) NOErC 100 mg a.s./L(nom)	EFSA Journal 2016;14(4):4432
Spirodela polyrhiza	imazamox	11 d (static in presence of sediment)	Fronds number: ErC50 0.085 mg a.s./L(nom) EyC50 0.051 mg a.s./L(nom) ErC10 0.016 mg a.s./L(nom) Dry weight: ErC50 > 1.0 mg a.s./L(nom) EyC50 > 1.0 mg a.s./L(nom) ErC10 0.10 mg a.s./L(nom)	EFSA Journal 2016;14(4):4432
Ceratophyllum demersum *(only parameters with lowest endpoints are reported)*	a.s.	8 d (static in presence of sediment)	Wet weight, ErC50 0.050 mg a.s./L(nom) EyC50 0.030 mg a.s./L(nom) NOErC 0.010 mg a.s./L(nom) Number of side shoots, EC50	EFSA Journal 2016;14(4):4432

Species	Substance	Exposure System	Results	Reference
			0.021 mg a.s./L(nom)	
Glyceria maxima (only parameters with lowest endpoints are reported)	a.s.	10 d (static in presence of sediment)	Total length, ErC50 0.032 mg a.s./L(nom) EyC50 0.021 mg a.s./L(nom) NOErC 0.010 mg a.s./L(nom) Number of leaves, EC50 0.021 mg a.s./L(nom)	EFSA Journal 2016;14(4):4432
Aquatic plants (Geomean EC50 from 4 different macrophyte species)	a.s.	-	ErC50 0.042 mg a.s./L EyC50 0.022 mg a.s./L	EFSA Journal 2016;14(4):4432
Lemna gibba	CL 312622	7 d (static)	Fronds number: ErC50 6.3 mg/L(mm) EyC50 2.8 mg/L(mm) NOErC 0.3 mg/L(mm) Dry weight: ErC50 59 mg/L(mm) EyC50 4.5 mg/L(mm) NOErC 0.3 mg/L(mm)	EFSA Journal 2016;14(4):4432
Lemna gibba	CL 354825	7 d (semi-static)	Fronds number: ErC50 43.1 mg/L(mm) EyC50 10.5 mg/L(mm) ErC10 2.6 mg/L(mm) Dry weight: ErC50 > 54.5 mg/L(mm) EyC50 47.7 mg/L(mm) ErC10 15.3	EFSA Journal 2016;14(4):4432

Species	Substance	Exposure System	Results	Reference
			mg/L(mm)	
Higher-tier studies (micro- or mesocosm studies)				
Not performed, not required				

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 – CHR/H/IMA 40 SL

Species	Substance	Exposure System	Results	Reference
Pseudokirchneriella subcapitata	CHR/H/IMA 40 SL	72 h, s	E_rC_{50} >100 mg product/L $_{nom}$ E_yC_{50} >100 mg product/L $_{nom}$	Brzozowska-Wojoczek K., 2019, study code: W/17/19
Anabaena flos aquae	CHR/H/IMA 40 SL	72 h, s	E_rC_{50} = 67.31 mg product /L $_{nom}$ LOEC = 100 mg product /L_{nom} NOEC = 40 mg product /L_{nom} E_yC_{50} = 27.09 mg product /L_{nom} LOEC = 6.4 mg product /L_{nom} NOEC = 2.56 mg product /L_{nom}	Nierzędska E., 2019, study code: W/18/19
Lemna gibba	CHR/H/IMA 40 SL	7d, s	Growth rate test: Frond number: E_rC_{50}: 1.314 mg/L LOEC: 0.74 mg/L NOEC: 0.25 mg/L Dry weight: E_rC_{50}: 8.591 mg/L LOEC: 0.25 mg/L NOEC: 0.08 mg/L Yield test: Frond number: E_rC_{50}: 0.552 mg/L LOEC: 0.74 mg/L NOEC: 0.25 mg/L Dry weight: E_rC_{50}: 0.897 mg/L LOEC: 0.25 mg/L NOEC: 0.08 mg/L	Brzozowska-Wojoczek K., 2019, study code: W/19/19

Species	Substance	Exposure System	Results	Reference
Daphnia magna	CHR/H/IMA 40 SL	48 h, s	EC_{50} (24h): >100 mg product/L EC_{50} (48h): >100 mg product/L	Brzozowska-Wojoczek K, 2019, study code: W/20/19
Higher-tier studies (micro- or mesocosm studies)				
Not performed, not required				

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

9.5.1.1 Justification for new endpoints

No new endpoints were established – it is no required

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).
The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use groups also covers the risk for aquatic organisms from all other intended uses. ~~in groups ma~~ (see 9.1.2).

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

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for imazamox for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in soybean

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plants**
Test species		***Cyprinodon variegatus***	***Cyprinodon variegatus***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	**Geomean for all species in this group**
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}=29100/ E_yC_{50}=7500	E_rC_{50}/E_yC_{50}
(µg/L)		97 000	1220	100 000	137 000		22
AF		100	10	100	10	10	10
RAC (µg/L)		970	122	1000	13 700	2910/750	2.2
FOCUS Scenario	**PEC gl-max (µg/L)**						
~~**Step 1**~~							
	~~15.89~~	~~0.016381~~	~~0.130246~~	~~0.01589~~	~~0.00116~~	~~0.021187~~	~~**7.22273**~~
~~**Step 2**~~							
~~N Europe~~	~~1.66~~	~~0.001711~~	~~0.013607~~	~~0.00166~~	~~0.000121~~	~~0.002213~~	~~0.754545~~
~~S Europe~~	~~2.90~~	~~0.00299~~	~~0.02377~~	~~0.0029~~	~~0.000212~~	~~0.003867~~	~~**1.318182**~~
~~**Step 3**~~							
~~R3/stream~~	~~1.573~~	~~0.001622~~	~~0.012893~~	~~0.001573~~	~~0.000115~~	~~0.002099~~	~~0.715455~~
~~R4/stream~~	~~0.1738~~	~~0.000179~~	~~0.001425~~	~~0.000174~~	~~1.27E-05~~	~~0.000232~~	~~0.079~~
Step 1							
	16.20	0.01670	0.13279	0.01620	0.00118	0.0056/0.02160	7.36364
Step 2							
N-Europe	2.57	0.00265	0.02107	0.00257	0.00019	0.00343	1.16818
S-Europe	4.70	0.00440	0.03500	0.00427	0.00031	0.00569	1.94091
Step 3							
R3/stream	1.767	0.00182	0.01448	0.00177	0.00013	0.00236	0.80318
R4/stream	0.1738	0.00018	0.00142	0.00017	0.00001	0.00023	0.07900

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 (soybean), calculated PEC/RAC ratios indicate an acceptable risk for all aquatic organisms (risk for Higher plants as characterised by an E_rC_{50} for species of 22 µg/L (geomean) in connection with an assessment factor of 10) in all FOCUS Step 3 scenarios. Therefore, further PEC/RAC ratio calculation is not required.

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for imazamox for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in sunflower

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plants**
Test species		***Cyprinodon variegatus***	***Cyprinodon variegatus***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	**Geomean for all species in this group**
Endpoint (µg/L)		LC_{50} 97 000	NOEC 1220	EC_{50} 100 000	NOEC 137 000	E_rC_{50}=29100/ E_yC_{50}=7500	E_rC_{50}/E_yC_{50} 22
AF		100	10	100	10	10	10
RAC (µg/L)		970	122	1000	13 700	2910/750	2.2
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**						
~~Step 1~~							
	~~15.89~~	~~0.016381~~	~~0.130246~~	~~0.01589~~	~~0.00116~~	~~0.02119~~	~~7.22273~~
~~Step 2~~							
~~N-Europe~~	~~2.40~~	~~0.002474~~	~~0.019672~~	~~0.0024~~	~~0.000175~~	~~0.0032~~	~~1.090909~~
~~S-Europe~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~
~~Step 3~~							
~~D5/pond~~	~~0.02268~~	~~2.34E-05~~	~~0.000186~~	~~2.27E-05~~	~~1.66E-06~~	~~3.02E-05~~	~~0.010309~~
~~D5/stream~~	~~0.2183~~	~~0.000225~~	~~0.001789~~	~~0.000218~~	~~1.59E-05~~	~~0.000291~~	~~0.099227~~
~~R1/pond~~	~~0.01318~~	~~1.36E-05~~	~~0.000108~~	~~1.32E-05~~	~~9.62E-07~~	~~1.76E-05~~	~~0.005991~~
~~R1/stream~~	~~0.7412~~	~~0.000764~~	~~0.006075~~	~~0.000741~~	~~5.41E-05~~	~~0.000988~~	~~0.336909~~
~~R3/stream~~	~~0.2456~~	~~0.000253~~	~~0.002013~~	~~0.000246~~	~~1.79E-05~~	~~0.000327~~	~~0.111636~~
~~R4/stream~~	~~0.8473~~	~~0.000874~~	~~0.006945~~	~~0.000847~~	~~6.18E-05~~	~~0.00113~~	~~0.385136~~
Step 1							
	16.20	0.01670	0.13279	0.01620	0.00118	0.0056/0.02160	7.36364
Step 2							
N-Europe	2.57	0.00265	0.02107	0.00257	0.00019	0.00343	1.16818
S-Europe	-	-	-	-	-	-	-
Step 3							
D5/pond	0.0267	0.00003	0.00022	0.00003	0.00000	0.00004	0.01214
D5/stream	0.2193	0.00023	0.00180	0.00022	0.00002	0.00029	0.09968
R1/pond	0.01354	0.0000140	0.00011	0.000014	0.000001	0.00002	0.006155
R1/stream	0.7848	0.0008091	0.00643	0.000785	0.000057	0.00105	0.356727

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
R3/stream	0.2060	0.0002124	0.00169	0.000206	0.000015	0.00027	0.093636
R4/stream	1.978	0.0020392	0.01621	0.001978	0.000144	0.00264	0.899091

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 (sunflower), calculated PEC/RAC ratios indicate an acceptable risk for all aquatic organisms (risk for Higher plants as characterised by an E_rC_{50} for species of 22 µg/L (geomean) in connection with an assessment factor of 10) in all FOCUS Step 3 scenarios. Therefore, further PEC/RAC ratio calculation is not required.

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for imazamox for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in legumes

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
Test species		***Cyprinodon variegatus***	***Cyprinodon variegatus***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	**Geomean for all species in this group**
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC50=29100/ EyC50=7500	E_rC_{50}/E_yC_{50}
(µg/L)		97 000	1220	100 000	137 000		22
AF		100	10	100	10	10	10
RAC (µg/L)		970	122	1000	13 700	2910/750	2.2
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**						
~~**Step 1**~~							
	~~15.89~~	~~0.016381~~	~~0.130246~~	~~0.01589~~	0.00116	0.021187	7.222727
~~**Step 2**~~							
~~N Europe~~	~~1.66~~	~~0.002474~~	~~0.019672~~	~~0.0024~~	0.000175	0.002213	0.754545
~~S Europe~~	-	-	-	-	-		
~~**Step 3**~~							
				~~Not required~~			
Step 1							
	16.20	0.01670	0.13279	0.01620	0.00118	0.0056/0.02160	7.36364
Step 2							
N-Europe	2.43	0.00251	0.01992	0.00243	0.00018	0.00324	1.10455
S-Europe	-	-	-	-	-		
Step 3							
D3 ditch	0.2815	0.00029	0.00231	0.00028	0.00002	0.00038	0.12795

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
D4 pond	0.1044	0.00011	0.00086	0.00010	0.00001	0.00014	0.04745
D4 stream	0.2386	0.0002460	0.00196	0.000239	0.000017	0.00032	0.108455
D5 pond	0.01709	0.0000176	0.00014	0.000017	0.000001	0.00002	0.007768
D5 stream	0.2119	0.0002185	0.00174	0.000212	0.000015	0.00028	0.096318
R1 pond	0.01018	0.0000105	0.00008	0.000010	0.000001	0.00001	0.004627
R1 stream	0.1741	0.0001795	0.00143	0.000174	0.000013	0.00023	0.079136
R3 stream	0.2463	0.0002539	0.00202	0.000246	0.000018	0.00033	0.111955
R4 stream	2.071	0.0021351	0.01698	0.002071	0.000151	0.00276	0.941364

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 (legumes), calculated PEC/RAC ratios indicate an acceptable risk for all aquatic organisms (risk for Higher plants as characterised by an E_rC_{50} for species of 22 µg/L (geomean) in connection with an assessment factor of 10) in FOCUS Steps 1-2. Therefore, further PEC/RAC ratio calculation is not required.

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for imazamox for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in spring oilseed rape

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
Test species		*Cyprinodon variegatus*	*Cyprinodon variegatus*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchneriella subcapitata*	Geomean for all species in this group
Endpoint (µg/L)		LC_{50} 97 000	NOEC 1220	EC_{50} 100 000	NOEC 137 000	ErC_{50}=29100/ EyC_{50}=7500	E_rC_{50}/E_yC_{50} 22
AF		100	10	100	10	10	10
RAC (µg/L)		970	122	1000	13 700	2910/750	2.2
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)						
~~Step 1~~							
	~~15.89~~	~~0.016381~~	~~0.130246~~	~~0.01589~~	~~0.00116~~	~~0.021187~~	~~7.222727~~
~~Step 2~~							
~~N Europe~~	~~1.91~~	~~0.001969~~	~~0.015656~~	~~0.00191~~	~~0.000139~~	~~0.002547~~	~~0.868182~~
~~S Europe~~	-	-	-	-	-	-	-
~~Step 3~~							
~~D3 ditch~~	~~0.3248~~	~~0.000335~~	~~0.002662~~	~~0.000325~~	~~2.37E-05~~	~~0.000433~~	~~0.147636~~
~~D4 pond~~	~~0.05003~~	~~5.16E-05~~	~~0.00041~~	~~5E-05~~	~~3.65E-06~~	~~6.67E-05~~	~~0.022741~~
~~D4 stream~~	~~0.2594~~	~~0.000267~~	~~0.002126~~	~~0.000259~~	~~1.89E-05~~	~~0.000346~~	~~0.117909~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
~~D5 pond~~	~~0.01638~~	~~1.69E-05~~	~~0.000134~~	~~1.64E-05~~	~~1.2E-06~~	~~2.18E-05~~	~~0.007445~~
~~D5 stream~~	~~0.2436~~	~~0.000251~~	~~0.001997~~	~~0.000244~~	~~1.78E-05~~	~~0.000325~~	~~0.110727~~
~~R1 pond~~	~~0.01048~~	~~1.08E-05~~	~~8.59E-05~~	~~1.05E-05~~	~~7.65E-07~~	~~1.4E-05~~	~~0.004764~~
~~R1 stream~~	~~0.2005~~	~~0.000207~~	~~0.001643~~	~~0.000201~~	~~1.46E-05~~	~~0.000267~~	~~0.091136~~
Step 1							
	16.20	0.01670	0.13279	0.01620	0.00118	0.0056/0.02160	7.36364
Step 2							
N-Europe	2.03	0.00209	0.01664	0.00203	0.00015	0.00271	0.92273
S-Europe	-	-	-	-	-	-	-
Step 3							
D1 ditch	0.4265	0.00044	0.00350	0.00043	0.00003	0.00057	0.19386
D1 stream	0.2696	0.00028	0.00221	0.00027	0.00002	0.00036	0.12255
D3 ditch	0.3444	0.0003551	0.00282	0.000344	0.000025	0.00046	0.156545
D4 pond	0.07815	0.0000806	0.00064	0.000078	0.000006	0.00010	0.035523
D4 stream	0.2665	0.0002747	0.00218	0.000267	0.000019	0.00036	0.121136
D5 pond	0.01918	0.0000198	0.00016	0.000019	0.000001	0.00003	0.008718
D5 stream	0.2445	0.0002521	0.00200	0.000245	0.000018	0.00033	0.111136
R1 pond	0.01048	0.0000108	0.00009	0.000010	0.000001	0.00001	0.004764
R1 stream	0.2005	0.0002067	0.00164	0.000201	0.000015	0.00027	0.091136

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 (spring oilseed rape) calculated PEC/RAC ratios indicate an acceptable risk for all aquatic organisms (risk for Higher plants as characterised by an E_rC_{50} for species of 22 µg/L (geomean) in connection with an assessment factor of 10) in all FOCUS Step 3 scenarios. Therefore, further PEC/RAC ratio calculation is not required.

~~**Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for imazamox for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in winter oilseed rape**~~

~~Group~~		~~Fish acute~~	~~Fish pro-longed~~	~~Inverteb. acute~~	~~Inverteb. prolonged~~	~~Algae~~	~~Higher plants~~
~~Test species~~		~~*Cyprinodon variegatus*~~	~~*Cyprinodon variegatus*~~	~~*Daphnia magna*~~	~~*Daphnia magna*~~	~~*Pseudokirchneriella subcapitata*~~	~~Geomean for all species in this group~~
~~Endpoint (µg/L)~~		~~LC_{50} 97 000~~	~~NOEC 1220~~	~~EC_{50} 100 000~~	~~NOEC 137 000~~	~~E_rC_{50}/E_yC_{50} 7500~~	~~E_rC_{50}/E_yC_{50} 22~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
AF		100	10	100	10	10	10
RAC (µg/L)		970	122	1000	13 700	750	2.2
FOCUS Scenario	PEC $_{gl\ max}$ (µg/L)						
Step 1							
	15.89	0.016381	0.130246	0.01589	0.00116	0.021187	**7.222727**
Step 2							
N Europe	4.13	0.004258	0.033852	0.00413	0.000301	0.005507	**1.877273**
S Europe	-						
Step 3							
D1 stream							
D3 ditch	0.6333	0.000653	0.005191	0.000633	4.62E-05	0.000844	0.287864
D4 pond	0.6406	0.00066	0.005251	0.000641	4.68E-05	0.000854	0.291182
D4 stream	0.4702	0.000485	0.003854	0.00047	3.43E-05	0.000627	0.213727
D5 pond	0.2950	0.000304	0.002418	0.000295	2.15E-05	0.000393	0.134091
D5 stream	0.2840	0.000293	0.002328	0.000284	2.07E-05	0.000379	0.129091
R1 pond	0.01048	1.08E-05	8.59E-05	1.05E-05	7.65E-07	1.4E-05	0.004764
R1 stream	0.2013	0.000208	0.00165	0.000201	1.47E-05	0.000268	0.0915
R3 stream	0.6269	0.000646	0.005139	0.000627	4.58E-05	0.000836	0.284955

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 (winter oilseed rape), calculated PEC/RAC ratios indicate an acceptable risk for all aquatic organisms (risk for Higher plants as characterised by an E_rC_{50} for species of 22 µg/L (geomean) in connection with an assessment factor of 10) in all FOCUS Step 3 scenarios. Therefore, further PEC/RAC ratio calculation is not required.

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for imazamox for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in cotton

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
Test species		*Cyprinodon variegatus*	*Cyprinodon variegatus*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchneriella subcapitata*	Geomean for all species in this group

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
Endpoint (µg/L)		LC_{50} 97 000	NOEC 1220	EC_{50} 100 000	NOEC 137 000	ErC50=29100/ EyC50=7500	E_rC_{50}/E_yC_{50} 22
AF		100	10	100	10	10	10
RAC (µg/L)		970	122	1000	13 700	2910/750	2.2
FOCUS Scenario	PEC gl-max (µg/L)						
~~Step 1~~							
	~~15.89~~	~~0.016381~~	~~0.130246~~	~~0.01589~~	~~0.00116~~	~~0.021187~~	~~7.222727~~
~~Step 2~~							
~~N-Europe~~	~~2.16~~	~~0.002227~~	~~0.017705~~	~~0.00216~~	~~0.000158~~	~~0.00288~~	~~0.981818~~
~~S-Europe~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~
~~Step 3~~							
~~D6 ditch~~	~~0.2495~~	~~0.000257~~	~~0.002045~~	~~0.00025~~	~~1.82E-05~~	~~0.000333~~	~~0.113409~~
Step 1							
	16.20	0.01670	0.13279	0.01620	0.00118	0.0056/0.02160	7.36364
Step 2							
N-Europe	2.30	0.00237	0.01885	0.00230	0.00017	0.00307	1.04545
S-Europe	-	-	-	-	-	-	-
Step 3							
D6 ditch	0.2532	0.00026	0.00208	0.00025	0.00002	0.00034	0.11509

For the intended uses (cotton), calculated PEC/RAC ratios indicate an acceptable risk for all aquatic organisms (risk for Higher plants as characterised by an E_rC_{50} for species of 22 µg/L (geomean) in connection with an assessment factor of 10) in all FOCUS Step 3 scenarios. Therefore, further PEC/RAC ratio calculation is not required.

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for imazamox for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in tobacco

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
Test species		*Cyprinodon variegatus*	*Cyprinodon variegatus*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchneriella subcapitata*	Geomean for all species in this group
Endpoint (µg/L)		LC_{50} 97 000	NOEC 1220	EC_{50} 100 000	NOEC 137 000	ErC50=29100/ EyC50=7500	E_rC_{50}/E_yC_{50} 22

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
AF		100	10	100	10	10	10
RAC (µg/L)		970	122	1000	13 700	2910/750	2.2
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**						
~~Step 1~~							
	~~15.89~~	~~0.016381~~	~~0.130246~~	~~0.01589~~	~~0.00116~~	~~0.021187~~	~~**7.222727**~~
~~Step 2~~							
~~N Europe~~	~~2.40~~	~~0.002474~~	~~0.019672~~	~~0.0024~~	~~0.000175~~	~~0.0032~~	~~**1.090909**~~
~~S Europe~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~
~~Step 3~~							
~~D6 ditch~~	~~0.3067~~	~~0.000316~~	~~0.002514~~	~~0.000307~~	~~2.24E-05~~	~~0.000409~~	~~0.139409~~
Step 1							
	16.20	0.01670	0.13279	0.01620	0.00118	0.0056/0.02160	7.36364
Step 2							
N-Europe	2.57	0.00265	0.02107	0.00257	0.00019	0.00343	1.16818
S-Europe	-	-	-	-	-	-	-
Step 3							
R3 stream	0.3426	0.00035	0.00281	0.00034	0.00003	0.00046	0.15573

For the intended uses (tobacco), calculated PEC/RAC ratios indicate an acceptable risk for all aquatic organisms (risk for Higher plants as characterised by an E_rC_{50} for species of 22 µg/L (geomean) in connection with an assessment factor of 10) in all FOCUS Step 3 scenarios. Therefore, further PEC/RAC ratio calculation is not required.

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for imazamox for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in maize

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
Test species		***Cyprinodon variegatus***	***Cyprinodon variegatus***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	**Geomean for all species in this group**
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC50=29100/ EyC50=7500	E_rC_{50}/E_yC_{50}
(µg/L)		97 000	1220	100 000	137 000		22
AF		100	10	100	10	10	10
RAC (µg/L)		970	122	1000	13 700	2910/750	2.2

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**						
~~Step 1~~							
	~~15.89~~	~~0.016381~~	~~0.130246~~	~~0.01589~~	~~0.00116~~	~~0.021187~~	~~**7.222727**~~
~~Step 2~~							
~~N-Europe~~	~~2.28~~	~~0.002351~~	~~0.018689~~	~~0.00228~~	~~0.000166~~	~~0.00304~~	~~1.036364~~
~~S-Europe~~	~~-~~						
~~Step 3~~							
~~D3 ditch~~	~~0.276~~	~~0.000285~~	~~0.002262~~	~~0.000276~~	~~2.01E-05~~	~~0.000368~~	~~0.125455~~
~~D4 pond~~	~~0.05452~~	~~5.62E-05~~	~~0.000447~~	~~5.45E-05~~	~~3.98E-06~~	~~7.27E-05~~	~~0.024782~~
~~D4 stream~~	~~0.2254~~	~~0.000232~~	~~0.001848~~	~~0.000225~~	~~1.65E-05~~	~~0.000301~~	~~0.102455~~
~~D5 pond~~	~~0.02993~~	~~3.09E-05~~	~~0.000245~~	~~2.99E-05~~	~~2.18E-06~~	~~3.99E-05~~	~~0.013605~~
~~D5 stream~~	~~0.2208~~	~~0.000228~~	~~0.00181~~	~~0.000221~~	~~1.61E-05~~	~~0.000294~~	~~0.100364~~
~~D6 ditch~~	~~0.2529~~	~~0.000261~~	~~0.002073~~	~~0.000253~~	~~1.85E-05~~	~~0.000337~~	~~0.114955~~
~~R1 pond~~	~~0.0143~~	~~1.47E-05~~	~~0.000117~~	~~1.43E-05~~	~~1.04E-06~~	~~1.91E-05~~	~~0.0065~~
~~R1 stream~~	~~0.4967~~	~~0.000512~~	~~0.004071~~	~~0.000497~~	~~3.63E-05~~	~~0.000662~~	~~0.225773~~
~~R2 stream~~	~~1.5~~	~~0.001546~~	~~0.012295~~	~~0.0015~~	~~0.000109~~	~~0.002~~	~~0.681818~~
~~R3 stream~~	~~1.751~~	~~0.001805~~	~~0.014352~~	~~0.001751~~	~~0.000128~~	~~0.002335~~	~~0.795909~~
~~R4 stream~~	~~2.241~~	~~0.00231~~	~~0.018369~~	~~0.002241~~	~~0.000164~~	~~0.002988~~	~~**1.018636**~~
Step 1							
	16.20	0.01670	0.13279	0.01620	0.00118	0.0056/0.02160	7.36364
Step 2							
N-Europe	2.43	0.00251	0.01992	0.00243	0.00018	0.00324	1.10455
S-Europe	-						
Step 3							
D3 ditch	0.2860	0.00029	0.00234	0.00029	0.00002	0.00038	0.13000
D4 pond	0.07537	0.00008	0.00062	0.00008	0.00001	0.00010	0.03426
D4 stream	0.2300	0.0002371	0.00189	0.000230	0.000017	0.00031	0.104545
D5 pond	0.03491	0.0000360	0.00029	0.000035	0.000003	0.00005	0.015868
D5 stream	0.2223	0.0002292	0.00182	0.000222	0.000016	0.00030	0.101045
R1 pond	0.01634	0.0000168	0.00013	0.000016	0.000001	0.00002	0.007427

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
R1 stream	0.5119	0.0005277	0.00420	0.000512	0.000037	0.00068	0.232682
R3 stream	1.916	0.0019753	0.01570	0.001916	0.000140	0.00255	0.870909
R4 stream	2.218	0.0022866	0.01818	0.002218	0.000162	0.00296	1.008182

For the intended uses (maize), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for Higher plants as characterised by an E_rC_{50} for species of 22 µg/L (geomean) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

Table 9.5-14a: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for imazamox based on FOCUS Step 4 calculations and toxicity data for group with mitigation of spray drift and run-off for the use of formulation in maize

Intended use **Active substance** **Application rate (g/ha)**			
~~**Nozzle reduction**~~	~~**No-spray buffer (m)**~~	~~10~~	~~20~~
	~~**Vegetated filter strip (m)**~~	~~10~~	~~20~~
~~None~~	~~R4/stream~~	~~1.019~~	~~0.5339~~
~~**RAC (µg/L)**~~ ~~2.2~~			
~~None~~	~~R4/stream~~	~~0.4632~~	
Nozzle reduction	**No-spray buffer (m)**	0.75	
	Vegetated filter strip (m)	10	
None	R4/stream	1.008	
RAC (µg/L) 2.2			
None	R4/stream	0.45818	

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

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for imazamox for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in pomefruits

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plants**
Test species		***Cyprinodon variegatus***	***Cyprinodon variegatus***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	**Geomean for all species in this group**
Endpoint (µg/L)		LC_{50} 97 000	NOEC 1220	EC_{50} 100 000	NOEC 137 000	E_rC_{50}/E_yC_{50} 7500	E_rC_{50}/E_yC_{50} 22

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
AF		100	10	100	10	10	10
RAC (µg/L)		970	122	1000	13 700	750	2.2
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**						
Step 1							
	17.96	0.01851546	0.147213	0.01796	0.001311	0.021187	**7.222727**
Step 2							
N Europe	4.41	0.00454639	0.036148	0.00441	0.000322	0.00588	2.004545
S Europe	-						
Step 3							
D3 ditch	3.734	0.00384948	0.030607	0.003734	0.000273	0.004979	**1.697273**
D4 pond	0.2317	0.00023887	0.001899	0.000232	1.69E-05	0.000309	0.105318
D4 stream	3.529	0.00363814	0.028926	0.003529	0.000258	0.004705	**1.604091**
D5 pond	0.2316	0.00023876	0.001898	0.000232	1.69E-05	0.000309	0.105273
D5 stream	3.700	0.00381443	0.030328	0.0037	0.00027	0.004933	**1.681818**
D6 ditch	0.2266	0.00023361	0.001857	0.000227	1.65E-05	0.000302	0.103
R1 pond	3.015	0.00310825	0.024713	0.003015	0.00022	0.00402	**1.370455**
R1 stream	3.994	0.00411753	0.032738	0.003994	0.000292	0.005325	**1.815455**
R2 stream	4.265	0.00439691	0.034959	0.004265	0.000311	0.005687	**1.938636**
R3 stream	3.032	0.00312577	0.024852	0.003032	0.000221	0.004043	**1.378182**
R4 stream	3.734	0.00384948	0.030607	0.003734	0.000273	0.004979	**1.697273**
Step 1							
	20.43	0.02106	0.16746	0.02043	0.00149	0.02724	9.28636
Step 2							
N-Europe	6.7	0.00691	0.05492	0.00670	0.00049	0.00893	3.04545
S-Europe	-						
Step 3							
D3 ditch	3.3736	0.00348	0.02765	0.00337	0.00025	0.00450	1.53345
D4 pond	0.2327	0.00024	0.00191	0.00023	0.00002	0.00031	0.10577
D4 stream	3.529	0.0036381	0.02893	0.003529	0.000258	0.00471	1.604091
D5 pond	0.2320	0.0002392	0.00190	0.000232	0.000017	0.00031	0.105455

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
D5 stream	3.700	0.0038144	0.03033	0.003700	0.000270	0.00493	1.681818
R1 pond	0.2266	0.0002336	0.00186	0.000227	0.000017	0.00030	0.103000
R1 stream	3.015	0.0031082	0.02471	0.003015	0.000220	0.00402	1.370455
R3 stream	4.265	0.0043969	0.03496	0.004265	0.000311	0.00569	1.938636
R4 stream	3.032	0.0031258	0.02485	0.003032	0.000221	0.00404	1.378182
Step 4 – 10meters of no spray and vegetative buffer zone							
D3 ditch	1.807	0.00186	0.01481	0.00181	0.00013	0.00241	0.82136
D4 stream	1.864	0.00192	0.01528	0.00186	0.00014	0.00249	0.84727
D5 stream	1.953	0.0020134	0.01601	0.001953	0.000143	0.00260	0.887727
R1 stream	1.591	0.0016402	0.01304	0.001591	0.000116	0.00212	0.723182
R3 stream	2.250	0.0023196	0.01844	0.002250	0.000164	0.00300	1.022727
R4 stream	1.600	0.0016495	0.01311	0.001600	0.000117	0.00213	0.727273
Step 4 – 20 meters of no spray and vegetative buffer zone							
R3 stream	0.5145	0.00053	0.00422	0.00051	0.00004	0.00069	0.23386

For the intended uses (pomefruit) calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for *Lemna gibba* as characterised by an E_rC_{50} for species of 22 µg/L in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

~~**Table 9.5-15a: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for imazamox based on FOCUS Step 4 calculations and toxicity data for group with mitigation of spray drift and run-off for the use of formulation in pomefruit**~~

~~**Intended use**~~ ~~**Active substance**~~ ~~**Application rate (g/ha)**~~			
~~**Nozzle reduction**~~	~~**No spray buffer (m)**~~	~~10~~	~~20~~
	~~**Vegetated filter strip (m)**~~	~~10~~	~~20~~
~~None~~	~~D3 ditch~~	~~1.805~~	~~0.4175~~
~~None~~	~~D4 stream~~	~~1.863~~	~~0.4282~~
~~None~~	~~D5 stream~~	~~1.953~~	~~0.4478~~

None	R1 stream	1.591	0.3637
None	R2 stream	2.107	0.4818
None	R3 stream	2.250	0.5146
None	R4 stream	1.600	0.3659
RAC (µg/L) 2.2			
None	D3 ditch	0.820454	0.189773
None	D4 stream	0.846818	0.194636
None	D5 stream	0.887727	0.203545
None	R1 stream	0.723182	0.165318
None	R2 stream	0.957727	0.219
None	R3 stream	**1.022727**	0.233909
None	R4 stream	0.727273	0.166318

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

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for imazamox for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in field beans

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plants**
Test species		***Cyprinodon variegatus***	***Cyprinodon variegatus***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	**Geomean for all species in this group**
Endpoint **(µg/L)**		LC_{50} 97 000	NOEC 1220	EC_{50} 100 000	NOEC 137 000	E_rC_{50}/E_yC_{50} 7500	E_rC_{50}/E_yC_{50} 22
AF		100	10	100	10	10	10
RAC (µg/L)		970	122	1000	13 700	750	2.2
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**						
Step 1							
	16.20	0.01670	0.13279	0.01620	0.00118	0.02160	7.36364
Step 2							
N-Europe	2.43	0.00251	0.01992	0.00243	0.00018	0.00324	1.10455
S-Europe	-						
Step 3							
D3 ditch	0.2800	0.00029	0.00230	0.00028	0.00002	0.00037	0.12727
D4 pond	0.06345	0.00007	0.00052	0.00006	0.00000	0.00008	0.02884

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
D4 stream	0.2217	0.0002286	0.00182	0.000222	0.000016	0.00030	0.100773
R1 pond	0.01018	0.0000105	0.00008	0.000010	0.000001	0.00001	0.004627
R1 stream	0.2274	0.0002344	0.00186	0.000227	0.000017	0.00030	0.103364
R3 stream	0.3942	0.0004064	0.00323	0.000394	0.000029	0.00053	0.179182
R4 stream	2.029	0.0020918	0.01663	0.002029	0.000148	0.00271	0.922273

For the intended uses (field beans) calculated PEC/RAC ratios indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for *Lemna gibba* as characterised by an E_rC_{50} for species of 22 µg/L in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios.

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for imazamox for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in cabbage

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
Test species		*Cyprinodon variegatus*	*Cyprinodon variegatus*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchneriella subcapitata*	Geomean for all species in this group
Endpoint (µg/L)		LC_{50} 97 000	NOEC 1220	EC_{50} 100 000	NOEC 137 000	E_rC_{50}/E_yC_{50} 7500	E_rC_{50}/E_yC_{50} 22
AF		100	10	100	10	10	10
RAC (µg/L)		970	122	1000	13 700	750	2.2
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)						
Step 1							
	16.20	0.01670	0.13279	0.01620	0.00118	0.02160	7.36364
Step 2							
N-Europe	2.43	0.00251	0.01992	0.00243	0.00018	0.00324	1.10455
S-Europe	-						
Step 3							
D3 ditch	0.3341	0.00034	0.00274	0.00033	0.00002	0.00045	0.15186
D3 ditch	0.6037	0.00062	0.00495	0.00060	0.00004	0.00080	0.27441
D4 pond	0.1230	0.0001268	0.00101	0.000123	0.000009	0.00016	0.055909
D4 stream	0.2763	0.0002848	0.00226	0.000276	0.000020	0.00037	0.125591

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants
R1 pond	0.01048	0.0000108	0.00009	0.000010	0.000001	0.00001	0.004764
R1 pond	0.01342	0.0000138	0.00011	0.000013	0.000001	0.00002	0.006100
R1 stream	0.2007	0.0002069	0.00165	0.000201	0.000015	0.00027	0.091227
R1 stream	0.2014	0.0002076	0.00165	0.000201	0.000015	0.00027	0.091545
R3 stream	2.378	0.0024515	0.01949	0.002378	0.000174	0.00317	1.080909
R3 stream	1.405	0.0014485	0.01152	0.001405	0.000103	0.00187	0.638636
R4 stream	0.2004	0.0002066	0.00164	0.000200	0.000015	0.00027	0.091091
Step 4 – 10 meters buffer zone							
R3 stream	1.076	0.00111	0.00882	0.00108	0.00008	0.00143	0.48909
R3 stream	0.6403	0.00066	0.00525	0.00064	0.00005	0.00085	0.29105

For the intended uses (cabbage), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for Higher plants as characterised by an ErC50 for species of 22 µg/L (geomean) in several FOCUS Steps 1 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PECSW considering reduced exposure of surface water bodies.

~~**Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite CL 312622 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in all intended uses (BBCH 10-89)**~~

~~**Group**~~		~~**Higher plants**~~
~~**Test species**~~		~~***Lemna gibba***~~
~~**Endpoint**~~ ~~**(µg/L)**~~		~~NOE~~~~,~~~~C~~ ~~300~~
~~**AF**~~		~~10~~
~~**RAC (µg/L)**~~		~~30~~
~~**FOCUS Scenario**~~	~~**PEC gl max (µg/L)**~~	
~~**Step 1**~~		
~~—~~	~~8.85~~	~~0.295~~

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

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite CL 312622 for each organism group based on FOCUS Steps 1calculations for the use of CHR/H/IMA 40 SL in soya, sunflower, peas, spring oilseed rape, cotton, tobacco, field beans, maize, cabbage

Group		**Higher plants**
Test species		***Lemna gibba***
Endpoint		NOE_rC
(µg/L)		300
AF		10
RAC (µg/L)		30
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**	
Step 1		
~~----~~	8.85	0.295

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

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite CL 312622 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in pomefruit

Group		**Higher plants**
Test species		***Lemna gibba***
Endpoint		NOE_rC
(µg/L)		300
AF		10
RAC (µg/L)		30
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**	
Step 1		
~~----~~	9.43	0.31433

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

~~**Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite CL 354825 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in all intended uses (BBCH 10-89)**~~

~~**Group**~~		~~**Higher plants**~~
~~**Test species**~~		~~***Lemna gibba***~~
~~**Endpoint**~~		~~E_rC_{50}~~
~~**(µg/L)**~~		~~10500~~
~~**AF**~~		~~10~~
~~**RAC (µg/L)**~~		~~1050~~
~~**FOCUS Scenario**~~	~~**PEC $_{gl\text{-}max}$ (µg/L)**~~	

~~Group~~		~~Higher plants~~
~~Step 1~~		
~~----~~	~~5.33~~	~~0.005076~~

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

Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite CL 354825 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in soya, sunflower, peas, spring oilseed rape, cotton, tobacco, field beans, maize, cabbage

Group		**Higher plants**
Test species		***Lemna gibba***
Endpoint		E_rC_{50}
(µg/L)		10500
AF		10
RAC (µg/L)		1050
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**	
Step 1		
----	5.33	0.005076

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

Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite CL 354825 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/IMA 40 SL in pomefruit

Group		**Higher plants**
Test species		***Lemna gibba***
Endpoint		E_rC_{50}
(µg/L)		10500
AF		10
RAC (µg/L)		1050
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**	
Step 1		
----	5.55	0.00529

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

9.5.2.1. Risk assessment for formulation to aquatic organisms

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites of CHR/H/IMA 40 SL for each organism group based on Drift Calculator SWASH MODEL ver 5.3 calculations for the use of CHR/H/IMA 40 SL in legumes, cotton, maize, soybeans and sunflowers

Intended use	Legumes/Cotton/Maize/Soybeans/Sunflowers (BBCH 10-19)
Formulation	CHR/H/IMA
Application rate (g[prod]/ha)	1 X 1290
Entry into surface water via spray drift (Drift calculator from SWASH)	
Buffer zone (m)	**PECsw [µg prod/L]**
1	6.8525
~~**5**~~	~~2.2465~~
~~**10**~~	~~1.1914~~
Entry into surface water via spraydrift (Drift calculator from SWASH)	
Buffer zone (m)	**PEC/RAC ratio** **Daphnia magna: 100 000 µg/L** **RAC=1000 (AF=100)**
1	0.00685
Buffer zone (m)	**PEC/RAC ratio** **Pseudokirchmeirella subcapitata: 100 000 µg/L** **RAC=1000 (AF=100)**
1	0.00685
Buffer zone (m)	**PEC/RAC ratio** **Anabaena flos-aque =EC50 27090 µg/L** **RAC=270.9 (AF=100)**
1	0.02530
Buffer zone (m)	**PEC/RAC ratio** **Lemna Gibba =EC50 552 µg/L** **RAC=55.2 (AF=10)**
1	0.12414

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites of CHR/H/IMA 40 SL for each organism group based on Drift Calculator SWASH MODEL ver 5.3 calculations for the use of CHR/H/IMA 40 SL in oilseed rape (spring and winter)

Intended use	Spring oilseed rape/Winter oilseed rape(BBCH 10-19)
Formulation	CHR/H/IMA
Application rate (g[prod]/ha)	1 x 1290
Entry into surface water via spray drift (Drift calculator from SWASH)	
Buffer zone (m)	**PECsw [µg prod/L]**
1	8.2878

~~5~~	~~2.2465~~
~~10~~	~~1.1914~~
Entry into surface water via spraydrift (Drift calculator from SWASH)	
Buffer zone (m)	**PEC/RAC ratio** **Daphnia magna: 100 000 µg/L** **RAC=1000 (AF=100)**
1	0.00829
Buffer zone (m)	**PEC/RAC ratio** **Pseudokirchmeirella subcapitata: 100 000 µg/L** **RAC=1000 (AF=100)**
1	0.00829
Buffer zone (m)	**PEC/RAC ratio** **Anabaena flos-aque =EC50 27090 µg/L** **RAC=270.9 (AF=100)**
1	0.03059
Buffer zone (m)	**PEC/RAC ratio** **Lemna Gibba =EC50 552 µg/L** **RAC=55.2 (AF=10)**
1	0.15014

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites of CHR/H/IMA 40 SL for each organism group based on Drift Calculator SWASH MODEL ver 5.3 calculations for the use of CHR/H/IMA 40 SL in tobacco

Intended use	Tobacco (BBCH 10-19)
Formulation	CHR/H/IMA
Application rate (g[prod]/ha)	1 x 1290
Entry into surface water via spray drift (Drift calculator from SWASH)	
Buffer zone (m)	**PECsw [µg prod/L]**
1	6.1506
Entry into surface water via spraydrift (Drift calculator from SWASH)	
Buffer zone (m)	**PEC/RAC ratio** **Daphnia magna: 100 000 µg/L** **RAC=1000 (AF=100)**
1	0.00615
Buffer zone (m)	**PEC/RAC ratio** **Pseudokirchmeirella subcapitata: 100 000 µg/L** **RAC=10000 (AF=100)**
1	0.00615
Buffer zone (m)	**PEC/RAC ratio** **Anabaena flos-aque =EC50 27090 µg/L** **RAC=270.9 (AF=100)**
1	0.02270
Buffer zone (m)	**PEC/RAC ratio** **Lemna Gibba =EC50 552 µg/L** **RAC=55.2 (AF=10)**
1	0.11142

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites of CHR/H/IMA 40 SL for each organism group based on Drift Calculator SWASH MODEL ver 5.3 calculations for the use of CHR/H/IMA 40 SL in pome fruit

Intended use	Pome fruit
Formulation	CHR/H/IMA
Application rate (g[prod]/ha)	1 x 1290
Entry into surface water via spray drift (Drift calculator from SWASH)	
Buffer zone (m)	**PECsw [µg prod/L]**
1	101.4743
5	79.7340
10	48.9652
Entry into surface water via spraydrift (Drift calculator from SWASH)	

Buffer zone (m)	**PEC/RAC ratio** ***Daphnia magna*: 100 000 µg/L** **RAC=1000 (AF=100)**
1	0.10147
Buffer zone (m)	**PEC/RAC ratio** ***Pseudokirchmeirella subcapitata*: 100 000 µg/L** **RAC=1000 (AF=100)**
1	0.10147
Buffer zone (m)	**PEC/RAC ratio** ***Anabaena flos-aque* =EC50 27090 µg/L** **RAC=270.9 (AF=100)**
1	0.37458
Buffer zone (m)	**PEC/RAC ratio** ***Lemna Gibba* =EC_{50} 552 µg/L** **RAC=55.2 (AF=10)**
1	**1.83830**
5	**1.44446**
10	0.88705

9.5.3 Overall conclusions

The risk to aquatic organisms following exposure to CHR/H/IMA 40 SL spray drift is not acceptable without drift reducing measures and buffer zones. The risk for the entry routes run-off and drainage is also not acceptable without buffer zones for the intended use of CHR/H/IMA 40 SL. Based on the above PECsw values, there are following designated buffer zones listed below:

- 20 meters vegetative and no-spray buffer zone for ornamental > 50 cm and *salix vininalis* (wicker)
- 10 meters vegetative and no-spray buffer zone meters for ornamental < 50 cm (R3 stream)
- 10 meters vegetative and spray buffer zone for sunflower, surrogate crop: maize
- without applying buffer zone for other uses

Review comments:

According to aquatic guideline for *P. subcapitata* in the risk assessment growth rate: ErC_{50}= 29.1 mg a.s./L (nom) should be used over yield rate of EyC_{50}= 7.5 mg a.s./L (nom). However since yield value is almost 3 times lower it would be worst case scenario and this approach would be accepted. However for the consistency of the report also calculations for growth rate values would be provided in the appropriate tables.

For Central Zone:

- 20 meters vegetative and no-spray buffer zone for Coniferous / deciduous forest nurseries,ornamental shrubs,ornamentals,salix, wicker all at h > 50 cm ornamental > 50 cm and *salix vininalis* (wicker) (R3 stream)

- 10 meters vegetative and no-spray buffer zone meters for Coniferous / deciduous forest nurseries, ornamental shrubs, ornamentals, salix, wicker all at h < 50 cm ornamental < 50 cm (R3 stream)
- 10 meters vegetative filter strip for sunflower, surrogate crop: maize (R4 stream)
- without applying buffer zone for other uses

For PL scenarios:

- 10 meters vegetative and no-spray buffer zone for Coniferous / deciduous forest nurseries, ornamental shrubs, ornamentals,salix, wicker all at h > 50 cm ornamental > 50 cm and salix vininalis (wicker)

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 imazamox and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on bees of CHR/H/IMA 40 SL were not evaluated as part of the EU assessment of active substance 1. New data submitted with this application are listed in Appendix 1 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
Apis mellifera	imazamox	Acute oral	LD_{50} > 40 µg a.s./bee	EFSA Journal 2016;14(4):4432
Apis mellifera	imazamox	Acute contact	LD_{50} > 58 µg a.s./bee	EFSA Journal 2016;14(4):4432
Apis mellifera	imazamox	Chronic 10d	LDD_{50} > 100.9 µg/bee per day (> 2.565 g a.s./kg food)	EFSA Journal 2016;14(4):4432
Apis mellifera	imazamox	Acute toxicity to honeybee larvae 72 h	LC_{50} > 99.4 µg/larva	EFSA Journal 2016;14(4):4432
Apis mellifera	CHR/H/IMA 40 SL	Acute oral 48 h	LD50 > 200 µg product/bee	Grzesica M., 2019, study code B/88/18
Apis mellifera	CHR/H/IMA 40 SL	Acute contact 48 h	LD50 > 200 µg product/bee	Grzesica M., 2019, study code B/89/18
Higher-tier studies (tunnel test, field studies)				
Not performed, not required				

9.6.1.1 Justification for new endpoints

No new endpoints were established – it is not required.

9.6.2 Risk assessment

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group: peas, soybean, sunflower, maize, oilseed rape, cotton, linseed, tobacco and apple (BBCH 10-19) also covers the risk for bees from all other intended uses (see 9.1.2).

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of CHR/H/IMA 40 SL in peas, soybean, sunflower, maize, oilseed rape, cotton, linseed, tobacco and ~~apple (BBCH 10-19)~~

Intended use	peas, soybean, sunflower, maize, oilseed rape, cotton, linseed, tobacco~~, apple (BBCH 10-19)~~		
Active substance	imazamox		
Application rate (g/ha)	1 × 48 g/ha		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>40 µg/bee	48 g as/ha	1.2000
Contact toxicity	>58 µg/bee		0.8276
Product	CHR/H/IMA 40 SL		
Application rate (g/ha)	1 × 1290 g prod/ha		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>200 µg/bee	1290 g prod/ha	6.45
Contact toxicity	>200 µg/bee		6.45

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

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

Not relevant.

Review Comments:
Since acceptable acute risk have been concluded for bees exposed to CHR/H/IMA 40 SL at the Tier 1, a higher-tier risk assessment is not required for the proposed uses of CHR/H/IMA 40 SL.

9.6.3 Effects on bumble bees

Not relevant.

Review Comments:

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

9.6.4 Effects on solitary bees

Not relevant.

Review Comments:

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

9.6.5 Overall conclusions

All hazard quotients (HQ) are considerably less than 50, indicating that CHR/H/IMA 40 SL applied at the maximum use rate in maize poses low risk to bees.

Review Comments:

The evaluation has been performed in line with SANCO/10329/2002 rev 2 final.
The risk assessment performed for the formulated product CHR/H/IMA 40 SL is agreed by the zRMS. All hazard quotients calculated are lower than 50, indicating that the acute oral and contact risk to bees is acceptable following the use according to the proposed use pattern of CHR/H/IMA 40 SL.

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 imazamox and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on non-target arthropods of CHR/H/IMA 40 SL were not evaluated as part of the EU assessment of imazamox. 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	Formulation	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	CHR/H/IMA 40 SL	Laboratory test glass plates (2D)	LR_{50} > 1.2 L/ha	Grzesica M., 2019, study code: B/90/18
Aphidius rhopalosiphi (adults)	CHR/H/IMA 40 SL	Laboratory test glass plates (2D)	LR_{50} > 1.2 L/ha	Grzesica M., 2019, study code: B/91/18 ~~B/90/18~~
Field or semi-field tests				
Not required				

9.7.1.1 Justification for new endpoints

No new endpoints were stablished.

9.7.2 Risk assessment

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

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group: peas, soybean, sunflower, maize, oilseed rape, cotton, linseed, tobacco ~~and apple (BBCH 10-19)~~ also covers the risk for the non-target arthropods from all other intended uses (see 9.1.2).

Table 9.7-2: First- ~~and higher-tier~~ assessment of the in-field risk for non-target arthropods due to the use of CHR/H/IMA 40 SL in cotton, maize, sunflower ~~(BBCH 10-19)~~

Intended use	Cotton, legumes, maize, oilseed rape, sunflower, tobacco ~~(BBCH 10-19)~~		
Active substance/product	CHR/H/IMA 40 SL		
Application rate (L/ha)	1 × 1.2		
MAF	1.0		
Test species Tier I	**LR_{50} (lab.) (L/ha)**	**$PER_{in\text{-}field}$ (L/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>1.2	1.2	1
Aphidius rhopalosiphi	>1.2		1
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Not required			

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

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

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. ~~Here, the assessment for the use group: peas, soybean, sunflower, maize, oilseed rape, cotton, linseed, tobacco and apple (BBCH 10-19) also covers the risk for non-target arthropods from all other intended uses (see 9.1.2).~~

Risk assessment was performed with the consideration of crop type (height), application rate and number of uses.

Calculations $PER_{off\text{-}field}$ values according to ESCORT 2 as:

Application rate × MAF × (drift factor/vegetation distribution factor)

Calculations the corrected $PER_{off\text{-}field}$ values according to ESCORT 2 as:

corr. PEROff-field = PEROff-field * correction factor

The HQ can be defined as:

$$Off-field\ \ HQ = \frac{application\ \ rate \times MAF \times drift\ \ \ factor}{LR_{50}} \times \frac{correction\ \ factor}{VDF}$$

Table 9.7-3: First- ~~and higher~~-tier assessment of the off-field risk for non-target arthropods due to the use of CHR/H/IMA in pulses, oilseeds, cotton, tobacco ~~(BBCH 10-19)~~ and ornamentals <50 cm ~~(BBCH 10-89)~~

Intended use	Pulses, oilseeds, cotton, tobacco ~~(BBCH 10-19),~~ ornamentals <50 cm ~~(BBCH 10-89~~)				
Active substance/product	CHR/H/IMA				
Application rate (L/ha)	1 × 1.2				
MAF	1.0				
vdf	10 (Tier 1) / ~~1 (Higher-tier)~~				
Test species Tier I	**LR_{50} (lab.) (L/ha)**	**Drift rate**	**$PER_{off-field}$ (L/ha)**	**CF**	**$HQ_{off-field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	1.2	0.0277	3.24 ~~0.03324~~	10 ~~1~~	0.0277
Aphidius rhopalosiphi	1.2				0.0277
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off-field}$ (g/ha)**	**CF**	**corr. $PER_{off-field}$ below rate with ≤ 50 % effect?**
Not required					

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

The endpoints are from the 2D studies thus CF is considered to be 10.

Table 9.7-4a: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of CHR/H/IMA in ornamentals >50 cm ~~(BBCH 10-89)~~

Intended use	Ornamentals > 50 cm ~~(BBCH 10-89)~~				
Active substance/product	CHR/H/IMA				
Application rate (L/ha)	1 × 1.2				
MAF	1.0				
vdf	10 (Tier 1) / ~~1 (Higher-tier)~~				
Test species Tier I	**LR_{50} (lab.) (L/ha)**	**Drift rate**	**$PER_{off-field}$ (L/ha)**	**CF**	**$HQ_{off-field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	1.2	0.0802	9.62 ~~0.09624~~	10 ~~1~~	0.0802
Aphidius rhopalosiphi	1.2				0.0802
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off-field}$ (g/ha)**	**CF**	**corr. $PER_{off-field}$ below rate with ≤ 50 % effect?**
Not required					

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.
* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with

≤ 50 % effect.
The endpoints are from the 2D studies thus CF is considered to be 10.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

All hazard quotients (HQ) are considerably less than 2, indicating that CHR/H/IMA 40 SL applied at the maximum use rate in maize poses no risk to non-target arthropods. No risk mitigation needed.

Review Comments:

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the guidance document ESCORT 2.
Based on the results of the conducted risk assessments it can be concluded that low risk for non-target arthropods is expected from the use of CHR/H/IMA 40 SL according to the proposed use pattern.

On this basis acceptable risk for in-field and off-field habitats may be concluded with no need for risk mitigation measures.

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

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with imazamox and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of CHR/H/IMA 40 SL were not evaluated as part of the EU assessment of imazamox. 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
Eisenia fetida	CL 312622	Mixed with soil/ 10% OM Chronic	Growth, reproduction, behaviour NOEC = 0.963 mg/kg	EFSA Journal 2016;14(4):4432

Species	Substance	Exposure System	Results	Reference
			soil	
Eisenia fetida	CL 354825	Mixed with soil/ 5% OM Chronic	Growth, reproduction, behaviour NOEC = 3.04 mg/kg soil	EFSA Journal 2016;14(4):4432
Folsomia candida	CL 354825	Mixed with soil/ 5% OM Chronic	Mortality, reproduction NOEC = 500mg/kg soil	EFSA Journal 2016;14(4):4432
Eisenia fetida	CHR/H/IMA 40 SL	28 d, acute 56 d, chronic	LC_{50} > 1000 mg/kg dw EC_{50} > 1000 mg/kg dw EC_{10} > 1000 mg/kg dw $NOEC_{reproduction} \geq$ 1000 mg/kg dw $LOEC_{reproduction}$ > 1000 mg/kg dw $NOEC_{survival} \geq$ 1000 mg/kg dw $LOEC_{survival}$ > 1000 mg/kg dw	Gierbuszewska A, 2019, study code: G/186/18
Folsomia candida	CHR/H/IMA 40 SL	14d, acute 28d, chronic	LC_{50} > 1000 mg/kg dw LC_{10} = 422.4 mg/kg dw EC_{50} > 1000 mg/kg dw EC10 > 1000 mg/kg dw $NOEC_{reproduction} \geq$ 1000 mg/kg dw $NOEC_{survival} \geq$ 1000 mg/kg dw	Gierbuszewska A, 2019, study code: G/187/18
Hypoaspis aculeifer	CHR/H/IMA 40 SL	Mixed into substrate 14 d, chronic 5 % peat content	LC_{50} > 1000 mg/kg dw EC_{50} > 1000 mg/kg dw EC_{10} 308.2 mg product /kg dw $NOEC_{reproduction}$ = 320 mg/kg dw $NOEC_{survival} \geq$ 1000 mg/kg dw	Gierbuszewska A, 2019, study code: G/188/18
Field studies				
Not performed, not required				
Litter bag test				

Species	Substance	Exposure System	Results	Reference
Not perfoormed, not required				

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

9.8.1.1 Justification for new endpoints

No new endpoints were established – it is not required

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 imazamox.
To achieve a concise risk assessment, the risk envelope approach is applied. ~~Here, the assessment for the use group: oilseeds, pulses, cotton, tobacco and ornamentals (BBCH 10-19) also covers the risk for the non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2).~~ Here, the assessment for the sunflower (worst case scenario) which covers the risk for the non-target soil organisms (meso- and macrofauna) for all other intended uses (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 CHR/H/IMA 40 SL in soybean and peas (BBCH 10-19)**~~

~~**Intended use**~~	~~Soybean/Peas (BBCH 10-19)~~		
~~**Acute effects on earthworms *Eisenia foetida***~~			
~~**Product/active substance**~~	~~**LC_{50} (mg/kg dw)**~~	~~**PEC_{soil} (mg/kg dw)**~~	~~**TER_a (criterion TER ≥ 10)**~~
~~Not required~~			
~~**Chronic effects on earthworms *Eisenia foetida***~~			
~~**Product/active substance**~~	~~**NOEC (mg/kg dw)**~~	~~**PEC_{soil} (mg/kg dw)**~~	~~**TER_{lt} (criterion TER ≥ 5)**~~
~~CL312622~~	~~0.963~~	~~0.0094~~	~~102.447~~
~~CL354825~~	~~304~~	~~0.0074~~	~~41081.1~~
~~CHR/H/IMA 40 SL~~	~~500~~	~~1.118~~	~~447.227~~
~~**Chronic effects on other soil macro- and mesofauna *Folsomia candida***~~			

~~Product/active substance~~	~~NOEC (mg/kg dw)~~	~~PEC_{soil} (mg/kg dw)~~	~~TER_{lt} (criterion TER ≥ 5)~~
~~CL 354825~~	~~500~~	~~0.0074~~	~~67567.6~~
~~CHR/H/IMA 40 SL~~	~~500~~	~~1.118~~	~~447.227~~
~~***Hypoaspis aculeifer***~~			
~~CHR/H/IMA 40 SL~~	~~160~~	~~1.118~~	~~143.113~~

TER values shown in bold fall below the relevant trigger.

Table 9.8-3: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of CHR/H/IMA 40 SL in sunflower ~~(BBCH 10-19)~~

Intended use	Sunflower ~~(BBCH 10-19)~~		
Acute effects on earthworms ***Eisenia foetida***			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Not required			
Chronic effects on earthworms ***Eisenia foetida***			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CL312622	0.4815 ~~0.963~~	0.0116	41.51 ~~83.0172~~
CL 354825	1.52 ~~304~~	0.0097	157.70 ~~31340.2~~
CHR/H/IMA 40 SL	250 ~~500~~	1.376	181.68 ~~363.372~~
Chronic effects on other soil macro- and mesofauna ***Folsomia candida***			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CL 354825	500	0.0097	51546.4
~~CHR/H/IMA 40 SL~~	~~500~~	~~1.376~~	~~363.372~~
CHR/H/IMA 40 SL	201.2	1.376	146.22
Hypoaspis aculeifer			
~~CHR/H/IMA 40 SL~~	~~160~~	~~1.376~~	~~116.279~~
CHR/H/IMA 40 SL	EC_{10}=154.1	1.376	111.99

TER values shown in bold fall below the relevant trigger.

~~**Table 9.8-4: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of CHR/H/IMA 40 SL in oilseed rape (BBCH 10-19)**~~

~~**Intended use**~~	~~Oilseed rape (BBCH 10-19)~~
~~**Acute effects on earthworms** ***Eisenia foetida***~~	

Product/active substance	LC_{50} (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_a (criterion TER ≥ 10)
Not required			
Chronic effects on earthworms ***Eisenia foetida***			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CL312622	0.963	0.0087	110.6897
CL 354825	304	0.0068	44705.88
CHR/H/IMA 40 SL	500	1.032	484.4961
Chronic effects on other soil macro- and mesofauna ***Folsomia candida***			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CL 354825	500	0.0068	73529.41
CHR/H/IMA 40 SL	500	1.032	484.4961
Hypoaspis aculeifer			
CHR/H/IMA 40 SL	160	1.032	155.0388

TER values shown in bold fall below the relevant trigger.

Table 9.8-5: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of CHR/H/IMA 40 SL in beans, cabbage, maize (BBCH 10-19)

Intended use	Beans/Cabbage/Maize (BBCH 10-19)		
Acute effects on earthworms ***Eisenia foetida***			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Not required			
Chronic effects on earthworms ***Eisenia foetida***			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CL312622	0.963	0.0108	89.167
CL 354825	304	0.0085	35764.7
CHR/H/IMA 40 SL	500	1.290	387.597
Chronic effects on other soil macro- and mesofauna ***Folsomia candida***			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CL 354825	500	0.0085	58823.6
CHR/H/IMA 40 SL	500	1.290	387.597

Hypoaspis aculeifer			
CHR/H/IMA 40 SL	160	1.290	124.031

TER values shown in bold fall below the relevant trigger.

Table 9.8-6: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of CHR/H/IMA 40 SL in cotton, linseed (BBCH 10-19)

Intended use	Cotton/Linseed (BBCH 10-19)		
Acute effects on earthworms ***Eisenia foetida***			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Not required			
Chronic effects on earthworms ***Eisenia foetida***			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CL312622	0.963	0.00101	95.3465
CL 354825	304	0.0074	41081.08
CHR/H/IMA 40 SL	500	1.204	415.2824
Chronic effects on other soil macro- and mesofauna ***Folsomia candida***			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CL 354825	500	0.0074	67567.57
CHR/H/IMA 40 SL	500	1.204	415.2824
Hypoaspis aculeifer			
CHR/H/IMA 40 SL	160	1.204	132.8904

TER values shown in bold fall below the relevant trigger.

Table 9.8-7: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of CHR/H/IMA 40 SL in tobacco (BBCH 10-19)

Intended use	Tobacco (BBCH 10-19)		
Acute effects on earthworms ***Eisenia foetida***			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Not required			

Chronic effects on earthworms *Eisenia foetida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CL312622	0.963	0.0072	133.75
CL 354825	304	0.0057	53333.33
CHR/H/IMA 40 SL	500	0.860	581.3953
Chronic effects on other soil macro- and mesofauna *Folsomia candida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CL 354825	500	0.0057	87719.3
CHR/H/IMA 40 SL	500	0.860	581.3953
Hypoaspis aculeifer			
CHR/H/IMA 40 SL	160	0.860	186.0465

TER values shown in bold fall below the relevant trigger.

Table 9.8-8: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of CHR/H/IMA 40 SL in apple (BBCH 10-19)

Intended use	Apple (BBCH 10-19)		
Acute effects on earthworms *Eisenia foetida*			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Not required			
Chronic effects on earthworms *Eisenia foetida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CL312622	0.963	0.0058	166.0345
CL 354825	304	0.0046	66086.96
CHR/H/IMA 40 SL	500	0.688	726.7442
Chronic effects on other soil macro- and mesofauna *Folsomia candida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CL 354825	500	0.0046	108695.7
CHR/H/IMA 40 SL	500	0.688	726.7442

~~*Hypoaspis aculeifer*~~			
~~CHR/H/IMA 40 SL~~	~~160~~	~~0.688~~	~~232.5581~~

TER values shown in bold fall below the relevant trigger.

Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

TER values for earthworms and other macro- and mesofauna does not exceed trigger values (10 for earthworms (acute toxicity) and 5 for other results). Therefore, results are acceptable.

Review comments:

The risk assessment for earthworms and other soil macro-organisms exposed to cyprodinil and its relevant metabolites following application of CHR/H/IMA 40 SL performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology" (SANCO/10329/2002) was generally accepted by the zRMS.

The risk assessment for earthworms and other soil macro-organisms exposed to imazamox and its relevant metabolites following application of CHR/H/IMA 40 SL was based on the risk envelope approach. In this case sunflower represent worst-case scenario and therefore covers all propose applications of the CHR/H/IMA 40 SL
The relevant PECsoil for risk assessments is taken from Section 8 (Environmental Fate), for details please, refer to Section 8.

TERlt values calculated for all considered compounds and CHR/H/IMA 40 SL were above the respective trigger indicating acceptable long-term risk to earthworms and other soil macro-organisms. No further evaluation is deemed necessary.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with imazamox and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on soil microorganisms of CHR/H/IMA were not evaluated as part of the EU assessment of imazamox. 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	imazamox	14 d, aerobic soil type	Nitrate formation rate 0.2 mg/kg soil dw ≤25 %	EFSA Journal 2016;14(4):4432
N-mineralisation	CL 312622	91 d, aerobic soil type	Nitrate formation rate 0.5 mg/kg soil dw ≤25 %	EFSA Journal 2016;14(4):4432
N-mineralisation	CL 354825	28 d, aerobic soil type	Nitrate formation rate 0.5 mg/kg soil dw ≤25 %	EFSA Journal 2016;14(4):4432
N-mineralisation	CHR/H/IMA 40 SL	42 d, aerobic soil type	Nitrate formation rate: Corresponding to PEC: 2.68 mg/kg soil dw ≤ 25 %; Corresponding to 5xPEC: 13.40 mg/kg soil dw ≤ 25 %;	Wołany M., 2019, study code: G/189/18
C-mineralisation	Not available, no data requested			

9.9.1.1 Justification for new endpoints

No new endpoints were established.

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: oilseeds, pulses, cotton, tobacco and ornamentals (BBCH 10-19) also covers the risk for the soil microorganisms from all other intended uses (see 9.1.2).~~ Here, the assessment for the sunflower (worst case scenario) which covers the risk for the non-target soil organisms (meso- and macrofauna) for all other intended uses (see 9.1.2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of CHR/H/IMA 40 SL in sunflower (worst case scenario) ~~oilseeds, pulses, cotton, tobacco and ornamentals~~ ~~(BBCH 10-19)~~

N-mineralisation	
~~**Intended use**~~	~~**Peas/Soybean (BBCH 10-19)**~~

~~**Product/active substance**~~	~~**Max. conc. with effects ≤ 25 % (mg/kg dw)**~~	~~**PEC_{soil} (mg/kg dw)**~~	~~**Risk acceptable?**~~
~~imazamox~~	~~0.2 (at 14 d)~~	~~0.0416~~	~~yes~~
~~CL 312622~~	~~0.5 (at 91 d)~~	~~0.0094~~	~~yes~~
~~CL 354825~~	~~0.5 (at 28 d)~~	~~0.0074~~	~~yes~~
~~CHR/H/IMA~~	~~2.68 (at 42d)~~	~~1.118~~	~~yes~~
Intended use	**Sunflower ~~(BBCH 10-19)~~**		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
imazamox	0.2 (at 14 d)	0.0512	yes
CL 312622	0.5 (at 91 d)	0.0116	yes
CL 354825	0.5 (at 28 d)	0.0097	yes
CHR/H/IMA	2.68 (at 42d)	1.376	yes
~~**Intended use**~~	~~**Beans/Cabbage/Maize (BBCH 10-19)**~~		
~~**Product/active substance**~~	~~**Max. conc. with effects ≤ 25 % (mg/kg dw)**~~	~~**PEC_{soil} (mg/kg dw)**~~	~~**Risk acceptable?**~~
~~imazamox~~	~~0.2 (at 14 d)~~	~~0.0480~~	~~yes~~
~~CL 312622~~	~~0.5 (at 91 d)~~	~~0.0108~~	~~yes~~
~~CL 354825~~	~~0.5 (at 28 d)~~	~~0.0085~~	~~yes~~
~~CHR/H/IMA~~	~~2.68 (at 42d)~~	~~1.290~~	~~yes~~
~~**Intended use**~~	~~**Oilseed rape (BBCH 10-19)**~~		
~~**Product/active substance**~~	~~**Max. conc. with effects ≤ 25 % (mg/kg dw)**~~	~~**PEC_{soil} (mg/kg dw)**~~	~~**Risk acceptable?**~~
~~imazamox~~	~~0.2 (at 14 d)~~	~~0.0384~~	~~yes~~
~~CL 312622~~	~~0.5 (at 91 d)~~	~~0.0087~~	~~yes~~
~~CL 354825~~	~~0.5 (at 28 d)~~	~~0.0051~~	~~yes~~
~~CHR/H/IMA~~	~~2.68 (at 42d)~~	~~1.032~~	~~yes~~
~~**Intended use**~~	~~**Cotton/Linseed (BBCH 10-19)**~~		
~~**Product/active substance**~~	~~**Max. conc. with effects ≤ 25 % (mg/kg dw)**~~	~~**PEC_{soil} (mg/kg dw)**~~	~~**Risk acceptable?**~~
~~imazamox~~	~~0.2 (at 14 d)~~	~~00.448~~	~~yes~~
~~CL 312622~~	~~0.5 (at 91 d)~~	~~0.0101~~	~~yes~~
~~CL 354825~~	~~0.5 (at 28 d)~~	~~0.0074~~	~~yes~~
~~CHR/H/IMA~~	~~2.68 (at 42d)~~	~~1.204~~	~~yes~~
~~**Intended use**~~	~~**Tobacco (BBCH 10-19)**~~		
~~**Product/active substance**~~	~~**Max. conc. with effects ≤ 25 % (mg/kg dw)**~~	~~**PEC_{soil} (mg/kg dw)**~~	~~**Risk acceptable?**~~
~~imazamox~~	~~0.2 (at 14 d)~~	~~0.0320~~	~~yes~~
~~CL 312622~~	~~0.5 (at 91 d)~~	~~0.0074~~	~~yes~~
~~CL 354825~~	~~0.5 (at 28 d)~~	~~0.0057~~	~~yes~~
~~CHR/H/IMA~~	~~2.68 (at 42d)~~	~~1.204~~	~~yes~~

Intended use	Apple (BBCH 10-19)		
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC_{soil} (mg/kg dw)	Risk acceptable?
imazamox	0.2 (at 14 d)	0.0256	yes
CL 312622	0.5 (at 91 d)	0.0058	yes
CL 354825	0.5 (at 28 d)	0.0046	yes
CHR/H/IMA	2.68 (at 42d)	1.204	yes

Overall conclusions

Risk assessment for effects on soil micro-organisms due to use of CHR/H/IMA in all assessed crops is acceptable. Max. concentration with effects ≤25% for each case is higher than PEC_{soil}.

Review comments:

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) and was accepted by the zRMS.

The risk assessment for soil microorganisms exposed to imazamox and its relevant metabolites following application of CHR/H/IMA 40 SL was based on the risk envelope approach. The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), for details please, refer to Section 8.

Based on the obtained results, soil nitrate formation rates were below the 25% trigger value. Thus, it is concluded that CHR/H/IMA 40 SL had no significant impact on soil microorganisms when applied at test item concentrations up to 13.40 mg formulation./kg of dry weight soil did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

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

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with imazamox and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on non-target terrestrial plants of CHR/H/IMA were not evaluated as part of the EU assessment of imazamox. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

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

Species	Substance	Exposure System	Results (for plant dry weight) [g prod/ha]	Reference
1)Linum usitatissimum *2)Trifolium pratense* *3)Pisum sativum* *4)Daucus carota* *5)Lolium perenne* *6)Avena sativa*	CHR/H/IMA 40 SL	14 d Seedling emergence	1)ER_{50} > 1256.5 2)ER_{50} = 1222.5 3)ER_{50} > 1256.5 4)ER_{50} = 986.8 5)ER_{50} = **62.3** 6)ER_{50} = 545.6	Wołany M., 2019, study code: G/191/18
1)Linum usitatissimum *2)Trifolium pratense* *3)Pisum sativum* *4)Daucus carota* *5)Lolium perenne* *6)Avena sativa*	CHR/H/IMA 40 SL	21 d Vegetative vigour	1)ER_{50} > 1256.5 2)ER_{50} > 1256.5 3)ER_{50} > 1256.5 4)ER_{50} = 195.1 5)ER_{50} = 388.8 **6)ER_{50} = 126.3**	Wołany M., 2019, study code: G/190/18

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

No new endpoints were established – it is not required.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

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

~~To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group peas, soybean, sunflower, maize, oilseed rape, cotton, linseed, tobacco and apple (BBCH 10-19) also covers the risk for non-target terrestrial plants from all other intended uses (see 9.1.2).~~

Limit tests at rates up to 1290 g prod/ha were conducted with formulation and effects were below the critical threshold as defined by the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). The limit test rates equal/exceed the highest field application rate in use groups oilseeds, pulses, cotton, tobacco and ornamentals (BBCH 10-19) and are thus considered an indicator for an acceptable risk.

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

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

~~To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use groups: oilseeds, pulses, cotton, tobacco and ornamentals (BBCH 10-19) also covers the risk for non-~~

~~target terrestrial plants from all other intended uses in these groups (see 9.1.2).~~

Table 9.10-2: Assessment of the risk for non-target plants due to the use of CHR/H/IMA 40 SL in oilseeds, pulses, cotton, tobacco ~~(BBCH 10-19)~~ and ornamentals < 50 cm ~~(BBCH 10-89)~~

Intended use	Oilseeds/Pulses/Cotton/Tobacco ~~(BBCH 10-19),~~ Ornamentals <50 cm ~~(BBCH 10-89)~~			
Active substance/product	CHR/H/IMA 40 SL			
Application rate (g/ha)	1 × 1290			
MAF	1.0			
Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Seedling emergence test, 14 d				
Linum usitatissimum	>1256.5	0.0277	35.733	35.164
Trifolium pratense	1222.5	0.0277	35.733	34.212
Pisum sativum	>1256.5	0.0277	35.733	35.164
Daucus carota	986.8	0.0277	35.733	27.616
Lolium perenne	62.3	0.0277	35.733	**1.7435**
Avena sativa	545.6	0.0277	35.733	15.269
Vegetative vigour test, 21 d				
Linum usitatissimum	1256.5	0.0277	35.733	35.164
Trifolium pratense	1256.5	0.0277	35.733	35.164
Pisum sativum	1256.5	0.0277	35.733	35.164
Daucus carota	195.1	0.0277	35.733	5.4599
Lolium perenne	388.8	0.0277	35.733	10.881
Avena sativa	126.3	0.0277	35.733	**3.5345**

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

Table 9.10-3a: Assessment of the risk for non-target plants due to the use of CHR/H/IMA 40 SL in ornamentals > 50 cm ~~(BBCH 10-89)~~

Intended use	Ornamentals >50 cm ~~(BBCH 10-89)~~			
Active substance/product	CHR/H/IMA 40 SL			
Application rate (g/ha)	1 × 1290			
MAF	1.0			
Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Seedling emergence test, 14 d				
Linum usitatissimum	>1256.5	0.0802	103.458	12.14502503
Trifolium pratense	1222.5	0.0802	103.458	11.81638926
Pisum sativum	>1256.5	0.0802	103.458	12.14502503
Daucus carota	986.8	0.0802	103.458	9.538170079
Lolium perenne	62.3	0.0802	103.458	0.602176729

Avena sativa	545.6	0.0802	103.458	5.273637611
Vegetative vigour test, 21 d				
Linum usitatissimum	1256.5	0.0802	103.458	12.14502503
Trifolium pratense	1256.5	0.0802	103.458	12.14502503
Pisum sativum	1256.5	0.0802	103.458	12.14502503
Daucus carota	195.1	0.0802	103.458	**1.885789402**
Lolium perenne	388.8	0.0802	103.458	**3.758046744**
Avena sativa	126.3	0.0802	103.458	**1.220785246**

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

9.10.2.3 Higher-tier risk assessment

Not 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 tables.

Table 9.10-4: Risk assessment for non-target terrestrial plants due to the use of CHR/H/IMA 40 SL in oilseeds, pulses, cotton, tobacco ~~(BBCH 10–19)~~ and ornamentals < 50 cm ~~(BBCH 10–89)~~ considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Oilseeds/Pulses/Cotton/Tobacco ~~(BBCH 10–19),~~ Ornamentals <50 cm ~~(BBCH 10–89)~~			
Active substance/product		CHR/H/IMA 40 SL			
Application rate (g/ha)		1 × 1290			
MAF		1.0			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
1	2.77	35.733	17.866	8.933	3.573
5	0.57	7.353	3.676	1.838	0.735
10	0.29	3.741	1.870	0.935	0.374
Toxicity value ER_{50} = 62.3 g/ha (*Lolium perenne*)		**TER** **criterion: TER ≥ 5**			
1		**1.7435**	**3.487**	6.974	17.435
5		8.473	16.945	33.891	84.73

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

Table 9.10-5a: Risk assessment for non-target terrestrial plants due to the use of CHR/H/IMA 40 SL in ornamentals >50 cm ~~(BBCH 10-89)~~ considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Ornamentals >50 cm ~~(BBCH 10-89)~~			
Active substance/product		CHR/H/IMA 40 SL			
Application rate (g/ha)		1 × 1290			
MAF		1.0			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
3	8.02	103.458	51.729	25.8645	10.3458
5	3.62	46.698	23.349	11.6745	4.6698
10	1.23	15.867	7.9335	3.96675	1.5867
15	0.65	8.385	4.1925	2.09625	0.8385
Toxicity value ER_{50} = 62.3 g/ha (*Lolium perenne*)		**TER** **criterion: TER ≥ 5**			
3		**0.602177**	**1.204353**	**2.408707**	6.021767
5		**1.334104**	**2.668208**	5.336417	13.34104
10		**3.926388**	7.852776	15.70555	39.26388
15		7.429934	14.85987	29.71974	74.29934

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

9.10.3 Overall conclusions

Based on the predicted rates of CHR/H/IMA 40 SL in off-field areas, the TER values describing the risk for non-target plants following exposure to CHR/H/IMA 40 SL according to the GAP of the formulation CHR/H/IMA 40 SL achieve the acceptability criteria TER ≥ 5, with applying:

For ornamentals <50 cm and other plants listed in GAP:

- 5 m without use of drift reducing nozzles
- 1 m and the use of 75% drift reducing nozzles

For ornamentals >50 cm:

- 15 m without use of drift reducing nozzles
- 10 m and the use of 50% drift reducing nozzles
- 5 m and the use of 75% drift reducing nozzles
- 3 m and the use of 90% drift reducing nozzles

Review comments:
Risk assessment performed by the Applicant for non-target terrestrial plants was accepted.
Based on the predicted rates of CHR/H/IMA 40 SL in off-field areas, the TER values describing the risk for non-target plants following exposure to formulation according to the GAP achieve the acceptability criteria TER ≥ 5. Following risk mitigation measures should be applied:

When using in oilseeds, pulses, cotton, tobacco, c**oniferous / deciduous forest nurseries, ornamental**

shrubs, ornamentals, salix, wicker all at h < 50 cm and ornamentals <50 cm ~~and other plants listed in GAP:~~
-5 m without use of drift reducing nozzles or
-1 m and the use of 75% drift reducing nozzles

When using in coniferous / deciduous forest nurseries, ornamental shrubs, ornamentals, salix, wicker all at h > 50 cm and **ornamentals >50 cm**
-15 m ~~without use of drift reducing nozzles~~ or,
-10 m and the use of 50% drift reducing nozzles or,
-5 m and the use of 75% drift reducing nozzles or,
-3 m and the use of 90% drift reducing nozzles

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

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

Not relevant

9.12 Monitoring data (KCP 10.8)

Please refer to the point 9.5 (KCP 10.2)

9.13 Classification and Labelling

Classification and Labelling is described in Part B, Section 6.

Since the Applicant did not present classification of the product. zRMS propose the classification according to current regulations:

Classification according tu CLP Regulation:

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

	comply with the instructions for use.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/01	K. Brzozowska-Wojoczek	2019	Imazamox 040 SL (CHR/H/IMA 40SL) Daphnia magna, Acute immobilization test W/20/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.2/02	K. Brzozowska-Wojoczek	2019	Imazamox 040 SL (CHR/H/IMA 40SL) Raphidocelis subcapitata SAG 61.81 (formerly Pseudokirchneriella subcapitata) Growth inhibition test W/17/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.2/03	E. Nierzędska	2019	Imazamox 040 SL (CHR/H/IMA 40SL) Anabaena flos-aquae UTEX B 1444 Growth inhibition test W/18/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.2/04	K. Brzozowska-Wojoczek	2019	Imazamox 040 SL (CHR/H/IMA 40SL) Lemna gibba CPCC 310, Growth inhibition test W/19/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 10.3/1	M. Grzesica	2019	Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] Honeybees (Apis mellifera L.), Acute Oral Toxicity Test B/88/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.3/2	M. Grzesica	2019	Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] Honeybees (Apis mellifera L.), Acute Contact Toxicity Test B/89/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.3/3	M. Grzesica	2019	A laboratory test for evaluating the effects of Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] on the predatory mite, Typhlodromus pyri (Sch.) B/90/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.3/4	M. Grzesica	2019	A laboratory test for evaluating the effects of Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL]on the parasitic wasp, Aphidius rhopalosiphi (De Stefani-Perez) B/91/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP	A. Gierbuszewska	2019	CHR/H/IMA 40 SL Earthworm Reproduction Test (Eisenia andrei)	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
10.4/1			G/186/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished		
KCP 10.4/2	A. Gierbuszewska	2019	CHR/H/IMA 40 SL Collembolan (Folsomia candida) Reproduction Test G/187/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.4/3	A. Gierbuszewska	2019	CHR/H/IMA 40 SL Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil G/188/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.5/1	M. Wołany	2019	CHR/H/IMA 40 SL Soil Microorganisms: Nitrogen Transformation Test G/189/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP 10.6/1	M. Wołany	2019	CHR/H/IMA 40 SL Terrestrial Plant Test: Vegetative Vigour Test G/190/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol
KCP	M. Wołany	2019	CHR/H/IMA 40 SL Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
10.6/2			G/191/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished		

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
KCA 10.1/1		1994a	14-D Acute Toxicity Test with AC 299263 Technical in Northern Bobwhite (Colinus virginianus). ECO 93-101 GLP Unpublished	Y	BASF
KCA 10.1/2		1994b	14-day acute toxicity test with AC 299, 263 technical in mallard duck (Anas platyrhynchos) ID-505-004 <none> Unpublished	Y	BASF
KCA 10.1/3		1994c	8-day acute dietary test with AC 299, 263 technical in northern bobwhite (Colinus virginianus) American ID-505-001 Yes Unpublished	Y	BASF
KCA 10.1/4		1994	8-day acute dietary test with AC 299, 263 technical in mallard duck (Anas ID-505-002	Y	BASF

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
			<none> unpublished		
KCA 10.1/5		1995	Pilot dietary toxicity study with AC 299, 263 technical in northern bobwhite (Colinus virginianus) ID-505-005 <none> Unpublished	Y	BASF
KCA 10.1/6		1995	Pilot dietary toxicity study with AC 299, 263 technical in mallard duck (Anas platyrhynchos) ID-505-006 <none> Unpublished	Y	BASF
KCPA 10.1/7		1995	Reproduction study with AC 299, 263 technical in the northern bobwhite (Colinus virginianus) ID-505-007 <none> unpublished	Y	BASF
KCA 10.1/8		1995	Reproduction study with AC 299, 263 technical in the mallard ducks (Anas platyrhynchos) ID-505-008 <none> Unpublished	Y	BASF
KCA 10.1/9		1994	Acute toxicity of AC 299,263 to the rainbow trout (Oncorhynchus mykiss) under flow-through test conditions ID-511-002 Yes Unpublished	Y	BASF
KCA 10.1/10		1994	Acute toxicity of AC 299, 263 to the bluegill sunfish (Lepomis macrochirus) under flow-through test conditions ID-511-001 Yes Unpublished	Y	BASF
KCA		1994	Acute toxicity of AC 299263 (Imazamox) technical to the sheepshead minnow (Cyprinodon variegatus)	Y	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
10.1/11			under flow-through test conditions (in the first place amendment # 1 included) ID-511-004 yes Unpublished		
KCA 10.2/1		1995	Toxicity of AC 299,263 to the rainbow trout (Oncorhynchus mykiss) after 28 days exposure under flow-through test conditions ID-512-001 <none> Unpublished	Y	BASF
KCA 10.2/2		1996	Toxicity of AC 299, 263 technical during the early life-stages of rainbow trout (Oncorhynchus mykiss) - Amendment included, in the first place ID-519-003 <none> Unpublished	Y	BASF
KCA 10.2/3		2013	BAS 720 H: Early life-stage toxicity test with the Sheepshead minnow, Cyprinodon variegatus, under flow-through conditions 2013/7001357 yes Unpublished	Y	BASF
KCA 10.2/4		1995	CL 299, 263: Uptake, depuration, bioconcentration and metabolism of [14C]-CL 299, 263 in bluegill sunfish (Lepomis macrochirus) under flow-through conditions ID-519-001 <none> Unpublished	Y	BASF
KCA 10.2/5	Yurk J.J., Wisk J.D.	1994	Acute toxicity of AC 299,263 to Daphnia magna under flow-through test conditions American Cyanamid Co.; Princeton NJ; United States of America ID-521-001 Yes Unpublished	N	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 10.2/6	Dorner S.	2012	Acute toxicity of Reg.No. 4096483 to Daphnia magna STRAUS in a 48 hour static test 2012/1182323 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	N	BASF
KCA 10.2/7	Olivieri C.E. et al.	1998	Acute toxicity of AC 299, 263 (Imazamox) technical to the mysid (Mysidopsis bahia) under flow-through test conditions (Amendment included, in the first place) ID-521-009 American Cyanamid Co., Princeton NJ, United States of America yes Unpublished	N	BASF
KCA 10.2/8	Yurk J.J., Wisk J.D.	1995	Chronic toxicity of AC 299,263 during the complete life-cycle of Daphnia magna under flow-through conditions American Cyanamid Co.; Princeton NJ; United States of America ID-523-001 <none> Unpublished	N	BASF
KCA 10.2/9	Canez V.M. Jr. et al.	1995	Effect of AC 299, 263 on the growth of Selenastrum capricornutum American Cyanamid Co.; Princeton NJ; United Statesof America ID-521-003 <none> unpublished	N	BASF
KCA 10.2/10	Hoffmann F.	2012	Effect of BAS 720 H (Imazamox, Reg.No. 4096483) on the growth of the green alga Pseudokirchneriella subcapitata 2012/1185673 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	N	BASF
KCA 10.2/11	Canez V.M. Jr. et al.	1995	Effect of AC 299, 263 on the growth of Anabaena flos-aquae American Cyanamid Co.; Princeton NJ; United States of America	N	BASF

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
			ID-521-004 <none> Unpublished		
KCA 10.2/12	Canez V.M. Jr. et al.	1995	Effect of AC 299, 263 on the growth of Skeletonema costatum American Cyanamid Co.; Princeton NJ; United States of America ID-521-006 <none> Unpublished	N	BASF
KCA 10.2/13	Canez V.M. Jr. et al.	1995	Effect of AC 299, 263 on the growth of Navicula pelliculosa American Cyanamid Co.; Princeton NJ; United States of America ID-521-002 <none> Unpublished	N	BASF
KCA 10.2/14	Canez V.M. Jr. et al.	1995	Effect of AC 299, 263 on the growth of Lemna gibba (Duckweed) American Cyanamid Co.; Princeton NJ; United States of America ID-521-005 <none> Unpublished	N	BASF
KCA 10.2/15	Backfisch K.	2013	Effect of BAS 720 H (Imazamox) on the growth of the aquatic plant Myriophyllum aquaticum 2013/1165858 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	N	BASF
KCA 10.2/16	Dorner S.	2013	Effect of Reg.No. 4096483 on the growth of Lemna gibba 2013/1090997 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	N	BASF
KCA	Dorner S.	2013	Effect of Reg.No. 4096483 (BAS 720 H, Imazamox) on the growth of Lemna gibba in presence of	N	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
10.2/17			sediment 2013/1246583 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished		
KCA 10.2/18	Backfisch K.	2013	Effect of BAS 720 H (Imazamox) on the growth of the aquatic plant Spirodela polyrhiza 2013/1246580 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	N	BASF
KCA 10.2/19	Backfisch K.	2013	Effect of BAS 720 H (Imazamox) on the growth of the aquatic plant Ceratophyllum demersum 2013/1246581 BASF SE, Limburgerhof, Germany Fed.Rep. Yes	N	BASF
KCA 10.2/20	Backfisch K.	2013	Effect of BAS 720 H (Imazamox) on the growth of the aquatic plant Glyceria maxima 2013/1246582 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	N	BASF
KCA 10.2/21	Baetscher R.	2007	CL 312622 (metabolite of BAS 720 H): Toxicity to the aquatic higher plant Lemna Gibba in a 7-day static growth inhibition test 2006/1030257 RCC Ltd., Itingen, Switzerland yes Unpublished	N	BASF
KCA 10.2/22	Rzodeczko H.	2011	Reg.No. 4110603 (metabolite of BAS 720 H, Imazamox, CL 354825) - Lemna gibba L. CPCC 310 - Growth inhibition test 2011/1150030 Institute of Industrial Organic Chemistry, Pszczyna, Poland Yes	N	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 10.2/23	Parrish J.R. et al.	1994	An acute contact toxicity study with AC 299, 263 in the honey bee (Apis mellifera L.) Bio/West Inc.; Logan UT; United States of America ID-541-001 <none> Unpublished	N	BASF
KCA 10.3/1	Weyman G.S.	1997	An acute contact and oral toxicity study with AC 299, 263 on the honey bee (Apis mellifera) Covance Laboratories; Harrogate North Yorkshire HG3 1PY; United Kingdom ID-541-003 <none> Unpublished	N	BASF
KCA 10.3/2	Kleebaum K.	2013	Acute toxicity of BAS 720 H (Reg.No. 4096483) to honeybee larvae (Apis mellifera L.) under laboratory conditions (in vitro) 2013/1355066 BioChem agrar Labor fuerbiologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	N	BASF
KCA 10.3/3	Ruhland S.	2014	Chronic toxicity of BAS 720 H to the honeybee Apis mellifera L. under laboratory conditions 2014/1083459 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	N	BASF
KCA 10.4/1	England D.C. et al.	1995	14-day acute toxicity study with AC 299, 263 in the earthworm (Eisenia foetida) American Cyanamid Co.; Princeton NJ; United States of America ID-531-001 Yes unpublished	N	BASF
KCA 10.4/2	Gossmann A.	1997	CL 312, 622: The effects of sublethal concentrations on earthworm (Eisenia fetida Savigny 1826) growth and reproduction Institut fuer Biologische Analytik und Consulting IBACON GmbH; Rossdorf; Germany Fed.Rep. ID-570-006 <none> Unpublished	N	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 10.4/3	Gossmann A.	1997	CL 354, 825 The effects of sublethal concentrations on earthworm (Eisenia fetida Savigny 1826) growth and reproduction Institut fuer Biologische Analytik und Consulting IBACON GmbH; Rossdorf; Germany Fed.Rep. ID-570-005 <none> Unpublished	N	BASF
KCA 10.4/4	Friedrich S.	2010	Sublethal toxicity of Reg.No. 4110603 (metabolite of BAS 720 H, CL 354825) to the earthworm Eisenia fetida in artificial soil with 5% peat 2010/1110722 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	N	BASF
KCA 10.4/5	Friedrich S.	2013	Effects of Reg.No. 4110603 (metabolite of BAS 720 H, Imazamox) on the reproduction of the collembolan Folsomia candida 2013/1177567 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, GermanyFed.Rep. yes Unpublished	N	BASF
KCA 10.5/1	Wuethrich V., Seyfried B.	1996	The effects of AC 299, 263 on the respiration and nitrification of soil microflora RCC Umweltchemie AG; Itingen; Switzerland ID-625-001 Yes Unpublished	N	BASF
KCA 10.5/2	Seyfried B.	1997	The effects of CL 312, 622 on the respiration and nitrification of soil microflora RCC Umweltchemie AG; Itingen; Switzerland ID-570-008 Yes Unpublished	N	BASF
KCA 10.5/3	Seyfried B.	1997	The effects of CL 354, 825 on the respiration and nitrification of soil microflora RCC Umweltchemie AG; Itingen; Switzerland	N	BASF

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
			ID-570-007 Yes Unpublished		

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

Appendix 2 Detailed evaluation of the new studies

Review Comment:

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

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

No new studies performed, not required.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

No new studies performed, not required.
Summarised in Section 6 (Mammalian Toxicology)

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

No new studies performed, not required.

A 2.2 KCP 10.2 Effects on aquatic organisms

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

A 2.2.1.1 Study 1

Comments of zRMS:	The study was conducted according to OECD guideline 202 and principles of GLP. No deviations were noted during the study. The analytical measurements demonstrated that the test item concentrations of imazamox was within 80-120% of nominal and for this reason endpoints are expressed as nominal concentrations. In the definitive test all the validity criteria were met. as follows: - the percentage of immobilisation of *Daphnia magna* in the control was 0% (criterion: not more than 10%), - the dissolved oxygen concentrations in the test vessels were within the range of 9.2 – 8.2 mg/L (criterion: not less than 3 mg/L).

	The study is reliable and suitable for the risk assessment. EC_{50}/48 h values is > 100 mg product /L

Reference: 10.2.1

Report: Brzozowska-Wojoczek K., *Daphnia magna*, Acute immobilisation test, 2019; Łukasiewicz Research Network; study code: W/20/19; GLP, unpublished

Guideline(s): according to the OECD Guideline No. 202 (2004)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Introduction

Immobilisation of Daphnia magna exposed to the test item, Imazamox 040 SL (CHR/H/IMA 40SL), was investigated during a 48-hour static test.

Materials and methods

Test item: Imazamox 040 SL (CHR/H/IMA 40SL); batch no.: 2018.08.21; content of imazamox: 3.820±0.007 [%]; production date: 08/2018, expiry date: 08/2020.

Test organism: Daphnia magna Straus (< 24 h old at exposure initiation); not first brood progeny; neonates collected from a laboratory culture cultivated at the Łukasiewicz Research Network, Institute of Industrial Organic Chemistry, Branch Pszczyna.

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

Nominal test item concentration: 100 mg/L plus the control (limit test).

Test conditions: Temperature: 20.1 – 20.3°C; pH of the control: 7.57 – 7.76; dissolved oxygen concentration in the control: 9.0 – 9.2 mg/L; daily cycle 16 h light : 8 h dark; fluorescent light source; no feeding; no aeration; medium: Elendt M7.

Chemical determinations: The concentrations of imazamox were chemically determined with a validated liquid chromatographic method with DAD detection

Endpoint values: EC_{50}/48 h

Analytical measurements

Samples of the test item concentration and the control collected at exposure initiation and at exposure termination were chemically determined. At exposure initiation the determined concentration of imazamox was 95.3%. The results confirm that the test item concentration was prepared correctly. At exposure termination the determined concentration of imazamox was 97.6% of the nominal concentration. Therefore, imazamox concentration was stable under test conditions.

Table 7. Concentration and stability of imazamox, definitive test

Nominal test item concentration [mg/L]	Nominal concentration of imazamox [mg/L]	Average determined concentration of imazamox in samples collected [mg/L]			
		at exposure initiation	% of nominal concentration	at exposure termination	% of nominal concentration
Control	---	<LoD	---	<LoD	---
100	3.82	3.64	95.3	3.73	97.6

LoQ = 0.001 mg/L
LoD = 0.0003 mg/L
--- no value

Results

The effect of the test item on immobilization of Daphnia magna was assessed. The Daphnia magna were considered immobile if they showed no ability to swim within 15 seconds after gentle swirling of the test vessel.

Table 6. Immobilisation of *Daphnia magna*, definitive test

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

The endpoint values based on nominal test item concentration is given below:
The EC_{50}/48 h is higher than 100 mg product/L.

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

No new studies performed, not required.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.2.3.1 Study 1

Comments of zRMS:	The study was conducted according to OECD guideline 201 and principles of GLP. No deviations were noted during the study. The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason end-points are expressed as nominal concentrations. In the definitive test all the validity criteria were met as follows: the biomass in the control increased by a factor of 141.8 within the 72-hour test period (criterion: at least a 16-fold growth), - the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 1.1% (criterion: it must not exceed 7%), - the mean coefficient of variation for the section-by-section growth rate in the control culture was 17.2% (criterion: it must not exceed 35%). The study is reliable and suitable for the risk assessment. Following endpoints are relevant for risk assessment purposes: The concentration causing a 50% inhibition of the growth rate of *Raphidocelis subcapitata:* The ErC_{50}/72 h value is > 100 mg/L

Reference:	10.2.3
Report	Brzozowska-Wojoczek K., *Raphidocelis subcapitata*, Growth inhibition test, 2019; Łukasiewicz Research Network; study code: W/17/19; GLP, un-published
Guideline(s):	according to the OECD Guideline No. 201 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item: Imazamox 040 SL (CHR/H/IMA 40 SL); batch no.: 2018.08.21; content of imazamox: 3.820 ± 0.007 [%]; production date: 08/2018, expiry date:08/2020.

Test organism: The unicellular freshwater green algae, Raphidocelis subcapitata SAG 61.81 (formerly Pseudokirchneriella subcapitata (Reinsch) Korshikov (syn. Selenastrum capricornutum Prinz) cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Department of Ecotoxicological Studies, Laboratory of Aquatic Toxicology. The algae were obtained from the Culture Collection of Algae at Göttingen University, Germany.

Test design: 72 hours of exposure; six replicates for the test item concentration and the

control; a background for the control and the test item concentration; initial algal cell density: 1 x 10^4 cells/mL.

Nominal test item concentration:
100 mg/L plus the control.

Test conditions: Temperature: 22.2 – 22.6ºC; pH of the control: 7.56 – 8.58; mean light intensity: 6268 – 6316 lux; constant illumination and shaking; medium: AAP.

Chemical determinations: The concentrations of imazamox were chemically determined with a validated liquid chromatographic method with DAD detection

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

Endpoint values: E_rC_{50}, E_yC_{50}

Analytical measurements

At exposure initiation, the determined concentration of imazamox was 95.3% of the nominal concentration. The results confirm that the test item concentration was prepared correctly. At exposure termination the determined concentration of imazamox was 88.7% of the nominal concentration. Therefore, the concentrations of imazamox was stable under test conditions.

Table 11. Concentration and stability of imazamox, definitive test

Nominal test item concentration [mg/L]	Nominal concentration of imazamox [mg/L]	Average determined concentration of imazamox in samples collected [mg/L]			
		at exposure initiation	% of nominal concentration	at exposure termination	% of nominal concentration
Control	---	<LoD	---	<LoD	---
100	3.82	3.64	95.3	3.39	88.7

LoQ = 0.001 mg/L
LoD = 0.0003 mg/L
--- no value

Results

The concentration causing a 50% inhibition of the growth rate of Raphidocelis subcapitata, i.e. the ErC50/72 h value is higher than 100 mg/L.
The concentration causing a 50% inhibition of yield of Raphidocelis subcapitata, i.e. the EyC50/72 h value is higher than 100 mg/L.

Table 10. Inhibition of growth rate and yield, definitive test

Nominal test item concentration [mg/L]	% inhibition after 72 h of exposure (growth rate)	% inhibition after 72 h of exposure (yield)
Control	0.0	0.0
100	2.9	13.5

A 2.2.3.2 Study 2

Comments of zRMS:	The study was conducted according to OECD guideline 201 and to the principles of GLP. No deviations were noted during the study. The analytical measurements demonstrated that the test item concentrations throughout the test was mainly within 80-120% of nominal concentrations. In the definitive test all the validity criteria were met. - the biomass in the control increased by a factor of 40.3 within the 72-hour test period (criterion: at least a 16-fold growth), - the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 1.0% (criterion: it must not exceed 10%). - the mean coefficient of variation for the section-by-section growth rate in the control culture was 21.1% (criterion: it must not exceed 35%). Following endpoints based on the growth rate are relevant for risk assessment purposes: E_rC_{50} = 67.31 mg product/L $_{nom}$ LOEC = 100 mg product /L_{nom} NOEC = 40 mg product /L_{nom} Following endpoints based on the Yield rate are relevant for risk assessment purposes: E_yC_{50} = 27.09 mg product /L_{nom} LOEC = 6.4 mg product /L_{nom} NOEC = 2.56 mg product /L_{nom}

Reference:	10.2.3
Report	Nierzędska E., *Anabaena flos-aquae UTEX B 1444*, Growth inhibition test, 2019; Łukasiewicz Research Network; study code: W/18/19; GLP, unpublished
Guideline(s):	according to the OECD Guideline No. 201 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Introduction

The growth of the green cyanobacteria Anabaena flos-aquae exposed to the test item, Imazamox 040 SL (CHR/H/IMA 40 SL) was investigated during a 72-hour test.

Materials and methods

Test item: Imazamox 040 SL (CHR/H/IMA 40 SL); batch no.: 2018.08.21; content of imazamox: 3.820 ± 0.007 [%]; production date: 08/2018, expiry date:08/2020.

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

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

Nominal test item concentrations:
100, 40, 16, 6.4, 2.56 mg/L plus the control.

Test conditions: Temperature: 23.4 – 23.9°C; pH of the control: 7.46 – 7.65; mean light intensity: 3961 – 4436 lux; constant illumination and shaking; medium: AAP.

Chemical determinations: The concentrations of imazamox were chemically determined with a validated liquid chromatographic method with DAD detection

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

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

Analytical measurements:

At exposure initiation, the determined concentrations of imazamox were in the range of 91.9 – 96.3% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination, the determined concentrations of imazamox were in the range of 87.8 – 89.5% of the nominal concentration. Therefore, the concentrations of imazamox were stable under test conditions.

Nominal test item concentration [mg/L]	Nominal concentration of imazamox [mg/L]	Average determined concentration of imazamox (n=3) in samples collected			
		at exposure initiation [mg/L]	% of nominal concentration	at exposure termination [mg/L]	% of nominal concentration
Control	---	< LoD	---	< LoD	---
2.56	0.0978	0.0899	91.9	0.0859	87.8
6.4	0.244	0.228	93.4	0.215	88.1
16	0.611	0.574	93.9	0.541	88.5
40	1.53	1.45	94.8	1.35	88.2
100	3.82	3.68	96.3	3.42	89.5

LoQ = 0.001 mg/L
LoD = 0.0003 mg/L
--- no value

Results

Table 11. Growth rate endpoint values based on the nominal test item concentrations, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_rC_{50}	30.23 (7.31 – 55.11)	21.43 (15.46 – 29.73)	67.31 (53.22 – 82.89)
E_rC_{20}	19.56 (0.06 – 28.59)	9.75 (4.67 – 13.85)	45.39 (29.21 – 56.61)
E_rC_{10}	15.58 (0.004 – 24.39)	6.47 (2.30 – 10.08)	36.94 (20.61 – 48.02)
LOEC	40	16	100
NOEC	16	6.4	40

(-) – 95% confidence interval
Calculations were made according to [8], [SOP/W/68]
n.d. – not determined

Table 12. Yield endpoint values based on the nominal test item concentrations, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_yC_{50}	26.84 (11.55 – 58.59)	11.30 (8.65 – 14.76)	27.09 (15.03 – 54.62)
E_yC_{20}	15.86 (0.48 – 24.23)	4.92 (2.81 – 6.72)	6.51 (1.23 – 12.34)
E_yC_{10}	12.05 (0.07 – 19.75)	3.19 (1.47 – 4.75)	3.09 (0.27 – 7.12)
LOEC	100	6.4	6.4
NOEC	40	2.56	2.56

(-) – 95% confidence interval
Calculations were made according to [8], [SOP/W/68]

The endpoint values based on the nominal test item concentrations are given below:
The ErC50/72 h value is 67.31 mg/L (with 95% confidence limits: 53.22 – 82.89)
The LOEC/72 h value for growth rate is 100 mg/L.
The NOEC/72 h value for growth rate is 40 mg/L.
The EyC50/72 h value is 27.09 mg/L (95% confidence interval: 15.03 – 54.62).
The LOEC/72 h value for yield 6.4 mg/L
The NOEC/72 h value for yield is 2.56 mg/L.

A 2.2.3.3 Study 3

Comments of zRMS:	Growth inhibition test was conducted according to OECD guideline 221 and to the principles of GLP. No deviations were noted during the study. In the definitive test all the validity criteria were met. The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason end-points are expressed as nominal concentrations. The study is reliable and suitable for the risk assessment. In the definitive test, the following validity criteria specified in the OECD Guideline No. 221 (2006) were met: - The doubling time of frond number in the control was 2.0 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 11.0). - The average specific growth rate in the control between day 0 and day 7 was 0.341 d-1 (minimum requirement: higher than 0.275 d-1). Growth rate test: Frond number: **ErC50: 1.314 mg/L** LOEC: 0.74 mg/L NOEC: 0.25 mg/L Dry weight: ErC50: 8.591 mg/L LOEC: 0.25 mg/L NOEC: 0.08 mg/L Yield test: Frond number: **ErC50: 0.552 mg/L** LOEC: 0.74 mg/L NOEC: 0.25 mg/L Dry weight: ErC50: 0.897 mg/L LOEC: 0.25 mg/L NOEC: 0.08 mg/L

Reference:	10.2.3
Report	Brzozowska-Wojoczek K., *Lemna gibba*, Growth inhibition test, 2019; Łukasiewicz Research Network; study code: W/19/19; GLP, unpublished
Guideline(s):	according to the OECD Guideline No. 201 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Introduction

The growth of Lemna gibba exposed to the test item, Imazamox 040 SL (CHR/H/IMA 40 SL), was investigated in a 7 day static test without renewals

Materials and methods

Test item: Imazamox 040 SL (CHR/H/IMA 40 SL); batch no.: 2018.08.21; content of imazamox: 3.820 ± 0.007 [%]; production date: 08/2018, expiry date:08/2020.

Test organism: The freshwater aquatic plant, Lemna gibba CPCC 310 cultivated at Łukasiewicz Resarch Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies, Laboratory of Aquatic Toxicology; the plants were obtained from the Canadian Phycological Culture Centre (CPCC), Department of Biology, University of Waterloo, Ontario, Canada.

Test design: Static system (no renewals) ;7 days of exposure; three replicates per each test item concentration; six replicates per the control;

Nominal test item concentrations:
20, 6.7, 2.2, 0.74, 0.25 and 0.08 mg/L plus the control.

Test conditions: 20X AAP medium, pH of the control: 7.51 – 8.59, mean light intensity: 8085-8123 lux, constant illumination, glass beakers containing 400 mL of a given test item concentration or control; initial frond number: 9, i.e. 3 plants per 3 fronds; temperature: 23.3 – 23.9ºC.

Chemical determinations: The concentrations of imazamox were chemically determined with a validated liquid chromatographic method with DAD detection

Statistics: Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, Multiple sequentially-rejective Welsh-t-test after Bonferroni-Holm
Endpoint values: E_rC_{50}, E_rC_{20}, E_rC_{10}, E_yC_{50}, E_yC_{20}, E_yC_{10}, LOEC and NOEC, based on frond number and dry weight.

Analytical measurements

At exposure initiation in samples the determined concentrations of imazamox were in the range of 87.7 – 94.8% of nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination in samples the determined concentrations of imazamox were in the range of 91.5 – 106.1% of nominal concentration. Therefore, the concentrations of imazamox were stable under test conditions

Table 12. Concentration and stability of imazamox, definitive test

Nominal test item concentration [mg/L]	Nominal concentration of imazamox	Average determined concentration of imazamox (n=3) in samples collected			
		at exposure initiation [mg/L]	% of nominal concentration	at exposure termination [mg/L]	% of nominal concentration
Control	---	< LoD	---	< LoD	---
0.08	0.00306	0.0029	94.8	0.0028	91.5
0.25	0.00955	0.00859	89.9	0.00909	95.2
0.74	0.0283	0.0263	92.9	0.0298	105.3
2.2	0.084	0.0788	93.8	0.0891	106.1
6.7	0.256	0.237	92.6	0.246	96.1
20	0.764	0.67	87.7	0.717	93.8

LoQ = 0.001 mg/L
LoD = 0.0003 mg/L

Results

The endpoint values based on the nominal test item concentrations:
Endpoint values based on the frond number:
The E_rC_{50}/7 d value is 1.314 mg/L (95% confidence interval 1.087 – 1.589).
The E_rC_{20}/7 d value is 0.385 mg/L (95% confidence interval 0.274 – 0.498).
The E_rC_{10}/7 d value is 0.203 mg/L (95% confidence interval 0.127 – 0.284).
For growth rate the NOEC/7 d value is 0.250 mg/L, whereas the LOEC/7 d value is 0.74 mg/L.
The E_yC_{50}/7 d value is 0.552 mg/L (95% confidence interval 0.480 – 0.634).
The E_yC_{20}/7 d value is 0.268 (95% confidence interval 0.206 – 0.322).
The E_yC_{10}/7 d value is 0.184 mg/L (95% confidence interval 0.129 – 0.233).
For yield the NOEC/7 d value is 0.25 mg/L, whereas the LOEC/7 d value is 0.74 mg/L.
Endpoint values based on the dry weight:
The E_rC_{50}/7 d value is 8.591 mg/L (95% confidence interval 6.336 – 12.466).
The E_rC_{20}/7 d value is 0.596 mg/L (95% confidence interval 0.361 – 0.869)
The E_rC_{10}/7 d value is 0.148 mg/L (95% confidence interval 0.068 – 0.257).
For growth rate the NOEC/7 d value is 0.08 mg/L, whereas the LOEC/7 d value is 0.25 mg/L.
The E_yC_{50}/7 d value is 0.897 mg/L (95% confidence interval 0.647 – 1.234).
The E_yC_{20}/7 d value is 0.136 mg/L (95% confidence interval 0.070 – 0.215).
The E_yC_{10}/7 d value is is 0.051 mg/L (95% confidence interval 0.020 – 0.093).
For yield the NOEC/7 d value is 0.08 mg/L, whereas the LOEC/7 d value is 0.25 mg/L.

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

A 2.3.1.1.1.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 213 and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met as follows: - the average mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%). - - the LD_{50}/24 h of the reference item (dimethoate) was 0.23 µg a.i./bee (criterion: 0.10 – 0.35 µg a.i./bee) The study is reliable and suitable for the risk assessment. Overall, the study is considered acceptable with following endpoints: 48 h LD_{50} > 200.0 µg product/honeybee

Reference:	10.2.3
Report	Grzesica M., Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test, Study code: B/88/18
Guideline(s):	according to the OECD Guideline for the Testing of Chemicals No. 213 (1998) and the EU Method C.16. (2008)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Introduction
The aims of the study were to use a laboratory method to determine the acute oral toxicity of Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] to adult worker honeybees and to demonstrate that the LD_{50} values are higher than the highest dose used in the test.

Materials and methods

Test item:	name: Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] active substance: 3.820 ± 0.007 % of Imazamox batch number: 2018.08.21 manufacturing date: 08.2018 expiry date: 08.2020
Biological test system:	the honeybee. *Apis mellifera* L. strain: carnica source: an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies age: approximately 3 weeks

Test design:	- test item: exposure time: 48 hours number of doses: 4 doses and a control number of replicates: 3 replicates number of bees: 10 bees/replicate - reference item: exposure time: 24 hours number of doses: 3 doses number of replicates: 3 replicates number of bees: 10 bees/replicate
Test item doses:	25.0, 50.0, 100.0 and 200.0 µg test item/bee and a control (0.0 µg/bee)
Reference item doses:	0.1, 0.2 and 0.4 µg a.i./bee
Test conditions:	temperature: 24 – 26°C, relative air humidity: 59 – 68% place: a dark room
Endpoints:	- honeybee mortality after 24 and 48 hours of exposure - LD50/24h and LD50/48h of the test item - LD50/24h of the reference item (dimethoate)
Statistical method:	regression analysis using the log-probit method

Results:

The acute oral toxicity study of the test item, Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] on honeybees (*Apis mellifera* L.) in the laboratory test are summarized below.

Dose [µg/bee]	**Number of tested bees [no.]**	**Mortality after 48 h**		**LD_{50} after 48 h [µg/bee]**
		Total		
		[no.]	**[%]**	
0.0 (Control)	30	0	**0.0**	> 200
25.0	30	1	**3.3**	
50.0	30	1	**3.3**	
100.0	30	0	**0.0**	
200.0	30	1	**3.3**	

Conclusions:

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

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

A 2.3.1.1.2.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 214 and according to the prin-ciples of GLP. According to the Guideline No. 214/ EU Method C.17., the honeybees may be anesthetized with carbon dioxide for application of the test item. Anesthesia was replaced with mechanical immobilisation. The mentioned deviation had not effect on the results of the study. In the definitive test all the validity criteria were met. - the average mortality for the control was 3.3% after 48 h (criterion: it must not exceed 10%), - - the LD_{50}/24 h of the reference item (dimethoate) was 0.26 µg a.i./bee (criterion: 0.10−0.30 µg a.i./bee). The study is reliable and suitable for the risk assessment. Overall, the study is considered acceptable with following endpoints: 48 h LD_{50} > 200.0 µg product/honeybee

Reference:	10.2.3
Report	Grzesica M., Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test, Study code: B/89/18
Guideline(s):	according to the OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method C.17. (2008)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Introduction

Mortality of honeybees, Apis mellifera, exposed to Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] was investigated during 48-hour test.

Materials and methods

Test item:	name: Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] active substance: 3.820 ± 0.007 % of Imazamox batch number: 2018.08.21 manufacturing date: 08.2018 expiry date: 08.2020
Biological test system:	the honeybee. *Apis mellifera* L. strain: carnica source: an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies age: approximately 3 weeks

Test design:	- test item: exposure time: 48 hours number of doses: 4 doses and a control number of replicates: 3 replicates number of bees: 10 bees/replicate - reference item: exposure time: 24 hours number of doses: 3 doses number of replicates: 3 replicates number of bees: 10 bees/replicate
Test item doses:	25.0, 50.0, 100.0 and 200.0 µg test item/bee and a control (0.0 µg/bee)
Reference item doses:	0.1, 0.2 and 0.4 µg a.i./bee
Test conditions:	temperature: 24 – 26°C, relative air humidity: 65 – 73% place: a dark room
Endpoints:	- honeybee mortality after 24 and 48 hours of exposure - LD50/24h and LD50/48h of the test item - LD50/24h of the reference item (dimethoate)
Statistical method:	regression analysis using the log-probit method

Results:

The acute oral toxicity study of the test item, Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] on honeybees (*Apis mellifera* L.) in the laboratory test are summarized below.

Dose [µg/bee]	**Number of tested bees [no.]**	**Mortality after 48 h**			**LD_{50} after 48 h [µg/bee]**
		Total			
		[no.]	**[%]**	**[%][c]**	
0.0 (Control)	30	1	3.3	-	> 200
25.0	30	1	3.3	0.0	
50.0	30	3	10.0	6.9	
100.0	30	1	3.3	0.0	
200.0	30	1	3.3	0.0	

[c]: mortality corrected using the formula of Abbott [10]

Conclusions:

The median lethal doses LD_{50}/24 h and LD50/48 h are higher than the highest dose used in the test, i.e. 200.0 µg/honeybee.

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

A 2.3.1.3 KCP 10.3.1.3 Effects on non-target arthropods (other than bees)

A 2.3.1.3.1 Study 1

Comments of zRMS:	The laboratory study follows the guideline specified by Blümel et al. (2000) and according to the principles of GLP. According to the guideline developed by the IOBC, BART, EPPO Joint Initiative, as a food source only pollen was used. However, in the experiment additional food in the form of the two-spotted spider mite (T. urticae) eggs, was used. Another food source prevents the mites from escaping from discs. Since n the definitive test all the validity criteria were met it didn't impact the results of the study. Considering the current test guideline (Blümel et al., 2000) the study is considered valid. The following validity criteria were met during the study: – mortality of the control group was 3.3% on day 7 of exposure (criterion: a maximum of 20%), – corrected mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 89.7% on day 7 of exposure (criterion: from 50 to 100%) LR_{50} > 1.2 L product/ha $NOER_{mortality}$ is < 0.3 Lproduct/ha

Reference:	10.2.3
Report	Grzesica M., A Laboratory test for evaluating the effects of Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] on the predatory mite, Typhlodromus pyri (Sch.), 2019, Study code: B/90/18
Guideline(s):	according to the ESCORT 1 (Barrett K. L. et al., 1994) and the ESCORT 2 (Candolfi M. P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Introduction
The laboratory test involved the evaluation of the test item effects, Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] on mortality of the predatory mite, Typhlodromus pyri (Sch.)
The mites, T. pyri at the protonymphal stage (24 hours old) were exposed to the test item applied to artificial discs. The mites were fed with pine pollen (Pinus sp.) and two-spotted spider mite (T. urticae) eggs. Mortality observations were made after 7 days of the treatment

Materials and methods

Test item:	name: Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] active substance: 3.820 ± 0.007 % of Imazamox batch number: 2018.08.21 manufacturing date: 08.2018 expiry date: 08.2020
Biological test system: **- age:** **- source:**	the predatory mite, *Typhlodromus pyri* (Sch.) (Acari: *Phytoseiidae*) 24-hour-old protonymphs a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented by a commercial breeder
Test design:	5 study groups: – a control group - Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] at the rate of 0.3 L/ha - Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] at the rate of 0.6 L/ha - Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] at the rate of 1.2 L/ha – Bi 58 Top 400 EC at the rate of 9.0 mL/ha number of replicates: 3; number of mites in each replicate: 20
Test conditions:	**– temperature:** 24 – 26°C **– relative air humidity:** 60 – 70% **– photoperiod:** 16 h light : 8 h dark **– light intensity:** 825 lux
Statistical method:	Probit analysis using max. likelihood regression, Chi_2 2x2 Table Test with Bonferroni Correction
Endpoints:	– mite mortality after 7 days of the treatment – LR_{50} and $NOER_{mortality}$

Results:
The effects of Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] on mortality of *Typhlodromus pyri* in the definitive test are summarized below.

Study group [application rate]	Parameter (endpoint)			
	Mortality (dead + escape mites)			
Test item [L/ha]	Total			LR_{50} [L/ha]
	No.	[%]	[%][c]	
Control (0.0)	2	3.3	-	
Imazamox 040 SL [CHR/H/IMA 40 SL]				
0.3 +	7	11.7	8.6	>1.2
0.6 +	9	15.0	12.1	
1.2 +	10	16.7	13.8	
$NOER_{mortality}$				<0.3 [L/ha]
Reference item Bi 58 Top 400 EC				
[mL/ha]	Total			–
	No.	[%]	[%]*	
9.0	58	90.0	89.7	not assessed

Conclusions:
In the definitive test, mortality of the control group after 7 days of exposure was 3.3%. After 7 days of exposure to Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] at the rates of 0.3, 0.6 and 1.2 L/ha, the *T. pyri*, percentages of mortality, corrected using the formula of Abbott [1], were equal to 8.6, 12.1 and 13.8%, respectively.
There were statistically significant difference in mortality between groups treated with the test item at the rates of 0.3, 0.6, 1.2 L/ha in comparison to the control group (Chi2 2x2 Table Test with Bonferroni Correction, $p(z)>\alpha$).
On the basis of the obtained results the LR50 value is higher than 1.2 L/ha. The NOERmortality value is below to 0.3 L/ha
After 7 days of exposure to Bi 58 Top 400 EC at the rate of 9.0 mL/ha, the mortality was 89.7%. Therefore, the validity criterion specified in the Method description was met. The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.
Based on the results it can be stated that Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] /ha has an adverse effect on mortality of the tested organisms at the rates of 0.3, 0.6 and 1.2 L/ha.

A 2.3.1.3.2 Study 2

Comments of zRMS:	The laboratory study follows the guideline specified by Mead Briggs M.A. et al. (2000) and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met Considering the current test guideline (Mead Briggs M.A. et al, 2000) the study is considered valid. The following validity criteria were met during the study – after 48 hours mortality of the control group was 0.0% (criterion: a maximum of 13.0%), – after 24 hours mortality of the group treated with the reference item at the rate of 0.12 mL/ha was 80.0% (criterion: from 75 to 100%), – the mean number of mummies per female in the control group was 8.3 (criterion: a minimum of 5.0 mummies/female), – all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring). LR_{50} > 1.2 L formulation /ha $NOER_{mortality}$ < 0.3 Lformulation/ha

Reference:	10.2.3
Report	Grzesica M., Laboratory test for evaluating the effects of Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL]on the parasitic wasp, Aphidius rhopalosiphi (De Stefani-Perez)Typhlodromus pyri (Sch.), 2019, Study code: B/91/18
Guideline(s):	according to the ESCORT 1 (Barrett K. L. et al., 1994) and the ESCORT 2 (Candolfi M. P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	name: Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] active substance: 3.820 ± 0.007 % of Imazamox batch number: 2018.08.21 manufacturing date: 08.2018 expiry date: 08.2020	
Biological test system: **- age:** **- source:**	the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Hymenoptera: Braconidae, Aphiidinae adult females (24–48 hours after emerging from mummies) a laboratory-bred culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was obtained from Bias Labs (UK).	
Test design:	6 study groups: – a control group - Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] at the rate of 0.15 L/ha - Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] at the rate of 0.3 L/ha - Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] at the rate of 0.6 L/ha - Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] at the rate of 1.2 L/ha – Bi 58 Top 400 EC at the rate of 9.0 mL/ha number of replicates: 3; number of mites in each replicate: 20	
Test conditions:	**– temperature:**	18 – 20°C
	– relative air humidity:	57 – 73%
	– photoperiod:	16 hours light (mortality assessment and oviposition: 1272 lx; fecundity assessment: 4930) : 8 hours dark
Statistical method:	Step-down Cochran-Armitage Test Procedure, Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogenity, Dunnett's Multiple t-test Procedure.	
Endpoints:	– wasp mortality after 48 hours of exposure	

	– determination of the LR_{50} and the $NOER_{mortality}$ – reduction in fecundity (Pr) of the surviving female wasps exposed to Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL], 12 days after the oviposition period – determination of the ER_{50} and the $NOER_{fecundity}$

Results:
The effects of the test item Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] at the rates of 0.15, 0.3, 0.6 and 1.2 L Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] /ha on mortality and fecundity of Aphidius rhopalosiphi in the laboratory test are summarized below.

Study group [application rate]	Parameter (endpoint)					
	Mortality after 48 h of exposure		Fecundity			
Test item [L/ha]	Mortality [%]	LR_{50} Test item [L/ha]	Test item [L/ha]	Mean no. of mummies/ female	Fecundity reduction Pr [%]	ER_{50} Test item [L/ha]
Control (0.0)	–	–	Control (0.0)	8.3	–	–
0.15	2.5	> 1.2	0.15	8.2	1.6	> 1.2
0.3	2.5		0.3	8.1	2.4	
0.6+	7.5		0.6	8.3	0.8	
1.2+	20.0		1.2	8.1	3.2	
$NOER_{mortality}$		0.30	$NOER_{fecundity}$			≥ 1.2
Reference item: Bi 58 Top 400 EC						
Reference item [mL/ha]	0.12					
Active ingredient [g/ha]	0.048					
Mortality after 24 h of exposure						
Total [%]						
80.0						

+: statistically significant difference

The validity criterion concerning mortality was met, because mortality of the control group was 0.0% (criterion: a maximum of 10.0%) after 48 hours of exposure.
Mortality of the wasps exposed to the test item at the rates of 0.15, 0.3, 0.6 and 1.2 L Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] /ha were 2.5, 2.5, 7.5 and 20.0 % after 48 hours of exposure.
The LR 50 value could not be determined On the basis of the obtained results the LR 50 value is highe r than 1.2 L/ha and the NOERmortality is equal 0.30 L/ha.
Mortality of the wasps exposed to Bi 58 Top 400 EC at the rate of 0.12 mL/ha was 80.0 % after 24 hours. Therefore, the validity criterion was met. The results showed that the insects were sensitive to dimethoate.
Fecundity reduction (Pr) caused by Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] at the rates of 0.15, 0.3, 0.6 and 1.2 L Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] /ha were 1.6, 2.4, 0.8 and 3.2% respectively. At the significance level of 0.05, statistically no significant differences in fecundity between the wasps exposed to the test item at the rates of 0.15, 0.3, 0.6 and 1.2 L/ha and the control group were stated (Dunnett's Multiple t-test Procedure, $p<0.05$).
The ER50 value could not be determined On the basis of the obtained results the ER50 value is higher than 1.2 L/ha ha. NOERfecundity appears to be higher than or equal 1.2 L/ha.

Conclusions:

Based on the above test results, it can be concluded that Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] at the rates of 0.6 and 1.2 L Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL]/ha had an adverse effects on mortality of *Aphidius rhopalosiphi*. Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL] at the rates of 0.15, 0.3, 0.6 and 1.2 L Imazamox 040 SL (Imazamox 40 g/L) [CHR/H/IMA 40 SL]/ha had not adverse effects on fecundity of *Aphidius rhopalosiphi*.

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 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 222 and according to the principles of GLP. No deviation were noted during the study. In the definitive test all the validity criteria were met according to OECD Guideline No. 222: - each replicate produced 95.8 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment), - the coefficient of variation of reproduction was 15.9% (criterion: ≤ 30%), - adult mortality over the initial 4 weeks of the experiment was 2.5% (criterion: ≤ 10%). The study is reliable and suitable for the risk assessment. LC_{50} > 1000 mg product /kg dw EC_{50} > 1000 mg product /kg dw EC10 >1000 mg product /kg dw $NOEC_{reproduction}$ ≥ 1000 mg product /kg dw $LOEC_{reproduction}$ > 1000 mg product /kg dw $NOEC_{survival}$ ≥ 1000 mg product /kg dw $LOEC_{survival}$ > 1000 mg product /kg dw

Reference:	10.2.3
Report	Gierbuszewska A., Earthworm Reproduction Test (*Eisenia andrei*), 2019, Study code: G/186/18
Guideline(s):	according to OECD Guideline No. 222 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Introduction
The aims of the study were to assess the impact of the test item on reproduction of the earthworm, Eisenia andrei and to determine the EC10, EC20, EC50, and NOEC.

Materials and methods

Test item:	**CHR/H/IMA 40 SL** batch no.: 2018.08.21
Active substance:	imazamox: 3.820 ± 0.007%
Artificial soil:	10% sphagnum peat, 20% kaolin clay, 70% airdried quartz sand
Test organism:	the earthworm, *Eisenia andrei* obtained from a standard laboratory culture cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies, Laboratory of Soil Toxicology
Test design: Concentrations of the test item:	test duration: 8 weeks; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate control, 3.2, 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0, and 1000.0 mg/kg dry weight of the artificial soil
Test conditions:	temperature: 18.5 – 21.0°C; pH at the beginning of the experiment: 5.50 – 5.63; pH at the end of the experiment: 5.52 – 5.80; soil moisture content at the beginning of the experiment: 24.8 – 29.9% (49.0 – 59.1% of the maximum water holding capacity); soil moisture content at the end of the experiment: 26.3 – 28.2% (51.9 – 55.6% of the maximum water holding capacity); light-dark cycle: 16h : 8h; light intensity at the beginning of the experiment: 528 – 543 lux light intensity at the end of the experiment: 569– 583 lux
Statistical analysis:	EC10, EC20, EC50, LC50 – probit analysis using linear max. likelihood regression NOEC (reproduction) – Shapiro-Wilk's Test on Normal Distribution, Bartlett's Test Procedure on Variance Homogeneity, Williams Multiple Sequential t-test Procedure NOEC (survival) – Fisher's Exact Binomial Test with Bonferroni Correction LOEC: a value suggested by the ToxRat Professional 2.10 statistical computer software
Endpoint:	EC10, EC20, EC50, NOEC, LOEC LC50, NOEC, LOEC

Results:
At concentrations ranging from 3.2 to 1000.0 mg of the test item/kg dry weight of artificial soil, after 4 weeks of exposure to the test item, mortality of the adult earthworms was ranging from 0.0 to 5.0%.
As for the control group, it was equal to 2.5%.
The concentration of the test item causing 50% mortality of the adult earthworms **(LC_{50}) is above 1000.0 mg/kg dry weight of artificial soil** (38.2 mg of imazamox / kg dry weight of artificial soil).
No changes in the appearance (morphology) and behavior of the living earthworms were noticed.
After the application of the test item at the concentrations ranging from 3.2 to 1000.0 mg/kg dry weight of artificial soil, the body weight increase was between 5.6 to 22.7%. As for the control group, it was equal to 18.2%.
After 8 weeks of the experiment, the obtained results led to the following conclusions:
After the application of the test item at the concentrations ranging from 3.2 to 1000.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 89.8 – 114.8 per replicate. The mean number of juveniles in the control group was equal to 95.8 per replicate.
After 8 weeks of the experiment, it was concluded that **CHR/H/IMA 40 SL** had no statistically significant impact on reproduction of the earthworms at the concentrations ranging from 3.2 to 1000.0 mg/kg dry weight of the artificial soil.
The endpoint values showing the impact of the test item on reproduction and survival of adult earthworms are presented in the table given below.

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of imazamox /kg dry weight of artificial soil]
EC_{10}	>1000	>38.2
EC_{20}	>1000	>38.2
EC_{50}	>1000	>38.2
NOEC (reproduction)	≥1000	≥ 38.2
LOEC (reproduction)	>1000	>38.2
LC50	>1000	>38.2
NOEC (survival)	≥1000	≥ 38.2
LOEC (survival)	>1000	> 38.2

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

A 2.4.2.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 226 and according to the principles of GLP. Following deviations from the guideline 232 were noted, however they did not affect the results since all the validity criteria of the method were met: 1. According to the OECD Guideline No. 226 (2016) the water content of the soil substrate should be maintained throughout the test by weighing and if needed re-watering the vessels periodically. In the study to maintain proper moisture content, a small sample of soil was drying at 105°C and re-weighing at the beginning, after 7 days of the test and at the end of the test 2. Due to the use of the temperature extraction method, there was no need for euthanasia of the extracted organisms, since the mites are fixed in a 70% ethanol solution 3. Due to the use of the temperature extraction method, it was not possible to record the symptoms with behavioural and morphology changes of the extracted predatory mites. The study is reliable and suitable for the risk assessment. EC_{50} > 1000 mg product /kg dw EC_{10} =308.2 mg product /kg dw $NOEC_{reproduction}$ = 320 mg product /kg dw $NOEC_{survival}$ ≥ 1000 mg product /kg dw

Reference: 10.2.3

Report: Gierbuszewska A., Predatory mite Reproduction Test (*Hypoaspis (Geolaelaps) aculeifer*), 2019, Study code: G/188/18

Guideline(s): according to OECD Guideline No. 226 (2016)

Deviations: Yes ~~No~~

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item:	**CHR/H/IMA 40 SL** batch no.: 2018.08.21
Active substance:	imazamox: 3.820 ± 0.007%
Artificial soil:	5% sphagnum peat, 20% kaolin clay, 75% airdried quartz sand
Test organism:	the predatory mites, Hypoaspis (Geolaelaps) aculeifer (adult female mites from a synchronized culture) obtained from a standard laboratory culture at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies, Laboratory of Soil Toxicology. The mites were introduced 7 – 14 days after becoming adult.
Test design: Concentrations of the test item:	test duration: 14 days number of replicates: 4 replicates / concentration + 8 replicates / control; number of mites: 10 mites / replicate a control, 5.6, 10, 18, 32, 56, 100, 180, 320, 560 and 1000 mg of the test item/kg of dry weight of the artificial soil
Test conditions:	temperature: 18.5 – 21.0°C pH at the beginning of the test: 5.50 – 5.54 pH at the end of the test: 5.43 – 5.50 soil moisture content at the beginning of the test: 13.4 – 14.7% (42.4 – 46.5% of the maximum water holding capacity) soil moisture content in the middle of the test: 13.5 – 14.9% (42.8 – 47.4% of the maximum water holding capacity) soil moisture content at the end of the test: 12.9 – 14.0% (40.8 – 44.5% of the maximum water holding capacity) light-dark cycle: 16 h light and 8 h dark light intensity at the beginning of the test: 535 – 551 lux light intensity at end of the test: 548 – 576 lux
Statistical analysis:	EC10, EC20, EC50 – a probit analysis using linear max. likelihood regression LC10, LC20, LC50 – a probit analysis using linear max. likelihood regression NOEC: - offspring number – Shapiro-Wilk's Test on Normal Distribution, Bartlett's Test Procedure on Variance Homogeneity, Williams Multiple Sequential t-test Procedure - survival – Fisher's Exact Binomial Test with Bonferroni Correction
Endpoint:	EC10, EC20, EC50, NOEC LC10, LC20, LC50, NOEC

Results:
Mortality of the predatory mites exposed to the test item at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of the artificial soil was between 0% and 10.0%. Mortality of the control group was equal to 2.5%.
After the application of the test item at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of the artificial soil the mean number of juveniles was between 47.8 – 61.5 per replicate. The mean number of juveniles in the control group was equal to 57.8 per replicate. The results are summarised in the table given below:

Concentration [mg/kg dry weight of the artificial soil]	Adult mites		Number of juveniles (mean)
	Number of tested mites	Number of dead mites after 14 days	
Control	80	2	57.8
5.6	40	4	57.3
10	40	4	53.8
18	40	4	58.5
32	40	0	61.5
56	40	2	58.0
100	40	0	56.8
180	40	4	53.8
320	40	3	54.5
560	40	2	49.3
1000	40	0	47.8

A 2.4.2.2 Study 2

Comments of zRMS:	The study was conducted to OECD guideline 232 and according to the principles of GLP. Following deviations from the guideline 232 were noted: - culturing of collembolans takes place in plastic containers containing an artificial substrate consisting of plaster and charcoal in ratio 9:1 and not 10:1 or 8:1 as is mentioned in OECD Guideline No. 232 - at the end of the test the soil moisture content was determined by drying small sample of the artificial soil in 105°C instead of weighing the test vessels as it is mentioned in OECD Guideline No. 232 (2016) - physiological or pathological symptoms or distinct changes in behaviour were not described The results are considered valid because the following criteria were satisfied in the controls: - mean adult mortality: 12.5% (criterion: ≤ 20%), - the mean number of juveniles per vessel at the end of the test: 829.8 (criterion: ≥ 100 juveniles at the end of the test), - - the coefficient of variation calculated for the number of juveniles: 17.8 (criterion: ≤ 30%). The study is reliable and suitable for the risk assessment. LC_{50} > 1000 mg/kg dw EC10 >1000 mg/kg dw EC_{50} > 1000 mg/kg dw $NOEC_{reproduction}$ ≥ 1000 mg/kg dw $NOEC_{survival}$ ≥ 1000 mg/kg dw

Reference: 10.2.3

Report: Gierbuszewska A., Collembolan Reproduction Test (*Folsomia candida*), 2019, Study code: G/187/18

Guideline(s): according to OECD Guideline No. 232 (2016)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item:	**CHR/H/IMA 40 SL** batch no.: 2018.08.21
Active substance:	imazamox: 3.820 ± 0.007%
Artificial soil:	5% sphagnum peat, 20% kaolin clay, 75% airdried quartz sand
Test organism:	the collembolan, Folsomia candida obtained from a standard laboratory culture at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Laboratory of Soil Toxicology. The collembolans used in the study were 9 – 12 days old.
Test design: Concentrations of the test item:	test duration: 28 days number of replicates: 4 replicates / concentration + 8 replicates / control; number of collembolans: 10 / replicate a control, 5.6, 10, 18, 32, 56, 100, 180, 320, 560 and 1000 mg of the test item/kg of dry weight of the artificial soil
Test conditions:	temperature: 18.5 – 19.5°C; pH at the beginning of the test: 5.69 – 5.88; pH at the end of the test: 5.63 – 5.69; soil moisture content at the beginning of the test: 13.7 – 14.6% (47.5 –50.5% of the maximum water holding capacity); soil moisture content at the end of the test: 12.8 – 13.7% (44.5 – 47.5% of the maximum water holding capacity); lighting: 16 h light and 8h dark; light intensity at the beginning of the experiment: 499.6– 579.2 lux light intensity at the end of the experiment: 508.5 – 564.2 lux
Statistical analysis:	EC10, EC20, EC50, LC10, LC20 and LC50 – a probit analysis NOEC (number of juveniles): - Shapiro-Wilk's Test on Normal Distribution, - Bartlett's Test Procedure on Variance Homogeneity, - Williams Multiple Sequential t-test Procedure, NOEC (survival): - Fisher's Exact Binomial Test with Bonferroni Correction
Endpoint:	EC10, EC20, EC50, NOEC LC10, LC20, LC50, NOEC

Results:
Mortality at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil ranged from 2.5 to 25.0%. As for the control group, it was equal to 12.5%.

The concentration of the test item causing a 50% mortality of adults within the exposure period **(LC50)** is **higher than 1000 mg/kg dry weight of the artificial soil (38.2 mg of imazamox / kg dry weight of the artificial soil)**.
The endpoint values showing the impact of the test item on the survival of adult collembolans are presented in the table given below.

Endpoint	**Value [mg test item /kg dry weight of the artificial soil]**	**Value [mg of imazamox/kg dry weight of the artificial soil]**
LC_{10}	422.4	16.1
LC_{20}	>1000	>38.2
LC_{50}	>1000	>38.2
NOEC	≥1000	>38.2

After the application of the test item at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 894.8 and 711.8 per replicate. As for the control group, the number of juveniles was equal to 829.8 per replicate. The endpoint values showing the impact of the test item on reproduction of *Folsomia candida* are presented in the table given below.

Endpoint	**Value [mg test item /kg dry weight of the artificial soil]**	**Value [mg of imazamox/kg dry weight of the artificial soil]**
EC_{10}	>1000	>38.2
EC_{20}	>1000	>38.2
EC_{50}	>1000	>38.2
NOEC	≥1000	>38.2

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Not performed, not required

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

Not performed, not required

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

A 2.5.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 216 and according to the principles of GLP. Following deviations from the OECD Guideline No. 216 (2000), the EU Method C.21were noted: - the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm for 24 hours. The modification resulted from the optimization of the nitrate extraction which showed that the extraction was more effective when the shaking rate was lower and the extraction lasted longer - The predicted environmental concentration (PEC) was calculated assuming 2.5 cm of the soil depth for the active substances with the mobility in soil KFoc > 500

	mL/g. Thus, the applied soil depth is a deviation from the OECD Guideline No. 216 (2000) and EU Method C.21 where the PEC is calculated by using 5 cm of the soil depth In the definitive test all the validity criteria were met as follows: The coefficients of variation (CV) in the control group were 9.2, 1.7, 13.3, 6.0 and 2.2%, after 0, 7, 14, 28 and 42 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15% On the basis of the results, it was concluded that the product CHR/H/IMA 40 SL did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils at the test concentrations: Nitrate formation rate: Corresponding to PEC: 2.68 mg/kg soil dw ≤ 25 %; Corresponding to 5xPEC: 13.40 mg/kg soil dw ≤ 25 %; on 42 day of analysis

Reference: 10.5

Report: Wołany M., Soil Microorganisms: Nitrogen Transformation Test, 2019, Study code: G/189/18

Guideline(s): according to OECD Guideline No. 216 (2000)/EU Method C.21.

Deviations: Yes ~~No~~

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Materials and methods

Test item:	**CHR/H/IMA 40 SL** batch no.: 2018.08.21
Active substance:	imazamox: 3.820 ± 0.007%
Soil:	Agricultural soil collected from a place belonging to the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna.
Test design:	Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500 g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. Test duration: 42 days.
Concentrations of the test item	control, PEC: 2.68 mg of the test item / kg dry weight of soil (0.1024 mg of imazamox / kg dry weight of soil), 5 x PEC: 13.40 mg of the test item / kg dry weight of soil (0.512 mg of imazamox / kg dry weight of soil).
Test conditions:	temperature: 20.0 – 22.0°C, soil moisture: 49.5% – 55.2% of the maximum water holding capacity, incubation in darkness
Statistical analysis:	- Shapiro-Wilk's test on Normal Distribution - Levene's Test on Variance Homogeneity (with Residuals) - Williams Multiple Sequential t-test Procedure

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

Results:
On 28 day of analysis the percent deviation from the control calculated on the basis of the nitrate formation rate of the soil treated with the test item at the concentrations corresponding to the PEC: 2.68 mg of the test item / kg dry weight of soil (0.1024 mg of imazamox / kg dry weight of soil) and 5 x PEC: 13.40 mg of the test item / kg dry weight of soil (0.512 mg of imazamox / kg dry weight of soil) exceeded 25% and according to the OECD No. 216 the experiment was continued.
The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentrations corresponding to the PEC: 2.68 mg of the test item / kg dry weight of soil (0.1024 mg of imazamox / kg dry weight of soil) and 5 x PEC: 13.40 mg of the test item / kg dry weight of soil (0.512 mg of imazamox / kg dry weight of soil) did not exceed 25% on 42 day of analysis.

Conclusions:
On the basis of the results, it was concluded that CHR/H/IMA 40 SL at the concentration corresponding to the PEC: 2.68 mg of the test item / kg dry weight of soil (0.1024 mg of imazamox / kg dry weight of soil) and 5 x PEC: 13.40 mg of the test item / kg dry weight of soil (0.512 mg of imazamox / kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

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

A 2.6.1 KCP 10.6.2 Testing on non-target plants

A 2.6.1.1 Study 1

Comments of zRMS:	The Vegetative vigour study was conducted to OECD guideline 227 and according to the principles of GLP. In the definitive test all the validity criteria were met. Following deviation from OECD 227 method was noted: - The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 55.4 – 216.4 µE/m2. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. This deviation did not affect results of the experiment. The following validity criteria were met: - the seedling emergence (validity criterion: at least 70%) was as follows: 85.0 – 95.0% – flax, 72.5 – 95.0%– red clover, 85.7 – 90.5%– pea, 82.5 – 90.0% – carrot, 72.5 – 87.5% – perennial ryegrass, 82.5 – 92.5% – oats, - the mean survival of the emerged control seedlings was 100% in flax, red clover, pea, carrot,perennial ryegrass and oats, - the control seedlings did not exhibit any visible phytotoxic symptoms,

	- environmental conditions for all plants belonging to the same species were identica The study is accepted and reliable for risk assessment purposes. 1) *Linum usitatissimum* ER_{50} > 1256.5 [g prod/ha] 2) *Trifolium pratense* ER_{50} > 1256.5 3) *Pisum sativum* ER_{50} > 1256.5 [g prod/ha] 4) *Daucus carota* ER_{50} = 195.1 prod/ha] 5) *Lolium perenne* ER_{50} = 388.8 [g prod/ha] 6) *Avena sativa* ER_{50} = **126.3** [g prod/ha]

Reference: 10.6.2

Report: Wołany M., Terrestrial Plant Test: Vegetative Vigour Test, 2019, Study code: G/190/18

Guideline(s): according to OECD Guideline No. 227 (2006)

Deviations: Yes ~~No~~

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Materials and methods:

Test item:	**CHR/H/IMA 40 SL** batch no: 2018.08.21 active substance: imazamox – 3.820 ± 0.007 [%] (Appendix No. 1)
Test species:	flax (*Linum usitstissimum*), red clover (*Trifolium pratense)*, pea (*Pisum sativum*), carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa)*.
Soil:	sandy loam
Study design:	number of rates: 8 application rates + control; number of replicates: 4 replicates/rate for flax, red clover, carrot, perennial ryegrass and oats; 7 replicates/rate for pea. The total number of plants per application rate – 20 for flax, red clover, carrot, perennial ryegrass, oats and 21 for pea. Test termination: 21 days after the spraying.
Application rates:	- 0.6, 1.7, 5.2, 15.5, 46.5, 139.6, 418.8 and 1256.5 g test item/ha (i.e. 0.02, 0.07, 0.2, 0.6, 1.8, 5.3, 16.0, and 48.0 g imazamox/ha) – flax, red clover, pea, carrot, perennial ryegrass and oats. volume of deionised water used to prepare the highest rate: 300 L water/ha
Test conditions:	temperature: 17.0 – 26.0°C, humidity: 46.5 – 93.8%, controlled light – dark cycles (16h:8h), light intensity: 55.4 – 216.4 µE/m2/s, carbon dioxide concentration: 329 – 363 ppm.
Statistical analysis:	ER_{25}, ER_{50} – probit analysis, logit analysis NOER (final number of plants) – Fisher's Exact Binomial Test with Bonferroni Correction. NOER (shoot length) - Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure. NOER (shoot dry weight) - Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-

	test Procedure.
Endpoints:	ER_{25}, ER_{50}, NOER.

Results:

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

Endpoint	**Flax** *Linum usitatissimum*	**Red clover** *Trifolium pratense*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Perennial ryegrass** *Lolium perenne*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER50	> 1256.5	> 1256.5	> 1256.5	> 1256.5	491.5	237.6 (201.1 – 281.7)
NOER	≥ 1256.5	≥ 1256.5	≥ 1256.5	≥ 1256.5	418.8	139.6
Shoot length (plants without roots)						
ER50	> 1256.5	> 1256.5	> 1256.5	737.9 (386.7 –>1256.5)	450.9 (396.7 – 635.7)	343.6 (189.1 – >1256.5)
NOER	418.8	139.6	46.5	46.5	139.6	15.5
Plant dry weight (plants without roots)						
ER50	> 1256.5	> 1256.5 (1179.6 – >1256.5)	> 1256.5 (647.4 –>1256.5)	195.1 (134.3 – 289.5)	388.8	126.3 (70.8 – >1256.5)
NOER	418.8	418.8	46.5	15.5	139.6	15.5

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

Endpoint	**Flax** *Linum usitatissimum*	**Red clover** *Trifolium pratense*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Perennial ryegrass** *Lolium perenne*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER50	> 48.0	> 48.0	> 48.0	> 48.0	18.8	9.1 (7.7 – 10.8)
NOER	≥ 48.0	≥ 48.0	≥ 48.0	≥ 48.0	16.0	5.3
Shoot length (plants without roots)						
ER50	> 48.0	> 48.0	> 48.0	28.2 (14.8 – > 48.0)	17.2 (15.2 – 24.3)	13.1 (7.2 – >48.0)
NOER	16.0	5.3	1.8	1.8	5.3	0.6
Plant dry weight (plants without roots)						
ER50	> 48.0	> 48.0 (45.1 – > 48.0)	> 48.0 (24.7 – > 48.0)	7.5 (5.1 – 11.1)	14.9	4.8 (2.7 – >48.0)
NOER	16.0	16.0	1.8	0.6	5.3	0.6

3. The test item, i.e. CHR/H/IMA 40 SL applied at rates ranging from 0.6 to 1256.5 g of the test item/ha had an impact on vegetative vigour of all analyzed species.

4. The test item did not cause mortality of flax, red clover, pea, and carrot at rates ranging from 0.6 to 1256.5 g of the test item/ha. The test item caused mortality of perennial ryegrass and oats at rates ranging from 418.8 to 1256.5 g of the test item/ha.
- On the basis of NOER, ER25 and ER50 values determined from the shoot length it was proved that the test item inhibit the process of growth of all analyzed species.
- On the basis of NOER, ER25 and ER50 values determined from the shoot dry weight, it was proved that the test item inhibit the process of growth of all analyzed species.
- Some phytotoxic symptoms were observed after 21 days of the exposure. These were:
- stunted growth (flax, red clover, pea, carrot, perennial ryegrass, oats);
- chlorosis (pea, carrot, perennial ryegrass, oats);
- wilting (carrot, perennial ryegrass, oats);
- necrosis (oats);
- deformations (oats).
- The following order of the test plant sensitivity was noticed:
oats > perennial ryegrass > carrot > pea > red clover > flax

A 2.6.1.2 Study 2

Comments of zRMS:	The seedling emergence study was conducted to OECD guideline 208 and according to the principles of GLP. In the definitive test all the validity criteria were met. Following deviation from OECD Guideline No. 208 was noted: According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 67.2 and 153.2 µE/m2 /s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. This deviation did not affect results of the experiment The study is acceptable and reliable for risk assessment purposes. 1) *Linum usitatissimum* ER_{50} > 1256.5 [g prod/ha] 2) *Trifolium pratense* ER_{50} = 1222.5 3) *Pisum sativum* ER_{50} > 1256.5 [g prod/ha] 4) *Daucus carota* ER_{50} = 986.8 prod/ha] 5) *Lolium perenne* ER_{50} = **62.3** [g prod/ha] 6) *Avena sativa* ER_{50} = 545.6 [g prod/ha]

Reference:	10.6.2
Report	Wołany M., Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test, 2019, Study code: G/191/18
Guideline(s):	according to OECD Guideline No. 208 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods:

Test item:	**CHR/H/IMA 40 SL** batch no: 2018.08.21 active substance: imazamox – 3.820 ± 0.007 [%] (Appendix No. 1)
Test species:	flax (*Linum usitstissimum*), red clover (*Trifolium pratense)*, pea (*Pisum sativum*), carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa)*.
Soil:	sandy loam
Study design:	number of rates: 8 application rates + control; number of replicates: 4 replicates/rate for flax, red clover, carrot, perennial ryegrass and oats; 7 replicates/rate for pea. The total number of plants per application rate – 20 for flax, red clover, carrot, perennial ryegrass, oats and 21 for pea. Test termination: 21 days after the spraying.
Application rates:	- 0.6, 1.7, 5.2, 15.5, 46.5, 139.6, 418.8 and 1256.5 g test item/ha (i.e. 0.02, 0.07, 0.2, 0.6, 1.8, 5.3, 16.0, and 48.0 g imazamox/ha) – flax, red clover, pea, carrot, perennial ryegrass and oats. volume of deionised water used to prepare the highest rate: 300 L water/ha
Test conditions:	temperature: 18.0 – 26.5 °C, humidity: 47.1 – 89.9 %, lighting: 16 h light : 8 h dark; light intensity: 67.2 – 153.2 µE/m2/s; carbon dioxide concentration: 359 – 392 ppm
Statistical analysis:	ER25, ER50: probit analysis, nonlinear regression using the 4-parameter logistic. NOER: – emergence – Fisher's Exact Binomial Test with Bonferroni Correction, – shoot length – Shapiro - Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment. – shoot dry weight - Shapiro - Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment.
Endpoints:	ER_{25}, ER_{50}, NOER.

Results and conclusions:

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

Endpoint	**Flax** *Linum usitatissimum*	**Red clover** *Trifolium pratense*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Perennial ryegrass** *Lolium perenne*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER50	> 1256.5	> 1256.5	> 1256.5	> 1256.5	> 1256.5	> 1256.5
NOER	≥ 1256.5	≥ 1256.5	≥ 1256.5	≥ 1256.5	≥ 1256.5	≥ 1256.5
Shoot length (plants without roots)						
ER50	> 1256.5	> 1256.5 (1077.2 – >1256.5)	> 1256.5	> 1256.5 (835.6 –>1256.5)	465.7 (276.6 – 962.3)	726.7 (603.0 – 879.1)
NOER	139.6	139.6	418.8	139.6	46.5	139.6
Plant dry weight (plants without roots)						

ER50	> 1256.5 (1187.1 – > 1256.5)	1222.5 (665.8 – >1256.5)	> 1256.5	986.8 (658.0 – >1256.5)	62.3	545.6 (432.2 – 695.3)
NOER	46.5	139.6	≥ 1256.5	139.6	15.5	139.6

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

Endpoint	**Flax** *Linum usitatissimum*	**Red clover** *Trifolium pratense*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Perennial ryegrass** *Lolium perenne*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER50	> 48.0	> 48.0	> 48.0	> 48.0	> 48.0	> 48.0
NOER	≥ 48.0	≥ 48.0	≥ 48.0	≥ 48.0	≥ 48.0	≥ 48.0
Shoot length (plants without roots)						
ER50	> 48.0	> 48.0 (41.1 – > 48.0)	> 48.0	> 48.0 (31.9 – > 48.0)	17.8 (10.6 – 36.8)	27.8 (23.0 – 33.6)
NOER	5.3	5.3	16.0	5.3	1.8	5.3
Plant dry weight (plants without roots)						
ER50	> 48.0 (45.3 – > 48.0)	46.7 (25.4 – > 48.0)	> 48.0	37.7 (25.1 – > 48.0)	2.4	20.8 (16.5 – 26.6)
NOER	1.8	5.3	≥ 48.0	5.3	0.6	5.3

3. The test item, i.e. **CHR/H/IMA 40 SL** applied at rates ranging from 0.6 to 1256.5 g of the test item/ha had a varied impact on the growth and seedling emergence of flax, red clover, pea, perennial ryegrass, carrot and oats. The impact depended on the rate and species.

4. Plants of all analyzed species emerged at all of analyzed concentrations. The delayed seedling emergence of plant was not observed at cultivation of all analyzed species.

5. The test item at rates ranging from 0.6 to 1256.5 g/ha did not cause mortality of oats. The test item caused mortality of: flax (rate: 418.8 g/ha), red clover (rate: 1256.5 g/ha), carrot (rate: 1256.5 g/ha), pea (rate: 139.6 g/ha) and perennial ryegrass (rates: 139.6; 418.8 and 1256.5 g/ha).

6. On the basis of NOER, ER_{25} and ER_{50} values determined from the shoot length it was proved that the test item inhibit the process of growth of all analyzed species.

7. On the basis of NOER, ER_{25} and ER_{50} values determined from the shoot dry weight, it was proved that the test item inhibit the process of growth of flax, red clover, carrot, perennial ryegrass and oats.

8. Some phytotoxic symptoms were observed after 14 days of the exposure: - stunted growth (flax, red clover, pea, carrot, perennial ryegrass, oats)

- chlorosis (flax, pea, oats)

9. The following order of the test plant sensitivity was noticed:
perennial ryegrass > flax > red clover, carrot, oats > pea

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

Not performed, not required

A 2.8 KCP 10.8 Monitoring data

Not performed, not required