FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: CHR/H/TERIZ 650 WG

Product name(s): Undito 650 WG, Jotamun 650 WG, Metodus 650 WG

Chemical active substances:

Terbuthylazine,400 g/kg
Isoxaflutole, 100 g/kg
Mesotrione, 150 g/kg

Central zone

Zonal Rapporteur Member State: Poland

Core Assessment-renewal of authorisation
(Poland)

Applicant: PUH Chemirol Sp. z o.o.

Submission date: October 2019

Update: November 2021; December 2021; June 2023;

January 2024

Version history

When	What
October 2019	New data for isoxaflutole based on the renewal of active substance. New data marked in yellow
November 2021	The update of cumulative mixture toxicity risk assessment for aquatic organisms. New data marked in green.
November 2021	Evaluation by zRMS.
December 2021	The application rate in the GAP Table has been changed, based on new calculation in Part B8.
December 2021	The zRMS evaluation after limited of application rate by the applicant.
June 2023	Final Registration Report
January 2024	GAP table revision

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9 Ecotoxicology (KCP 10)

zRMS comments:

This report was prepared following renewal of the active substance Isaxoflutole.
As a result all authorisations of plant protection products containing Isaxoflutole have to be reviewed in order to comply with the new list of endpoints (EFSA 2016).
Evaluation presented in this report is focused on **Isoxaflutole.**
Overall conclusions of the zRMS are presented in commenting boxes below each point of the report.
Conclusions regarding two othe a.s.were nor taken into evaluation in the current dossier.
The combined risk assessment for birds and mammals was updated by zRMS.at MSs level.

December 2021:
It should be indicated that applicant in meantime changed the GAPTable by limitation of the application rate from 1 kg product/ha to only 0/8 kg product/ha
Due to the fact that applicant did not provide the risk assessment for lower rate tha risk asseesment for max. application rate of 1 kg product/ha is remained valid.

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs- evaluated by zRMS in November 2021

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	Maize (ZEAMX)	F	Mono and di-cotsweeds	Spray, medium sprayer	Spring BBCH 00, max. 3 days after sowing	a)1 b)1	n/a	a) 0.8 – 1.0 kg/ha b) 0.8 – 1.0 kg/ha	a) 0.52 kg a.s./ha (T 0.32 + I 0.08 + M 0.12) - 0.65 kg a.s./ha (T 0.4 + I 0.1 + M 0.15 b) 0.52 kg a.s./ha (T 0.32 + I 0.08 + M 0.12)- 0.65 kg a.s./ha (T 0.4 + I 0.1 + M 0.15	200-250	n/a								
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				

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

Critical GAP and overall conclusions, December 2021 January 2024 GAP table revision

Table 9.11

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	Maize (ZEAMX)	F	Mono and dicotsweeds	Spray, medium sprayer	Spring BBCH 00, max. 3 days after sowing	a)1 b)1	n/a	a) 0.8 kg/ha b) 0.8 kg/ha	a) 0.52 kg a.s./ha (T 0.32 + I 0.08 + M 0.12) b) 0.52 kg a.s./ha (T 0.32 + I 0.08 + M 0.12)	200-250	n/a		A	A	R	A	A	A	R
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 (field uses)																				
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
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(1) Numeration necessary to allow references
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(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

zRMS comments:

New GAP TABLE, December 2021

The risk assessment provided by the applicant and evaluated by zRMS-PL in November 2019 was concered on the max application rate of 1 kg product/ha which covered the risk assessment for lower rate of 0.8 kg product/ha. The reduction of the application rate was required by Section B8 and B10.
The risk mitigation measures for relevant organism remaind for 1 kg product/ha as no additional calculation were provided by the applicant.

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)

CHR/H/TERIZ 650 WG pose no unacceptable acute and long-term risk to birds used according to the label and pose no unacceptable acute and long risk for mammals.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

CHR/H/TERIZ 650 WG pose no unacceptable risk to aquatic organisms according to the label with appropriate 20 meter vegetative buffer zone and drift reducing techniques.

9.1.1.3 Effects on bees (KCP 10.3.1)

CHR/H/TERIZ 650 WG pose no unacceptable risk to bees according to the label

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

CHR/H/TERIZ 650 WG pose no unacceptable risk to NTA according to the label

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

CHR/H/TERIZ 650 WG pose no unacceptable risk to non-target soil meso- and macrofauna and microbial activity according to the label.

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

CHR/H/TERIZ 650 WG pose 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/TERIZ 650 WG in off-field areas, the TER values describing the risk for non-target plants following exposure to CHR/H/TERIZ 650 WG according to the GAP of the formulation CHR/H/TERIZ 650 WG achieve the acceptability criteria TER ≥ 5, with applying:

- 20 m buffer zone
- 5 m and the use of 75% drift reducing nozzles
- 10 m and use of 50% drift reducing nozzles

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

Not relevant

9.1.2 Grouping of intended uses for risk assessment

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

Table 9.1-2: Critical use pattern of CHR/H/TERIZ grouped according to crop, application rate, number of applications, timing, etc.

Grouping according to crop, application rate, number of applications, timing criterion			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
1	Maize BBCH 00 1000 g[Profuct]/ha* (covering 800 g product/ha)	crop, application rate, number of applications, timing,	crop, application rate, number of applications, timing,

9.1.3 Consideration of metabolites

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

Table 9.1-3 Metabolites of Terbuthylazine

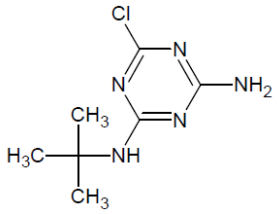
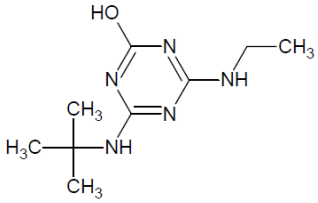
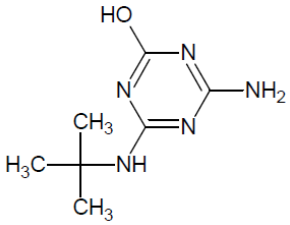
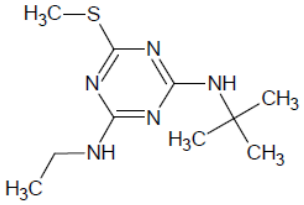
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Risk assessment required?
MT1 desethyl-terbuthylazine (GS 26379)	201.7		Soil (lab): max 25.1% AR Maximum occurrence observed in sediment/ water studies: 7.3 %	Yes
MT13 Hydroxy-terbuthylazine Or 2-hydroxy ter-buthylazine GS 23158	211.3		Soil (Lab): max 34.5 % AR Maximum occurrence observed in sediment/ water studies: 20.0 %	Yes
MT14 desethyl-hydroxyterbuthylazine or desethyl-2-hydroxy terbuthylazine GS 28620	183.2		Soil (Lab): mx 1.7% AR Maximum occurrence observed in sediment/ water studies: N/A (soil metabolite only)	Yes
MT26	241.4		Maximum occurrence observed in sediment/ water studies: 7.4 %	Yes

Table 9.1-4 Metabolites of Isoxaflutole

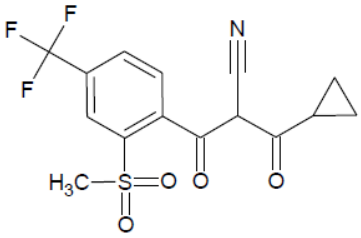
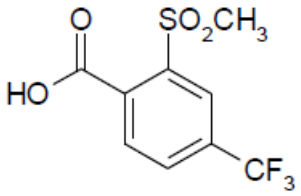
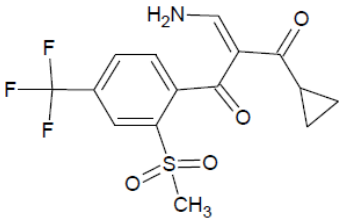
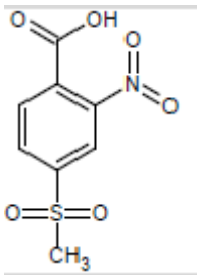
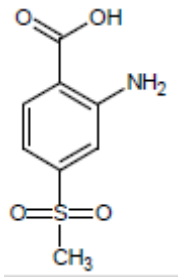
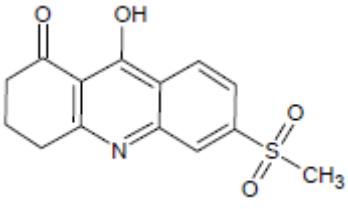
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
RPA 202248	359.32		Soil (lab): max 96.4 % AR Maximum occurrence observed in sediment/ water studies: 70.3 %	Yes
RPA 203328	268.22		Soil (Lab): max 90 % AR Maximum occurrence observed in sediment/ water studies: 10.8 %	Yes
RPA 205834	361.34		Soil (Lab): mx 2.3 % AR Maximum occurrence observed in sediment/ water studies: 26.4%	Yes

Table 9.1-5 Metabolites of Mesotrione

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
MNBA	245		Soil (lab): max 57.2 % AR Maximum occurrence observed in sediment/ water studies: 7.9 %	Yes
AMBA	215		Soil (Lab): max 9.7 % AR Maximum occurrence observed in sediment/ water studies: 24.6 %	Yes
SYN546974	291		Soil (Lab): mx 1E-10 % AR Maximum occurrence observed in sediment/ water studies: 33%	Yes

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

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

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

Species	Substance	Exposure System	Results	Reference
Bobwhite quail	Terbuthylazine	Oral 1 d Acute	LD50 = 1236 mg a.s./kg bw	EFSA Journal 2011; 9(1):1969
Mallard duck	Terbuthylazine	Dietary 8 d Short-term	LC50 > 395 mg a.s./kg bw/d	EFSA Journal 2011; 9(1):1969
Japanese quail	Terbuthylazine	Dietary Reproductive toxicity	NOEL = 13.85 mg a.s./kg bw/d	EFSA Journal 2011; 9(1):1969
Bobwhite quail	Isoxaflutole	Oral 1 d Acute	LD50 = 2150 mg a.s./kg bw	EFSA Journal 2016;14(3):4416
Mallard duck	Isoxaflutole	Dietary 8 d Short-term	LC50 > 5000 mg a.s./kg bw/d	EFSA Journal 2016;14(3):4416
Bobwhite quail	RPA 202248	Dietary Reproductive toxicity	NOEL = 25 mg a.s./kg bw/d	EFSA Journal 2016;14(3):4416
Bobwhite quail (Colinus virginianus)	Mesotrione	Oral 1 d Acute	LD50>2000 mg a.s./kg bw (corrected to 3776 mg a.s./kg bw)	EFSA Journal 2016;14(3):4419
Mallard duck (Anas platyrhynchos)	Mesotrione	Dietary 8 d Short-term	LC50>5200 mg/kg diet	EFSA Journal 2016;14(3):4419
Mallard duck (Anas platyrhynchos)	Mesotrione	Dietary Reproductive toxicity	NOEL= 20.6 mg a.s./kg bw/d	EFSA Journal 2016;14(3):4419

9.2.2 Risk assessment for spray applications

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

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

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

Table 9.2.2.1.-1: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/H/TERIZ in maize for the Terbuthylazine.

Intended use	**Maize**				
Active substance/product	Terbuthylazine				
Application rate (g/ha)	1 X 400 g a.s/ha				
Acute toxicity (mg/kg bw)	1236				
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	63.52	19.5
Reprod. toxicity (mg/kg bw/d)	13.85				
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	13.74	1.0
Bare soil BBCH < 10	Small granivorous bird “finch” Small seeds 100% weed seeds	11.4	1.0	-	5.7
Bare soil BBCH < 10	Small insectivorous bird “wagtail” ground invertebrates without interception 100% soil dwelling invertebrates	5.9	1.0	-	11.1
Bare soil BBCH < 10	Small omnivorous bird “lark” Combination (ground invertebrates without interception) 50% seeds, 50% ground arthropods	8.2	1.0	-	8.0

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 9.2.2.1.-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/H/TERIZ in maize for the Isoxaflutole.

Intended use	**Maize**				
Active substance/product	Isoxaflutole				
Application rate (g/ha)	1 X 100 g a.s/ha				
Acute toxicity (mg/kg bw)	2150				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1.0	15.88	135.4
Reprod. toxicity (mg/kg bw/d)	25 (for RPA 202248)				

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	3.43	7.3
Tier 1					
Bare soil BBCH < 10	Small granivorous bird "finch" Small seeds 100% weed seeds	11.4	1.0	0.6	41.66
Bare soil BBCH < 10	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	5.9	1.0	0.31	83.33
Bare soil BBCH < 10	Small omnivorous bird "lark" Combination (ground invertebrates without interception) 50% seeds, 50% ground arthropods	8.2	1.0	0.43	58.14

zRMS comments:

zRMS verified the risk assessment for the reviewed a.s.TFS for birds.
The risk is considered acceptable.

Table 9.2.2.1-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/H/TERIZ in maize for the Mesotrione.

Intended use	**Maize**				
Active substance/product	Mesotrione				
Application rate (g/ha)	1 X 150 g a.s/ha				
Acute toxicity (mg/kg bw)	2000				
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	23.82	84.0
Reprod. toxicity (mg/kg bw/d)	20.6				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small omnivorous bird	64.8	1.0	5.15	4.0
Bare soil BBCH < 10	Small granivorous bird "finch" Small seeds 100% weed seeds	11.4	1.0	-	22.7
Bare soil BBCH < 10	Small insectivorous bird "wagtail" ground inverte-brates without interception 100% soil dwelling inverte-	5.9	1.0	-	43.9

	brates				
Bare soil BBCH < 10	Small omnivorous bird "lark" Combination (ground invertebrates without interception) 50% seeds, 50% ground arthropods	8.2	1.0	-	31.6

Two major metabolites were identified in the plant metabolism studies, NMSBA (in wheat) and AMBA (in maize; mainly in conjugated forms). Both metabolites are observed in mammalian metabolism studies it is reasonable to assume that their risks to birds could also therefore be considered to be covered by the parent risk assessment. However, no data on hen metabolism or bird toxicity data are available and therefore, as a conservative approach, equal toxicity of the two metabolites as compared to the parent compound is assumed. The DDD for the metabolites are adjusted by taking into account the molecular weight of the metabolites and the formation rates:

AMBA
- M(AMBA) / M(mesotrione) = 215.2 g/mol / 339.3 g/mol = 0.63 g/mol
- The highest formation rate in the plant metabolism study was seen in maize forage and fodder with AMBA accounting for *ca.* 12% TRR and *ca.* 28% TRR, respectively.

NMBA
- M(NMBA) / M(mesotrione) = 245.2 g/mol / 339.3 g/mol = 0.72 g/mol
- The highest formation rate in the plant metabolism study was seen in wheat forage with NMBA accounting for 33% TRR.

Adjusted DDD = Application rate × shortcut value × M(metabolite)/M(mesotrione) × formation rate.
Additionally, the DDD is adjusted by the ftwa for the long-term risk assessment.

Table 9.2.2.1-4: Acute and long-term TER calculations at the screening step for AMBA and NMBA

Metabolite	EFSA Crop category	GAP Scenario	Indicator species	Shortcut value[1]	MAF[1]	DDD[1]	TER	Trigger[2]
Acute exposure risk								
AMBA	Maize	1 x 0.150 kg a.s./ha	Small omnivorous bird	158.8	1.0	4.20	>476	10
NMSBA	Maize	1 x 0.150 kg a.s./ha	Small omnivorous bird	158.8	1.0	5.66	>353	10
Long-term exposure risk[3]								
AMBA	Maize	1 x 0.150 kg a.s./ha	Small omnivorous bird	64.8	1.0	0.91	13.2	5
NMBA	Maize	1 x 0.150 kg a.s./ha	Small omnivorous bird	64.8	1.0	1.18	9.8	5

[1] Values defined in EFSA 2009 Guidance document for birds and mammals
[2] Acute toxicity based on an LD_{50} >2000 mg a.s/kg bw/d. Long-term toxicity based on NOEL = 20.6 mg/kg bw/d. Endpoints taken from Review Report; SANCO/1416/2001-Final, 14 April 2003
[3] ftwa = 0.53, applied to long term DDD

Combined risk assessment for CHR/H/TERIZ mixture

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

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

where:

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

TER_A terbuthylazine	**TER_A isoxaflutole**	**TER_A mesotrione**	**$TER_{mix\ birds\ acute}$**	**Trigger value**
19.5	135.4	84.0	**14.22**	**10**

Conclusion
The calculated TERmix value is higher than the trigger value of 10, indicating CHR/H/TERIZ does not posses unacceptable acute risk for birds. No further risk refinement is needed. The combined risk for TER long term is not necessary since these is no agreed enpoint for long term toxicity for isoxaflutole.

zRMS comments:

No additional calculations are required. The calculated TERmix value is higher than the trigger value of 10, indicating CHR/H/TERIZ does not posses unacceptable acute risk for birds

9.2.2.2 Higher-tier risk assessment

Since for all three active substance acute TER is above 10 and TER long term is above 5, no higher-tier risk assessment is required.

zRMS comments:

zRMS recalculated the TERmix for long-term exposure.

TER_{LT}terbuthylazine	**TER_{Lt} isoxaflutole**	**TER_{Lt} mesotrione**	**$TER_{mix\ birds\ long\text{-}term}$**	**Trigger value**
5.7* (finch)	7.3	22.7	**2.81**	5
8 (sklylark)	58.14	31.6	5.78	
11.2 (wagtail)	83.33	43.9	8.08	

The trigerr value is below 5 for finch indicating further refinement.
Based on the field study by Wolf 2005 evaluated in the DAR for TBT the finch species was not present in early growth stages in maize. Therefore, the risk for omnivorus birds – sklylark and wagtail were considered in refined TERmix calculatios by zRMS.
TERmix for sklylark and wagtail ws above 5 iddicating an acceptable risk to birds form combined exposure of 3 active substances.

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/TERIZ is not a product 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 151, Terbuthylazine 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 on maize:

Effective application rate (g/ha)	=	400		
Acute toxicity (mg/kg bw)	=	1236	quotient	=	0.32
Reprod. toxicity (mg/kg bw/d)	=	13.85	quotient	=	29

With a K(f)oc of 79.8, Isoxaflutole 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 on maize:

Effective application rate (g/ha)	=	100		
Acute toxicity (mg/kg bw)	=	2150	quotient	=	0.05
Reprod. toxicity (mg/kg bw/d)	=	25	quotient	=	4

With a K(f)oc of 156.7, Mesotrione 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 on maize:

Effective application rate (g/ha)	=	150		
Acute toxicity (mg/kg bw)	=	2000	quotient	=	0.075
Reprod. toxicity (mg/kg bw/d)	=	20.6	quotient	=	7.3

Hazard quotient for Puddle scenario for Terbuthylazine, Isoxaflutole and mesotrione are below trigger value 50, so no specific calculations of exposure and TER are necessary.

zRMS comments:

We agree with hazard quotient for Puddle scenario for Terbuthylazine, Isoxaflutole and mesotrione are below trigger value 50, so no specific calculations of exposure and TER are necessary

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Terbuthylazine amounts to 3.4 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required. For other 2 active substances (mesotrione and Isoxaflutole) the log P_{ow} is below trigger value of 3, so risk assessment for effects due to secondary poisoning are not required.

Risk assessment for earthworm-eating birds via secondary poisoning

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

Table 9.2-2: Assessment of the risk for earthworm-eating birds due to exposure to Terbuthylazine via bioaccumulation in earthworms (secondary poisoning) for the intended use in maize

Parameter	Terbuthylazine	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.4581	Escape ver 2.
log P_{ow} / P_{ow}	3.4/2512	Confirmatory Data Terbuthylazine November 2015
Koc	151	Confirmatory Data Terbuthylazine November 2015
foc	Organic carbon content of soil (0.02 taken as a default value)	Default
BCF_{worm}	10.25	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.12 \times P_{ow}) / foc \times Koc$
PEC_{worm}	4.695525	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	4.93	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	13.85	EFSA Journal 2011; 9(1):1969
TER_{lt}	**2.8**	Below trigger value 5. Risk refinement required

TER values shown in bold fall below the relevant trigger.

Risk refinement for earthworm-eating birds due to exposure to Terbuthylazine via bioaccumulation in earthworms (secondary poisoning) for the intended use in maize

To address this risk, the joint Notifiers have submitted an earthworm bioaccumulation study (Batscher 2007 (Section B 9.1.3.3.2)) to measure more realistic body burdens within earthworms from the proposed uses. Therefore, a new refined risk assessment has been performed using this measured BAF (0.86) in place of the BCF calculated in the TIER I assessment. The parameters used in the risk assessment and the resultant TER are summarised in Table 9.2-7.

Table 9.2-7 Risk refinement for earthworm-eating birds due to exposure to Terbuthylazine via bioaccumu-lation in earthworms (secondary poisoning) for the intended use in maize

Parameter	Terbuthylazine	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.4581	Escape ver 2 model
log P_{ow} / P_{ow}	3.4/2512	DAR Terbuthylazine
Koc	151	DAR Terbuthylazine

Parameter	Terbuthylazine	comments
foc	Organic carbon content of soil (0.02 taken as a default value)	Default
BAF	0.86	DAR Terbuthylazine-Vol 3 B9 2010
PEC_{worm}	0.393966	$PEC_{worm} = PEC_{soil} \times BAF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.4136643	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	13.85	EFSA Journal 2011; 9(1):1969
TER_{lt}	33.45	Above trigger value 5

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

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

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

Parameter	Terbuthylazine	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.0002046	Focus STEP 3 R1 Stream
BCF_{fish}	34	EFSA Journal 2011; 9(1):1969
BMF	Not relevant	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.0069564	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.0011060676	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	13.85	EFSA Journal 2011; 9(1):1969
TER_{lt}	12.522	

TER values shown in bold fall below the relevant trigger.

zRMS comments:

No additional calculation are 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 risk and long term to birds from the proposed uses of terbuthylazine, isoxaflutole, mesotrione was found acceptable.
With regards to the risk to earthworm-eating birds an acceptable risk was identified for the proposed uses of terbuthylazine (based on an earthworm bioaccumulation study).
An acceptable risk could be identified for fish-eating birds for the proposed uses.

CHR/H/TERIZ 650 WG pose no unacceptable risk to birds with according to the label.

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 Terbuthylazine/Isoxaflutole/mesotrione and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Section 6 (Mammalian Toxicology) of this report (new studies).

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

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

Species	Substance	Exposure System	Results	Reference
Rat	Terbuthylazine	Acute	LD_{50} = 1000 mg/kg bw	EFSA Journal 2011; 9(1):1969
Rat	Terbuthylazine	Long-term	NOAEL = 3.3 mg/kg bw/d	EFSA Journal 2011; 9(1):1969
Rat	isoxaflutole	Acute	LD50 =5000 mg/kg bw	EFSA Journal 2016;14(3):4416
Rat	isoxaflutole	Long term	NOAEL=2 mg/kg bw	EFSA Journal 2016;14(3):4416
Rat	mesotrione	Acute	LD50>5000 mg a.s./kg bw	EFSA Journal 2016;14(3):4419
Rat	mesotrione	Long term	NOEL=0.3 mg a.s./kg bw/d	EFSA Journal 2016;14(3):4419

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 on the maize crop .

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

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

Table 9.3.2.1-1: First-tier assessment of the acute and long-term/reproductive risk for mammals due terbuthylazine the use of CHR/H/TERIZ in maize

Intended use	maize				
Active substance/product	Terbuthylazine				
Application rate (g/ha)	1 × 400				
Acute toxicity (mg/kg bw)	1000				
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	47.36	21.1
Reprod. toxicity (mg/kg bw/d)	3.3				
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	10.24	**0.32**
Bare soil BBCH < 10	Small omnivorous mammal "mouse" Combination (ground invertebrates without interception) 50% weed seeds, 50% ground arthropods	5.7	1.0	-	**2.7**

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

Since the TER terbuthylzine long term is below trigger value of 5, the risk refinement in necessary. Such risk refinement is presented in point 9.3.2.2

Table 9.3.2.1-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to isoxaflutole the use of CHR/H/TERIZ in maize

Intended use	maize
Active substance/product	isoxaflutole
Application rate (g/ha)	1 × 100
Acute toxicity (mg/kg bw)	5000
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1.0	11.84	422.3
Reprod. toxicity (mg/kg bw/d)	2				
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	2.56	**0.78**
Bare soil BBCH < 10	Small omnivorous mammal "mouse" Combination (ground invertebrates without interception) 50% weed seeds, 50% ground arthropods	5.7	1.0	-	6.6

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 9.3.2.1-3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to mesotrione the use of CHR/H/TERIZ in maize

Intended use	maize				
Active substance/product	mesotrione				
Application rate (g/ha)	1 × 150				
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	17.76	281.5
Reprod. toxicity (mg/kg bw/d)	0.3				
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	3.84	**0.08**
Bare soil BBCH < 10	Small omnivorous mammal "mouse" Combination (ground invertebrates without interception) 50% weed seeds, 50% ground arthropods	5.7	1.0	-	**0.7**

9.3.2.2 Higher-tier risk assessment

Below is presented only conclusion for risk assessment. The details of weight of evidence is presented in the report ***Long-term Mammalian Risk Assessment for Mesotrione Jennifer Duncan and Rachel Clarke; Exponent, 2016.***

The following higher tier risk assessment focuses on the wood mouse (omnivorous) as relevant focal species for the proposed use of terbuthylazine and mesotrione on maize. For pre-emergence/early post-

emergence maize (BBCH < 10) hare are not expected to be presented in the crop, due to the lack of a vegetative food source, thus hare have not been considered for this scenario.

Radio-tracking studies of wood mice caught in arable land have been conducted in the UK and are reported by Prosser (2010). The PT for wood mice for the proposed uses of terbuthylazine on pre-emergence/early post-emergence maize (i.e. bare soil; BBCH < 10). The results of this study indicate the 90th percentile PT of wood mice in newly drilled cereals fields (i.e. bare soil) to be 0.51 (data for consumers only). **Higher-tier risk assessment for Terbuthylazine**

Table 9.3.2.2-1: Higher-tier assessment of the long term risk for mammals due to the terbuthylazine use of CHR/H/TERIZ in maize – refined parameters (*) are further described and justified in the text

Intended use	Maize
Active substance/product	Terbuthylazine
Application rate (g/ha)	1 X 400
Reprod. toxicity (mg/kg bw/d)	3.3 mg/kg bw/d
TER criterion	5

Focal species	**Food category, % in diet**	**FIR/bw$_a$**	**RUD$_a$**	**MAF$_m$ × TWA**	**PT^b**	**Ftwa**	**DDD$_m$ (mg/kg bw/d)**	**TER$_{lt}$**
Wood mice	Weed seeds, 50 %	0.24	23.8	1.0	0.51	0.53	0.3085	
	Ground arthropods, 50%	0.24					0.3085	
	whole diet						0.617	5.35

PD: proportion of food item in the diet; RUD: residues per unit dose; MAF: multiple application factor; Ftwa: time weighted average factor; PT: proportion of diet obtained in the treated area; DDD: daily dietary dose; TER: toxicity exposure ratio
[a] EFSA default values
[b] Based on radio tracking work by Prosser (2010)

Higher-tier risk assessment for mesotrione

Risk refinement was performed by expert Exponent and presented in a separate document: Jennifer Duncan and Rachel Clarke (EXPONENT), Long-term Mammalian Risk Assessment for Mesotrione, Exponent Project No.: 1502169.UK0; 2016.
A brief summary of expert opinion is presented below:

Relevant Long-term endpoint:

In terms of the long-term endpoint for use in the risk assessment the following text is included in the RAR (2015):
There is no new data presented regarding the reproductive/developmental toxicity to mammals. However, the relevant reproductive endpoint for the ecotoxicology risk assessment has been considered and is discussed further under section B.6 (Toxicology and metabolism). ***The NOAEL for reproductive performance is 1.2 mg/kg bw/d****. It is concluded that the NOAEL of 1.2 mg/kg bw/d specific to F0 and F1 is appropriate for the reproductive risk assessment. Given the proposed GAP and persistence of mesotrione, effects observed in the F2 generation are considered less relevant. In this NOAEL value both of the effects on litter size and plasma tyrosine level have been considered, along with the uncertainties of lacking data on female's tyrosine level. It should be noted that this value is accompanied by a 6.8 % reduction in rat litter size but that this reduction in litter size is not statistically significant.*
Therefore the NOAEL of 1.2 mg/kg bw/d has been used in the risk assessment.

„The lowest first tier TER is for small herbivorous mammals "voles". Although voles are listed as relevant focal species, it is widely acknowledged that voles are not relevant for arable crops. Gurney, *et al.* (1998) reports the feeding habit of field voles (*Microus agrestis*) to be mainly rough, ungrazed grassland, including thick grass ground cover. In a two year study of small mammals on Scottish arable land and set-aside (Rodgers 1993[1]) 159 field voles were caught, which were reported to have an almost exclusive preference for rough grassland and were completely absent from the wood and also infrequent in set-aside and crops. Field voles prefer dense grassy habitats in which they can conceal runways (Eldridge 1971[1]).
In a three year study of small mammals on an arable farm in Oxfordshire Tew (1994[1]) failed to capture any field voles away from hedgerows around cereal fields. In the Boxworth project, field voles were occasionally caught in the fields but this was restricted to areas with dense ground cover, such as patches infested with blackgrass (Johnson *et al.*, 1992[1]).

Furthermore, information from DEFRA's research project on "Estimating wildlife exposure to pesticides in crops: additional scenarios and data" (2009) supports the non-relevance of the vole. The aim of this work was to provide further information on use of crops by wildlife by extensive surveying and by review of public literature. The following table taken from this report shows the number of captures of small mammals in the various habitat types.

Table Captures of small mammals during 11,000 trap-events in different agricultural habitats (Table 3 from DEFRA 2009)

	Captures per 100 trap events						
	Potatoes	**Arable hedge**	**Cereal**	**Sugar beet**	**Other non-crop**	**Orchard hedge**	**Orchard crop**
Field vole	0	0.15	0.08	0	0	1.52	1.31
Pygmy shrew	0.02	0.53	0.23	0	0.34	1.82	0.51
Common shrew	0.38	6.43	1.36	1.00	6.38	3.33	1.85
Bank vole	0.02	6.43	1.44	0	1.55	4.24	0.27
Woodmouse	0.82	8.06	7.04	0.50	2.76	7.88	2.49
Total	1.24	21.6	10.15	1.5	11.03	18.79	6.43
Trap events in this habitat	5020	2630	2570	200	580	330	2970

Although the study did not specifically include maize fields, the results clearly show that wood mice are much more prevalent in arable crops (including potatoes, cereal and sugar beet) than voles. A follow on research project by DEFRA, on "Small mammal activity in soft fruit, cane fruit and top fruit orchards" (2012), states that wood mice are omnivorous and forage above ground, while shews and voles tend to forage beneath thatch and litter layers.
Taking all of the above into consideration and the fact that maize fields do not contain thatch and litter layers, voles are not considered to be a relevant focal species. Instead the wood mouse is considered a relevant focal species. The wood mouse is widespread and common in the agricultural landscape and occurs in a number of farmland habitats (Jensen & Hansen 2003[2]). The wood mouse was also considered to be the most relevant small mammal focal species in the RAR (2015), based on observations from field monitoring studies submitted by the Notifier.

However, as voles are not considered to be appropriate focal species, consideration should be given to the relevance of another herbivorous focal species. EFSA's Bird and Mammal Guidance Document (2009) identifies the European rabbit (Oryctolagus cuniculus) as the representative species for large herbivorous mammals. This species is abundant across Europe and may be associated with arable crops. Gurney et al. (1998) reports the feeding habitat of the rabbit to be areas of short grass; naturally occurring, dry heaths or closely grazed agricultural pastures with secure refuge nearby. The brown hare (Lepus europaeus) is also widespread and abundant across Europe. It is found in all sorts of open agricultural landscape such as

intensively farmed areas, areas with mixed farming and pastoral landscapes (Northern Zone Guidance). Gurney et al. (1998) reports the preferred feeding habitat of the brown hare to be arable land where cereals predominate with available grass fields for summer feeding. Based on this, the brown hare is considered the most relevant focal species to represent herbivorous mammals in the following risk assessment.

The brown hare was also considered to be the most relevant herbivorous mammal focal species in the RAR (2015), based on observations from field monitoring studies submitted by the Notifier.
Overall the following higher tier risk assessment focuses on the wood mouse (omnivorous) and the brown hare (herbivorous) as relevant focal species for the proposed use of mesotrione on maize. This selection of focal species is in line with the approach taken in the RAR (2015), which considered use of mesotrione on maize at BBCH 12-18. For pre-emergence/early post-emergence maize (BBCH < 10) hare are not expected to be presented in the crop, due to the lack of a vegetative food source, thus hare have not been considered for this scenario.

Determination of PT for focal species

The first tier risk assessment assumes that PT equals 1.0, i.e. the mammal obtains all its food from the treated crop. However, it is likely that the focal species will not feed exclusively in maize fields – part of its diet being obtained in other crops/habitats (i.e. PT < 1.0).
Radio-tracking studies of wood mice caught in arable land have been conducted in the UK and are reported by Prosser (2010). The PT for wood mice for the proposed uses of mesotrione on pre-emergence/early post-emergence maize (i.e. bare soil; BBCH < 10) and post-emergence maize (BBCH 10 – 18) can be refined using this data. The results of this study indicate the 90th percentile PT of wood mice in newly drilled cereals fields (i.e. bare soil) to be 0.51 (data for consumers only). The study by Prosser (2010) does not include a PT value specifically for wood mice in maize fields, however, data on potatoes and established cereals, indicates the maximum 90th percentile PT to be 0.82 (for consumers only), thus this value has been applied to the risk assessment for maize at BBCH 10 – 18, as a worst-case approach.

Prosser (2010) also reports radio-tracking data for brown hare, although again, data specifically on maize are not available. The 90th percentile PT values ranged from 0.88 to 1.0 for "all crops" during spring/summer (data for consumers only). Without specific data on maize crops, as a worst-case approach a PT value of 1.0 has been applied to the risk assessment for hare. However, as brown hare have large home ranges (29 - 138 ha reported in the Northern Guidance Document and 20 – 40 ha reported by Gurney *et al.* 1998) this implies that hare would not feed only in the treated field over a long-term period.
It should also be noted that, it would be more appropriate to use mean rather then 90th percentile PT values in a long-term risk assessment, along with the general approach taken in EFSA (2009). However, mean values have not been presented in the report by Prosser (2010).

Mesotrione residue decline in maize

Data from field trials in maize (White, 2001) are discussed in the RAR (2015) in relation to refining the mammalian risk assessment. Mesotrione was applied in 4 field trials at maize growth stage of 14-17 and sampled on day 0, 1, 3-4, 7 and 14. Three of the four trials showed a marked decrease in the residue to ≤ 5% and < 0.01 mg/kg (LOQ) after 1 day and 1 week, respectively. In the 4th trial (no. 396) residues after 1 day were still 92%. However, this is clearly an anomaly, as residue in all other sites were a maximum of only 5% on Day 1 and in trial no. 396 after 3 days residues had dropped to 0.2%, which is in line with the data for the other 3 sites. Overall, mesotrione residues on maize declined to <1% after 3-4 days.

In the RAR, the RMS raises concerns that, due to the lack of a full comparison of the environmental conditions in the study conducted in Canada with those in Europe, it is not possible to be sure that the relevant worst-case conditions in Europe are covered. Therefore, we have conducted a full comparison with the environmental conditions in the Canadian trial sites (taken from Table B.9.2.2-11 of the RAR B.9 (PPP)) with those in the central European Member States where registration is sought (Poland, Romania, Hungary, Slovakia and Czech Republic), refer to Table below.

Comparison of climatic conditions of Canadian trials to Central Europe

Parameter	Canadian trial sites	Poland	Romania	Hungary	Slovakia	Czech Republic
Latitude*	Quebec: 53°N Ontario: 50°N	52.82°N	45.37°N	46.94°N	48.66°N	50.02°N
Annual average precipitation (mm/year)[1]	537	600	637	589	824	677
Precipitation in June-July	Long term average: 7.9-12.4 mm/m in June-July No. 394: 8.9-12.4 mm No. 395: 8.9-12.4 mm No. 396: 7.9-9.0 mm No. 397: 7.9-9.0 mm	Long term average: 70.09- 83.59 mm/m [2]	Long term average: 92.4-109.06 mm/m [2]	Long term average: 67-77 mm/m [2]	Long term average: 95.1-97.2 mm/m [2]	Long term average: 82-89.7mm/m [2]
Temperature in June-July (min-max)	Long term average: 10.7-26.1°C No. 394: 12.7-24.1 °C No. 395: 12.7-24.1 °C No. 396: 13.2-23.8 °C No. 397: 13.4-24.7 °C	Long term average: 15.83-18.04°C [2]	Long term average: 16.7-18.7 °C [2]	Long term average: 18.5-20.3°C [2]	Long term average: 15.8-17.7°C [2]	Long term average: 15.4-17.3°C [2]

Notes: m- month; * Latitude influences day length and quality of daylight.
[1] Food and Agriculture Organization
[2] Climatic Research Unit (CRU) of University of East Anglia (UEA)

The soil types in Canada are standard agricultural soils and the growing regions in central Europe (Poland, Romania, Hungary, Slovakia and Czech Republic) are not expected to deviate significantly with respect to soil type. Poland at latitude 52.82°N and Czech Republic at latitude 50.02°N are equivalent to the Canadian trial sites with respect to daylight hours and quality; latitudes for Romania, Hungary and Slovakia result in minimally shorter days which would not be expected to have a significant impact on residue decline. The average temperatures in June and July at the Canadian trial sites are comparable to the long term average of the Central European countries. However, the average precipitation in June and July at the Canadian trial sites was lower than for the Central European countries. As a result, the residue situation is likely to be more critical in the Canadian trials as there will be less wash-off to affect residue decline. Consequently, it would be expected that for central European countries with a higher average rainfall during June and July that residue decline would occur in at least the same timeframe as the Canadian trials, if not more rapidly.

On the basis of the available climatic data in can be considered that trials conducted in Canada would be broadly representative of the conditions experienced in central Europe. The only potential deviation is the higher rainfall that might be expected in central Europe. On this basis, it is concluded that residue decline in Canada would be expected to proceed at a similar or slightly slower rate than in central Europe and can be relied on for the purposes of refining the mammalian risk assessment.

Due to the rapid decline of the active substance and the spacing of the sampling points, it is not possible to determine a reliable quantitative estimate of the DT_{50}. However, it is clear that the DT_{50} is much less than one day and as a worst-case approach a DT_{50} of 1 day, relating to a twa of 0.07, has been applied to the risk assessment.

Table 9.3-4: Higher-tier assessment of the long term risk for mammals due to the mesotrione use of CHR/H/TERIZ in maize – refined parameters are further described and justified in the text

Intended use **Active substance/product** **Application rate (g/ha)**	Maize Mesotrione 1 X 150
Reprod. toxicity (mg/kg bw/d)	0.3 mg/kg bw/d

TER criterion	5							
Focal species	**Food category, % in diet**	**FIR/bw$_a$**	**RUD$_a$**	**MAF$_m$ × TWA**	**PT^b**	**Ftwa**	**DDD$_m$ (mg/kg bw/d)**	**TER$_{lt}$**
Wood mice	Weed seeds, 50 %	0.24	23.8	1.0	0.51	0.07 (based on DT50 1 d)	0.015	
	Ground arthro-pods, 50%	0.24					0.015	
	whole diet						0.03	10
Intended use	Maize							
Active substance/product	Mesotrione							
Application rate (g/ha)	1 X 150							
Reprod. toxicity (mg/kg bw/d)	1.2 mg/kg bw/d*							
TER criterion	5							
Focal species	**Food category, % in diet**	**FIR/bw$_a$**	**RUD$_a$**	**MAF$_m$ × TWA**	**PT^b**	**Ftwa**	**DDD$_m$ (mg/kg bw/d)**	**TER$_{lt}$**
Wood mice	Weed seeds, 50 %	0.24	23.8	1.0	0.51	0.53	0.116	
	Ground arthro-pods, 50%	0.24					0.116	
	whole diet						0.232	5.17

PD: proportion of food item in the diet; RUD: residues per unit dose; MAF: multiple application factor; Ftwa: time weighted average factor; PT: proportion of diet obtained in the treated area; DDD: daily dietary dose; TER: toxicity exposure ratio
[a] EFSA default values
[b] Based on radio tracking work by Prosser (2010)
[c]According to **EFSA Journal 2016;14(3):4419** From the results of 2 monitoring studies a maximum PT of 0.139 has been taken for the omnivorous wood mouse in early maize for use in risk assessment
***** *There is no new data presented regarding the reproductive/developmental toxicity to mammals. However, the relevant reproductive endpoint for the ecotoxicology risk assessment has been considered and is discussed further under section B.6 (Toxicology and metabolism). The NOAEL for reproductive performance is 1.2 mg/kg bw/d. It is concluded that the NOAEL of 1.2 mg/kg bw/d specific to F0 and F1 is appropriate for the reproductive risk assessment. Given the proposed GAP and persistence of mesotrione, effects observed in the F2 generation are considered less relevant. In this NOAEL value both of the effects on litter size and plasma tyrosine level have been considered, along with the uncertainties of lacking data on female's tyrosine level. It should be noted that this value is accompanied by a 6.8 % reduction in rat litter size but that this reduction in litter size is not statistically significant.*

ZRMS comments:

Refined reproductive risk assessment for wood mouse based on the relevant diet and PT values was provided in the previous zRMS's evaluation of the product Metodus 650 WG and is presented accordinigly below:

Focal species	**Food category, % in diet**	**FIR/bw**	**RUD$_m$ × DF (mg/kg food)**	**MAF$_m$ × TWA**	**PT**	**DDD$_m$ (mg/kg bw/d)**	**TER$_{lt}$**
Wood mouse (*Apodemus sylvaticus*) BBCH 00-05 **April**	Inv., 45% [d)]	0.6	7.5 a)	1 × 0.53	0.10	0.016	-
	Worms, 26%		0.1546 [b)]	1 × 1.0	0.10	0.00036	-
	Weeds, 24%		28.7 [a)] × 1	1 × 0.53	0.10	0.032	-
	Seeds, 5% [c)]		40.2 [a)] × 1	1 × 0.53	0.10	0.0095	-
	NOEL=0.3 mg a.s/kg bw						

	whole diet	0.019	**15.78**

[a)] RUD value in accordance with Guidance of EFSA – Risk assessment for birds and mammals (No EFSA-Q-2009-00223, 17 December 2009).
[b)] PEC_{worm} as predicted based on $PEC_{soil,\ 21\text{-day twa, PT value based on Project DEFRA}}$

The trigger value is above 5 indicating an acceptable risk for mammals. This value will be used in the TERmix-long-term by zRMS in the current dossier.

Combined risk assessment for CHR/H/TERIZ mixture

Since Terbethylazine, mesotrione and isoxaflutole have different effects on mammals it is not possible to calculate TERmix for long term mammals.

zRMS comments:

zRMS recalculated the refined TERmix for long-term exposure for wood mouse

TER_{LT}terbuthylazine	**TER_{Lt} isoxaflutole**	**TER_{Lt} mesotrione**	**$TER_{mix\ birds\ long\text{-}term}$**	**Trigger value**
5.35	6.6	15.78	27.02	5

TERmix for wood mouse is above 5 indicating an acceptable risk to mammals form combined exposure of 3 active substances.

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 for terbuthylazine

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 151, Terbuthylazine 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 on maize

Effective application rate (g/ha) =400
Acute toxicity (mg/kg bw) =1000 quotient = 0.4
Reprod. toxicity (mg/kg bw/d) =3.3 quotient = **121**

With a K(f)oc of 151, Terbuthylazine belongs to the group of less sorptive substances. Since the ratio of effective application rate (400 g/ha) to relevant endpoint (3.3 mg/kg bw/d) exceeds the critical value of 50 for at least one use scenario, a quantitative risk assessment (calculation of TER values) is necessary and presented in Table

Table 9.3.2.3-1: Assessment of the risk for mammals due to exposure to Terbuthylazine via contaminated drinking water in puddles

Intended use	Maize				
Active substance	Terbuthylazine				
Application rate (g/ha)	1 × 400				
Reprod. toxicity (mg/kg bw/d)	3.3				
TER criterion	5				
Soil-relevant applic. rate (g/ha)	**Koc (L/kg)**	**PEC_{puddle} (mg/L)**	**DW uptake (L/kg bw/d)**	**Daily dose (mg/kg bw/d)**	**TER_{lt}**
400	151	0.1623	0.24	0.0390	85

PEC_{puddle}: concentration in puddles; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

PEC puddle calculated with equation:

$$PEC_{puddle} = \frac{AR/10}{1000\ (w + Koc \times s)}$$

where:

AR = application rate [g/ha]; divisor of 10 to achieve rate in mg/m²
w = 0.02 (pore water term; volume)
s = 0.0015 (soil term: volume, density, organic carbon content

Puddle scenario for Isoxaflutole

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 112, Isoxaflutole 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 on maize

Effective application rate (g/ha) =100
Acute toxicity (mg/kg bw) =5000 quotient = 0.02
Reprod. toxicity (mg/kg bw/d) = 2 quotient = 50

With a K(f)oc of 112 Isoxaflutole belongs to the group of less sorptive substances. Since the ratio of effective application rate (100 g/ha) to relevant endpoint (2 mg/kg bw/d) is equal the critical value of 50 a aquantitative risk assessment (calculation of TER values) is not necessary.

Puddle scenario for mesotrione

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 151, mesotrione 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 on maize

Effective application rate (g/ha) =150
Acute toxicity (mg/kg bw) =5000 quotient = 0.027
Reprod. toxicity (mg/kg bw/d) =0.3 quotient = **500**

With a K(f)oc of 14 (as a worst case), mesotrione belongs to the group of less sorptive substances. Since the ratio of effective application rate (150 g/ha) to relevant endpoint (0.3 mg/kg bw/d) exceeds the critical value of 50 for at least one use scenario, a quantitative risk assessment (calculation of TER values) is necessary and presented in Table 9.3-6

Table 9.3-2: Assessment of the risk for mammals due to exposure to mesotrione via contaminated drinking water in puddles

Intended use	Maize				
Active substance	mesotrione				
Application rate (g/ha)	1 × 150				
Reprod. toxicity (mg/kg bw/d)	0.3				
TER criterion	5				
Soil-relevant applic. rate (g/ha)	**Koc (L/kg)**	**PEC_{puddle} (mg/L)**	**DW uptake (L/kg bw/d)**	**Daily dose (mg/kg bw/d)**	**TER_{lt}**
150	52.2 (log fit, pH 6.5 value)	0.1526	0.24	0.0366	8.2

PEC_{puddle}: concentration in puddles; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

PEC puddle calculated with equation:

$$PEC_{puddle} = \frac{AR/10}{1000\,(w + Koc \times s)}$$

where:

AR = application rate [g/ha]; divisor of 10 to achieve rate in mg/m²
w = 0.02 (pore water term; volume)
s = 0.0015 (soil term: volume, density, organic carbon content

.

9.3.2.4 Effects of secondary poisoning

The log Pow of Terbuthylazine amounts to 3.4 and thus exceeds the trigger value of 3. A risk as-sessment for effects due to secondary poisoning is required. For other 2 active substances (mesotrione and Isoxaflutole) the log Pow is below trigger value of 3, so risk assessment for effects due to secondary poisoning are not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

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

Table 9.3.2.4-1: Assessment of the risk for earthworm-eating mammals due to exposure to Terbuthylazine via bioaccumulation in earthworms (secondary poisoning) for the intended use in maize.

Parameter	Terbuthylazine	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.4581	Escape ver 2 calculations
log P_{ow} / P_{ow}	3.4/2512	EFSA Journal 2011; 9(1):1969
Koc	151	Addendum to DAR 2015
foc	0.02	Default
BCF_{worm}	10.25	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.12 \times P_{ow}) / foc \times Koc$
PEC_{worm}	4.695525	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	6.010272	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	3.3	EFSA Journal 2011; 9(1):1969
TER_{lt}	**0.55**	Risk refinement required

TER values shown in bold fall below the relevant trigger.

Risk refinement for risk for earthworm-eating mammals due to exposure to Terbuthylazine via bioaccumulation in earthworms (secondary poisoning) for the intended use in maize

To address this risk, the joint Notifiers have submitted an earthworm bioaccumulation study (Batscher 2007 (Section B 9.1.3.3.2)) to measure more realistic body burdens within earthworms from the proposed uses. Therefore, a new refined risk assessment has been performed using this measured BAF (0.86) in place of the BCF calculated in the TIER I assessment. The parameters used in the risk assessment and the resultant TER are summarised in Table 9.3-6

Table 9.3-8 Risk refinement for risk for earthworm-eating mammals due to exposure to Terbuthylazine via bioaccumulation in earthworms (secondary poisoning) for the intended use in maize

Parameter	Terbuthylazine	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.4581	EFSA Journal 2011; 9(1):1969
log P_{ow} / P_{ow}	3.4/2512	Confirmatory Data Terbuthylazine November 2015
Koc	151	Confirmatory Data Terbuthylazine November 2015
foc	Organic carbon content of soil (0.02 taken as a default value)	Default
BAF	0.86	DAR Terbuthylazine Volume 3 B9 2010
PEC_{worm}	0.393966	$PEC_{worm} = PEC_{soil} \times BAF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.50427648	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	3.3	EFSA Journal 2011; 9(1):1969
TER_{lt}	6.55	Above trigger value 5

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

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

dicted concentrations in surface water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of Terbuthylazine in water.

Table 9.3.2.4-2: Assessment of the risk for fish-eating mammals due to exposure to Terbuthylazine via bioaccumulation in fish (secondary poisoning) for the intended use in maize

Parameter	Terbuthylazine	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.0002046	Focus Step 3 R1 Stream Scenario
BCF_{fish}	34	EFSA Journal 2011; 9(1):1969
PEC_{fish}	0.0069564	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.0009878088	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	3.3	EFSA Journal 2011; 9(1):1969
TER_{lt}	3341	

TER values shown in bold fall below the relevant trigger.

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 terbuthylazine, mesotrione, isoxaflutole was found acceptable.
With regards to the risk to earthworm-eating mammals an acceptable risk was identified for the proposed uses of terbuthylazine (based on an earthworm bioaccumulation study).
An acceptable risk could be identified for fish-eating mammals for the proposed uses.
CHR/H/TERIZ 650 WG pose no unacceptable to mammals with according to the label.

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

N/A

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 Terbuthylazine, isoxaflutole, mesotrione and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of CHR/H/TERIZ were not evaluated as part of the EU assessment of Terbuthylazine, isoxaflutole, mesotrione. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Table 9.5.1-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Terbuthylazine and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	Terbuthylazine	96 h, static	LC_{50} = 2.2 mg a.s./L $_{mm}$	EFSA Journal 2011; 9(1):1969
Oncorhynchus mykiss	Terbuthylazine	90 d (flow-through)	Early life cycle NOEC = 0.09 mg a.s./L $_{mm}$	EFSA Journal 2011; 9(1):1969
Oncorhynchus mykiss	Metabolite MT1 (GS 26379, desethyl-terbuthylazine)	96 hr (static)	LC_{50} = 18 mg a.s./L mm	EFSA Journal 2011; 9(1):1969
Oncorhynchus mykiss	Metabolite MT13 (GS 23158, 2-hyrdoxy-terbuthylazine)	96 hr (static)	LC_{50} > 2.5mg a.s./L mm	EFSA Journal 2011; 9(1):1969
Daphnia magna	Terbuthylazine	48 hr	EC_{50} = No definitive endpoint available[2]	EFSA Journal 2011; 9(1):1969
Daphnia magna	Terbuthylazine	21 d (semi-static)	Reproduction, NOEC = 0.019 mg a.s./L $_{mm}$	EFSA Journal 2011; 9(1):1969
Daphnia magna	Metabolite MT1 (GS 26379, desethyl-terbuthylazine)	48 h (static)	EC_{50}=42 mg a.s./L mm	EFSA Journal 2011; 9(1):1969
Daphnia magna	Metabolite MT13 (GS 23158, 2-hyrdoxy-terbuthylazine)	48 h (static)	EC_{50}>2.8 mg a.s./L mm	EFSA Journal 2011; 9(1):1969
Chironomus riparius	Terbuthylazine	27 d (static)	nomNOEC (water phase)= 0.5 mg a.s./L	EFSA Journal 2011; 9(1):1969
Chironomus riparius	Metabolite MT13 (GS 23158, 2-hydroxy-terbuthylazine)	28 d (static)	nomNOEC (sediment phase)= 400 mg/kg (sediment)	EFSA Journal 2011; 9(1):1969
Chironomus riparius	Metabolite MT26 (GS 14260, terbutryn)	28 d (static)	nomNOEC (sediment phase)= 16 mg/kg (sediment)	EFSA Journal 2011; 9(1):1969
Blue green algae (Microcystis aeruginosa)	Terbuthylazine	72 h (static)	E_rC_{50} = 0.102 mg a.s./L E_bC_{50} = 0.016 mg a.s./L	EFSA Journal 2011; 9(1):1969
Pseudokirchneriella subcapitata	Terbuthylazine	72 h (static)	E_rC_{50} = 0.028 mg a.s./L E_bC_{50} = 0.012 mg	EFSA Journal 2011; 9(1):1969

Species	Substance	Exposure System	Results	Reference
			a.s./L	
Selenastrum capricornutum	Metabolite MT1 (GS 26379, desethyl-terbuthylazine)	72 h (static)	ErC50 = 0.38 mg a.s./L EbC50 = 0.14 mg a.s./L	EFSA Journal 2011; 9(1):1969
Desmodesmus subspicatus	Metabolite MT13 (GS 23158) 2-hydroxy-terbuthylazine)	72 h (static)	EbC50 > 3.96 mg a.s./L	EFSA Journal 2011; 9(1):1969
Selenastrum capricornutum	Metabolite MT13 (GS 23158) 2-hydroxy-terbuthylazine)	72 h (static)	ErC50 >3.8 mg/L	EFSA Journal 2011; 9(1):1969
Pseudokirchneriella subcapitata	Metabolite MT26(GS 14260) terbutryn)	72 h (static)	ErC50 = 0.0036 mg a.s./L EbC50 = 0.0017 mg a.s./L	EFSA Journal 2011; 9(1):1969
Lemna gibba	Terbuthylazine	14 d (static)	Frond number: nom $E_{fn}C_{50}$ = 0.0128 mg a.s./L Growth rate: nom ErC50=0.412 mg a.s./L Biomass: nom EbC50= 0.0133 mg a.s./L	EFSA Journal 2011; 9(1):1969
Lemna gibba	Metabolite MT26 (GS 14260, terbutryn)	14 d (static)	Frond density: mm EC50=0.025 mg/L	EFSA Journal 2011; 9(1):1969
Myriophyllum aquaticum	Metabolite MT26 (GS 14260, terbutryn)	14 d (static)	Root fresh weight: nom EC50=2.0 mg/kg (sediment)	EFSA Journal 2011; 9(1):1969
Higher-tier studies (micro- or mesocosm studies)				
Higher tier data are available, but insufficient information is currently available to derive an endpoint.				

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

[2]As discussed in Section B.9.2.4.3.1 of the DAR no definitive acute toxicity endpoint was derived from the submitted aquatic invertebrate studies as neither of the submitted studies used a suitable method to determine the amount of terbuthylazine in solution. However, the studies were considered to be of adequate quality to clearly demonstrate that terbuthylazine is of less toxicity to aquatic invertebrates than other aquatic species and therefore the risk assessment for fish is deemed to cover the aquatic invertebrate risk assessment.

Table 9.5.1-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Isoxafutole and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Lepomis macrochirus	Isoxaflutole	Acute 96 h (flow-through)	LC_{50} = 2.7 mg a.s./L $_{mm}$	EFSA Journal 2016;14(3):4416
Oncorhynchus	Isoxaflutole	Acute 96 h (flow-	**LC50 >1.7 mg a.s./L**	EFSA Journal

Species	Substance	Exposure System	Results	Reference
mykiss		through)	**mm**	2016;14(3):4416
Cyprinodon variegatus	Isoxaflutole	Acute 96 h (flow-through)	LC50 >6.4 mg a.s./L mm	EFSA Journal 2016;14(3):4416
Oncorhynchus mykiss	Isoxaflutole	Chronic 28 d (flow-through)	**Growth NOEC= 0.08 mg a.s./L (mm)**	EFSA Journal 2016;14(3):4416
Pimephales promelas	Isoxaflutole	Chronic 33 d (flow-through)	Growth NOEC= 0.102 mg a.s./L (mm)	EFSA Journal 2016;14(3):4416
Oncorhynchus mykiss	RPA 202248	Acute 96 h (semi-static)	**LC_{50}>15 mg a.s/L**	EFSA Journal 2016;14(3):4416
Cyprinodon variegatus	RPA 202248	Acute 96 h (static)	LC50>78 mg a.s/L	EFSA Journal 2016;14(3):4416
Oncorhynchus mykiss	RPA 203328	Acute 96 h (flow-through)	**LC50>160 mg a.s/L**	EFSA Journal 2016;14(3):4416
Oncorhynchus mykiss	RPA 205834	Acute 96 h (semi-static)	**LC50>35 mg a.s/L**	EFSA Journal 2016;14(3):4416
Daphnia magna	Isoxaflutole	48 h (flow-through)	Immobility, EC_{50}>1.5 mg a.s/L	EFSA Journal 2016;14(3):4416
Chironomus riparius	Isoxaflutole	48 h (static)	Immobility, EC50>1.5 mg a.s/L	EFSA Journal 2016;14(3):4416
Americamysis bahia	Isoxaflutole	48 h (flow-through)	Mortality, LC_{50}> 0.077 mg a.s./L	EFSA Journal 2016;14(3):4416
Daphnia magna	Isoxaflutole	21 d (flow-through)	Survival, Body length, Reproduction, NOEC= 0.35 mg a.s./L (mm)	EFSA Journal 2016;14(3):4416
Daphnia magna	Isoxaflutole	21 d (semi-static)	Reproduction and survival, NOEC=2 mg a.s/L	EFSA Journal 2016;14(3):4416
Americamysis bahia	Isoxaflutole	28 d (flow-through)	**Survival, NOEC=0.001 mg a.s./L**	EFSA Journal 2016;14(3):4416
Daphnia magna	RPA 202248	48 h (semi-static)	Immobility, EC50 >59.6 mg a.s./L (mm)	EFSA Journal 2016;14(3):4416
Americamysis bahia	RPA 202248	48 h (semi-static)	**Mortality, LC50= 24 mg a.s./L (mm)**	EFSA Journal 2016;14(3):4416
Daphnia magna	RPA 203328	48 h (flow-through)	**Immobility, EC50>150 mg a.s./L (mm)**	EFSA Journal 2016;14(3):4416
Americamysis bahia	RPA 203328	48 h (static)	Mortality, LC50= 160 mg a.s./L (mm)	EFSA Journal 2016;14(3):4416
Daphnia magna	RPA 205834	48 h (semi-static)	**Immobility, EC50 >60.1 mg a.s./L (mm)**	EFSA Journal 2016;14(3):4416
Chironomus riparius	Isoxaflutole	22 d (static)	**NOEC=0.1 mg a.s./L**	EFSA Journal

Species	Substance	Exposure System	Results	Reference
			(nom)	2016;14(3):4416
Navicula pelliculosa	Isoxaflutole	72h (static)	**Growth rate: ErC50 > 0.44 mg a.s./L (based on final measured at 120 hrs)**	EFSA Journal 2016;14(3):4416
Pseudokirchneriella subcapitata	isoxaflutole	72h (static)	ErC50= 1.7126 mg a.s./L (mm) EyC50= 0.4696 mg a.s./L	EFSA Journal 2016;14(3):4416
Scenedesmus subspicatus	RPA 202248	72 h (static)	ErC50 >20 mg a.s./L (nom) EbC50>20 mg a.s./L (nom)	EFSA Journal 2016;14(3):4416
Scenedesmus subspicatus	RPA 205834	72 h (static)	**ErC50>11.98mg/L (mm)**	EFSA Journal 2016;14(3):4416
Lemna gibba	isoxaflutole	14 d (semi-static)	**Fronds number, ErC50= 0.0045 mg a.s./L**	EFSA Journal 2016;14(3):4416
Lemna gibba	isoxaflutole	14 d (3d exposure + 11d recovery)	**EbC50= 1 mg a.s./L (mm)**	EFSA Journal 2016;14(3):4416
Lemna gibba	RPA 202248	14 d (semi-static)	**Dry weight, EbC50= 0.055 mg a.s./L (mm)**	EFSA Journal 2016;14(3):4416
Lemna gibba	RPA 203328	14 d (semi-static)	**Fronds/dry weight, EbC50 >9.8 mg a.s./L (mm)**	EFSA Journal 2016;14(3):4416
Lemna gibba	RPA 205834	14 d (semi-static)	**Dry weight, EbC50=1.1 mg a.s./L (mm)**	EFSA Journal 2016;14(3):4416
Higher-tier studies (micro- or mesocosm studies)				
No further tests submitted				

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

Table 9.5.1-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Mesotrione and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Rainbow trout (Oncorhynchus mykiss)	Mesotrione	Acute 96-hr (static)	LC_{50} >120 mg a.s./L $_{mm}$	EFSA Journal 2016;14(3):4419

Species	Substance	Exposure System	Results	Reference
Bluegill sunfish (Lepomis macrochirus)	Mesotrione	Acute 96-hr (static)	LC_{50} >120 mg a.s./L $_{mm}$	EFSA Journal 2016;14(3):4419
Fathead minnow (Pimephales promelas)	Mesotrione	Chronic 36-d (flow-through)	NOEC=12.5 mg a.s./L $_{mm}$	EFSA Journal 2016;14(3):4419
Rainbow trout (Oncorhynchus mykiss)	MNBA	Acut 96-hr (static)	LC50 >120 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Rainbow trout (Oncorhynchus mykiss	AMBA	Acut 96-hr (static)	LC50 =150 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Daphnia magna	Mesotrione	Acute 48-h (static)	EC_{50}> 622 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Daphnia magna	Mesotrione	Chronic 21-d (semi-static)	NOEC (reproduction & length)=180 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Daphnia magna	MNBA	Acute 48-h (static)	EC_{50}=130 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Daphnia magna	AMBA	Acute 48-h (static)	EC_{50}=160 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Pseudokirchneriella subcapitata	Mesotrione	Chronic 120-hr (static	EbC50= 3.5 mg a.s./L mm ErC50= 13 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Pseudokirchneriella subcapitata	MNBA	Chronic 72-hr (static)	EbC50= 38 mg a.s./L mm ErC50= 42 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Pseudokirchneriella subcapitata	AMBA	Chronic 72-hr (static)	EbC50= 9.4 mg a.s./L mm ErC50= 14 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Lemna gibba	Mesotrione	14-d chronic (semi-static)	EbC50 (for frond no.)= 0.022 mg a.s./L (nom) EbC50 (for dry weight)= 0.0077 mg a.s./L (nom)	EFSA Journal 2016;14(3):4419
Lemna gibba	MNBA	7-d chronic (semi-static)	ErC50/ EyC50 (for both)>97 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Lemna gibba	AMBA	7-d chronic (semi-static)	ErC50/ EyC50 (for both)>90 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Lemna gibba	SYN546974	7-d chronic (semi-static)	ErC50 (for both)>95 mg a.s./L	EFSA Journal 2016;14(3):4419

Species	Substance	Exposure System	Results	Reference
			EyC50 (for frond no.)=93 mg a.s./L	
Higher-tier studies (micro- or mesocosm studies)				
No further tests submitted				

Table 9.5.1-4: Endpoints and effect values relevant for the risk assessment for aquatic organisms – CHR/H/TERIZ

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	CHR/H/TERIZ 650 WG	96-hour Static Test	LC_{50} = 9.13 mg test item/L $_{nom}$	xxx, xxx; 2016; xxx No: 105461230
Daphnia magna	CHR/H/TERIZ 650 WG	48 h, static	EC_{50} = 27.7 mg test item/L	Dr. Carmen Börschig, Anja Kobel; 2016; IBACON No: 105461220
Pseudokirchneriella subcapitata	CHR/H/TERIZ 650 WG	72 h, static	EyC50= 26.0 µg test item/L ErC50 = 110 µg test item/L	Dr. Carmen Börschig, Anja Kobel; 2016; IBACON No: 105461210
Anabaena flos-aquae	CHR/H/TERIZ 650 WG	72 h, static	EyC50= 0.195 mg test item/L ErC50 = 1.44 mg test item/L	Dr. Carmen Börschig Anja Kobel; 2016; IBACON No: 105461218
Lemna Gibba	CHR/H/TERIZ 650 WG	7d, static	EyC50 frond number= 18.9 µg test item/L EyC50 dry weight= 17.3 µg test item/L ErC50 frond number= 40.8 µg test item/L ErC50 dry weight= 27.2 µg test item/L	Dr. Carmen Börschig Anja Kobel; 2016; IBACON No: 105461240
Higher-tier studies (micro- or mesocosm studies)				
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 data for active substances is presented with this application.

9.5.2 Risk assessment

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

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

Table 9.5.2-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Terbuthylazine for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ in maize

Group		**Fish acute**	**Fish pro-longed**	**Inver-teb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. prolonged**	**Aquat-ic plants**
Test species		***Oncorhyn-chus mykiss***	***Oncorhyn-chus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudo-kirchn. sub-capitata***	***Chirono-mus ripari-us***	***Lemna Gibba***
Endpoint (µg/L)		LC_{50} 2200	NOEC 90	EC_{50} N/A	NOEC 19	EbC50 12	NOEC 500	EfnC50 12.8
AF		100	10	100	10	10	10	10
RAC (µg/L)		22	9	-	1.9	1.2	50	1.28
Exposure	**PEC $_{gl-max}$ (µg/L)**							
Step 1								
	114.6665	**5.21**	**12.74**		**60.35**	**95.56**	**2.29**	**89.58**
Step 2								
	22.5483	**1.02**	**2.51**		**11.87**	**18.79**	0.45	**17.62**
Step 3								
D3/ditch	2.097	0.10	0.23		**1.10**	**1.75**	0.04	**1.64**
D4/pond	0.1279	0.01	0.01		0.07	0.11	0.00	0.10
D4/stream	1.800	0.08	0.20		0.95	**1.50**	0.04	**1.41**
D5/pond	0.1253	0.01	0.01		0.07	0.10	0.00	0.10
D5/stream	1.805	0.08	0.20		0.95	**1.50**	0.04	**1.41**
D6/ditch	2.104	0.10	0.23		**1.11**	**1.75**	0.04	**1.64**
R1/pond	0.1866	0.01	0.02		0.10	0.16	0.00	0.15
R1/stream	5.826	0.26	0.65		**3.07**	**4.86**	0.12	**4.55**

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

For the intended uses not, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for Pseudokirchn. subcapitata as characterised by an EC_{50} for species of 12 µg/L in connection with an assessment factor of 10) in FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on risk mitigation in FOCUS Step 4 PECSW considering reduced exposure of surface water bodies.

Table 9.5.2-2: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Terbuthylazine based on FOCUS Step 4 calculations and toxicity data for most sensitive species Pseudokirchn. Subcapitata. with mitigation of spray drift and run-off for the use of CHR/H/TERIZ in crop (maize)

Intended use		maize	
Active substance		Terbuthylazine	
Application rate (g/ha)		1 × 400	
Nozzle reduction	**No-spray buffer (m)**	10m	10m VFSmod
	Vegetated filter strip (m)	10m	10m VFSmod
None	D3/ditch	0.3644	0.3644
None	D4/pond	0.1216	0.1216
None	D4/stream	0.4043	0.4043
None	D5/pond	0.09497	0.09497
None	D5/stream	0.4136	0.4136
None	D6/ditch	0.3660	0.3660
None	R1/pond	0.09135	0.05438
None	R1/stream	2.356	0.3237
RAC (µg/L)			
1.2		**PEC/RAC ratio**	
None	D3/ditch	0.30	0.30
None	D4/pond	0.10	0.10
None	D4/stream	0.34	0.34
None	D5/pond	0.08	0.08
None	D5/stream	0.34	0.34
None	D6/ditch	0.31	0.31
None	R1/pond	0.08	0.05
None	R1/stream	1.96	0.27

Table 9.5.2-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite (MT1 – desethyl-terbuthylazine) of Terbuthylazine for each organism based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ in maize

MT1 – desethyl-terbuthylazine

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Selenastrum capricornutum***	***Chironomus riparius***	***Lemna Gibba***
Endpoint (µg/L)		LC_{50} 18000	-	EC_{50} 42000	-	EbC50 140	-	- -
AF		100	-	100	-	10	-	-
RAC (µg/L)		180	-	420	-	14	-	-
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							
Step 1								
	65.2686	0.36	-	0.16	-	**4.7**	-	-
Step 2								
	11.8999	0.07		0.03		0.85		

Table 9.5.2.3-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite (MT13 -hydroxy-terbuthylazine) of Terbuthylazine for each organism based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ in maize

MT13 -hydroxy-terbuthylazine								
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Selenestrum capricornutum***	***Chironomus riparius***	***Lemna Gibba***
Endpoint (µg/L)		LC_{50} 2500	-	EC_{50} 2800	-	EbC50 3800	NOEC 400mg/kg	- -
AF		100	-	100	-	10	10	-
RAC (µg/L)		25	-	28	-	380	40	-
Exposure	**PEC $_{gl-max}$ (µg/L)**							
Step 1								
PEC/RAC	54.1762	2.17	-	1.93	-	0.14	2.52(sed)	-
Step 2								

MT13 -hydroxy-terbuthylazine								
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
PEC/RAC	10.7289	0.43	-	0.38	-	0.03	0.5	-

Table 9.5.2.3-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite (MT26-terbutyryn) of Terbuthylazine for each organism based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ in maize

MT26-terbutyryn									
Group			**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species			***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Chironomus riparius***	***Lemna Gibba***
Endpoint (µg/L)			LC_{50} -	-	EC_{50} -	-	EbC50 1.7	NOEC 16	EfnC50 25
AF			-	-	-	-	10	10	10
RAC (µg/L)			-	-	-	-	0.17	1.6	2.5
Exposure	**PEC $_{gl-max}$ (µg/L)**	**PEC $_{gl-max}$ (µg/L) sed**							
STEP 1									
PEC/RAC	6.4201	32.5320	-	-	-	-	37.765	20.333	2.568
STEP 2									
PEC/RAC	1.2627	6.3792	-	-	-	-	7.428	3.987	0.505
STEP 3									
D3/ditch	0.000046	0.001932	-	-	-	-	0.000	0.001	0.000
D4/pond	0.000309	0.011211	-	-	-	-	0.002	0.007	0.000
D4/stream	0.000047	0.001322	-	-	-	-	0.000	0.001	0.000
D5/pond	0.000747	0.01782	-	-	-	-	0.004	0.011	0.000

MT26-terbutyryn									
Group			**Fish acute**	**Fish pro-longed**	**Inver-teb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. prolonged**	**Aquat-ic plants**
D5/stream	0.000073	0.001834	-	-	-	-	0.000	0.001	0.000
D6/ditch	0.000108	0.003808	-	-	-	-	0.001	0.002	0.000
R1/pond	0.000614	0.016227	-	-	-	-	0.004	0.010	0.000
R1/stream	0.000446	0.003561	-	-	-	-	0.003	0.002	0.000

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Isoxaflutole for each organism based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ in maize

Group		**Fish acute**	**Fish pro-longed**	**Inver-teb. acute**	**Inverteb. acute**	**Inver-teb. pro-longed**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. pro-longed**	**Aqua tic plants**
Test species		***Oncorhyn-chus mykiss***	***Oncorhyn-chus mykiss***	***Daph-nia magna***	***America-mysis bahia***	***Daph-nia magna***	***America-mysis bahia***	***Navicu-la pel-liculosa***	***Chi-ronomus riparius***	***Lem-na Gibba***
End-point		LC_{50}	NOEC	EC_{50}	EC_{50}	NOEC	NOEC	ErC50	NOEC	ErC50
(µg/L)		1700	80	1500	77	350	1	440	100	4.5
AF		100	10	100	100	10	10	10	10	10
RAC (µg/L)		17	8	15	0.77	35	0.1	44	10	0.45
Expo-sure	**PEC $_{gl-max}$ (µg/L)**									
Step 1										
PEC/RAC	31.0474	**1.83**	**3.88**	**2.07**	**40.32**	0.89	**310.47**	0.71	**3.10**	**68.99**
Step 2										
PEC/RAC	0.9197	0.05	0.11	0.06	**1.19**	0.03	**9.20**	0.02	0.09	**2.04**
Step 3										
D3/ditch	0.5244	0.03	0.07	0.03	0.68	0.01	**5.24**	0.01	0.05	**1.17**
D4/pond	0.02117	0.00	0.00	0.00	0.03	0.00	0.21	0.00	0.00	0.05
D4/stream	0.4493	0.03	0.06	0.03	0.58	0.01	**4.49**	0.01	0.04	**1.00**

Group		Fish acute	Fish pro-longed	Inver-teb. acute	Inverteb. acute	Inver-teb. pro-longed	Inverteb. prolonged	Algae	Sed. dwell. pro-longed	Aquatic plants
D5/pond	0.02116	0.00	0.00	0.00	0.03	0.00	0.21	0.00	0.00	0.05
D5/stream	0.4477	0.03	0.06	0.03	0.58	0.01	**4.48**	0.01	0.04	0.99
D6/ditch	0.5259	0.03	0.07	0.04	0.68	0.02	**5.26**	0.01	0.05	**1.17**
R1/pond	0.02116	0.00	0.00	0.00	0.03	0.00	0.21	0.00	0.00	0.05
R1/stream	0.3625	0.02	0.05	0.02	0.47	0.01	**3.63**	0.01	0.04	0.81

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

zRMS comments:

We agree with the risk assessment provided for Isoxaflutole for each organism based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ
in maize. Further refinement was required A. bahia and Lemna sp.

For the intended uses not, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for ***Americamysis bahia*** as characterised by an NOEC for species of 1 µg/L in connection with an assessment factor of 10) in FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on risk mitigation in in FOCUS Step 4 PECSW considering reduced exposure of surface water bodies.

Table 9.5-9: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for isoxaflutole based on FOCUS Step 4 calculations and toxicity data for most sensitive species *Americamysis bahia* with mitigation of spray drift and run-off for the use of CHR/H/TERIZ in crop (maize)

Intended use		maize	
Active substance		isoxaflutole	
Application rate (g/ha)		1 × 100	
Nozzle reduction	**No-spray buffer (m)**	10	20
	Vegetated filter strip (m)	10	20
None	D3/ditch	0.09112	0.04737
None	D4/pond	0.01358	0.009085
None	D4/stream	0.1002	0.05220
None	D5/pond	0.01358	0.009083
None	D5/stream	0.09983	0.05202
None	D6/ditch	0.09139	0.04751
None	R1/pond	0.01357	0.009082
None	R1/stream	0.08082	0.04212
RAC (µg/L)			
0.1		**PEC/RAC ratio**	
None	D3/ditch	0.9112	0.4737
None	D4/pond	0.1358	0.09085
None	D4/stream	1.002	0.522
None	D5/pond	0.1358	0.09083
None	D5/stream	0.9983	0.5202
None	D6/ditch	0.9139	0.4751
None	R1/pond	0.1357	0.09082
None	R1/stream	0.8082	0.4212

zRMS cooments:

We agree with the risk assessment provided for Isoxaflutole for each organism based on FOCUS Steps 4 calculations for the use of CHR/H/TERIZ in maize.
The PEC/RAC ratio is below 1 when 10 m vegetative buffer strip is applied to surface water bodies.

Table 9.5-10a: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites RPA 202248 of Isoxaflutole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ in maize

	RPA 202248								
Group		**Fish acute**	**Fish pro-longed**	**Inver-teb. acute**	**Inver-teb. acute**	**Inver-teb. pro-longed**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhyn-chus mykiss***	***Oncorhyn-chus mykiss***	***Daphnia magna***	***America-mysis bahia***	***Daphnia magna***	***Scenedesmus subspicatus***	***Chirono-mus ripari-us***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	EC50	-	EbC50	-	EC50
(µg/L)		15000	-	59600	24000		20000		55
AF		100	-	100	100	-	10	-	10
RAC (µg/L)		150	-	596	240	-	2000	-	5.5
Exposure	**PEC gl-max (µg/L)**								
Step 1									
PEC/RAC	56.4972	0.377		0.095	0.235		0.028		**10.272**
Step 2									
PEC/RAC	6.3473	0.042		0.011	0.026		0.003		**1.154**
Step 3									
D3/ditch	0.1756	0.0012		0.0003	0.0007		0.0001		0.0319
D4/pond	0.07457	0.0005		0.0001	0.0003		0.0000		0.0136
D4/stream	0.06562	0.0004		0.0001	0.0003		0.0000		0.0119
D5/pond	0.03193	0.0002		0.0001	0.0001		0.0000		0.0058
D5/stream	0.05288	0.0004		0.0001	0.0002		0.0000		0.0096
D6/ditch	0.2255	0.0015		0.0004	0.0009		0.0001		0.0410
R1/pond	0.02004	0.0001		0.0000	0.0001		0.0000		0.0036
R1/stream	1.476	0.0098		0.0025	0.0062		0.0007		0.2684

Table 9.5-10b: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites RPA 203328 of Isoxaflutole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ in maize

	RPA 203328								
Group		**Fish acute**	**Fish pro-longed**	**Inver-teb. acute**	**Inver-teb. acute**	**Inver-teb. pro-longed**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhyn-chus mykiss***	***Oncorhyn-chus mykiss***	***Daphnia magna***	***America-mysis bahia***	***Daphnia magna***	-	***Chirono-mus ripari-us***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	EC50	-	-	-	EC50
(µg/L)		160000	-	150000	160000		-		9800
AF		100	-	100	100	-	-	-	10
RAC (µg/L)		1600	-	1500	1600	-	-	-	980
Exposure	**PEC gl-max (µg/L)**								
Step 1									
PEC/RAC	18.1884	0.01136775		0.0121	0.0114				0.0186

Table 9.5-10c: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites RPA 205834 of Isoxaflutole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ in maize

	RPA 205834								
Group		**Fish acute**	**Fish pro-longed**	**Inver-teb. acute**	**Inver-teb. acute**	**Inver-teb. pro-longed**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhyn-chus mykiss***	***Oncorhyn-chus mykiss***	***Daph-nia magna***	***Ameri-camysis bahia***	***Daphnia magna***	***Scenedesmus subspicatus***	***Chirono-mus ripar-ius***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	-	-	EC_{50}	-	EC50
(µg/L)		35000	-	60100	-		11980		1100
AF		100	-	100	-	-	10	-	10
RAC (µg/L)		350	-	601	-	-	1198	-	110
Exposure	**PEC gl-max (µg/L)**								
Step 1									
PEC/RAC	9.8646	0.03	-	0.0164	-	-	0.0082	-	0.0897

zRMS cooments:

We agree with the risk assessment provided for metabolites RPA 205834, RPA 203328, and RPA 202248 for each organism based on FOCUS Steps1-3 calculations for the use of CHR/H/TERIZ in maize.

Table 9.5.2.3-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ in maize

Group		**Fish acute**	**Fish pro-longed**	**Inver-teb. acute**	**Inver-teb. acute**	**Inver-teb. pro-longed**	**Inver-teb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Aquatic plants**
Test species		***On-corhyn-chus mykiss***	***On-corhyn-chus mykiss***	***Daphnia magna***	***Ameri-camysis bahia***	***Daphnia magna***	***Ameri-camysis bahia***	***P.Subca pitata***	***Chi-rono-mus riparius***	***Lemna Gibba***
End-point (µg/L)		LC_{50} 120000	NOEC 12500	EC_{50} 622000	- -	NOEC 180000	- -	EbC50 3500	- -	EbC50 7.7
AF		100	10	100	-	10	-	10	-	10
RAC (µg/L)		1200	1250	6220	-	18000	-	350	-	0.77
Expo-sure	**PEC $_{gl-max}$(µg /L)**									
Step 1										
pH 5.1	42.7383	0.03561525	0.03419064	0.006871109		0.00237435		0.122109429		**55.50428571**
pH 7.9	50.2458	0.0418715	0.04019664	0.008078103		0.00279 1433		0.143559429		**65.25428571**
Step 2										
pH 5.1	8.2207	0.006850583	0.00657656	0.001321656		0.000456706		0.023487714		**10.67623377**
pH 7.9	6.7242	0.0056035	0.00537936	0.001081061		0.000373567		0.019212		**8.732727273**
Step 3 pH 5.1										
D3/ditch	0.7865	0.000655417	0.0006292	0.000126447		4.36944 E-05		0.002247143		1.021428571
D4/pond	0.08332	6.94333 E-05	0.000066656	1.33955 E-05		4.62889 E-06		0.000238057		0.108207792
D4/stream	0.6771	0.00056425	0.00054168	0.000108859		3.76167 E-05		0.001934571		0.879350649

Group		Fish acute	Fish pro-longed	Inver-teb. acute	Inver-teb. acute	Inver-teb. pro-longed	Inver-teb. pro-longed	Algae	Sed. dwell. pro-longed	Aquatic plants
D5/pond	0.04569	0.000038075	0.000036552	7.34566E-06		2.53833E-06		0.000130543		0.059337662
D5/stream	0.6845	0.00057 0417	0.00054 76	0.00011 0048		3.80278E-05		0.001955714		0.88896 1039
D6/ditch	0.7893	0.00065 775	0.00063 144	0.00012 6897		0.00004 385		0.002255 143		1.02506 4935
R1/pond	0.05675	4.72917E-05	0.00004 54	9.12379E-06		3.15278E-06		0.000162 143		0.07370 1299
R1/stream	2.223	0.00185 25	0.00177 84	0.00035 7395		0.00012 35		0.006351 429		**2.88701 2987**
Step 3 pH pH 7.9										
D3/ditch	0.7866	0.00065 55	0.00062 928	0.00012 6463		0.00004 37		0.002247 429		1.02155 8442
D4/pond	0.03178	2.64833E-05	0.00002 5424	5.10932E-06		1.76556E-06		0.000090 8		0.04127 2727
D4/stream	0.6742	0.00056 1833	0.00053 936	0.00010 8392		3.74556E-05		0.001926 286		0.87558 4416
D5/pond	0.03175	2.64583E-05	0.00002 54	5.1045E-06		1.76389E-06		9.07143E-05		0.04123 3766
D5/stream	0.6718	0.00055 9833	0.00053 744	0.00010 8006		3.73222E-05		0.001919 429		0.87246 7532
D6/ditch	0.7893	0.00065 775	0.00063 144	0.00012 6897		0.00004 385		0.002255 143		1.02506 4935
R1/pond	0.03174	0.00002 645	0.00002 5392	5.10289E-06		1.76333E-06		9.06857E-05		0.04122 0779
R1/stream	1.761	0.00146 75	0.00140 88	0.00028 3119		9.78333E-05		0.005031 429		**2.28701 2987**

For the intended uses calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms for mesotrione (risk for *Lemna Gibba* as characterised by an EC_{50} for species of 7.7 µg/L in connection with an assessment factor of 10) FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on risk mitigation in in FOCUS Step 4 PECSW considering reduced exposure of surface water bodies.

Table 9.5.2.3-11: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for mesotrione based FOCUS Step 4 calculations and toxicity data for most sensitive species Lemna Gibba with mitigation of spray drift and run-off for the use of CHR/H/TERIZ in crop (maize)

Intended use	**maize**	**maize**
Active substance	**mesotrione**	**mesotrione**

Application rate (g/ha)		**1 × 150 pH 5.1**		**1 × 150 pH 7.9**	
Nozzle reduction	**No-spray buffer (m)**	10	20	10	20
	Vegetated filter strip (m)	10	20	10	20
None	D3/ditch	0.1368	0.07106	0.1369	0.07108
None	D4/pond	0.08331	0.08331	0.02040	0.01361
None	D4/stream	0.1537	0.1354	0.1507	0.07827
None	D5/pond	0.04568	0.04568	0.02037	0.01358
None	D5/stream	0.1629	0.09071	0.1501	0.07789
None	D6/ditch	0.1378	0.07181	0.1376	0.07165
None	R1/pond	0.02486	0.01357	0.02036	0.01357
None	R1/stream	0.9430	0.4810	0.7469	0.3811
RAC (µg/L) 0.77		**PEC/RAC ratio**		**PEC/RAC ratio**	
None	D3/ditch	0.18	0.09	0.18	0.09
None	D4/pond	0.11	0.11	0.03	0.02
None	D4/stream	0.20	0.18	0.20	0.10
None	D5/pond	0.06	0.06	0.03	0.02
None	D5/stream	0.21	0.12	0.19	0.10
None	D6/ditch	0.18	0.09	0.18	0.09
None	R1/pond	0.03	0.02	0.03	0.02
None	R1/stream	**1.22**	0.62	0.97	0.49

Tablle 9.5.2.3-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite (MNBA) of mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ in maize.

MNBA									
Group		Fish acute	Fish prolonged	**Inverteb. acute**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Americamysis bahia***	***Daphnia magna***	***Pseudokirchneriella***	***Chironomus riparius***	***Lemna Gibba***
Endpoint (µg/L)		LC_{50} 120000	-	EC_{50} 130000	- -	-	EbC50 38000	-	EC50 97000
AF		100	-	100	-	-	10	-	10
RAC (µg/L)		1200	-	1300	-	-	3800	-	9700
Exposure	**PEC gl-max (µg/L)**								

MNBA									
Group		Fish acute	Fish pro-longed	**Inver-teb. acute**	**Inver-teb. acute**	**Inver-teb. pro-longed**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Step 1									
PEC/RAC	23.5032	0.020	-	0.018	-	-	0.006	-	0.002

Table 9.5.2.3-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite (AMBA) of mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ in maize.

AMBA									
Group		**Fish acute**	**Fish pro-longed**	**Inver-teb. acute**	**Inver-teb. acute**	**Inver-teb. pro-longed**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhyn-chus mykiss***	***Oncorhyn-chus mykiss***	***Daphnia magna***	***America-mysis bahia***	***Daphnia magna***	***Pseudokirch-neriella***	***Chirono-mus ripari-us***	***Lemna Gibba***
Endpoint (µg/L)		LC_{50} 150000	-	EC_{50} 160000	- -	-	EbC50 9400	-	EC50 90000
AF		100	-	100	-	-	10	-	10
RAC (µg/L)		1500	-	1600	-	-	940	-	9000
Exposure	**PEC $_{gl-max}$ (µg/L)**								
Step 1									
PEC/RAC	10.8371	0.0072	-	0.0067	-	-	0.0115	-	0.0012

Table 9.5.2.3-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite (SYN 546974) of mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/TERIZ in maize.

SYN546974									
Group		**Fish acute**	**Fish pro-longed**	**Inver-teb. acute**	**Inver-teb. acute**	**Inver-teb. pro-longed**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhyn-chus mykiss***	***Oncorhyn-chus mykiss***	***Daphnia magna***	***America-mysis bahia***	***Daphnia magna***	***Pseudokirch-neriella***	***Chirono-mus ripari-us***	***Lemna Gibba***
Endpoint (µg/L)		-	-	-	- -	-	-	-	EyC50 93000
AF		-	-	-	-	-	-	-	10

SYN546974									
Group		**Fish acute**	**Fish pro-longed**	**Inver-teb. acute**	**Inver-teb. acute**	**Inver-teb. pro-longed**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
RAC (µg/L)		-	-	-	-	-	-	-	9300
Exposure	**PEC gl-max (µg/L)**								
Step 1									
PEC/RAC	0.7732	-	-	-	-	-	-	-	8.31398 E-05

9.5.2.1 Risk assessment for formulation to aquatic organisms

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites of CHR/H/TERIZ 650 WG for each organism group based on Drift Calculator SWASH MODEL ver 5.3 calculations for the use of CHR/H/TERIZ 650 WG in maize

Intended use	maize
Formulation	CHR/H/TERIZ
Application rate (g[prod]/ha)	1 X 1000
Entry into surface water via spraydrift (Drift alculator from SWASH)	
Buffer zone (m)	**PECsw [µg prod/L**
1	5.3119
5	1.7415
10	0.9236
Entry into surface water via spraydrift (Drift alculator from SWASH)	
Buffer zone (m)	**RAC/PEC ratio** **Oncorhynchus mykiss =EC50 9130 µg/L RAC=91.3 (AF=100)**
1	0.058
5	0.019
10	0.010
Buffer zone (m)	**RAC/PEC ratio** **Daphnia magna =EC50 27700 µg/L RAC=277 (AF=100)**
1	0.019
5	0.006
10	0.003
Buffer zone (m)	**RAC/PEC ratio** **Pseudokirchmeirella subcapitata =EC50 26 µg/L RAC=2.6 (AF=10)**
1	**2.043**
5	0.670
10	0.355

Buffer zone (m)	**RAC/PEC ratio** **Anabaena flos-aque =EC50 195 µg/L RAC=19.5 (AF=10)**
1	0.272
5	0.089
10	0.047
Buffer zone (m)	**RAC/PEC ratio** **Lemna Gibba =EC50 17.3 µg/L RAC=1.73 (AF=10)**
1	**3.070**
5	1.007
10	0.534

~~Based on the calculated concentrations of the formulation CHR/H/TERIZ (spray drift) respectively its active ingredients terbuthylazine, isoxaflutole and mesotrione (run-off and drainage) in surface water (PECSW according to FOCUS STEP 1-2, STEP 3 and STEP 4), the calculated RAC/PEC (mix) values for the risk resulting from an exposure of aquatic organisms to CHR/H/TERIZ according to the GAP of the formulation do not achieve the acceptability criterium <1 for run-off exposure.~~

~~According to the results of the RAC/PEC calculations, the implementation of risk mitigation measures will be necessary to reduce the exposure of aquatic organisms to CHR/H/TERIZ, therefore, risk mitigation is required of buffer zone 10 m for mesotrione and terbuthylazine.~~

~~For Plant Protection product CHR/H/TERIZ 650 WG, for the most sensetive species Lemna Gibba is required buffer zone of 10 m.~~

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

$$EC_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{LC_{50}(a.s._i)} \right)^{-1}$$

~~where:~~

~~**X(a.s. i) = fraction of active substance (i) in the mixture expressed as:**~~

~~**X(terbuthylazine)** = 400g teruthylazine/kg / (400 g terbuthylazine /kg + 100 g isoxaflutole /kg + 150 g mesotrione /kg)~~
~~**X(isoxaflutole)** = 100g isoxaflutole/kg / (400 g terbuthylazine /kg + 100 g isoxaflutole /kg + 150 g mesotrione /kg)~~
~~**X(mesotrione)** = 150g mesotrione/kg / (400 g terbuthylazine /kg + 100 g isoxaflutole /kg + 150 g mesotrione /kg)~~

~~LC50(a.s. i) = acute toxicity value for active substance (i)~~

Table 9.5-16: The surrogate EC50 for the mixture of active substances with known toxicity assuming dose additivity

Aquatic organism	EC50/LC50/NOEC for the mixture	Endpoint derived from the studies on CHR/H/TERIZ 650 WG
Fish LC50 Terbuthylazine =2.2 mg/L Isoxaflutole= 1.7 mg/L Mesotrione= 120 mg/L	**LC50(mix)= 2.687 mg/L**	**LC50=9.13 mg[prod]/L equivalent to LC50=5.93 mg[sum a.s]/L**
Algae P.Subcapitata EC50 Terbuthylazine =0.012 mg/L Isoxaflutole= 0.12 mg/L Mesotrione= 3.5 mg/L	**EC50(mix)= 0.019 mg/L**	**EyC50=0.026 mg[prod]/L equivalent to EC50=0.0169 mg[sum a.s]/L**
Lemna Gibba EC50 Terbuthylazine =0.0128 mg/L Isoxaflutole= 0.016 mg/L Mesotrione= 0.0077 mg/L	**EC50 (mix)=0.011mg/L**	**EyC50=0.0173 mg[prod]/L equivalent to EC50=0.0112 mg[sum a.s]/L**

Decision scheme for mixture toxcitiy risk assessment for CHR/H/TERIZ 650 WG

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

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

Answer: Measured toxicity data for the formulation and the a.s. are available for fish, algae and macrophytes. Go to 2

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

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

Equation 13:

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

Equation 15:

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

Calculation of the acute mixture toxicity of the formulation

Table 1. Composition of CHR/H/TERIZ 650 WG

Name/code of the product	CHR/H/TERIZ	
Name of the active substance A	Terbuthylazine	

Name of the active substance B	Isoxaflutole		
Name of the active substance C	Mesotrione		
Density [g product/cm³]	1		
	Nominal [g a.s./kg or L product]	Fraction considering density [%]	$p_{i\ mix}$ = Fraction of active substance i in the mixture with $\sum p_{i\ mix} = 100$ [%]
Concentrations of the active substance Terbithylazine in the product	400	40.0%	61.5%
Concentrations of the active substance Isoxaflutole in the product	100	10.0%	20.0%
Concentrations of the active substance Mesotrione in the product	150	15.0%	23.1%

Table 2. Toxicity of CHR/H/TERIZ 650 WG and active substance

End-point/Test species	Toxicity of the product [mg product/L]	Toxicity of the product (a.s. based) ($EC_{x\ PPP}$) [mg a.s./L]	Toxicity of the a.s. Nicosulfuron ($EC_{x\ A}$) [mg a.s./L]	Toxicity of the a.s. Thifensulfuron-methyl ($EC_{x\ B}$) [mg a.s./L]	Toxicity of the a.s. Florasulam ($EC_{x\ C}$) [mg a.s./L]	Triggers (from EFSA Journal 2013;11(7):3290)
LC_{50} fish	9.13	5.935	2.2	1.7	120	0.01
ErC_{50} algae	0.026	0.013	0.012	0.44	3.5	0.1
E_rC_{50} higher plant	0.0173	0.011	0.0128	0.0045	0.0077	0.1

Table 3. Calculation of toxicity exposure in CHR/H/TERIZ 650 WG

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

where:

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

Toxicity per fraction of the Nicosulfuron ($1/TU_A$) [mg a.s./L]	Toxicity per fraction of the Thifensulfuron-methyl ($1/TU_B$) [mg a.s./L]	Toxicity per fraction of the Florasulam ($1/TU_C$) [mg a.s./L]	Calculated mixture toxicity (a.s. in product) ($EC_{x\ mix-CA} = 1/\sum(TU_i)$) [mg a.s./L]	Model deviation ratio (MDR = $EC_{x\ mix-CA}/EC_{x\ PPP}$)	$EC_{x\ mix-CA}$ (a.s. in product)/$EC_{x\ mix-CA}$ (a.s. in PEC_{mix}) (at lower exposure tier)
3.575	8.5	520	2.504	0.422	0.858
0.0195	2.2	15.167	0.019	1.487	1.149
0.0208	0.0225	0.03337	0.008	0.726	0.782

Answer: MDRs for fish, algae and macrophytes is in the range of 0.2 – 5, therefore, go to Step 3.

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

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

		Triggers	
Endpoint/Test species	**ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix)**	**0.8-1.2**	**<0.8 or >1.2**
LC50 fish	0.858	**Yes**	
ErC50 algae	1.149	**Yes**	
ErC50 higher plants	0.782		**Yes**

Answer: Calculated factors for higher plant gives results outside 0.8-1.2 Therefore, go to step 5. Calculated factors for fish and algae gives results in the range of 0.8-1.2 Therefore, go to step 4.

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

Table 5. Results of exposure of mixture toxicity's calculation to aquatic species

Expo-sure		**(lower expo-sure tier)**	**(higher exposure tier)**							
Expo-sure tier (FO-CUS step)	Ter-buthyla zine	Step 2	Step 4 (D3 ditch)	Step 4 (D4 pond)	Step 4 (D4 stream)	Step 4 (D5 pond)	Step 4 (D5 stream)	Step 4 (D6 ditch)	Step 4 (R1 pond)	Step 4 (R1 stream)
PECsw [mg a.s./L]		0.022548	0.000364	0.000122	0.000404	0.000095	0.000414	0.000366	0.000054	0.000324
Expo-sure tier (FO-CUS step)	Isoxafl utole	Step 2	Step 4 (D3 ditch)	Step 4 (D4 pond)	Step 4 (D4 stream)	Step 4 (D5 pond)	Step 4 (D5 stream)	Step 4 (D6 ditch)	Step 4 (R1 pond)	Step 4 (R1 stream)
PECsw [mg a.s./L]		0.000920	0.000047	0.000009	0.000052	0.000009	0.000052	0.000048	0.000009	0.000042
Expo-sure tier (FO-CUS step)	Meso-trione	Step 2	Step 4 (D3 ditch)	Step 4 (D4 pond)	Step 4 (D4 stream)	Step 4 (D5 pond)	Step 4 (D5 stream)	Step 4 (D6 ditch)	Step 4 (R1 pond)	Step 4 (R1 stream)
PECsw [mg a.s./L]		0.008221	0.000071	0.000083	0.000135	0.000046	0.000091	0.000072	0.000014	0.000481
Total expo-sure concen-tration of the mixture (a.s. based) (PECmix) [mg/L]		0.031689	0.000483	0.000214	0.000592	0.000150	0.000556	0.000485	0.000077	0.000847

Table 6. Results of exposure of mixture toxicity's calculation to aquatic species

Endpoint/Test species	Toxicity of the product (a.s. based) (ECx PPP)	ETRmix = PECmix/ECx PPP

	[mg a.s./L]										
LC50 fish	5.935	0.005	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
ErC50 algae	0.013	2.438	0.037	0.016	0.046	0.012	0.043	0.037	0.006	0.065	0.000

Risk assessment for fish and algae were acceptable based on Step 4 and therefore

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

Table 7. Results of toxicity driver's calculation

		Terbuthylazine		Isoxaflutole		Mesotrione		**Triggers**	
End-point/Test species	Calculated mixture toxicity (a.s. in product) ($EC_{x\ mix-CA}$) [mg a.s./L]	Toxicity per fraction ($1/TU_i$) [mg a.s./L]	Deviation from mixture toxicity = 1-$EC_{x\ mix-CA}$ x ($1/EC_{x\ mix-CA}$-TU_i) [%]	Toxicity per fraction ($1/TU_i$) [mg a.s./L]	Deviation from mixture toxicity = 1-$EC_{x\ mix-CA}$ x ($1/EC_{x\ mix-CA}$-TU_i) [%]	Toxicity per fraction ($1/TU_i$) [mg a.s./L]	Deviation from mixture toxicity = 1-$EC_{x\ mix-CA}$ x ($1/EC_{x\ mix-CA}$-TU_i) [%]	>=90 % for one a.s.	>=90 % for no a.s.
ErC50 higher plant	0.008	0.021	39.2%	0.023	36.3%	0.033	24.5%		Yes

Equation 14:

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

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

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

Table 8. Results of exposure of mixture toxicity's calculation to aquatic species

Exposure		**(lower exposure tier)**	**(higher exposure tier)**								
Exposure tier (FOCUS step)	Terbuthylazine	Step 2	Step 4 (D3 ditch)	Step 4 (D4 pond)	Step 4 (D4stream)	Step 4 (D5 pond)	Step 4 (D5 stream)	Step 4 (D6 ditch)	Step 4 (R1 pond)	Step 4 (R1 stream)	
PECsw [mg a.s./L]		0.022548	0.000364	0.000122	0.000404	0.000095	0.000414	0.000366	0.000054	0.000324	
Exposure tier (FOCUS step)	Isoxaflutole	Step 2	Step 4 (D3 ditch)	Step 4 (D4 pond)	Step 4 (D4 stream)	Step 4 (D5 pond)	Step 4 (D5 stream)	Step 4 (D6 ditch)	Step 4 (R1 pond)	Step 4 (R1 stream)	
PECsw [mg a.s./L]		0.000920	0.000047	0.000009	0.000052	0.000009	0.000052	0.000048	0.000009	0.000042	

Expo-sure tier (FO-CUS step)	Meso-trione	Step 2	Step 4 (D3 ditch)	Step 4 (D4 pond)	Step 4 (D4 strea m)	Step 4 (D5 pond)	Step 4 (D5 strea m)	Step 4 (D6 ditch)	Step 4 (R1 pond)	Step 4 (R1 stream)	
PECsw [mg a.s./L]		0.008 221	0.0000 71	0.000 083	0.000 135	0.000 046	0.000 091	0.000 072	0.000 014	0.000481	
Total expo-sure concen-tration of the mixture (a.s. based) (PECmi x) [mg/L]		0.031 689	0.0004 83	0.000 214	0.000 592	0.000 150	0.000 556	0.000 485	0.000 077	0.000847	
End-point/T est species		Calculated mixture toxicity (a.s. in PEC_{mix}) ($EC_{x\ mix\text{-}CA} = \sum (p_{i\ PEC}/EC_{x\ i})$) [mg a.s./L]									
ErC50 higher plant		0.010	0.010	0.010	0.010	0.010	0.010	0.010	0.010	0.009	
End-point/T est species		$ETR_{mix} = PEC_{mix}/EC_{x\ PPP}$									Trig-gers
ErC50 higher plant		3.034	0.048	0.022	0.061	0.015	0.056	0.048	0.008	0.097	0.10

Answer: ETRmix for higher exposure tier are below the triggers. Therefore, CHR/H/TERIZ 650 WG does not pose unacceptable mixture toxicity to aquatic species.

9.5.3 Overall conclusions

The risk to aquatic organisms following exposure to CHR/H/TERIZ 650 WG via spraydrift 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/TERIZ. Therefore using buffer zone of **20 m vegetative buffer zone** (the worst case scenario - R1 stream), the use CHR/H/TERIZ 650 WG according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1).

zRMS comment:
Based on the risk assessment for a.s- mesotrione for aquatic organism the **20 m vegetative buffer zone** (the worst case scenario - R1 stream) should be applied to surface water bodies for use CHR/H/TERIZ 650 WG according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1).

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 all three active substances terbuthylazine, isoxaflutole and mesotrione. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of CHR/H/TERIZ were not evaluated as part of the EU assessment of terbuthylazine/isoxaflutole/mesotrione. New data submitted with this application are listed in **Błąd! Nie można odnaleźć źródła odwołania.** and summarised in Appendix 2.

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

Table 9.6.1-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Terbuthylazine	Oral	LD_{50} >22.6 µg/bee	EFSA Journal 2011; 9(1):1969
Apis mellifera	Terbuthylazine	Contact	LD_{50} >32 µg/bee	EFSA Journal 2011; 9(1):1969
Apis mellifera	Isoxaflutole	Oral	LD_{50} >108.9 µg/bee	EFSA Journal 2016;14(3):4416
Apis mellifera	Isoxaflutole	Contact	LD_{50} >100 µg/bee	EFSA Journal 2016;14(3):4416
Apis mellifera	Mesotrione	Oral	LD_{50} >11 µg/bee	EFSA Journal 2016;14(3):4419
Apis mellifera	Mesotrione	Contact	LD_{50} >100 µg/bee	EFSA Journal 2016;14(3):4419
Apis mellifera	CHR/H/TERIZ	Oral	LD_{50} = 198 µg/bee	Tatsuya Sekine;2015/Study code105461035 IBACON

Species	Substance	Exposure System	Results	Reference
Apis mellifera	CHR/H/TERIZ	Contact	LD_{50}> 200 µg/bee	Tatsuya Sekine;2015/Study code105461035 IBACON
Higher-tier studies (tunnel test, field studies)				
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).

9.6.2.1 Hazard quotients for bees

Table 9.6.2.1-1: First-tier assessment of the risk for bees due to the use of CHRH/TERIZ in maize

Intended use **Active substance** **Application rate (g/ha)**	Maize Terbuthylazine 1 × 400		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	22.6	400	17.7
Contact toxicity	32		12.5
Intended use **Active substance** **Application rate (g/ha)**	Maize Mesotrione 1 ×150		
Test design	**LD_{50} (lab.) (µg/bee)**	**Test design**	**LD_{50} (lab.) (µg/bee)**
Oral toxicity	11	Oral toxicity Contact toxicity	11
Contact toxicity	100		100
Intended use **Active substance** **Application rate (g/ha)**	Maize Isoxaflutole 1 ×100		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	108.9	100	0.92
Contact toxicity	100		1
Product	CHR/H/TERIZ		

Application rate (g/ha)	1 × 1000		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	198	1000	5.05
Contact toxicity	200		5

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

zRMS comment:

We agree with the risk assessment for reviewed a.s.- isoxaflutole and ppp Metodus 650 WG for adult bees.
According to EU Reg. 284/2009 the chronic tests for adult bees and larva shoul be provided by the applicant.

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

Not relevant.

9.6.3 Effects on bumble bees

Not available

9.6.4 Effects on solitary bees

Not available

9.6.5 Overall conclusions

All hazard quotients (HQ) are considerably less than 50, indicating that CHR/H/TERIZ 650 WG applied at the maximum use rate in maize poses low risk to bees.

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 three active substances terbuthylazine/isoxaflutole/mesotrione. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of CHR/H/TERIZ were not evaluated as part of the EU assessment of any active substances. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.7.1-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	CHR/H/TERIZ 650 WG	Laboratory test glass plates (2D)	LR_{50} = 650 g a.s/ha which is equal to 1 kg[prod]/ha	Monika Moll;2015/Study code: 105461063 IBACON
Aphidius rhopalosiphi (adults)	CHR/H/TERIZ 650 WG	Laboratory test glass plates (2D)	LR_{50} = 650 g a.s/ha which is equal to 1 kg[prod]/ha	Monika Moll;2015/Study code: 105461001 IBACON
Field or semi-field tests				
Not required				

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 on maize covers the risk for non-target arthropods from all other intended uses.

Table 9.7.2.1-1: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of CHR/H/TERIZ 650 WG in maize

Calculations PERin-field values according to ESCORT 2 as:
Application rate × MAF.

Intended use	Maize
product	CHR/H/TERIZ
Application rate (g/ha)	1000
MAF	1

Test species Tier I	**LR_{50} (lab.) (g[prod]/ha)**	**$PER_{in\text{-}field}$ (g [prod]/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	1000	1000	1
Aphidius rhopalosiphi	1000		1

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

9.7.2.2 Risk assessment for off-field exposure

Table 9.7.2.2-1: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of CHR/H/TERIZ 650 WG in Maize

Intended use	maize
product	CHR/H/TERIZ
Application rate (g/ha)	1 × 1000
MAF	1
vdf	10

Test species Tier I	**LR_{50} (lab.) (g[prod]/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	1000	2.77	2.77	10	0.0277
Aphidius rhopalosiphi	1000				0.0277

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.

Calculations PERoff-field values according to ESCORT 2 as:
Application rate × MAF × (drift factor/vegetation distribution factor)
Calculations the corrected PERoff-field values according to ESCORT 2 as:
corr. PERoff-field = PERoff-field * correction factor

zRMS comments:

The risk assessment was previously accepted in the Registration Report for Metodus 650 W , B9.
No additional information are provided aand evaluated in the current Dossier.

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/TERIZ 650 WG applied at the maximum use rate in maize poses no risk to non-target arthropods. No risk mitigation needed.

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 three active substances Terbuthylazine/isoxaflutole/mesotrione and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of CHR/H/TERIZ 650 WG were not evaluated as part of the EU assessment of any of three active substances. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.8.1-1: 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	Terbuthylazine	Mixed into substrate 14 d, acute 10 % peat content	LC50 corr > 141.7 mg tba/kg soil dw OXON	EFSA Journal 2011; 9(1):1969
Eisenia fetida	Terbuthylazine	Mixed into substrate 56 d, chronic 10 % peat content	NOEC corr = 0.500 mg tba/ kg soil	EFSA Journal 2011; 9(1):1969
Folsomia candida	Terbuthylazine	Mixed into substrate 28 d, chronic 10 % peat content	NOECcorr = 21.12 mg tba/ kg soil dw SYN	EFSA Journal 2011; 9(1):1969
Eisenia fetida	Metabolite MT1 (desethyl-terbuthylazine)	Mixed into substrate 14 d, acute 10 % peat content	LC50 corr = 120 mg/kg soil dw SYN	EFSA Journal 2011; 9(1):1969
Eisenia fetida	Metabolite MT1 (desethylterbuthylazine	Mixed into substrate 56 d, chronic 10 % peat content	NOECcorr 2.8 mg/ kg soil dw	EFSA Journal 2011; 9(1):1969
Eisenia fetida	Metabolite MT13 (hydroxy-terbuthylazine)	Mixed into substrate 14 d, acute 10 % peat content	LC50 > 1000 mg/kg soil dw	EFSA Journal 2011; 9(1):1969
Eisenia fetida	Metabolite MT13 (hydroxyterbuthylazine)	Mixed into substrate 56 d, chronic 10 % peat content	NOEC 7 mg/kg soil dw	EFSA Journal 2011; 9(1):1969
Eisenia fetida	Metabolite MT14 (desethyl-hydroxy-terbuthylazine)	Mixed into substrate 14 d, acute 10 % peat content	LC50 > 1000 mg/kg soil dw	EFSA Journal 2011; 9(1):1969
Eisenia fetida	isoxaflutole	Acute (14d) Incorporated into soil / 10% OM	LC50 corr >500 mg a.s./kg d.w.soil	EFSA Journal 2016;14(3):4416
Eisenia fetida	isoxaflutole	Chronic (56d) Incorporated into soil / 5% OM	NOEC corr = 8.9 mg a.s./kg d.w.soil	EFSA Journal 2016;14(3):4416
Folsomia candida	isoxaflutole	Chronic (28d) Incorporated into soil	NOEC corr > 500 mg a.s./kg d.w.soil	EFSA Journal 2016;14(3):4416

Species	Substance	Exposure System	Results	Reference
		/ 5% OM		
Hypoaspis aculeifer	isoxaflutole	Chronic (14d) Incorporated into soil / 5% OM	NOECcorr = 158mg a.s. /kg d.w.soil	EFSA Journal 2016;14(3):4416
Eisenia fetida	RPA 203328	Acute (14d) Incorporated into soil / 10% OM	LC50 >1000 metabolite /kg d.w.soil	EFSA Journal 2016;14(3):4416
Eisenia fetida	RPA 203328	Chronic (56d) Incorporated into soil / 10% OM	NOEC >1000 metabolite /kg d.w.soil	EFSA Journal 2016;14(3):4416
Eisenia fetida	RPA 202248	Chronic (56d) Incorporated into soil / 5% OM	NOEC= 9 mg metabolite /kg d.w.soil	EFSA Journal 2016;14(3):4416
Folsomia candida	RPA202248	Chronic (28d) Incorporated into soil / 5% OM	NOEC >100 metabolite /kg d.w.soil	EFSA Journal 2016;14(3):4416
Folsomia candida	RPA 203328	Chronic (28d) Incorporated into soil / 5% OM	NOEC >100 metabolite /kg d.w.soil	EFSA Journal 2016;14(3):4416
Hypoaspis aculeifer	RPA202248	Chronic (14d) Incorporated into soil / 5% OM	NOEC >100 metabolite /kg d.w.soil	EFSA Journal 2016;14(3):4416
Hypoaspis aculeifer	RPA 203328	Chronic (15d) Incorporated into soil / 5% OM	NOEC >100 metabolite /kg d.w.soil	EFSA Journal 2016;14(3):4416
Eisenia fetida	mesotrione	Mixed into substrate 14 d, acute 10 % peat content	LC50 > 2000 mg a.s./kg d.w. soil	EFSA Journal 2016;14(3):4419
Eisenia fetida	mesotrione	Chronic (56d) Incorporated into soil / 10% OM	NOEC = equivalent to 10.85 mg a.s./kg d.w. soil	EFSA Journal 2016;14(3):4419
Eisenia fetida	MNBA	Mixed into substrate 14 d, acute 10 % peat content	LC50 > 1000 mg a.s./kg d.w. soil	EFSA Journal 2016;14(3):4419
Eisenia fetida	MNBA	Chronic (56d) Mixed with soil using quartz sand / 5%	NOEC = 1050 mg /kg d.w. soil	EFSA Journal 2016;14(3):4419
Eisenia fetida	AMBA	Chronic (56d) Mixed with soil using quartz sand / 5%	NOEC = 1050 mg /kg d.w. soil	EFSA Journal 2016;14(3):4419
Folsomia candida	mesotrione	Chronic (14 days) Mixed with soil as a solution / 5%	NOEC = 50.54 mg a.s. /kg d.w. soil	EFSA Journal 2016;14(3):4419

Species	Substance	Exposure System	Results	Reference
Hypoaspis aculeifer	mesotrione	Chronic (28 days) Mixed with soil as a solution / 5%	NOEC = 90.9 mg a.s. /kg d.w. soil	EFSA Journal 2016;14(3):4419
Eisenia fetida	CHR/H/TERIZ	Mixed into substrate 56 d, chronic 10 % peat content	NOEC **(day 28 mortality)=**26.68 mg test it. /kg d.w. soil NOEC **(day 28 weight change)** =6.67 mg test it /kg d.w. soil NOEC **(day 56 reproduction)=**1.65 mg test it /kg d.w. soil	Matthias Ganßmann; 2016; Study code: 105461022 IBACON
Folsomia candida	CHR/H/TERIZ	Mixed into substrate 28 d, chronic 5 % peat content	NOEC (reproduction)= 62.5 [mg test item/kg soil dry weight]	Matthias Ganßmann; 2015; Study code: 105461016 IBACON
Hypoaspis aculeifer	CHR/H/TERIZ	Mixed into substrate 14 d, chronic 5 % peat content	NOEC (reproduction)>250 [mg test item/kg soil dry weight]	Matthias Ganßmann; 2015; Study code: 105461089 IBACON
Field studies				
In EFSA Journal 2011; 9(1):1969. was presented field study with Terbuthylazine on the representative formulation. With the Preparation -'Gardoprim' /'GS 13529 SC 500' ('A-5435 E') there were presented two studies: - Field study – 1 yr (Denmark) and 1 yr in Germany, indicatting relevant endpoint No significant ecologically adverse effects at 1.69 L form.n/ha (**844 g tba/ha**) after 1 yr. With the Preparation -'Terbuthylazine 500 g/L SC was also performed 1 yr study deriving and endpoint No significant ecologically adverse effects at 1.5 L form.n/ha (750 g tba/ha) after 1 yr:				
Litter bag test				
For Terbuthylazine was performed litter bag test. According to **EFSA Journal 2011; 9(1):1969.** **The litter bag test was performed with terbuthylazine, desethylterbuthylazine, 2 hydroxyter-buthylazine. Derived endpoint from the study : no significant impact on organic matter breakdown at applications considered to cover an application of terbuthylazine of 1 kg/ha, plus any long term accumulation.**				

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

9.8.2 Risk assessment

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

9.8.2.1 First-tier risk assessment

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

Table 9.8.2.1-1: 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/TERIZ in maize

Intended use	Maize		
Acute effects on earthworms			
Product/active substance/metabolite	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Terbuthylazine	141.7	0.5333	265.7
Desethyl-terbuthylazine	120	0.1020	1176.5
Hydroxy-terbuthylazine	1000	0.1208	8278.1
isoxaflutole	500	0.1333	3750.9
RPA 202248	Not required		
RPA 203328	1000	0.0908	11013.2
mesotrione	2000	0.2000	10000.0
MNBA	1000	0.0229	43668.1
CHR.H/TERIZ	1.65		
AMBA	Not required		
~~CHR.H/TERIZ~~	~~Not required~~		
Chronic effects on earthworms			
Product/active substance/metabolite	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Terbuthylazine	0.500	0.5333	**0.94**
Desethyl-terbuthylazine	2.8	0.1020	27.45
Hydroxy-terbuthylazine	7	0.1208	57.95
isoxaflutole	8.9	0.1333	66.77
RPA 202248	9	0.1092	82.42
RPA 203328	1000	0.0908	11013.22
mesotrione	10.85	0.2000	54.25
MNBA	1050	0.0229	45851.53
AMBA	1050	0.0110	95454.55
CHR.H/TERIZ	1.65	1.3333	**1.24**
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)**
Terbuthylazine	21.12	0.5333	39.60

isoxaflutole	158	0.1333	1185.30
RPA 202248	100	0.1092	915.75
RPA 203328	100	0.0908	1101.32
mesotrione	50.54	0.2000	252.70
CHR.H/TERIZ	250	1.3333	187.50
Chronic effects on other soil macro- and mesofauna *Hypoaspis aculeifer*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Terbuthylazine	N/A		
isoxaflutole	500	0.1333	3750.9
RPA 202248	100	0.1092	915.8
RPA 203328	100	0.0908	1101.3
mesotrione	90.9	0.2000	454.5
CHR.H/TERIZ	62.5	1.3333	46.9

The long-term risk assessment for Terbuthylazine and CHR/H/TERIZ 650 WG indicates unacceptable long term risk to earthworms. Therefore, the risk refinement is needed. Such risk refinement is available based on weight of evidence and field studies and presented in point 9.8.2.2.

zRMS comment:
Tha long-term risk assessment for earthworms and other soil macroorganism for reviewed a.s.-isoxaflutole and its metabolites with consideration the toxicicty endpoinst included in LoEP, EFSA 2016 was accepted by zRMS.
The TER_{LT} values were above trigger value of 5 indicating an acceptable risk assessment for theses group of organism.

9.8.2.2 Higher-tier risk assessment

The low endpoint for long term effect of CHR/H/TERIZ on maize is indicated from toxicity of Terbuthylazine to earthworms. The lowest endpoint for terbuthylazine NOEC is equal to 0.5 mg a.s/kg bare soil, this indicates TER value 0.94. The NOEC reproduction derived from long term study on earthworms is 1.65 mg test item/kg soil, which indicates TER 1.24. For other two active substance TERlt for earthworms is 74 for isoxaflutole and 60 for mesotrione.

The NOEC mix for three active substances is equal 0.782 mg a.s mix/kg dw which comparable with the NOEC derived from the study 1.65 mg test item/kg (equal to 1.07 mg a.s/kg). So it can be concluded that the low endpoint is caused by terbuthylazine effect.

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

$$\mathrm{NOEC}\left(mix\right)=\left(\sum_{i}\frac{X\left(a.s._{i}\right)}{\mathrm{NOEC}\left(a.s._{i}\right)}\right)^{-1}$$

where:

X(a.s. i) = fraction of active substance (i) in the mixture expressed as:

X(terbuthylazine) = 400g teruthylazine/kg / (400 g terbuthylazine /kg + 100 g isoxaflutole /kg + 150 g mesotrione /kg)
X(isoxaflutole) = 100g isoxaflutole/kg / (400 g terbuthylazine /kg + 100 g isoxaflutole /kg + 150 g mesotrione /kg)
X(mesotrione) = 150g mesotrione/kg / (400 g terbuthylazine /kg + 100 g isoxaflutole /kg + 150 g mesotrione /kg)

NOEC(a.s. i) = acute toxicity value for active substance (i)

However in EFSA Journal 2011; 9(1):1969 and DAR (2007) Terbuthylazine Vol 3 B9 were evaluated several field studies terbuthylazine. In DAR (2007) Terbuthylazine Vol 3 B9 is stated an acceptable long-term risk to earthworms from technical terbuthylazine applied at rate of 844 g a.s/ha, based on two field studies submitted in original DAR (2007). As standard, the long-term riskfrom the active substance as oppose to the formulation is assessed, as the active substance and co-formulants are considered to rapidly disperse after application, therefore long-term exposure to the intact formulation will not occur. **Therefore it is considered that the application of formulation CHR/H/TERIZ 650 WG at rate 1.0 kg prod/ha (which is equal to 400 g tbt/ha) is unlikely to pose a long term risk to earthworms.**
No new studies are necessary.

zRMS comment:

The long-term risk assessment for Terbuthylazine in Metodis 650 WG indicates unacceptable long term risk to earthworms. Therefore, further refinement was needed. zRMS considered refinement based on the results from two field studies evaluated in the DAR (2007) where technical terbuthylazine was applied at rate of 844 g a.s/ha.
In the DAR (2007) Terbuthylazine Vol 3 B9 for dose of 844 g a.s./ha an acceptable long-term risk to earthworms was concluded.
Therefore it is considered that the application of formulation Metodus 650 WG at rate 0.8-1.0 kg prod/ha which is equal to 320-500 g tbt/ha) is unlikely to pose a long term risk to earthworms.

9.8.3 Overall conclusions

The acute risk to earthworms and other non-target soil organisms (meso- and macrofauna) was assessed as low for CHR/H/TERIZ 650 WG in a first-tier risk assessment. But a potential high risk was indicated on the long-term time scale for erthworms, but based on Risk refinement for terbuthylazine it can be concluded that application of formulation CHR/H/TERIZ 650 WG at rate 1 kg prod/ha (which is equal to 400 g tbt/ha) is unlikely to pose a long term risk to earthworms and other non-target soil organisms (meso- and macrofauna).

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with three active substances terbuthylazine/isoxaflutole/mesotrione and its relevant metabolites. Full details of these studies are provided

in the respective EU DAR and related documents.

Effects on soil microorganisms of CHR/H/TERIZ 650 WG were not evaluated as part of the EU assessment of any three active substances terbuthylazine.isoxaflutole.mesotrione. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.9.1-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation C-mineralisation	Terbuthylazine	28 d/14d, aerobic soil type	No significant effects of > 25 % on carbon mineralisation or nitrogen transformation up to a max tested concentration of 10.9 mg/kg soil dw	EFSA Journal 2011; 9(1):1969
N-mineralisation C-mineralisation	Metabolite MT1 (desethyl-terbuthylazine)	28 d/14 d, aerobic soil type	No effects of > 25 % on carbon mineralisation or nitrogen transformation up to a max tested concentration of 1.84 mg/kg soil dw	EFSA Journal 2011; 9(1):1969
N-mineralisation C-mineralisation	Metabolite MT13 (hydroxy-terbuthylazine)	28 d/14 d, aerobic soil type	No effects of > 25 % on carbon mineralisation or nitrogen transformation up to a max tested concentration of 3.45 mg/kg soil dw	EFSA Journal 2011; 9(1):1969
N-mineralisation C-mineralisation	Metabolite MT14 (desethyl-hydroxyterbuthylazine)	28 d/14 d, aerobic soil type	No effects of > 25 % on carbon mineralisation or nitrogen transformation up to a max tested concentration of 0.52 mg/kg soil dw	EFSA Journal 2011; 9(1):1969
N-mineralisation	isoxaflutole	28 d, aerobic soil type	Sandy loam: <18% effect at day 28 at 1 mg a.s./kg d.w.soil (=750 g a.s/ha)	EFSA Journal 2016;14(3):4416
C-mineralisation	isoxaflutole	28 d, aerobic soil type	Clay loam: 7% effect at day 28 at 1 mg a.s./kg d.w.soil (=750 g a.s/ha) Sandy loam: 10.5%	EFSA Journal 2016;14(3):4416

Endpoint	Substance	Exposure System	Results	Reference
			effect at day 63 at 1 mg a.s./kg d.w.soil (=750 g a.s/ha)	
N-mineralisation	RPA 202248	28 d, aerobic soil type	Sandy loam: 9.1% effect at day 84 at 0.67 mg a.s./kg d.w.soil (=500 g metabolite/ha)	EFSA Journal 2016;14(3):4416
N-mineralisation	RPA 203328	28 d, aerobic soil type	Sandy loam: 13% effect at day 28 at 0.1 mg a.s./kg d.w.soil (=75 g metabolite/ha)	EFSA Journal 2016;14(3):4416
N-mineralisation	isoxaflutole	28 d, aerobic soil type	Sandy loam: <18% effect at day 28 at 1 mg a.s./kg d.w.soil (=750 g a.s/ha)	EFSA Journal 2016;14(3):4416
N-mineralisation	Mesotrione	28 d, aerobic soil type	7.8% effect at day 28 at 0.53 mg a.s./kg d.w. soil (equivalent to 5.84 mg A12739A/kg d.w. soil)	EFSA Journal 2016;14(3):4419
N-mineralisation	AMBA	28 d, aerobic soil type	-7.6% effect at day 28 at 1.13 mg /kg d.w. soil	EFSA Journal 2016;14(3):4419
N-mineralisation	MNBA	28 d, aerobic soil type	4.8% effect at day 28 at 1.13 mg /kg d.w. soil	EFSA Journal 2016;14(3):4419
N-mineralisation	CHR/H/TERIZ	28 d, aerobic soil type	No adverse effects of the test item on nitrate content in soil were observed at day 28. At day 28 differences to the control were 0.94% and 4.78% in the 1.33 mg and 6.67 mg test item/kg soil dry weight treatment, respectively.	Ute Hammesfahr,2015, Study code: 105461080 IBACON
C-mineralisation	CHR/H/TERIZ	Not required		

9.9.2 Risk assessment

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

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

Table 9.9.2-1: Assessment of the risk for effects on soil micro-organisms due to the use of CHR/H/TERIZ in Mazie

Intended use	Maize		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Terbuthylazine	10.9 mg/kg soil dw/ 28 d	0.5333	YES
Desethyl-terbuthylazine	1.84 mg/kg soil dw /28d	0.1020	YES
Hydroxy-terbuthylazine	3.45 mg/kg soil dw/28 d	0.1208	YES
isoxaflutole	1 mg a.s./kg d.w.soil/ 28d	0.1333	YES
RPA 202248	0.67 mg a.s./kg d.w.soil/ 84d	0.1092	YES
RPA 203328	13% 0.1 mg a.s./kg d.w.soil/28 d	0.0908	YES
mesotrione	7.8% effect at day 28 at 0.53 mg a.s./kg d.w. soil	0.2000	YES
MNBA	4.8% effect at day 28 at 1.13 mg /kg d.w. soil	0.0229	YES
AMBA	-7.6% effect at day 28 at 1.13 mg /kg d.w. soil	0.0110	YES
CHR.H/TERIZ	4.78% / 6.67 mg test item/kg soil 28d	1.3333	YES
C-mineralisation Not required			

zRMS comments:

The risk assessment for reviewed a.s. – Isoxaflutole and its metabolite for soil micro-organism has been accepted by zRMS. The risk is considered acceptable.

9.9.3 Overall conclusions

The Predicted Environmental Concentrations of the formulation CHR/H/TERIZ 650 WG and its active substances terbuthylazine, isoxaflutole and mesotrione in soil are below the concentrations at which no una ceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days or more of exposure, indicating that the proposed use of CHR/H/TERIZ 650 WG poses an acceptable risk to soil microorganisms.

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 three active substances terbuthylazine/isoxafutole/mesotrione. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of CHR/H/TERIZ 650 WG were not evaluated as part of the EU assessment of any of three active substances. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
Brassica napus	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 19.6 g/ha	Dr. Ruth Bützler Dr. Norbert Knebel;2016; Study code: 105461086 IBACON
Brassica napus (per plant)	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 18.8 g/ha	
Glycine max	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 1357 g/ha	
Glycine max (per plant)	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 1284 g/ha	
Solanum lycopersicum	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 80 g/ha	
Solanum Lycopersicum (per plant)	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 81.4 g/ha	
Beta vulgaris	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 16.7 g/ha	
Beta vulgaris(per plant)	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 17.0 g/ha	
Daucus carota	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 82.2 g/ha	
Daucus carota(per plant)	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 78.6 g/ha	
Lactuca sativa	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 31.8g/ha	
Lactuca sativa(per plant)	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 33.6 g/ha	
Cucumis sativus	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 163 g/ha	
Avena sativa/(per	CHR/H/TERIZ	21 d	NOER >1000g/ha	

Species	Substance	Exposure System	Results	Reference
plant)		Seedling emergence		
Lolium perenne/ (per plant)	CHR/H/TERIZ	21 d Seedling emergence	NOER >1000g/ha	
Allium cepa	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 226 g/ha	
Allium cepa (per plant)	CHR/H/TERIZ	21 d Seedling emergence	ER_{50} fresh weight = 213 g/ha	
Brassica napus	CHR/H/TERIZ	21 d Vegetative vigour	ER_{50} fresh weight =103 g/ha	Dr. Ruth Bützler Dr. Norbert Knebel;2016; Study code: 105461087 IBACON
Glycine max	CHR/H/TERIZ	21 d Vegetative vigour	ER_{50} plant weight =169 g/ha	
Solanum lycopersicum	CHR/H/TERIZ	21 d Vegetative vigour	ER_{50} fresh weight =103 g/ha	
Beta vulgaris	CHR/H/TERIZ	21 d Vegetative vigour	ER_{50} plant weight =52.1 g/ha	
Daucus carota	CHR/H/TERIZ	21 d Vegetative vigour	ER_{50} fresh weight =118 g/ha	
Lactuca sativa	CHR/H/TERIZ	21 d Vegetative vigour	ER_{50} fresh weight =7.66 g/ha	
Cucumis sativus	CHR/H/TERIZ	21 d Vegetative vigour	ER_{50} fresh weight =679 g/ha	
Avena sativa	CHR/H/TERIZ	21 d Vegetative vigour	NOER>1000 g/ha	
Lolium perenne	CHR/H/TERIZ	21 d Vegetative vigour	ER_{50} fresh weight >1000 g/ha	
Allium cepa	CHR/H/TERIZ	21 d Vegetative vigour	NOER>333g/ha	

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

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

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

Table 9.10.2.2-1: Assessment of the risk for non-target plants due to the use of CHR/H/TERIZ in Maize

Intended use	Maize
Active substance/product	CHR/H/TERIZ
Application rate (g/ha)	1X 1000
MAF	1

Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Brassica napus	19.6	0.0277	27.7	**0.71**
Brassica napus (per plant)	18.8	0.0277	27.7	**0.68**
Glycine max	1357	0.0277	27.7	48.99
Glycine max (per plant)	1284	0.0277	27.7	46.35
Solanum lycopersicum	80	0.0277	27.7	**2.89**
Solanum Lycopersicum (per plant)	81.4	0.0277	27.7	**2.94**
Beta vulgaris	16.7	0.0277	27.7	**0.60**
Beta vulgaris(per plant)	17.0	0.0277	27.7	**0.61**
Daucus carota	82.2	0.0277	27.7	**2.97**
Daucus carota(per plant)	78.6	0.0277	27.7	**2.84**
Lactuca sativa	31.8	0.0277	27.7	**1.15**
Lactuca sativa(per plant)	33.6	0.0277	27.7	**1.21**
Cucumis sativus	163	0.0277	27.7	5.88
Avena sativa/(per plant)	1000	0.0277	27.7	36.10
Lolium perenne/ (per plant)	1000	0.0277	27.7	36.10
Allium cepa	226	0.0277	27.7	8.16
Allium cepa (per plant)	213	0.0277	27.7	7.69
Brassica napus	103	0.0277	27.7	**3.72**
Glycine max	169	0.0277	27.7	6.10
Solanum lycopersicum	103	0.0277	27.7	**3.72**
Beta vulgaris	52.1	0.0277	27.7	**1.88**
Daucus carota	118	0.0277	27.7	**4.26**
Lactuca sativa	7.66	0.0277	27.7	**0.28**

Cucumis sativus	679	0.0277	27.7	24.51
Avena sativa	1000	0.0277	27.7	36.10
Lolium perenne	1000	0.0277	27.7	36.10
Allium cepa	333	0.0277	27.7	12.02

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

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

Table 9.10.2.4-1: Risk assessment for non-target terrestrial plants due to the use of CHR/H/TERIZ 650 WG in maize considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) for the most sensitive species Lactuca sativa based on 21 d Vegetative vigour

Intended use		Maize			
Active substance/product		CHR/H/TERIZ			
Application rate (g/ha)		1X1000			
MAF		1			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
1	2.77	27.7	13.85	6.925	2.77
5	0.57	5.7	2.85	1.425	0.57
10	0.29	2.9	1.45	0.725	0.29
20	1.5	1.5	0.75	0.375	0.15
Toxicity value for most sensitive NTP *Lactuca sativa* ER_{50} = 7.66 g/ha		**TER** **criterion: TER ≥ 5**			
1		**0.28**	**0.55**	**1.11**	**2.77**
5		**1.34**	**2.69**	5.38	13.44
10		**2.64**	5.28	10.57	26.41
20		5.11	10.21	20.43	51.07

9.10.3 Overall conclusions

Based on the predicted rates of CHR/H/TERIZ 650 WG in off-field areas, the TER values describing the risk for non-target plants following exposure to CHR/H/TERIZ 650 WG according to the GAP of the formulation CHR/H/TERIZ 650 WG achieve the acceptability criteria TER ≥ 5, with applying:

- **20 m buffer zone**
- **5 m and the use of 75% drift reducing nozzles**
- **10 m and use of 50% drift reducing nozzles**

zRMS comments:

The risk assessment for non target plants previously accepted by zRMS in Corr Dossier , B9 is still valid.

Based on the predicted rates of CHR/H/TERIZ 65 WG in off-field areas, the TER values describing the risk for non-target plants following exposure to CHR/H/TERIZ 650 WG according to the GAP of the formulation CHR/H/TERIZ 650 WG achieve the acceptability criteria TER ≥ 5, with applying:

- **20 m buffer zone**
- **5 m and the use of 75% drift reducing nozzles**
- **10 m and use of 50% drift reducing nozzles**

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

Hazard pictograms:	
Signal word:	warning
Hazard statement(s):	H400 – Very toxic to aquatic life. H410 – Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	P270- Do not eat, drink or smoke when using the product P391 – Collect spillage. P501 - Dispose of contents of as hazardous waste.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use.

	[EUH401]
-	-
-	-

Special rule for labelling of plant protection product (PPP):	
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 10.1.1	**L. Lupicki**	2016	**CHR/H/TERIZ - TER Calculations for Terrestial Verterbrates** Chemirol GLP No Unpublished	N	Chemirol
KCP 10.1.2/01	**L. Lupicki**	2016	**CHR/H/TERIZ - TER Calculations for Terrestial Verterbrates** Chemirol GLP No Unpublished	N	Chemirol
KCP 10.1.2/02	**Duncan J., Clarke R.**	2016	Long-term Mammalian Risk Assessment for Mesotrione Exponent International Ltd. CENTRE FOR CHEMICAL REGULATION AND FOOD SAFETY (EUROPE) The Lenz, Hornbeam Business Park, Harrogate. HG2 8RE UK Exponent Project No.: 1502169.UK0 GLP no Unpublished	N	Chemirol
KCP 10.2/01	xxx	2016	**CHR/H/TERIZ 650 WG: Acute Toxicity to Rainbow Trout (Oncorhynchus mykiss) in a 96-hour Static Test** xxx 17 64380 xxx Study code: 105461230 GLP Unpublished	Y	Chemirol
KCP 10.2/02	Börschig C. Kobel A.	2016	**CHR/H/TERIZ 650 WG: Acute Toxicity to Daphnia magna in a Static 48-hour Immobilisation Test** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461220 GLP Unpublished	N	Chemirol
KCP 10.2/03	Börschig C. Kobel A.	2016	**CHR/H/TERIZ 650 WG: Toxicity to Pseudokirchneriella subcapitata in an Algal Growth Inhibition Test** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461210 GLP Unpublished	N	Chemirol
KCP	Börschig C. Kobel A.	2016	**CHR/H/TERIZ 650 WG: Toxicity to Anabaena flos-aquae in**	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
10.2/04			**an Algal Growth Inhibition Test** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461218 GLP Unpublished		
KCP 10.2/05	Börschig C. Kobel A.	2016	**CHR/H/TERIZ 650 WG:** **Toxicity to the Aquatic Plant Lemna gibba in a Static Growth Inhibition Test** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461240 GLP Unpublished	N	Chemirol
KCP 10.3.1/01	**Sekine T.**	2015	**Isoxaflutole/Mesotrione/ Terbuthylazine 100/150/400 g/kg WG:Effects (Acute Contact and Oral) on Honey Bees (Apis mellifera L.) in the Laboratory** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461035 GLP Unpublished	N	Chemirol
KCP 10.3.1/02	**Sekine T.**	2015	**Isoxaflutole/Mesotrione/ Terbuthylazine 100/150/400 g/kg WG:Effects (Acute Contact and Oral) on Honey Bees (Apis mellifera L.) in the Laboratory** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461035 GLP Unpublished	N	Chemirol
KCP 10.3.2/01	**Moll M.**	2015	**Isoxaflutole/Mesotrione/ Terbuthylazine 100/150/400 g/kg WG: Effects on the Predatory Mite Typhlodromus pyri in the Laboratory** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461063 GLP Unpublished	N	Chemirol
KCP 10.3.2/02	**Moll M.**	2015	**Isoxaflutole/Mesotrione/ Terbuthylazine 100/150/400 g/kg WG: Effects on the Parasitoid Aphidius rhopalosiphi in the Laboratory** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461001 GLP Unpublished	N	Chemirol
KCP 10.4/01	**Ganßmann M.**	2015	**CHR/H/TERIZ 650 WG: Effects on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil with 10% Peat** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461022 GLP Unpublished	N	Chemirol
KCP 10.4/02	**Ganßmann M.**	2015	**CHR/H/TERIZ 650 WG: Effects on Reproduction of the Collembola *Folsomia candida* in Artificial Soil with 5% Peat** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461016 GLP Unpublished	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4/03	**Ganßmann M.**	2015	**CHR/H/TERIZ 650 WG: Effects on Reproduction of the Predatory Mite *Hypoaspis aculeifer* in Artificial Soil with 5% Peat** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461089 GLP Unpublished	N	Chemirol
KCP 10.5/01	**Hammesfahr U.**	2015	**Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG: Effects on the Activity of the Soil Microflora in theLaboratory(Nitrogen Transformation)** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461080 GLP Unpublished	N	Chemirol
KCP 10.6/01	**Bützler R. Knebel N.**	2016	**CHR/H/TERIZ 650 WG: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461086 GLP Unpublished	N	Chemirol
KCP 10.6/02	**Bützler R. Knebel N.**	2016	**CHR/H/TERIZ 650 WG: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test** ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461087 GLP Unpublished	N	Chemirol

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.1/01	xxx	1994	Acute oral toxicity study with GS 13529 technical in Japanese quail Novartis Crop Protection AG, Basel, Switzerland [redacted] Report No 104412 GLP Not Published	Y	Syngenta
KCP 10.1.1/02	xxx	1983	Acute oral LD50 in Mallard duck Novartis Crop Protection AG, Basel, Switzerland [redacted] [redacted]Report No 108-213 GLP Not Published	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.1/03	xxx	1994b	5-day Dietary Toxicity Study in Japanese Quail with GS 13529 Technical Novartis Crop Protection AG, Basel, Switzerland [redacted] Report No 104434 GLP Not Published	Y	Syngenta
KCP 10.1.1/04	xxx	1983a	8-day dietary LC50 with Bobwhite quail Novartis Crop Protection AG, Basel, Switzerland [redacted]Report No 108-211 Not GLP Not Published	Y	Syngenta
KCP 10.1.1/05	xxx	1983b	8-day Dietary LC50 with Mallard Duck Novartis Crop Protection AG, Basel, Switzerland [redacted]Report No 108-212 Not GLP Not Published	Y	Syngenta
KCP 10.1.1/06	xxx	1995	Reproduction study with GS 13529 technical in the Japanese quail (by dietary admixture) Novartis Crop Protection AG, Basel, Switzerland [redacted] Report No 104445 GLP Not Published	Y	Syngenta
KCP 10.1.1/07	-	1994	RPA201772 technical - 14-day acute oral LD50 study in bobwhite quail Report No.: R004940, Edition Number: M-166860-01-1 Date: 1994-03-15 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.1.1/08	-	1994	RPA201772 technical: 14-day acute oral LD50 study in mallard ducks Report No.: R004941, Edition Number: M-166863-01-1 Date: 1994-03-15 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.1.1/09	-	1994	RPA201772 technical - acute dietary LC50 study in bobwhite quail Report No.: R004938, Edition Number: M-166855-01-1 Date: 1994-05-25 GLP/GEP: yes, unpublished	Y	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.1/11	-	1994	RPA201772 technical - 8-day acute dietary LC50 study in mallard ducklings Report No.: R004939, Edition Number: M-166858-01-1 Date: 1994-05-25 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.1.1/12	-	1995	Subacute dietary toxicity (LC_{50}) to the bobwhite quail RPA 202248 Report No.: C022448, Report includes Trial Nos.: RNP479 Edition Number: M-213116-01-1 Date: 1995-12-08 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.1.1/13	-	1998	RPA 203328: A Dietary LC50 Study with the Northern Bobwhite Report No.: B004404, Edition Number: M-241327-01-1 EPA MRID No.: 44693501 Date: 1998-10-15 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.1.1/14	-	1999	The Reproductive Toxicity Test of RPA-202248 with the Northern Bobwhite (*Colinus virgianicus*): RPA 202248 Report No.: B002788, Report includes Trial Nos.: 029809 14518 Edition Number: M-238510-01-1 Date: 1999-12-15 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.1.1/15	-	1995a	Acute oral toxicity of mesotrione to *Colinus virginianus* GLP, not published Original DAR (1999)	Y	Syngenta
KCP 10.1.1/16	-	1997a	Reproductive toxicity of mesotrione to *Colinus virginianus* GLP, not published Original DAR (1999)		
KCP 10.1.1/17	Taylor S., Taylor J.	2013	ZA1296 - Statistical Re-analysis: Effects on reproduction in Bobwhite Quail (Colinus virginianus) Syngenta Cambridge Environmental Assessments, United Kingdom, CEA.1056 Not GLP, not published	N	Syngenta
KCP 10.1.1/18	-	1997b	Reproductive toxicity of mesotrione to *Anas platyrhynchos* GLP, not published Original DAR (1999)	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.1/19	Taylor S., Taylor J.	2013a	ZA1296 - Statistical Re-analysis: Effects on reproduction in mallard duck (Anas platyrhynchos) Syngenta Cambridge Environmental Assessments, United Kingdom, CEA.1054 Not GLP, not published	N	Syngenta
KCP 10.2/01	xxx	2002	GS13529 (Terbuthylamine technical): Acute toxicity to rainbow trout (Oncorhynchus mykiss) Syngenta Crop Protection AG, Basel, Switzerland [redacted] Report No BL7395/B GLP Not Published	Y	Syngenta
KCP 10.2/02	xxx	2002	GS13529 (Terbuthylazine technical): Acute toxicity to mirror carp (Cyprinus carpio) Syngenta Crop Protection AG, Basel, Switzerland [redacted] Report No BL7396/B GLP Not Published	Y	Syngenta
KCP 10.2/03	xxx	1990	GS 13529, Terbuthylazin technical, 21-day prolonged toxicity study in the Rainbow trout under flow-through conditions Novartis Crop Protection AG, Basel, Switzerland [redacted] Report No 227248 GLP Not Published	Y	Syngenta
KCP 10.2/04	xxx	1990	Accumulation and elimination of 14C-terbuthylazine by Bluegill sunfish in a dynamic flow-through system Novartis Crop Protection AG, Basel, Switzerland [redacted] Report No 217451 GLP Not Published	Y	Syngenta
KCP 10.2/05	An, der Kolk J.	1996	GS 13529, static acute toxicity test with daphnids (Daphnia magna) Novartis Crop Protection AG, Basel, Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, Report No 96-075-1008 GLP Not Published	N	Syngenta

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 10.2/06	Shillabeer, N, Maynard, S.J, Woodyer, JM	2002	GS13529 (Terbuthylazine technical): Chronic toxicity to Daphnia magna Syngenta Crop Protection AG, Basel, Switzerland Brixham Environmental Laboratory, Brixham, United Kingdom, Report No BL7397/B GLP Not Published	N	Syngenta
KCP 10.2/07	Grade, R.	1993a	Report on the growth inhibition test of GS 13529 tech. to Green algae (Scenedesmus subspicatus) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 928431 GLP Not Published	N	Syngenta
KCP 10.2/08	Grade, R.	1993b	Growth inhibition test of GS 13529 tech. to Blue algae (Microcystis aeruginosa) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 928432 GLP Not Published	N	Syngenta
KCP 10.2/09	Grade, R.	1993c	Report on the growth inhibition test of GS 13529 tech. to Diatoms (Navicula pelliculosa) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland, Report No 928433 GLP Not Published	N	Syngenta
KCP 10.2/10	Palmer, S. Kendall, T, Kreuger, H	2001	A 96-Hour Growth Inhibition Test of GS-26379 (Metabolite of GS-13529) to the Green Alga, Selenastrum capricornutum Syngenta Crop Protection AG, Basel, Switzerland Wildlife International Ltd., Easton, MD, United States, Report No 528A-109 GLP Not Published	N	Syngenta
KCP 10.2/11	Grade, R.	2000b	Growth inhibition of GS 23158 (metabolite of GS 13529) to green algae (Selenastrum capricornutum) under static conditions Novartis Crop Protection AG, Basel, Switzerland, Report No 2001571 GLP Not Published	N	Syngenta

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 10.2/12	Vial, A.	1991g	Report on the growth inhibition test of GS 28620 to Green algae (Scenedesmus subspicatus) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 918160 GLP Not Published	N	Syngenta
KCP 10.2/13	Vial, A.	1991h	Report on the growth inhibition test of G 28273 to Green algae (Scenedesmus subspicatus) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 918140 GLP Not Published	N	Syngenta
KCP 10.2/14	Grade,R.	1997	Growth inhibition test of GS 14260 tech. to green algae (Selenastrum capricornutum) under static conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 961714 GLP Not Published	N	Syngenta
KCP 10.2/15	Memmert, U.	1998	Effects of 14C-labelled GS 13529 (Terbuthylazine tech.) on the development of sediment-dwelling larvae of Chironomus riparius in a water-sediment system Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 690524 GLP Not Published	N	Syngenta
KCP 10.2/16	Grade, R.	2000c	Toxicity test of GS 23158 (Metabolite of GS 13529) on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions Novartis Crop Protection AG, Basel, Switzerland, Report No 2001572 GLP Not Published	N	Syngenta

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 10.2/17	Hoberg, J.	1993	GS 13529 - Toxicity to Duckweed, Lemna gibba Novartis Crop Protection AG, Basel, Switzerland Springborn Laboratories Inc., Wareham, United States, Report No 93-9-4947 GLP Not Published	N	Syngenta
KCP 10.2/18	Douglas M.T., Handley J.W., Macdonald I.A.	1988c	THE ACUTE TOXICITY OF TERBUTHYLAZINE TO DAPHNIA MAGNA Huntingdon Research Centre Ltd., Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 10(a)/88505 GLP: yes published: no	N	Oxon
KCP 10.2/19	Wuntrich V.	1995b	INFLUENCE OF THE SOIL LEACHATES OF THE LYSIMETER STUDY WITH 14C-TERBUTHYLAZINE ON DAPHNIA MAGNA RCC AG., Itingen, Switzerland Oxon Italia S.P.A, Pero, Italy Report-no. 399778 GLP: yes published: no	N	Oxon
KCP 10.2/20	Bell G.	1995	TERBUTHYLAZINE: PROLONGED TOXICITY TO DAPHNIA MAGNA Huntingdon Research Centre Ltd., Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 18(a)/942069 GLP: yes published: no	N	Oxon
KCP 10.2/21	Kelly C.	1996	TERBUTHYLAZINE TECHNICAL ALGAL GROWTH INHIBITION Huntingdon Life Sciences Limited, Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 180/962297 GLP: yes published: no	N	Oxon

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 10.2/22	Wuthrich V.	1995c	INFLUENCE OF THE SOIL LEACHATES OF THE LYSIMETER STUDY WITH 14C-TERABUTHYLAZINE ON THE GROWTH OF SCENEDESMUS SUBSPICATUS RCC AG., Itingen, Switzerland Oxon Italia S.P.A, Pero, Italy Report-no. 399791 GLP: yes published: no	N	Oxon
KCP 10.2/23	Dengler D.	2004a	TESTING OF TOXIC EFFECTS OF DESETHYL-TERBUTHYLAZINE ON THE SINGLE CELL GREEN ALGA DESMODESMUS SUBSPICATUS (FORMERLY SCENEDESMUS SUBSPICATUS) GAB Biotechnologie GmbH, Niefern-Öschelbron, Germany Oxon Italia S.P.A, Pero, Italy Report-no. 20041034/01-AADs GLP: yes published: no	N	Oxon
KCP 10.2/24	Dengler D.	2004b	TESTING OF TOXIC EFFECTS OF 2-HYDOXY-TERBUTHYLAZINE ON THE SINGLE CELL GREEN ALGA DESMODESMUS SUBSPICATUS (FORMERLY SCENEDESMUS SUBSPICATUS) GAB Biotechnologie GmbH, Niefern-Öschelbron, Germany Oxon Italia S.P.A, Pero, Italy Report-no. 20041035/01-AADs GLP: yes published: no	N	Oxon
KCP 10.2/25	Migchielsen M.H.J	2002a	120-HOUR FRESH WATER CYANOBACTERIA GROWTH INHIBITION TEST WITH TERBUTHYLAZINE TECHNICAL Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 314055 GLP: yes published: no	N	Oxon

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 10.2/26	Migchielsen M.H.J	2002b	FRESH WATER ALGAL GROWTH INHIBITION TEST WITH TERBUTHYLAZINE TECHNICAL Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 346444 GLP: yes published: no	N	Oxon
KCP 10.2/27	Dengler D.	2001	ASSESSMENT OF TOXIC EFFECTS OF TERBUTHYLAZINE TECHNICAL ON THE DUCKWEED LEMNA GIBBA IN A SEMI STATIC TEST AND A RECOVERY PERIOD GAB Biotechnologie GmbH, Niefern-Öschelbron Oxon Italia S.P.A, Pero, Italy Report-no. 20001420/01-ARLg GLP: yes published: no	N	Oxon
KCP 10.2/28	-	1993a	Acute toxicity to bluegill sunfish (*Lepomis macrochirus*) under flow-through conditions RPA210772 Report No.: R004943, Report includes Trial Nos.: 10566.0493.6283.105 Edition Number: M-166868-01-1 EPA MRID No.: 435732-35 Date: 1993-11-15 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.2/29	-	1993b	RPA201772 - Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) under flowthrough conditions Report No.: R004946, Report includes Trial Nos.: 10566.0493.6284.108 Edition Number: M-166876-01-1 EPA MRID No.: 435732-36 Date: 1993-12-08 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.2/30	-	1995a	RPA202248 - Acute toxicity (96 hours) to rainbow trout (*Oncorhynchus mykiss*) under semi-static conditions Report No.: R005355, Edition Number: M-170804-01-1 EPA MRID No.: 439048-22 Date: 1995-11-03 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.2/31	-	1995	RPA203328 - Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) under flowthrough	Y	Bayer CropScience

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
			conditions Report No.: R005254, Report includes Trial Nos.: 10566.0194.6328.108 Edition Number: M-170722-01-1 EPA MRID No.: 43904825 Date: 1995-06-22 GLP/GEP: yes, unpublished		
KCP 10.2/32	-	1995	RPA 205834 - Acute toxicity (96 hours) to rainbow trout (*Oncorhynchus mykiss*) under semi-static conditions Report No.: C022449, Edition Number: M-213119-01-1 Date: 1995-11-10 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.2/33	-	1994	RPA201772 technical - Acute toxicity to sheepshead minnow (*Cyprinodon variegatus*) under flow-through conditions Report No.: R002592, Report includes Trial Nos.: 10566.0194.6320.505 Edition Number: M-162973-01-1 Date: 1994-07-01 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.2/34	-	2000	RPA 202248 - Acute Toxicity to the Sheepshead Minnow (*Cyprinodon variegatus*) under Static Conditions Report No.: B002804, Report includes Trial Nos.: 10566.6574 GOod #18308 Edition Number: M-238523-01-1 Date: 2000-02-22 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.2/35	-	1995	Isoxaflutole: Fish, juvenile growth test - 28 days Report No.: C022450, Edition Number: M-213121-01-1 Date: 1995-11-23 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.2/36	-	2013	Early-life stage toxicity of isoxaflutole (tech.) to fish (*Pimephales promelas*) under flow-through conditions Report No.: EBISX074, Edition Number: M-469327-01-1 Date: 2013-11-13 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 10.2/37	Putt, A. E.	1993	RPA201772 - Acute toxicity to daphnids (*Daphnia magna*) under flow-through conditions	N	Bayer CropScience

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
			Springborn Laboratories, Inc., Environmental Sciences Division, USA Bayer CropScience, Report No.: R004944, Report includes Trial Nos.: 10566.0493.6285.115 Edition Number: M-166871-01-1 Date: 1993-10-06 GLP/GEP: yes, unpublished		
KCP 10.2/38	McElligott, A.; McCahon, P.	1995	RPA202248 - Acute toxicity (48 hours) to daphnids (*Daphnia magna*) under semistatic conditions Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: SA95142, Edition Number: M-170841-03-1 Date: 1995-12-19 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/39	Putt, A. E.	1994	RPA203328 - Acute toxicity to daphnids (*Daphnia magna*) under flow-through conditions Springborn Laboratories, Inc. (SLS), Environmental Sciences Division, Wareham, MA, USA Bayer CropScience, Report No.: R005204, Report includes Trial Nos.: 10566.0194.6329.115 Edition Number: M-170649-01-1 EPA MRID No.: 43573241 Date: 1994-09-16 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/40	Suteau, P.	1995	RPA205834 - Acute toxicity (48 hours) to daphnids (*Daphnia magna*) under semistatic conditions Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: R005379, Edition Number: M-170847-01-1 Date: 1995-12-13 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/41	McCahon, P.; Suteau, P.	1995	RPA205834: Acute toxicity (48 hours) to daphnids (*Daphnia magna*) under semistatic conditions Rhone-Poulenc Agro, Sophia Antipolis, France Report No.: R005380, Edition Number: M-170850-01-1 GLP/GEP: no, unpublished	N	Bayer CropScience

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 10.2/42	Silke, G.	2013	Acute toxicity of isoxaflutole (tech.) to larvae of *Chironomus riparius* in a 48 h static laboratory test system - LIMIT - test Bayer CropScience, Report No.: EBISN014, Edition Number: M-468785-01-1 Date: 2013-11-05 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/43	Bettencourt, M.J.	1994	RPA201772 technical - Acute toxicity to mysid shrimp (*Mysidopsis bahia*) under flow through conditions Springborn Laboratories, Inc., Wareham, MA, USA Bayer CropScience, Report No.: R002591, Report includes Trial Nos.: 10566.0194.6319.515 10566.1094.6319.515 Edition Number: M-227961-02-1 Date: 1994-07-22 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/44	Collins, M. K.	1995	RPA202248 - Acute toxicity to mysids (*Mysidopsis bahia*) under static renewal conditions Springborn Laboratories, Inc. (SLS), Environmental Sciences Division, Wareham, MA, USA Bayer CropScience, Report No.: R005386, Report includes Trial Nos.: 10566.0895.6369.510 Edition Number: M-170861-01-1 EPA MRID No.: 439048-24 Date: 1995-12-22 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/45	Sousa, J. V.	1998	RPA 203328 - Acute toxicity to mysids (*Mysidopsis bahia*) under static acute conditions Springborn Laboratories, Inc., Wareham, MA, USA Report No.: C026471, Report includes Trial Nos.: 10566.0797.6436.510 Edition Number: M-211469-01-1 EPA MRID No.: 44718801 Date: 1998-12-10 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/46	McElligott, A.	1995	Isoxaflutole - *Daphnia magna* life cycle (21 day flow-through) chronic toxicity study Rhone-Poulenc Agro, Sophia Antipolis,	N	Bayer CropScience

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
			France Bayer CropScience, Report No.: C022451, Edition Number: M-213123-01-1 Date: 1995-11-30 GLP/GEP: yes, unpublished		
KCP 10.2/47	Putt, A. E.	1998	IFT Technical RPA201772 - The chronic toxicity to *Daphnia magna* under static renewal conditions Springborn Laboratories, Inc. (SLS), Wareham, MA, USA Bayer CropScience, Report No.: 98-10-7505, Report includes Trial Nos.: 10566,0898.6516.130 Edition Number: M-210464-01-2 EPA MRID No.: 48660702 Date: 1998-11-10 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/48	Sousa, J. V.	1995	Isoxaflutole - Chronic toxicity to mysids (*Mysidopsis bahia*) under flow-through conditions Springborn Laboratories, Inc., Environmental Sciences Division, USA Bayer CropScience, Report No.: R004949, Report includes Trial Nos.: 10566.1294.6352.530 Edition Number: M-166884-01-1 EPA MRID No.: 439048-21 Date: 1995-12-01 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/49	Odin-Feurtet, M.	1997	Isoxaflutole - Toxicity to the sediment dwelling chironomid larvae (*Chironomus riparius*) - 28 days Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: C026473, Edition Number: M-211474-01-1 Date: 1997-12-18 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/50	Odin-Feurtet, M.	1997	Isoxaflutole - Toxicity to the sediment dwelling chironomid larvae (*Chironomus riparius*) - 28 days Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: C026473, Edition Number: M-211474-01-1 Date: 1997-12-18 GLP/GEP: yes, unpublished	N	Bayer CropScience

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 10.2/51	Hoberg, J. R.	1993	RPA201772 - Toxicity to the the freshwater green alga, *Selenastrum capricornutum* Springborn Laboratories, Inc. (SLS), Environmental Sciences Division, Wareham, MA, USA Bayer CropScience, Report No.: R004955, Report includes Trial Nos.: 10566.0493.6286.430 Edition Number: M-166898-01-1 Date: 1993-09-10 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/52	Sewell, J. G.; Bartlett, A. J.	1995	RPA 202248: Algal inhibition test Safepharm Lab. Ltd., Derby, United Kingdom Bayer CropScience, Report No.: C022452, Edition Number: M-213125-01-1 Date: 1995-10-23 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/53	Hoberg, J. R.	1995	5-day toxicity to the freshwater green alga, *Selenastrum capricornutum* RPA203328 Springborn Laboratories, Inc. (SLS), Environmental Sciences Division, Wareham, MA, USA BCS, Report No.: R005374, Report includes Trial Nos.: 10566.0595.6367.430 Edition Number: M-170835-01-1 EPA MRID No.: 43904826 Date: 1995-11-22 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/54	Sewell, I. G.; Bartlett, A. J.	1995	RPA 205834: Algal inhibition test Safepharm Lab. Ltd., Derby, United Kingdom Bayer CropScience, Report No.: C022453, Edition Number: M-213127-01-1 Date: 1995-10-23 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/55	Hoberg, J. R.	1997	RPA202248 technical - Toxicity to the freshwater green alga, (Selenastrum capricornutum) Springborn Laboratories, Inc. (SLS), Environmental Sciences Division, Wareham, MA, USA BCS, Report No.: R004952, Report includes Trial Nos.: 10566.0797.6435.430	N	Bayer CropScience

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
			Edition Number: M-166891-01-1 EPA MRID No.: 44399908 Date: 1997-09-17 GLP/GEP: yes, unpublished		
KCP 10.2/56	Khul, K.	2015	*Pseudokirchneriella subcapitata* growth inhibition test with isoxaflutole (tech.) Bayer CropScience AG, BCS-D-EnSa-Testing, 40789 Monheim Germany Report No.: E 201 4803-8 Edition Number M-533501-01-1 Date: 2015-09-16 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/57	Hoberg, J. R.	1999	Isoxaflutole (IFT) - Toxicity to the duckweed, *Lemna gibba* - Code: AE B197278 Springborn Laboratories, Inc., Wareham, MA, USA Bayer CropScience, Report No.: C024183, Report includes Trial Nos.: 10566.1198.6532.410 Edition Number: M-216432-01-1 Date: 1999-03-19 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/58	Hoberg, J. R.	1997	RPA 202248 technical - Toxicity to duckweed, *Lemna gibba* Springborn Laboratories, Inc., Wareham, MA, USA Bayer CropScience, Report No.: R004951, Report includes Trial Nos.: 10566.0797.6434.410 Edition Number: M-166889-01-1 EPA MRID No.: 44399909 Date: 1997-09-16 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/59	Bruns, E.; Solga, A.	2013	Isoxaflutole technical: Recalculation of 9-days endpoints for *Lemna gibba* (Original Study Report No. 94-6-5319) Bayer CropScience, Report No.: M-449195-01-1, Edition Number: M-449195-01-1 GLP/GEP: n.a., unpublished	N	Bayer CropScience
KCP 10.2/60	Banman, C.S., Moore, S.	2013	Toxicity of isoxaflutole technical to the aquatic macrophyte, *Myriophyllum spicatum* SynTech Research Laboratory, Stilwell, Kansas, USA Bayer CropScience, Report No.: EBISX046,	N	Bayer CropScience

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
			Edition Number: M-452561-01-1 Date: 2013-04-22 GLP/GEP: yes, unpublished		
KCP 10.2/61	Hoberg, J. R.	1997	RPA203328 technical - Toxicity to the duckweed, *Lemna gibba* Springborn Laboratories, Inc., Wareham, MA, USA Bayer CropScience, Report No.: R004953, Report includes Trial Nos.: 10566.0797.6441.410 Edition Number: M-166893-01-1 EPA MRID No.: 44399910 Date: 1997-09-17 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/62	Hoberg, J. R.	2004	RPA 205834 - Toxicity To Duckweed, *Lemna gibba* Springborn Smithers Laboratories Bayer CropScience, Report No.: B004561, Report includes Trial Nos.: 13798.6107 Edition Number: M-241470-01-1 Date: 2004-01-08 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.2/63		1994a	Acute toxicity of mesotrione to *Oncorhynchus mykiss* GLP, not published Original DAR (1999)	Y	Syngenta
KCP 10.2/64		1994b	Acute toxicity of mesotrione to *Lepomis macrochirus* GLP, not published Original DAR (1999)	Y	Syngenta
KCP 10.2/65		1997a	Acute toxicity of MNBA (97.1% purity) to *Oncorhynchus Mykiss* GLP, not published Original DAR (1999)	Y	Syngenta
KCP 10.2/66		1998a	Acute toxicity of AMBA (99% purity) to *Oncorhynchus mykiss* GLP, not published Original DAR (1999)	Y	Syngenta
KCP 10.2/67		1997	Chronic toxicity of mesotrione to *Pinephales promelas* GLP, not published Original DAR (1999)	Y	Syngenta
KCP 10.2/68	Taylor S., Taylor J.	2013b	ZA1296 - Statistical Re-analysis: Chronic toxicity to fathead minnow (Pimephales promelas) embryos and larvae	N	Syngenta

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
			Syngenta Cambridge Environmental Assessments, United Kingdom, CEA.1043 Not GLP, not published		
KCP 10.2/69	Gentle & Hamer	1995	Acute toxicity of mesotrione to *Daphnia magna* GLP, not published Original DAR (1999)	N	Syngenta
KCP 10.2/70	Kent & Shillaber	1997	Acute toxicity of MNBA (97.1% purity) to *Daphnia magna* GLP, not published Original DAR (1999)	N	Syngenta
KCP 10.2/71	Magor & Gore	1998b	Acute toxicity of AMBA (99% purity) to *Daphnia magna* GLP, not published Original DAR (1999)	N	Syngenta
KCP 10.2/72	Morris *et al.*	1996	Chronic toxicity of mesotrione to *Daphnia magna* GLP, not published Original DAR (1999)	N	Syngenta
KCP 10.2/73	Liedtke A.	2013	ZA1296 - Statistical Re-analysis: Chronic Toxicity to Daphnia magna Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D79284 Not GLP, not published	N	Syngenta
KCP 10.2/74	Shillabeer, kent & Smith	1997	Chronic toxicity of mesotrione to *Pseudokirchneriella subcapitata* GLP, not published Original DAR (1999)	N	Syngenta
KCP 10.2/75	Dark R.	2013	ZA1296 - Statistical Re-analysis: Toxicity to the Green Alga Selenastrum capricornutum Syngenta tecsolve, North Ascot, United Kingdom, ZA1296/0214/1 Not GLP, not published	N	Syngenta
KCP 10.2/76	Smyth *et al.*	1997c	Chronic toxicity of MNBA (97.1% purity) to *Pseudokirchneriella subcapitata* GLP, not published Original DAR (1999)	N	Syngenta
KCP 10.2/77	Dark R.	2013a	MNBA - Statistical Re-analysis: Toxicity to the Green Alga Selenastrum capricornutum Syngenta tecsolve, North Ascot, United Kingdom, ZA1296/0533/1 Not GLP, not published	N	Syngenta
KCP 10.2/78	Smith, Magor & Shillabeer	1998c	Chronic toxicity of AMBA (99% purity) to *Pseudokirchneriella subcapitata* GLP, not published	N	Syngenta

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
			Original DAR (1999)		
KCP 10.2/79	Dark R.	2013b	AMBA - Statistical Re-analysis: Toxicity to the Green Alga Selenastrum capricornutum Syngenta tecsolve, North Ascot, United Kingdom, AMBA/0220/1 Not GLP, not published	N	Syngenta
KCP 10.2/80	Smyth *et al.*	1997b	Chronic toxicity of mesotrione to *Navicula pelliculosa* GLP, not published Original DAR (1999)	N	Syngenta
KCP 10.2/81	Dark R.	2012	ZA1296 - Statistical Re-analysis: Toxicity to the Freshwater Diatom Navicula pelliculosa Syngenta tecsolve, North Ascot, United Kingdom, ZA1296/0184/1 Not GLP, not published	N	Syngenta
KCP 10.2/82	Smyth *et al.*	1997d	Chronic toxicity of mesotrione to *Lemna gibba* GLP, not published Original DAR (1999)	N	Syngenta
KCP 10.2/83	Liedtke A.	2013a	ZA1296 - Statistical Re-analysis: Toxicity to Lemna gibba Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D83053 Not GLP, not published	N	Syngenta
KCP 10.2/84	Liedtke A.	2013b	R44276 - Toxicity to the Aquatic Higher Plant Lemna gibba in a 7-Day Growth Inhibition Test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D55614 GLP, not published	N	Syngenta
KCP 10.2/85	Liedtke A.	2013c	R169649 - Toxicity to the Aquatic Higher Plant Lemna gibba in a 7-Day Growth Inhibition Test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D55592 GLP, not published	N	Syngenta
KCP 10.2/86	Liedtke A.	2013d	SYN546974 - Toxicity to the aquatic higher plant Lemna gibba in a 7-day growth inhibition test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D77394 GLP, not published	N	Syngenta
KCP 10.3.1/01	Petto,R., Klepka, S.	1994	Laboratory testing for toxicity (acute contact and oral LD50) of GS 13529 to honey bees (Apis mellifera L.) (Hymenoptera, Apidae) Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 416902 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.1/02	Bell G.	1994b	TERBUTHYLAZINE: ACUTE TOXICITY TO HONEY BEES (APIS MELLIFERA) Huntingdon Life Sciences Limited, Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 25/931946 GLP: yes published: no	N	Oxon
KCP 10.3.1/03	Bell G.	1994b	TERBUTHYLAZINE: ACUTE TOXICITY TO HONEY BEES (APIS MELLIFERA) Huntingdon Life Sciences Limited, Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 25/931946 GLP: yes published: no	N	Oxon
KCP 10.3.1/04	Petto, R.	1994	Laboratory testing for toxicity (acute contact and oral LD50) of RPA201772 to honey bees (*Apis mellifera* L.) (Hymenoptera, Apidae) RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany Bayer CropScience, Report No.: M-170652-02-1, Edition Number: M-170652-02-1 Date: 1994-09-26 **...Amended: 1996-02-14** GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.3.1/05	Schmitzer, S.	2012	Effects of isoxaflutole tech. (acute contact and oral) on honey bees (*Apis mellifera* L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 72931035, Edition Number: M-441348-01-1 Date: 2012-11-08 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.3.1/06	Petto, R.	1994	Laboratory testing for toxicity (acute contact and oral LD50) of RPA201772 to honey bees (*Apis mellifera* L.) (Hymenoptera, Apidae) RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany Bayer CropScience, Report No.: M-170652-02-1, Edition Number: M-170652-02-1 Date: 1994-09-26 **...Amended: 1996-02-14** GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP	Schmitzer,	2012	Effects of isoxaflutole tech. (acute contact	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
10.3.1/07	S.		and oral) on honey bees (*Apis mellifera* L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 72931035, Edition Number: M-441348-01-1 Date: 2012-11-08 GLP/GEP: yes, unpublished		CropScience
KCP 10.3.1/08	Jackson, D. & Gough, H.J.	1995	ZA 1296: Acute Contact and Oral Toxicity to the Honey Bees (*Apis mellifera*) of Technical Material GLP, not published Original DAR (1999)	N	Syngenta
KCP 10.4/01	Rufli, H.	1989	GS 13529, Earthworm, acute toxicity test Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 891347 GLP Not Published	N	Syngenta
KCP 10.4/02	Van, Erp Y.	2000a	Acute toxicity study in the earthworm with GS13529 (terbuthylazine) Novartis Crop Protection AG, Basel, Switzerland NOTOX B.V., 'S Hertogenbosch, Netherlands, Report No 281677 GLP Not Published	N	Syngenta
KCP 10.4/03	Knops, M.	2000	Acute toxicity of GS 26379 to the earthworm Eisenia fetida Novartis Crop Protection AG, Basel, Switzerland BioChem GmbH, Cunnersdorf, Germany, Report No 001048066 GLP Not Published	N	Syngenta
KCP 10.4/04	Van, Erp Y.	2000b	Acute toxicity study in the earthworm with GS 26379 (deethylterbuthylazine) Novartis Crop Protection AG, Basel, Switzerland NOTOX B.V., 'S Hertogenbosch, Netherlands, Report No 281699 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4/05	Van, Erp Y.	2000c	Acute toxicity study in the earthworm with GS 23158 (hydroxy-terbuthylazine) Novartis Crop Protection AG, Basel, Switzerland NOTOX B.V., 'S Hertogenbosch, Netherlands, Report No 281688 GLP Not Published	N	Syngenta
KCP 10.4/06	Van, Erp Y.	2000d	Acute toxicity study in the earthworm with GS 28620 (deethylhydroxyterbuthylazine) Novartis Crop Protection AG, Basel, Switzerland NOTOX B.V., 'S Hertogenbosch, Netherlands, Report No 281701 GLP Not Published	N	Syngenta
KCP 10.4/07	Gossmann, A.	1998	Effects of GS 13529 / CGA 77102 SC 500 (A-9476 B) on reproduction and growth of earthworms Eisenia fetida (Savigny 1826) in artificial soil Novartis Crop Protection AG, Basel, Switzerland IBACON GmbH, Rossdorf, Germany, Report No 3450022 GLP Not Published	N	Syngenta
KCP 10.4/08	Kleiner, R.	2000	Sublethal toxicity (on reproduction and growth) of GS13529 SC 500 (A5435E) to the earthworm Eisenia fetida Novartis Crop Protection AG, Basel, Switzerland BioChem GmbH, Cunnersdorf, Germany, Report No 991048021 GLP Not Published	N	Syngenta
KCP 10.4/09	Klein, O.	2006	S-metolachlor (A9396A), terbuthylazine (A5435E) and S-metolachlor + terbuthylazine (A9476C): A field study to evaluate effects on the earthworm fauna in maize in southern Germany. GAB Biotechnologie GmbH & GAB Analytik GmbH, Niefern-Öschelbronn, Germany. Report No. 20051078/G1-NFEw. GLP: Yes Published: No	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4/10	Pease G., Foster A., Milanesi F.	2006	S-metolachlor (A9396C), terbuthylazine (A5435E) and s-metolachlor + terbuthylazine (A9476C): A field study to evaluate effects on the earthworm fauna of a maize field in Denmark. Ecotox Limited, Devon, UK. Report No. ER-06-KCB 215. Non GLP report from GLP study. Published: No	N	Syngenta
KCP 10.4/11	Meister, A	2002	Effects of GS 13529/CGA77102 SC 500 (A9476 B) on Reproduction of the Collembola Folsomia candida in Artificial Soil Syngenta Crop Protection AG, Basel, Switzerland IBACON GmbH, Rossdorf, Germany, Report No 11661016 GLP Not Published	N	Syngenta
KCP 10.4/12	Stabler D.	2003	ACUTE TOXICITY OF TERBUTHYLAZINE-DESETHYL ON EARTHWORMS, EISENIA FETIDA USING AN ARTIFICIAL SOIL TEST ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Oxon Italia S.P.A, Pero, Italy Report-no. 20021389/01-NLEf GLP: yes published: no	N	Oxon
KCP 10.4/13	Stabler D.	2002	ACUTE TOXICITY OF 2-HYDROXY-TERBUTHYLAZINE ON EARTHWORMS, EISENIA FETIDA USING AN ARTIFICIAL SOIL TEST ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Oxon Italia S.P.A, Pero, Italy Report-no. 20011377/01-NLEf GLP: yes published: no	N	Oxon
KCP 10.4/14	Luhrs U.	1999	EFFECTS OF CLICK (TERBUTHYLAZINE 500 G/L SC) ON REPRODUCTION AND GROWTH OF EARTHWORMS EISENIA FETIDA (SAVIGNY 1826) IN ARTIFICIAL SOIL IBACON, Rossdorf, Germany Oxon Italia S.P.A, Pero, Italy Report-no. 4580022 GLP: yes published: no	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4/15	Handley, J. W.; Wetton, P. M.	1993	The acute toxicity of RPA201772 to earthworms (*Eisenia foetida*) Safepharm Lab. Ltd., Derby, United Kingdom Bayer CropScience, Report No.: R002139, Edition Number: M-162062-01-1 Date: 1993-07-21 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.4/16	Odin-Feurtet, M.	1997	RPA 203328 - Acute toxicity (14-day) to earthworms (*Eisenia foetida*) - Artificial soil method Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: C026475, Edition Number: M-211477-01-1 Date: 1997-10-28 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.4/17	Kratz, M. A.	2013	Isoxaflutole (AE B197278) technical: Effects on survival, growth and reproduction on the earthworm *Eisenia fetida* tested in artificial soil Bayer CropScience, Report No.: kra-Rg-R-129/12, Edition Number: M-450435-01-1 Date: 2013-03-25 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.4/18	Kratz, M. A.	2012	Isoxaflutole-RPA202248: Effects on survival, growth and reproduction on the earthworm *Eisenia fetida* tested in artificial soil Bayer CropScience, Report No.: KRA-RG-R-132/12, Edition Number: M-442776-01-1 Date: 2012-11-29 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.4/19	Moser, T.; Scheffczyk, A.	2004	Isoxaflutole-RPA203328 (AE B197555): Reproduction toxicity to earthworm *Eisenia fetida* in artificial soil ECT Oekotoxikologie GmbH, Floersheim, Germany Bayer CropScience, Report No.: C041342, Edition Number: M-230530-01-1 Date: 2004-04-26 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.4/20	Frommholz, U.	2011	Isoxaflutole a.s.: Influence on the reproduction of the collembolan species *Folsomia candida* tested in artificial soil	N	Bayer CropScience

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
			Bayer CropScience, Report No.: FRM-COLL-124/11, Edition Number: M-416012-01-1 Date: 2011-10-14 GLP/GEP: yes, unpublished		
KCP 10.4/21	Kratz, M.A.	2011	Isoxaflutole a. s.: Influence on mortality and reproduction on the soil mite species *Hypoaspis aculeifer* tested in artificial soil Bayer CropScience, Report No.: KRA-HR-46/11, Edition Number: M-416751-01-1 Date: 2011-11-08 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.4/22	Frommholz, U.	2011	Isoxaflutole-RPA202248 (AE 0540092): Influence on the reproduction of the collembolan species *Folsomia candida* tested in artificial soil Bayer CropScience, Report No.: FRM-COLL-134/11, Edition Number: M-420112-01-1 Date: 2011-12-16 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.4/23	Kratz, M.A.	2011	Isoxaflutole-RPA202248 (AE 0540092): Influence on mortality and reproduction on the soil mite species *Hypoaspis aculeifer* tested in artificial soil Bayer CropScience, Report No.: KRA-HR-63/11, Edition Number: M-417912-01-1 Date: 2011-11-25 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.4/24	Frommholz, U.	2011	Isoxaflutole-RPA203328 (AE B197555): Influence on the reproduction of the collembolan species *Folsomia candida* tested in artificial soil Bayer CropScience, Report No.: FRM-COLL-135/11, Edition Number: M-420062-01-1 Date: 2011-12-15 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.4/25	Kratz, M.A.	2011	Isoxaflutole-RPA203328 (AE B197555): Influence on mortality and reproduction on the soil mite species *Hypoaspis aculeifer* tested in artificial soil Bayer CropScience, Report No.: KRA-HR-64/11, Edition Number: M-419849-01-1 Date: 2011-12-14 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP	Bembridge	1996	ZA 1296: Toxicity of Technical Material to the Earthworm	N	Syngenta

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
10.4/26	, J.D. & Jackson, D.		*Eisenia fetida* in an Artificial Soil Test GLP, not published Original DAR (1999)		
KCP 10.4/27	Friedrich S.	2011	Mesotrione SC (A12739A) - Sublethal toxicity to the earthworm Eisenia fetida in artificial soil Syngenta - Jealott's Hill, Bracknell, United Kingdom BioChem Agrar, Gerichshain, Germany, 11 10 48 003 S GLP, not published	N	Syngenta
KCP 10.4/28	Friedrich S.	2013	R44276 - Sublethal Toxicity to the Earthworm Eisenia fetida in Artificial Soil with 5 % Peat Syngenta BioChem Agrar, Gerichshain, Germany, 13 10 48 111 S GLP, not published	N	Syngenta
KCP 10.4/29	Friedrich S.	2013a	R169649 - Sublethal Toxicity to the Earthworm Eisenia fetida in Artificial Soil with 5 % Peat Syngenta BioChem Agrar, Gerichshain, Germany, 13 10 48 086 S GLP, not published	N	Syngenta
KCP 10.4/30	Friedrich S.	2013b	Mesotrione SC (A12739A) - Effects on the Reproduction of the Collembolan Folsomia candida Syngenta BioChem Agrar, Gerichshain, Germany, 13 10 48 009 S GLP, not published	N	Syngenta
KCP 10.4/31	Schulz L.	2013	Mesotrione SC (A12739A) - Effects on the Reproduction of the Predatory Mite Hypoaspis aculeife Syngenta BioChem Agrar, Gerichshain, Germany, 13 10 48 010 S GLP, not published	N	Syngenta
KCP 10.5/01	Lemnitzer, B.	2001	Effects of terbuthylazine tech. (GS 13529 U) on the activity of soil microflora Syngenta Crop Protection AG, Basel, Switzerland BioChem agrar, Gerichshain, Germany, Report No 0110351004 GLP Not Published	N	Syngenta
KCP 10.5/02	Suter, P.	1987	Influence of the herbicide Terbuthylazine (GS 13529) on soil microorganisms Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 22-87 GLP Not Published	N	Syngenta

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 10.5/03	Van, der Kolk J.	2001	GS23158, GS26379 and GS28620 (metabolites of GS13529 Terbuthylazine): Determination of effects on soil microflora activity Syngenta Crop Protection AG, Basel, Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, Report No 1047.110.747 GLP Not Published	N	Syngenta
KCP 10.5/04	Carter J.N.	1996	TERBUTHYLAZINE TECHNICAL AI EFFECTS ON SOIL NON-TARGET MICRO-ORGANISMS Huntingdon Life Sciences Limited, Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 165/952682 GLP: yes published: no	N	Oxon
KCP 10.5/05	Kolzer U.	2003	ASSESSMENT OF THE SIDE EFFECTS OF DESETHYL TERBUTHYLAZINE ON THE ACTIVITY OF THE SOIL MICROFLORA ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Oxon Italia S.P.A, Pero, Italy Report-no. 20021389/01-ABMF GLP: yes published: no	N	Oxon
KCP 10.5/06	Kolzer U.	2002	ASSESSMENT OF THE SIDE EFFECTS OF 2-HYDROXY-TERBUTHYLAZINE ON THE ACTIVITY OF THE SOIL MICROFLORA ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Oxon Italia S.P.A, Pero, Italy Report-no. 20011377/01-ABMF GLP: yes published: no	N	Oxon
KCP 10.5/07	Carter J.N.	1996	TERBUTHYLAZINE TECHNICAL AI EFFECTS ON SOIL NON-TARGET MICRO-ORGANISMS Huntingdon Life Sciences Limited, Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 165/952682 GLP: yes published: no	N	Oxon

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 10.5/08	Kolzer U.	2003	ASSESSMENT OF THE SIDE EFFECTS OF DESETHYL TERBUTHYLAZINE ON THE ACTIVITY OF THE SOIL MICROFLORA ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Oxon Italia S.P.A, Pero, Italy Report-no. 20021389/01-ABMF GLP: yes published: no	N	Oxon
KCP 10.5/09	Kolzer U.	2002	ASSESSMENT OF THE SIDE EFFECTS OF 2-HYDROXY-TERBUTHYLAZINE ON THE ACTIVITY OF THE SOIL MICROFLORA ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Oxon Italia S.P.A, Pero, Italy Report-no. 20011377/01-ABMF GLP: yes published: no	N	Oxon
KCP 10.5/10	Forster, J.	1994	A laboratory assessment of the effects of RPA 201772 on soil microflora respiration and nitrogen turnover according to BBA guidelines VI 1-1 (1990) Euro Laboratories Ltd., Bedfordshire, United Kingdom Bayer CropScience, Report No.: C022454, Edition Number: M-213129-01-1 Date: 1994-12-02 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.5/11	McMurray, A.	1997	A laboratory assessment of the effects of RPA 203328 on soil microflora respiration and nitrogen transformations according to EPPO Bulletin 24, 1-16 (1994) Chemex International plc, United Kingdom Bayer CropScience, Report No.: C038791, Edition Number: M-225762-01-1 Date: 1997-12-18 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.5/12	Schulz, L.	2013	Isoxaflutole-RPA202248 (BCS-AB59005): Effects on the activity of soil microflora (nitrogen transformation test) BioChem Agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 084 N, Edition Number: M-469915-01-1 Date: 2013-11-19 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 10.5/13	Schulz L.	2013a	Mesotrione SC (A12739A) - Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests)	N	Syngenta

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
			Syngenta BioChem Agrar, Gerichshain, Germany, 13 10 48 006 C/N GLP, not published		
KCP 10.5/14	Schulz L.	2013b	R169649 and R44276 - Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests) Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 045 C/N GLP, not published	N	Syngenta

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

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 additional studies were performed.

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

No additional studies were performed.

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

No additional studies were performed.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

No additional studies were performed.

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

No additional studies were performed.

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

No additional studies were performed.

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

No additional studies were performed.

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

Reference:	KCP 10.2.1
Report	CHR/H/TERIZ 650 WG: Acute Toxicity to Rainbow Trout (Oncorhynchus mykiss) in a 96-hour Static Test;2016; xxx.; xxx 17 64380 xxx; Study code: 105461230; GLP Unpublished
Guideline(s):	(GLP compliant study based on the Commission Regulation (EC) No 440/2008, C.1, 2008 and the OECD No. 203, 1992)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No (new product on the market)

Materials and methods

Test Item:	CHR/H/TERIZ 650 WG; Batch No.: 54191-74; content of a.i.: Mesotrione: 14.15 % w/w; Terbuthylazine: 39.43 % w/w; Isoxaflutole: 9.83 % w/w, according to certificate of analysis.
Test Species:	Juvenile Rainbow Trout (*Oncorhynchus mykiss)* mean length: 5.34 cm ± 0.5 cm; source: Forellenzuchtbetrieb Störk, 88348 Bad Saulgau, Germany
Test Design:	This study encompassed 6 treatment groups (5 dose rates of the test item and a control) each containing 7 individuals. The acute toxicity to unfed juvenile Rainbow Trout was determined in an aerated, static, 96-hour test. The test fish were observed at test start and after approximately 2, 24, 48, 72 and 96 hours test duration for sublethal effects and mortality. Dead fish were removed at least once daily and discarded. The samples of the test medium taken at start and after 96 hours, or when all fish were dead, were analysed using liquid chromatography with MS/MS detection.
Endpoints:	NOEC after 96 h, LOEC after 96 h; LC_{50}: lethal concentration producing 50 % mortality after 96 h of exposure.
Test Concentrations:	100, 45.5, 20.7, 9.4 and 4.3 mg test item/L, and a control
Test Conditions:	Water temperature: 14 °C; pH value: 6.8 to 8.0; dissolved oxygen concentration: 92 to 101 % of the air saturation value; photoperiod: 16 h light - 8 h dark; light intensity: 430 to 530 lux and thus were within the ranges requested by guideline OECD 203.

Results and discussions

Biological test results:
In the control and the concentration of 4.3 mg test item/L, all fish survived until the end of the exposure period.
After two hours of exposure all fish displayed sublethal effects at 45.5 and 100 mg test item/L. The fish were mainly on the bottom, showed dark colouration and tumbling during swimming and in the higher concentration the fish were lying on the side.
After 24 hours of exposure all fish were dead in the highest test concentration of 100 mg test item/L. Four fish died in the concentration of 45.5 mg test item/L, the remaining animals showed sublethal effects like swimming mainly on the bottom, dark colouration, tumbling during swimming, lying on the side and distended abdomen. In the concentrations of 20.7 and 9.4 mg test item/L all fish were swimming mainly on the bottom and had dark colouration. In the concentration of 20.7 mg test item/L the fish had addition-

ally distended abdomen.
After 48 hours all fish were dead in the concentration of 45.4 mg test item/L. Due to animal welfare reasons, in the concentrations of 20.7 and 9.4 mg test item/L two and one fish, respectively, were assessed as moribund, discarded and were counted dead. Accordingly 5 and 3 fish were dead in the concentrations of 20.7 and 9.4 mg test item/L, respectively. The remaining fish showed sublethal effects like dark colouration, swimming mainly on the bottom, tumbling during swimming, and distended abdomen. One fish in the lowest concentration of 4.3 mg test item/L showed dark colouration.
After 72 hours two additional fish died in the concentration of 9.4 mg/L. The occurring sublethal effects were the same as after 48 hours.
At the end of the test sublethal effects in the lowest concentration were no longer visible. In the concentration of 9.4 mg test item/L one additional fish died and the remaining fish showed sublethal effects like dark colouration, swimming mainly on the bottom and distended abdomen. At 20.7 mg test item/L no additional fish died and the two remaining fish were still mainly on the bottom, had dark colouration, showed tumbling during swimming and had distended abdomen.
Analytical results:
The quantification of the active ingredient Mesotrione, Terbuthylazine, and Isoxaflutole in the test item CHR/H/TERIZ 650 WG was performed using liquid chromatography with MS/MS detection.
Mesotrione:
At the start of the test 131 % of the nominal test concentrations were found (average of all test concentrations). After 96 hours test duration (24 hours and 48 hours for test concentrations 100 mg test item/L and 45.5 mg test item/L, respectively), 124 % of the nominal value was determined (average of all test concentrations). During the test the fish were exposed to a mean of 128 % of nominal.
Terbuthylazine:
At the start of the test 112 % of the nominal test concentrations were found (average of all test concentrations). After 96 hours test duration (24 hours and 48 hours for test concentrations 100 mg test item/L and 45.5 mg test item/L, respectively), 104 % of the nominal value was determined (average of all test concentrations). During the test the fish were exposed to a mean of 108 % of nominal.
Isoxaflutole:
At the start of the test 96 % of the nominal test concentrations were found (average of all test concentrations). After 96 hours test duration (24 hours and 48 hours for test concentrations 100 mg test item/L and 45.5 mg test item/L, respectively), 72 % of the nominal value was determined (average of all test concentrations). During the test the fish were exposed to a mean of 84 % of nominal. Since a formulation was tested, all results refer to nominal concentrations.

Conclusion

Based on the test results the 96-hour LC50 of CHR/H/TERIZ 650 WG for Rainbow Trout (Oncorhynchus mykiss) was determined to be 9.13 mg test item/L based on nominal concentrations. The LC0 was determined to be 4.3 mg test item/L also based on nominal concentrations.

A 2.2.1.2. Study 2

Reference:	KCP 10.2.1
Report	CHR/H/TERIZ 650 WG: Acute Toxicity to Daphnia magna in a Static 48-hour Immobilisation Test; 2016 Börschig C. Kobel A.;, ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany; Study code: 105461220;GLP, Unpublished
Guideline(s):	GLP compliant study based on the OECD Guideline 202, adopted April 13, 2004, equivalent to the Commission Regulation (EC) No 440/2008, C.2., 2008
Deviations:	No
GLP:	Yes

Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:

Test Item:	CHR/H/TERIZ 650 WG; Batch No.: 54191-74; content of a.i.: Mesotrione: 14.15 % w/w; Terbuthylazine: 39.43 % w/w; Isoxaflutole: 9.83 % w/w, according to certificate of analysis.
Test Species:	*Daphnia magna*, clone 5; 5.25 to 22.5 hours old Source: The Daphnia introduced in the test were taken from ibacon's in-house laboratory culture.
Test Design:	This study encompassed 6 treatment groups (5 dose rates of the test item and a control) each containing 20 individuals. The mobility of the Daphnia was determined in a static 48-hour test by visual observation after 24 and 48 hours.
Endpoints:	Number of immobile organisms after 24 and 48 hours
Test Concentrations:	100, 45.5, 20.7, 9.4, and 4.3 mg test item/L and a control
Test Conditions:	Water temperature: 20 °C; pH value: 7.8 to 8.1; dissolved oxygen concentration: 8.5 to 9.0 mg/L; photoperiod: 16 h light - 8 h dark; light intensity: 440 to 800 lux; and thus were within the ranges requested by guideline OECD 202

Results and discussions

Biological test results:

After 48 hours of exposure no immobilisation of the test animals was observed in the control. At the concentration of 4.3 mg test item/L, five animals were immobile and four animals were immobile at the concentration of 9.4 mg test item/L. 9 animals were immobile at the concentration of 20.7 mg test item/L and in the higher concentrations of 45.4 and 100 mg test item/L, 12 and 15 animals were immobile, respectively.

Analytical Results:

The quantification of the active ingredients Mesotrione, Terbuthylazine, and Isoxaflutole in the test item CHR/H/TERIZ 650 WG was performed using liquid chromatography with MS/MS detection.

Mesotrione:

At the start of the test 111 % of the nominal test concentrations were found (average of all test concentrations). After 48 hours test duration, 108 % of the nominal value was determined (average of all test concentrations). During the test the daphnids were exposed to a mean of 110 % of nominal.

Terbuthylazine:

At the start of the test 108 % of the nominal test concentrations were found (average of all test concentrations). After 48 hours test duration, 88 % of the nominal value was determined (average of all test concentrations). During the test the daphnids were exposed to a mean of 98 % of nominal.

Isoxaflutole:

At the start of the test 108 % of the nominal test concentrations were found (average of all test concentrations). After 48 hours test duration, 76 % of the nominal value was determined (average of all test concentrations). During the test the daphnids were exposed to a mean of 92 % of nominal.

Since a formulation was tested, all results refer to nominal concentrations.

Conclusions:

The toxic effect of the test item CHR/H/TERIZ 650 WG to Daphnia magna was assessed in a static dose-response test. The 48-hour NOEC was determined to be < 4.3 mg test item/L. The 48-hour LOEC was determined to be ≤ 4.3 mg test item/Land the 48-hour EC50 value was determined to be 27.7 mg test item/L.

A 2.2.1.3. Study 3

Reference:	KCP 10.2.1
Report	CHR/H/TERIZ 650 WG: Toxicity to Pseudokirchneriella subcapitata in an Algal Growth Inhibition Test; 2016; Börschig C. Kobel A. ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany; Study code: 105461210 ;GLP;Unpublished
Guideline(s):	GLP compliant study based on OECD No. 201, adopted March 2006, corrected July 28, 2011, equivalent to Commission Regulation (EC) No 761/2009, C.3., 2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:

Test Item:	CHR/H/TERIZ 650 WG; Batch No.: 54191-74; content of a.i.: Mesotrione: 14.15 % w/w; Terbuthylazine: 39.43 % w/w; Isoxaflutole: 9.83 % w/w, according to certificate of analysis.
Test Species:	*Pseudokirchneriella subcapitata*, Strain No. 61.81 SAG cultivated in the laboratories of ibacon; original source: "Sammlung von Algenkulturen, Albrecht-von-Haller-Institut für Pflanzenwissenschaften, Universität Göttingen", 37073 Göttingen, Germany.
Test Design:	This study encompassed 6 treatment groups (5 dose rates of the test item and a control) with three replicates per test concentration and six replicates for the control. At test start 50 mL of the test concentrations were inoculated with 5433 algal cells per mL test medium and defined volumes of the algal suspensions were sampled after 24, 48 and 72 hours for determination of cell densities by spectrophotometrical measurement.
Endpoints:	Yield and growth rate of the algae
Test Concentrations:	1000, 317, 100, 31.7 and 10.0 µg test item/L, and a control.
Test Conditions:	Water temperature: 23 to 24 °C; pH values at test start 8.0, at the end of the test 8.0 to 10.2; continuous illumination; mean light intensity: 6172 lux (5680 to 6670 lux).

Results and discussion:

Biological Results:

Parameter	Yield [µg test item/L]	Growth rate [µg test item/L]
72-hour EC_{50}	26.0	110
95 % conf. interval	22.5 - 30.0	106 - 114
72-hour EC_{20}	< 10.0	57.5
95 % conf. interval	< 10.0 – 12.0	54.0 - 60.8
72-hour EC_{10}	< 10.0	41.0
95 % conf. interval	n.d.	37.6 - 44.2
72-hour NOEC	< 10.0	< 10.0
72-hour LOEC	10.0	10.0

Analytical Results:

The quantification of the active ingredients Mesotrione, Terbuthylazine, and Isoxaflutole in the test item CHR/H/TERIZ 650 WG was performed using liquid chromatography with MS/MS detection.

Mesotrione: At the start of the test 116 % of the nominal test concentrations were found (average of the nominal concentrations of 1000, 317, 100 and 31.7 µg test item/L). After 72 hours test duration, 111 % of the nominal value was determined (average of the nominal concentrations of 1000, 317, 100 and 31.7 µg test item/L). During the test the algae were exposed to a mean of 114 % of nominal.

Terbuthylazine: At the start of the test 106 % of the nominal test concentrations were found (average of the nominal concentrations of 1000, 317, 100 and 31.7 µg test item/L). After 72 hours test duration, 102 % of the nominal value was determined (average of the nominal concentrations of 1000, 317, 100 and 31.7 µg test item/L). During the test the algae were exposed to a mean of 104 % of nominal.
Isoxaflutole: At the start of the test 106 % of the nominal test concentrations were found (average of the nominal concentrations of 1000, 317, 100 and 31.7 µg test item/L). After 72 hours test duration, 62 % of the nominal value was determined (average of the nominal concentrations of 1000, 317 and 100 µg test item/L). During the test the algae were exposed to a mean of 87 % of nominal. Since a formulation was tested, all reported results refer to nominal concentrations.

Conclusion:

The influence of CHR/H/TERIZ 650 WG on the growth of the freshwater green algae Pseudokirchneriella subcapitata was assessed in a static dose-response test. The 72-hour EyC50 was calculated to be 26.0 µg test item/L, and the 72-hour ErC50 value was calculated to be 110 µg test item/L. The 72-hour NOEyC was determined to be < 10.0 µg test item/L and the associated 72-hour LOEyC was 10.0 µg test item/L. The 72-hour NOErC was determined to be < 10.0 µg test item/L and the associated 72-hour LOErC was 10.0 µg test item/L**.**

A 2.2.1.4. Study 4

Reference:	KCP 10.2.1
Report	CHR/H/TERIZ 650 WG: Toxicity to Anabaena flos-aquae in an Algal Growth Inhibition Test2016; Börschig C. Kobel A ibacon GmbH Arheilger Weg 17 64380 Rossdorf, Germany Study code: 105461218; GLP Unpublished
Guideline(s):	GLP compliant study based on OECD No. 201, adopted March 2006, corrected July 28, 2011, equivalent to Commission Regulation (EC) No 761/2009, C.3., 2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:

Test Item:	CHR/H/TERIZ 650 WG; Batch No.: 54191-74; content of a.i.: Mesotrione: 14.15 % w/w; Terbuthylazine: 39.43 % w/w; Isoxaflutole: 9.83 % w/w, according to certificate of analysis.
Test Species:	*Anabaena flos-aquae*, UTEX B1444 cultivated in the laboratories of ibacon; original source: "The University of Texas at Austin, UTEX Culture Collection of Algae, 1 University Station", Austin, TX 78712, USA
Test Design:	This study encompassed 9 treatment groups (8 dose rates of the test item and a control) with three replicates per test concentration and six replicates for the control. At test start 50 mL of the test concentrations were inoculated with 15000 algal cells per mL test medium and defined volumes of the algal suspensions were sampled after 24, 48 and 72 hours for determination of cell densities by spectrophotometrical measurement.
Endpoints:	Yield and growth rate of the algae
Test Concentrations:	100, 32, 10, 3.2, 1.0, 0.32, 0.1 and 0.03 mg test item/L, and a control.
Test Conditions:	Water temperature: 23 °C; pH values at test start 7.4, at the end of the test 8.5 to 8.6; continuous illumination; mean light intensity: 3845 lux (3440 to 4050 lux).

Results and discussion:

Biological results:

Parameter	Yield [mg test item/L]	Growth rate [mg test item/L]
72-hour EC_{50}	0.195	1.44
95 % conf. interval	0.182 - 0.208	1.26 - 1.65
72-hour EC_{20}	0.032	0.270
95 % conf. interval	< 0.03 - 0.035	0.216 - 0.328
72-hour EC_{10}	< 0.03	0.113
95 % conf. interval	n.d.	0.083 - 0.146
72-hour NOEC	< 0.03	0.03
72-hour LOEC	≤ 0.03	0.1

Analytical Results:

The quantification of the active ingredients Mesotrione, Terbuthylazine, and Isoxaflutole in the test item CHR/H/TERIZ 650 WG was performed using liquid chromatography with MS/MS detection.

Mesotrione:

At the start of the test 92 % of the nominal test concentrations were found (average of all test concentrations). After 72 hours test duration, 93 % of the nominal value was determined (average of all test concentrations). During the test the algae were exposed to a mean of 92 % of nominal.

Terbuthylazine:

At the start of the test 96 % of the nominal test concentrations were found (average of all test concentrations except for test concentration nominal 0.03 mg test item/L which was below the LOQ). After 72 hours test duration, 99 % of the nominal value was determined (average of all test concentrations except for test concentration nominal 0.03 mg test item/L which was below the LOQ). During the test the algae were exposed to a mean of 97 % of nominal.

Isoxaflutole:

At the start of the test 95 % of the nominal test concentrations were found (average of all test concentrtions). After 72 hours test duration, 17 % of the nominal value was determined (average of all test concentrations except for test concentration nominal 0.03 mg test item/L which was below the LOQ). During the test the algae were exposed to a mean of 59 % of nominal.

Since a formulation was tested, all reported results refer to nominal concentrations.

Conclusions:

The influence of CHR/H/TERIZ 650 WG on the growth of the freshwater green algae Anabaena flos-aquae was assessed in a static dose-response test. The 72-hour EyC50 was calculated to be 0.195 mg test item/L, and the 72-hour ErC50 value was calculated to be 1.44 mg test item/L. The 72-hour NOEyC was determined to be < 0.03 mg test item/L and the associated 72-hour LOEyC was ≤ 0.03 mg test item/L. The 72-hour NOErC was determined to be 0.03 mg test item/L and the associated 72-hour LOErC was 0.1 mg test item/L.

A 2.2.1.5. Study 5

Reference:	KCP 10.2.1
Report	CHR/H/TERIZ 650 WG: Toxicity to the Aquatic Plant Lemna gibba in a Static Growth Inhibition Test, 2016; Börschig C. Kobel A ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461240 GLP Unpublished
Guideline(s):	GLP compliant study based on OECD No. 201, adopted March 2006, corrected July 28, 2011, equivalent to Commission Regulation (EC) No 761/2009, C.3., 2009
Deviations:	No

GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:

Test Item:	CHR/H/TERIZ 650 WG; Batch No.: 54191-74; content of a.i.: Mesotrione: 14.15 % w/w; Terbuthylazine: 39.43 % w/w; Isoxaflutole: 9.83 % w/w, according to certificate of analysis.
Test Species:	*Lemna gibba* G 3
Test Design:	This study encompassed 6 treatment groups (5 dose rates of the test item and a control) with three replicates per test concentration and control. At test start 12 fronds were introduced in each replicate and incubated for 7 days under static conditions. The frond numbers were determined on day 3, 5 and 7. The dry weight of each replicate was determined at test termination.
Endpoints:	Yield and growth rate based on frond number and dry weight.
Test Concentrations:	100, 32, 10, 3.2 and 1.0 µg test item/L and a control.
Test Conditions:	Water temperature: 21 to 23 °C; pH values at test start 7.5 to 7.6, at the end of the test 8.7 to 9.2; continuous illumination; mean light intensity: 8230 lux (7800 to 8810 lux).

Results and discussion:

Biological results:

Parameter	Yield (frond number) [µg test item/L]	Growth rate (frond number) [µg test item/L]	Yield (dry weight) [µg test item/L]	Growth rate (dry weight) [µg test item/L]
EC_{50} (7-day)	18.9	40.8	17.3	27.2
95 % conf. limits	14.6 - 24.3	36.2 - 46.0	14.4 - 20.8	25.4 - 29.1
EC_{20} (7-day)	8.77	17.1	11.5	16.7
95 % conf. limits	6.18 - 12.6	14.4 - 20.4	9.43 - 14.2	14.7 - 18.8
EC_{10} (7-day)	5.88	10.9	9.25	12.9
95 % conf. limits	3.65 - 9.33	8.58 - 13.7	7.26 - 11.9	10.9 - 15.3
7-day NOEC	3.2	3.2	3.2	10
7-day LOEC	10	10	10	32

Analytical results:

The quantification of the active ingredients Mesotrione, Terbuthylazine, and Isoxaflutole in the test item CHR/H/TERIZ 650 WG was performed using liquid chromatography with MS/MS detection.

Mesotrione: At the start of the test 105 % of the nominal test concentrations were found (average of the nominal concentrations of 3.2, 10, 32 and 100 µg test item/L). After 7 days test duration, 102 % of the nominal value was determined (average of the nominal concentrations of 3.2, 10, 32 and 100 µg test item/L). During the test the lemna were exposed to a mean of 103 % of nominal.

Terbuthylazine: At the start of the test 146 % of the nominal test concentrations were found (average of all test concentrations). After 7 days test duration, 151 % of the nominal value was determined (average all test concentrations). During the test the lemna were exposed to a mean of 148 % of nominal.

Isoxaflutole: At the start of the test 123 % of the nominal test concentrations were found (average of all test concentrations). After 7 days test duration, 1 % of the nominal value was determined (in the highest test concentration of 100 µg test item/L). A mean value to which the lemna were exposed during the test is not given since the amount of Isoxaflutole by the end of the test was below the detection limit for all samples except one.

The lowest test concentration of 1 µg test item/L could only be quantified for the active ingredients Terbuthylazine and Isoxaflutole, where the recovery resulted in 299 and 247 % of the nominal value, respectively. The test item was probably dosed incorrectly for this test concentration, but since the NOEC of the study lies at 3.2 µg test item/L or higher for all endpoints, all values are given as nominal concentrations.

Conclusions:

The influence of CHR/H/TERIZ 650 WG on the growth of the freshwater plant Lemna gibba was assessed in a static dose-response test.

The 7-day EyC50 was calculated to be 18.9 and 17.3 µg test item/L for frond number and dry weight, respectively.

The 7-day ErC50 was calculated to be 40.8 and 27.2 µg test item/L for frond number and dry weight, respectively.

The 7-day NOEyC and the LOEyC were determined to be 3.2 and 10 µg test item/L for frond number and dry weight, respectively.

The 7-day NOErC and the LOErC were determined to be 3.2 and 10 µg test item/L for frond number and 10 and 32 µg test item/L for dry weight, respectively.

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

No additional studies were performed.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

No additional studies were performed.

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

Reference:	KCP 10.3/01
Report	Isoxaflutole/Mesotrione/ Terbuthylazine 100/150/400 g/kg WG:Effects (Acute Contact and Oral) on Honey Bees (Apis mellifera L.) in the Laboratory 2015, Sekine T ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461035 GLP Unpublished
Guideline(s):	GLP compliant study based on OECD 213 and 214 (1998))
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:

1. Summary

Test Item:	Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG, Batch No.: 54191-74, content: Mesotrione: 14.15 % w/w (analysed); Terbuthylazine: 39.43 % w/w (analysed); Isoxaflutole: 9.83 % w/w (analysed), according to certificate of analysis
Test Species:	Honey bee (*Apis mellifera* L.); female worker bees; obtained from a healthy and queen-right colony, bred by ibacon, collected on the morning of use.
Test Design:	Limit acute oral and contact toxicity test; duration 48 h; 5 replicates, each consisting of 10 bees per cage per treatment; assessment of mortality after 4, 24 and 48 hours; reference item: dimethoate 400 g/L (nominal).
Test Concentrations:	Contact test: 200.0 µg Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG/bee* Oral test (nominal): 200.0 µg Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG/bee* Oral test (measured): 198.0 µg Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG/bee*

*in the following, *e.g.* 200.0 µg of Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG/bee, will be referred to as 200.0 µg/bee. The dose levels are presented as µg product/bee without taking into consideration the content of the a.i.

Test Conditions: Temperature: 25 °C; relative humidity: 50 % - 78 %; photoperiod: 24 h darkness.

Results and discussion:

Contact Test:

At the end of the contact toxicity test (48 hours after application), there was 4.0 % mortality at 200.0 µg product/bee. No mortality occurred in the control group (water + 0.5 % Adhäsit).

Behavioural abnormalities were observed 4 hours after application. One bee was found to be affected after 4 hours. No further behavioural abnormalities attributed to exposure of the test item to the bees were observed 24 and 48 hours after application.

Oral Test:

In the oral toxicity test the maximum nominal test level of Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG (200 µg product/bee) corresponded to an actual intake of 198.0 µg product/bee. 2.0 % mortality was observed at this dose level after 48 hours. No mortality occurred in the control (50 % w/v sucrose solution = 500 g sucrose/L tap water).

No test item induced behavioural effects were observed at any time in the oral toxicity tests

Conclusions:

The toxicity of Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG was tested in both an acute contact and an oral toxicity test on honey bees.

The contact LD50 (48 h) was > 200.0 µg product/bee.

The oral LD50 (48 h) was > 198.0 µg product/bee.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Reference:	KCP 10.3/02
Report	Isoxaflutole/Mesotrione/ Terbuthylazine 100/150/400 g/kg WG:Effects (Acute Contact and Oral) on Honey Bees (Apis mellifera L.) in the Laboratory 2015, Sekine T ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461035 GLP Unpublished
Guideline(s):	GLP compliant study based on OECD 213 and 214 (1998))
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication	-

(if vertebrate study)

Materials and methods:

1. Summary

Test Item:	Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG, Batch No.: 54191-74, content: Mesotrione: 14.15 % w/w (analysed); Terbuthylazine: 39.43 % w/w (analysed); Isoxaflutole: 9.83 % w/w (analysed), according to certificate of analysis
Test Species:	Honey bee (*Apis mellifera* L.); female worker bees; obtained from a healthy and queen-right colony, bred by ibacon, collected on the morning of use.
Test Design:	Limit acute oral and contact toxicity test; duration 48 h; 5 replicates, each consisting of 10 bees per cage per treatment; assessment of mortality after 4, 24 and 48 hours; reference item: dimethoate 400 g/L (nominal).
Test Concentrations:	Contact test: 200.0 µg Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG/bee* Oral test (nominal): 200.0 µg Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG/bee* Oral test (measured): 198.0 µg Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG/bee*

*in the following, *e.g.* 200.0 µg of Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG/bee, will be referred to as 200.0 µg/bee. The dose levels are presented as µg product/bee without taking into consideration the content of the a.i.

Test Conditions:	Temperature: 25 °C; relative humidity: 50 % - 78 %; photoperiod: 24 h darkness.

Results and discussion:

Contact Test:

At the end of the contact toxicity test (48 hours after application), there was 4.0 % mortality at 200.0 µg product/bee. No mortality occurred in the control group (water + 0.5 % Adhäsit).

Behavioural abnormalities were observed 4 hours after application. One bee was found to be affected after 4 hours. No further behavioural abnormalities attributed to exposure of the test item to the bees were observed 24 and 48 hours after application.

Oral Test:

In the oral toxicity test the maximum nominal test level of Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG (200 µg product/bee) corresponded to an actual intake of 198.0 µg product/bee. 2.0 % mortality was observed at this dose level after 48 hours. No mortality occurred in the control (50 % w/v sucrose solution = 500 g sucrose/L tap water).

No test item induced behavioural effects were observed at any time in the oral toxicity tests

Conclusions:

The toxicity of Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG was tested in both an acute contact and an oral toxicity test on honey bees.

The contact LD50 (48 h) was > 200.0 µg product/bee.

The oral LD50 (48 h) was > 198.0 µg product/bee.

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

No additional studies were performed.

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

No additional studies were performed.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

No additional studies were performed.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

No additional studies were performed.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

No additional studies were performed.

A 2.3.1.7 KCP 10.3.1.7 Non target arthropods studies

Study 1

Reference:	KCP 10.3.2/01
Report	Isoxaflutole/Mesotrione/ Terbuthylazine 100/150/400 g/kg WG: Effects on the Predatory Mite Typhlodromus pyri in the Laboratory; 2016, M.Moll ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461063
Guideline(s):	GLP compliant study based on Mead-Briggs et al. 2000
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:

Test Item: Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG; batch no.: 54191-74; content of a.s.: 14.15 ± 0.27 % w/w Mesotrione, 39.43 ± 0.73 % w/w Terbuthylazine, 9.83 ± 0.26 % w/w Isoxaflutole (nominal: 15.0 % w/w Mesotrione, 40.0 % w/w Terbuthylazine, 10.0 % w/w Isoxaflutole).

Test Species: Predatory Mite *(Typhlodromus pyri)*, protonymphs less than 24 hours old; source: Katz Biotech AG, Baruth, Germany.

Test Design: This study encompassed 3 treatment groups (1 dose rate of the test item, control, reference item) with 5 replicates each containing 20 mites. The mites were exposed to dried residues on treated glass plates. Survival of the mites was assessed after 3 and 7 days.

Endpoints: Mortality after 7 days of exposure.

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

Test Rates: Control, 650 g a.s./ha and reference item. The reference item was applied at an application rate of 8.0 mL Perfekthion/ha. All treatments were applied in 200 L water/ha. The spraying dilutions were sprayed onto glass plates *via* laboratory spraying equipment, which were then air dried.

Test Conditions: Temperature: 24 - 26 °C; relative humidity: 66 - 78 %; photoperiod: 16 h light : 8 h dark; light intensity: 310 - 555 lux.

Results and discussion:

	Rate [1)]	Mortality [2)] [%]	Corrected Mortality [3)] [%]
Control	0	5.0	--
Test Item	650 g a.s./ha	4.0 n.s.	-1.1
Reference Item (Perfekthion)	8.0 mL product/ha	100.0 *	100.0

1) Application rate in 200 L water/ha

2) Mortality: after 7 days of exposure to spray residues on glass plates (Fisher´s Exact Test, α = 0.05; n.s. = not significant, * = significant)

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

Conclusion:

Under worst case laboratory conditions mortality of *T. pyri* was not affected compared to the control at 650 g a.s./ha.

Therefore the LR_{50} of Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG is estimated to be greater than 650 g a.s./ha in 200 L water/ha.

Study 2

Reference:	KCP 10.3.2/02
Report	Isoxaflutole/Mesotrione/ Terbuthylazine 100/150/400 g/kg WG: Effects on the Parasitoid Aphidius rhopalosiphi in the Laboratory; 2016, M.Moll ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461001
Guideline(s):	GLP compliant study based on Mead-Briggs et al. 2000
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:

Test Item: Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG; batch no.: 54191-74; content of a.s.: 14.15 ± 0.27 % w/w Mesotrione, 39.43 ± 0.73 % w/w Terbuthylazine, 9.83 ± 0.26 % w/w Isoxaflutole (nominal: 15.0 % w/w Mesotrione, 40.0 % w/w Terbuthylazine, 10.0 % w/w Isoxaflutole).

Test Species: Parasitoid *(Aphidius rhopalosiphi),* adults not older than 48 hours; source: Katz Biotech AG, Baruth, Germany.

Test Design: This study encompassed 3 treatment groups (1 dose rate of the test item, control, reference item) with 4 replicates each containing 10 parasitoids. The parasitoids were exposed to dried residues on treated glass plates. Survival of the parasitoids was assessed after 2, 24 and 48 hours.

Endpoints: Mortality of exposed parasitoids after 48 h of exposure.

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

Test Rates: Control, 650 g a.s./ha and reference item. The reference item was applied at an application rate of 0.3 mL Perfekthion/ha. All treatments were applied in 200 L water/ha. The spraying dilutions were sprayed onto glass plates *via* laboratory spraying equipment, which were then air dried.

Test Conditions: Temperature: 19 - 20 °C; relative humidity: 68 - 78 %; photoperiod: 16 h light : 8 h dark; light intensity: 480 - 610 lux.

Results and discussion:

	Rate [1)]	Mortality [2)] [%]	Corrected Mortality [3)] [%]
Control	-	0.	--
Test Item	650 g a.s./ha	5.0 n.s.	5.0
Reference Item (Perfekthion)	0.3 mL product/ha	100.0 *	100.0

1) Application rate in 200 L water/ha

2) Mortality: after 48 hours of exposure to spray residues on glass plates, (Fisher's Exact Test, α = 0.05; n.s. = not significant, * = significant)

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

Conclusion:

Under worst case laboratory conditions mortality of A. rhopalosiphi was not affected compared to the control at 650 g a.s./ha.

Therefore the LR50 of Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG is estimated to be greater than 650 g a.s./ha in 200 L water/ha.

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

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Reference:	KCP 10.4/01
Report	CHR/H/TERIZ 650 WG: Effects on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil with 10% Peat ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461022
Guideline(s):	GLP compliant study based on OECD 222, 2004 and ISO 11268-2, 2012
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:

Test Item:	CHR/H/TERIZ 650 WG; batch no.; 54191-74 content: Mesotrione: 14.15 ± 0.27% w/w; Terbuthylazine: 39.43 ± 0.73% w/w; Isoxaflutole: 9.83 ± 0.26% w/w
Test Species:	Earthworm (*Eisenia fetida),* adult worms **In the 1st experiment**: approximately 7 to 8 months old with clitellum and weight range from 309 to 580 mg; source: from an in-house culture.

	In the 2nd experiment: approximately 5 months old with clitellum and weight range from 300 to 588 mg; source: from an in-house culture.
Test Design:	Two 56-day tests in treated artificial soil prepared according to OECD 222 were performed; in both experiments the test concentrations were incorporated into the soil. In the both experiments 6 treatment groups (5 test item concentrations, control); 4 replicates for the test item treatments and 8 replicates for the control with 10 worms each were tested. In both experiments assessment of adult worm mortality, behavioural effects and biomass development was carried out after 28 days exposure of adult worms in treated artificial soil. Reproduction rate (number of offspring) was assessed after additional 28 days (assessed 56 days after application).
Endpoints:	Mortality, weight change, feeding activity and reproduction rate were determined.
Reference Item:	Carbendazim 600 g/L SC (600 g/L nominal). The effects of the reference item were investigated in a separate study.
Test Concentrations:	In the 1st experiment: 3.34, 6.67, 13.34, 26.68 and 53.36 mg CHR/H/TERIZ 650 WG/kg soil[1]. In the 2nd experiment: 0.21, 0.41, 0.83, 1.65 and 3.30 mg CHR/H/TERIZ 650 WG/kg soil
Test Conditions:	**In the 1st experiment:** Artificial soil according to OECD 222; initial pH 5.8 to 6.0, pH at experimental end 6.4 to 6.5; water content 27.3% to 28.6% (51.5% to 53.9% of maximum water holding capacity, WHC) at experimental start and 27.6% to 29.8% (52.1% to 56.2% of the maximum WHC) at experimental end; temperature: within the range of 18 °C to 22 °C; photoperiod: 16 h light : 8 h dark, light intensity: within the range of 400 lux to 800 lux. **In the 2nd experiment:** Artificial soil according to OECD 222; initial pH 6.2, pH at experimental end 6.2 to 6.5; water content 24.1% to 27.7% (44.7% to 51.3% of maximum water holding capacity, WHC) at experimental start and 27.8% to 32.3% (51.5% to 59.8% of the maximum WHC) at experimental end; temperature: within the range of 18 °C to 22 °C; photoperiod: 16 h light : 8 h dark, light intensity: within the range of 400 lux to 800 lux.

Results and discussion:

1st experiment

CHR/H/TERIZ 650 WG [mg/kg soil dry weight]	Control	3.34	6.67	13.34	26.68	53.36
Mortality (day 28) [%]	0.0	0.0	0.0	0.0	5.0	7.5
Statistical Significance 1)	-	n.s.	n.s.	n.s.	n.s.	*
Body weight change (day 28) [%]	35.4	37.2	30.2	22.4	20.0	11.8
Statistical Significance 2)	-	n.s.	n.s.	*	*	*
Mean No. of juveniles (day 56)	203	157	162	158	163	113

[1] All concentrations are indicated per kg soil dry weight.

1st experiment

CHR/H/TERIZ 650 WG [mg/kg soil dry weight]	**Control**	**3.34**	**6.67**	**13.34**	**26.68**	**53.36**
Statistical Significance [2)]	-	*	*	*	*	*
Reproduction in [%] of control (day 56)	-	77.1	79.6	77.6	80.2	55.4
Food consumption [g]	25.0	25.0	25.0	25.0	25.0	24.8

2nd experiment

CHR/H/TERIZ 650 WG [mg/kg soil dry weight]	Control	0.21	0.41	0.83	1.65	3.30
Mortality (day 28) [%]	0.0	0.0	0.0	0.0	0.0	0.0
Statistical Significance	-	-	-	-	-	-
Body weight change (day 28) [%]	66.5	76.7	69.7	67.1	76.5	65.9
Statistical Significance [2)]	-	n.s.	n.s.	n.s.	n.s.	n.s.
Mean No. of juveniles (day 56)	233	244	254	233	211	196
Statistical Significance [2)]	-	n.s.	n.s.	n.s.	n.s.	*
Reproduction in [%] of control (day 56)	-	104.4	108.9	99.8	90.2	84.1
Food consumption [g]	25.0	25.0	25.0	25.0	25.0	25.0
Endpoints [mg/kg soil dry weight]						
NOEC (day 28 mortality)	26.68					
LOEC (day 28 mortality)	53.36					
NOEC (day 28 weight change)	6.67					
LOEC (day 28 weight change)	13.34					
NOEC (day 56 reproduction)	1.65					
LOEC (day 56 reproduction)	3.30					

Conclusions:

In an earthworm reproduction and growth study with CHR/H/TERIZ 650 WG the No Observed Effect Concentration (NOEC) for mortality of the earthworm *Eisenia fetida* was determined to be 26.68 mg test item/kg soil. The Lowest Observed Effect Concentration (LOEC) for mortality was determined to be 53.36 mg test item/kg soil.

The NOEC for weight change was determined to be the concentration of 6.67 mg test item/kg soil. The LOEC for weight changes was determined to be the concentration of 13.34 mg test item/kg soil.

The NOEC for reproduction was determined to be the concentration of 1.65 mg test item/kg soil. The LOEC for reproduction was determined to be the concentration of 3.30 mg test item/kg soil.

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

No additional studies were performed.

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

Study 1

Reference: KCP 10.4/02

Report CHR/H/TERIZ 650 WG: Effects on Reproduction of the Collembola Folso-

	mia candida in Artificial Soil with 5% Peat; 2015; Ganßmann M. ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461016
Guideline(s):	GLP compliant study based on OECD 232, 2009 and ISO 11267, 2014
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:

Test Item:	CHR/H/TERIZ 650 WG; batch no.; 54191-74 content: Mesotrione: 14.15 ± 0.27% w/w; Terbuthylazine: 39.43 ± 0.73% w/w; Isoxaflutole: 9.83 ± 0.26% w/w
Test Species:	Collembola *Folsomia candida*, 10-12 days old, from cultures held at the laboratory.
Test Design:	28-d exposure in treated artificial soil. Different concentrations of the test item were mixed homogeneously into the soil which was placed into glass vessels before the Collembola were introduced on top of the soil; 5 concentrations and one control; 4 replicates/concentration with 10 Collembola each (8 replicates for the control). Feeding of Collembola with approximately 2 mg dry yeast for each test vessel at the beginning of the test and on day 14. Assessment of adult mortality, behavioural effects and reproduction was performed after 28 d.
Endpoints:	Mortality of adult Collembola, behavioural effects, number of juveniles.
Reference Item:	Boric acid (The effects of the reference item were investigated in a separate study.)
Test Concentrations:	Control, 15.63, 31.25, 62.5, 125 and 250 mg CHR/H/TERIZ 650 WG/kg soil$_{1}$.
Test Conditions:	Artificial soil according to OECD 232; pH at experimental start 5.8 to 5.9, pH at experimental end 5.7 to 5.8; water content at experimental start 21.7% to 22.7% (50.4% to 52.9% of the maximum water holding capacity); at experimental end 17.8% to 20.8% (41.5% to 48.4% of the maximum water holding capacity); temperature: within the range of 18°C to 22°C; illumination: 16 h light : 8 h dark, light intensity within the range of 400 to 800 lux.
Statistics:	Standard procedures, Fisher's Exact Test (mortality), Williams t-test (reproduction).

RESULTS AND DISCUSSION:

All validity criteria for the study were met.

A statistically significantly increased mortality was observed at the test item concentration of 250 mg test item/kg soil compared to the control (Fisher's Exact test, $\alpha = 0.05$, one-sided greater).

Reproduction of the Collembolan exposed to CHR/H/TERIZ 650 WG was not statistically significantly different compared to the control up to and including the test concentration of 62.5 mg test item/kg soil (Williams t-test, $\alpha = 0.05$, one-sided smaller).

No behavioural abnormalities were observed in any of the treatment groups.

CHR/H/TERIZ 650 WG [mg/kg soil dry weight]	Control	15.63	31.25	62.5	125	250
Mortality (day 28) [%]	10	18	13	18	15	30
Significance [1)]	-	n.s.	n.s.	n.s.	n.s.	*
No. of juveniles (day 28)	592	553	589	593	487	412
Significance [2)]	-	n.s.	n.s.	n.s.	*	*
Reproduction in [%] of control (day 28)	-	94	100	100	82	70
Endpoints [mg test item/kg soil dry weight]						
NOEC (mortality)	125					
LOEC (mortality)	250					
NOEC (reproduction)	62.5					
LOEC (reproduction)	125					

n.s. = not significantly different compared to the control
* = significantly different compared to the control
[1)] Fisher's Exact Test, α = 0.05, one-sided greater
[2)] Williams t-test, α = 0.05, one-sided smaller
- not applicable

Conclusion:
CHR/H/TERIZ 650 WG caused no significant effects on mortality of *Folsomia candida* up to and including the concentration of 125 mg test item/kg soil. On reproduction no effect were observed up to and including the concentration of 62.5 mg test item /kg soil.
Therefore, the No Observed Effect Concentration (NOEC) for mortality was determined to be 125 mg test item/kg soil. The NOEC for reproduction was determined to be 62.5 mg test item/kg soil.

Study 2

Reference:	KCP 10.4/03
Report	CHR/H/TERIZ 650 WG: Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil with 5% Peat Study code: 10546108; 2015; Ganßmann M. ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany
Guideline(s):	GLP compliant study according to OECD 226, 2008
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:

Test Item:	CHR/H/TERIZ 650 WG; batch no.; 54191-74 content: Mesotrione: 14.15 ± 0.27% w/w; Terbuthylazine: 39.43 ± 0.73% w/w; Isoxaflutole: 9.83 ± 0.26% w/w
Test Species:	Predatory mite *Hypoaspis aculeifer*, adult females, approximately 7 days after reaching the adult stage (28 days after placing adult females in clean rearing vessels), cultured by ibacon.

Test Design:	14-d exposure in treated artificial soil. Different concentrations of the test item were mixed homogeneously into the soil which was filled in glass vessels before the predatory mites were introduced on top of the soil; 5 concentrations and one control were tested; 4 replicates/concentration and 8 replicates for the control, with 10 female predatory mites each. Feeding of the mites with cheese mites (*Tyrophagus putrescentiae) ad libitum* at test start and on day 2, 4, 7, 9 and 11. Assessment of adult mortality and reproduction performed after 14 d.
Endpoints:	Adult mortality, number of juveniles.
Reference Item:	Perfekthion (a.s. dimethoate, 400.0 g/L, nominal). The effects of the reference item are investigated at least once a year in a separate study.
Test Concentrations:	Control, 15.63, 31.25, 62.5, 125 and 250 mg CHR/H/TERIZ 650 WG/kg soil$_{1}$.
Test Conditions:	Artificial soil based on OECD 226; initial pH 5.8 to 5.9, pH at experimental end 6.0 to 6.4; water content at experimental start 21.7% to 22.7% (50.4% to 52.9% of the maximum water holding capacity); at experimental end 19.6% to 20.7% (45.5% to 48.1% of the maximum water holding capacity); temperature: within the range of 18°C to 22°C; illumination: 16 h light : 8 h dark (within the range of 400 to 800 lux).
Statistics:	Standard procedures, Fisher's Exact Test (mortality), Williams t-test (reproduction).

RESULTS AND DISCUSSION:

All validity criteria for the study were met.

A mortality of up to 5% was observed in the test item treated groups, which was not statistically significantly different compared to the control, where 1% of the adult mites died (Fisher's Exact Test, $\alpha = 0.05$, one-sided greater).

Reproduction of the predatory mites exposed to CHR/H/TERIZ 650 WG was not statistically significantly different compared to the control up to and including the highest test concentration of 250 mg/kg soil (Williams t-test, $\alpha = 0.05$, one-sided smaller).

No behavioural abnormalities were observed in any of the treatment groups.

CHR/H/TERIZ 650 WG [mg/kg soil dry weight]	Control	15.63	31.25	62.5	125	250
Mortality (day 14) [%]	1	0	0	0	5	0
Statistical significance[1)]	-	n.s.	n.s.	n.s.	n.s.	n.s.
No. of juveniles (day 14)	229	241	239	238	237	217
Reproduction in [%] of control (day 14)	-	105	104	104	103	95
Statistical significance[2)]	-	n.s.	n.s.	n.s.	n.s.	n.s.
Endpoints [mg/kg soil dry weight]						
NOEC (mortality)	250					
LOEC (mortality)[3)]	>250					
LC_{50} (mortality)[3)]	>250					
NOEC (reproduction)	250					
LOEC (reproduction)[3)]	>250					
EC_{50} (reproduction)[3)]	>250					

n.s. = not statistically significantly different compared to the control
[1)] Fisher's Exact Test, α = 0.05, one-sided greater
[2)] Williams t-test, α = 0.05, one-sided smaller
[3)] estimated value
- not applicable

Conclusion:
CHR/H/TERIZ 650 WG caused no statistically significant effects on mortality or reproduction of Hypoaspis aculeifer up to and including the concentration of 250 mg test item/kg soil.
Therefore, the overall No Observed Effect Concentration (NOEC) was determined to be 250 mg test item/kg soil. The overall Lowest Observed Effect Concentration (LOEC) was estimated to be greater than 250 mg test item/kg soil.

A 2.4.2.1 KCP 10.4.2.1 Species level testing

No additional studies were performed.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

No additional studies were performed.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Reference: KCP 10.5/01

Report: Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG: Effects on the Activity of the Soil Microflora in theLaboratory(Nitrogen Transformation) 2016, Hammesfahr U.
ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany
Study code: 105461080

Guideline(s):	GLP compliant study based on Organization for Economic Cooperation and Development (OECD), Guidelines for Testing of Chemicals, Guideline No. 216, "Soil Microorganisms: Nitrogen Transformation Test" adopted January 21, 2000
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:
Test Item: Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG, Batch No. 54191-74
Test System: Biologically active agricultural soil: Silty sand
Test Design: Determination of nitrogen-transformation in soil enriched with lucerne meal. Comparison of test item treated soil with a non-treated soil. Three replicates per treatment. NH4-, NO2- and NO3-nitrogen formed in the nitrification process was determined by continuous flow analysis.
Sampling scheme: 0, 7, 14 and 28 days after treatment
Test Rates: Control 1.33 mg Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG/kg soil dry weight 6.67 mg Isoxaflutole/Mesotrione/Terbuthylazine 100/150/400 g/kg WG/kg soil dry weight
Endpoints: Effects on NO3-nitrogen production after 28 days exposure (soil nitrogen transformation).
Reference Item: Effects of sodium chloride were determined at a rate of 16 g/kg dry soil in a separate study (ibacon study code: 30699080) within one year before start of the experimental phase of this study
Test Conditions: Moisture: 44% to 49% of maximum water holding capacity (WHCmax).
Temperature: 20°C ± 2°C, in the dark.
Statistics: Calculation of mean values per treatment, standard deviation and coefficient of variation. Normality and homogeneity of variances were tested using the R/S-Test ($\alpha = 0.01$) and Levene´s test ($\alpha = 0.01$), respectively and pair-wise comparisons of treated and control values according to Student t-test ($\alpha = 0.05$) were conducted.
Results and discussion:
Nitrogen Transformation -
Nitrate Content:
No adverse effects of the test item on nitrate content in soil were observed at day 28. At day 28 differences to the control were 0.94% and 4.78% in the 1.33 mg and 6.67 mg test item/kg soil dry weight treatment, respectively.
Nitrogen Transformation -
Mineral Nitrogen Content:
The mineral nitrogen contents in soil were within the trigger range of ± 25% set by EPPO and SETAC guidelines at day 28. At day 28 differences to the control were 1.03% and 4.77% in the 1.33 mg and 6.67 mg test item/kg soil dry weight treatment, respectively.
Nitrogen Transformation -
Nitrate Formation Rate:
The soil nitrate formation rates did not exceed the trigger range of ± 25% set by OECD guideline 216 at the 14 - 28 day determination. Differences to the control were 8.05% and 11.58% in the 1.33 mg and 6.67 mg test item/kg soil dry weight treatment, respectively.
Validity Criteria: The variation between the replicate control samples did not exceed the validity criterion of 15% for both tests throughout the study.
Conclusions:
The test item had no impact on nitrogen transformation (nitrate content, mineral nitrogen content and nitrate formation rate) of soil microorganisms when applied at 1.33 mg and 6.67 mg test item/kg soil dry weight treatment.

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

A 2.6.1 KCP 10.6.1 Summary of screening data

Not available

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Study 1

Reference:	KCP 10.6/01
Report	CHR/H/TERIZ 650 WG: Effects on Terrestrial (Non Target) Plants: Seedling Emergence and Seedling Growth Test ; Bützler R. Knebel N.; 2016 ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461086
Guideline(s):	GLP compliant study based on OECD Guideline 208, 2006
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:

Test Item:

CHR/H/TERIZ 650 WG; Batch No.: 54191-74; Active ingredients: Mesotrione: 14.15 ± 0.27 % w/w Terbuthylazine: 39.43 ± 0.73 % w/w Isoxaflutole: 9.83 ± 0.26 % w/w according to certificate of analysis

Test Species and Rates:

Based on a non GLP range finding test following rates were tested: see Table 1.

Test Design:	On the day after sowing different rates of the test item were sprayed in 200 L/ha of deionised water onto the soil. 30 seeds were tested per rate and species. The exposure time was 14 to 21 days after 50% germination in the control depending on the growth of the seedlings. The concentration of the active ingredient in the stock solution was verified analytically.
Endpoints:	ER_{10}, ER_{20}, ER_{50} and NOER based on fresh weight; Observation of mortality and phytotoxicity.
Dates of Work:	Sowing: January 05, 2016 Application: January 06, 2016 Exposure period: 14 to 21 days after 50% germination in the control
Test Conditions:	The study was performed in a growth chamber. Exposure conditions were as follows: Mean temperature was 21.6 °C (16.2 °C to 25.6 °C). Mean humidity was 60% (48% to 87%). Photoperiod: 16 hours light / 8 hours dark. Mean light intensity during the day was 14346 lux (9550 to 20520 lux).

Table 1. Plant species and rates

Species	Rate (g test item/ha)												
	0.792	1.37	2.38	4.12	7.13	12.3	21.4	37.0	64.2	111	192	333	577	1000
Brassica napus	x	x	x	x	x	x	x	x						
Glycine max										x	x	x	x	x
Solanum lycopersicum							x	x	x	x	x	x		
Beta vulgaris		x		x		x		x		x				
Daucus carota							x	x	x	x	x			
Lactuca sativa		x		x		x		x		x				
Cucumis sativus								x	x	x	x	x		
Avena sativa													x	x
Lolium perenne										x	x	x	x	x
Allium cepa									x	x	x	x	x	

Results and discussion:

	NOER	LOER	Statistical		ER_{10}	ER_{20}	ER_{50}	Statistical
	[g test item/ha]		Analysis		[g test item/ha]			Analysis
Brassica napus	2.38	4.12	[1]		2.76	6.03	19.6	[5]
				lower 95%-cl	0.490*	2.06	13.6	
				upper 95%-cl	5.36	9.48	29.8	
				r^2 = 0.817				
Brassica napus (per plant)	2.38	4.12	[1]		2.05	4.95	18.8	[5]
				lower 95%-cl	0.207*	1.22	12.1	
				upper 95%-cl	4.48	8.43	32.1	
				r^2 = 0.789				
Glycine max	111	192	[1]		45.1*	145	1357*	[6]
				lower 95%-cl	7.80*	58.4*	865	
				upper 95%-cl	93.0*	221	3682*	
				r^2 = 0.443				
Glycine max (per plant)	111	192	[2]		61.2*	174	1284*	[6]
				lower 95%-cl	19.4*	95.0*	889	
				upper 95%-cl	108*	243	2564*	
				r^2 = 0.536				
Solanum lycopersicum	37.0	64.2	[3]		40.4	51.1	80.0	[6]
				lower 95%-cl	12.6*	22.6	59.4	
				upper 95%-cl	55.8	66.3	108	
				r^2 = 0.834				
Solanum lycopersicum (per plant)	37.0	64.2	[1]		42.4	53.1	81.4	[6]
				lower 95%-cl	25.4	36.8	68.9	
				upper 95%-cl	53.5	63.7	96.2	
				r^2 = 0.916				

	NOER	LOER	Statistical		ER_{10}	ER_{20}	ER_{50}	Statistical
	[g test item/ha]		Analysis		[g test item/ha]			Analysis
Beta vulgaris	1.37	4.12	[3]		4.98	8.06	16.7	[5]
				lower 95%-cl	0.014*	0.194*	6.27	
				upper 95%-cl	9.87	13.8	36.6	
				r^2 = 0.834				
Beta vulgaris (per plant)	4.12	12.3	[3]		5.41	8.53	17.0	[5]
				lower 95%-cl	0.345*	1.44	9.36	
				upper 95%-cl	9.66	13.4	29.3	
				r^2 = 0.875				
Daucus carota	64.2 (37.0**)	111 (64.2**)	[4]		29.7	42.1	82.2	[6]
				lower 95%-cl	18.2*	29.7	69.4	
				upper 95%-cl	39.1	52.0	97.9	
				r^2 = 0.972				
Daucus carota (per plant)	64.2 (37.0**)	111 (64.2**)	[4]		28.5	40.4	78.6	[6]
				lower 95%-cl	18.2*	29.2	67.0	
				upper 95%-cl	37.2	49.5	92.5	
				r^2 = 0.975				
Lactuca sativa	12.3	37.0	[3]		13.1	17.8	31.8	[6]
				lower 95%-cl	3.72	7.30	23.1	
				upper 95%-cl	19.4	24.1	42.1	
				r^2 = 0.913				
Lactuca sativa (per plant)	12.3	37.0	[4]		15.2	20.0	33.6	[6]
				lower 95%-cl	13.4	18.2	32.2	
				upper 95%-cl	16.8	21.5	35.0	
				r^2 = 0.995				

	NOER	LOER	Statistical		ER_{10}	ER_{20}	ER_{50}	Statistical
	[g test item/ha]		Analysis		[g test item/ha]			Analysis
Cucumis sativus	64.2	111	[4]		47.7	72.6	163	[6]
				lower 95%-cl	11.4*	27.5*	115	
				upper 95%-cl	76.8	105	247	
				r^2 = 0.919				
Avena sativa	≥ 1000	> 1000	[1]		n.d.	n.d.	n.d.	
Avena sativa	≥ 1000	> 1000	[1]		n.d.	n.d.	n.d.	
Lolium perenne	≥ 1000	> 1000	[1]		n.d.	n.d.	n.d.	
Lolium perenne	≥ 1000	> 1000	[1]		n.d.	n.d.	n.d.	
Allium cepa	< 64.2	64.2	[3]		58.8*	101	226	[5]
				lower 95%-cl	30.1*	64.4	188	
				upper 95%-cl	85.0	130	267	
				r^2 = 0.973				
Allium cepa	< 64.2	64.2	[3]		47.4*	86.3	213	[5]
(per plant)				lower 95%-cl	8.86*	28.8*	146	
				upper 95%-cl	85.5	131	289	
				r^2 = 0.931				

results represent rounded values based on exact data

per plant = effect rates calculated on fresh weight per replicate divided by the number of seedlings of this replicate

n.d. not determined due to mathematical reasons

* the ERx-value is extrapolated

[1] multiple comparison Dunnett's t-test, α = 0.05

[3] multiple comparison Bonferroni-Holm U-test, α = 0.05

[4] multiple comparison Bonferroni-Welch t-test, α = 0.05

[5] Weibull Analysis, cl = confidence limits

[6] Probit Analysis, cl = confidence limits

Conclusions:

CHR/H/TERIZ 650 WG was tested for effects on seedling emergence and seedling growth of ten plant species out of nine different plant families.

The analytical recovery rates of the active ingredients in the stock solution were 107% of the nominal value for Mesotrione, 94% of the nominal value for Isoxaflutole and 106% of the nominal value for Terbuthylazine. In the control solution no test item ingredient was detected.

The most sensitive species in terms of fresh weight were *Brassica napus* and *Beta vulgaris* with ER_{50} values of 19.6 g/ha and 16.7 g CHR/H/TERIZ 650 WG/ha, respectively (ER_{50} values for fresh weight per plant: 18.8 g/ha and 17.0 g/ha, respectively). They were followed by *Lactuca sativa* with an ER_{50} value of 31.8 g CHR/H/TERIZ 650 WG/ha (ER_{50} value of 33.6 g/ha for fresh weight per plant), followed by *Solanum lycopersicum* and *Daucus carota* with ER_{50} values of 80.0 g/ha and 82.2 g CHR/H/TERIZ 650 WG/ha, respectively (ER_{50} values for fresh weight per plant: 81.4 g/ha and 78.6 g/ha, respectively). They were followed by *Cucumis sativus* and *Allium cepa* with ER_{50} values of 163 g/ha and 226 g CHR/H/TERIZ 650 WG/ha, respectively (ER_{50} value of 213 g/ha for fresh weight per plant for *Allium cepa*). For *Glycine max* the ER_{50} values were higher than the highest tested rate of 1000 g/ha, but a NOER value of 111 g

CHR/H/TERIZ 650 WG/ha could be determined. The least sensitive species were *Avena sativa* and *Lolium perenne* which showed a NOER value of ≥ 1000 g CHR/H/TERIZ 650 WG/ha.
The germination rate was not statistically significantly reduced for any species tested.
Statistical significant mortality was observed for *Solanum lycopersicum* at 111 g, 192 g and 333 g CHR/H/TERIZ 650 WG/ha (30%, 38% and 81%), for *Beta vulgaris* at 37 g and 111 g CHR/H/TERIZ 650 WG/ha (60% and 80%), for *Daucus carota* at 111 g and 192 g CHR/H/TERIZ 650 WG/ha (50% and 82%), for *Lactuca sativa* at 111 g CHR/H/TERIZ 650 WG/ha (72%), for *Cucumis sativus* at 333 g CHR/H/TERIZ 650 WG/ha (33%) and for *Allium cepa* at 192 g, 333 g and 577 g CHR/H/TERIZ 650 WG/ha (23%, 39% and 82%).
Clear phytotoxic effects observed were chlorosis (all species except *Avena sativa, Lolium perenne* and *Allium cepa*), necrosis (all species except *Avena sativa* and *Lolium perenne*) and growth reduction (all species except *Avena sativa* and *Lolium perenne*). Additionally *Glycine max* and *Beta vulgaris* showed abnormal growth of leaves.

Study 2

Reference:	KCP 10.6/02
Report	CHR/H/TERIZ 650 WG: Effects on Terrestrial (Non Target) Plants: Vegetative Vigour Test ; Bützler R. Knebel N.; 2016 ibacon GmbH Arheilger Weg 17 64380 Rossdorf,Germany Study code: 105461087
Guideline(s):	GLP compliant study based on OECD Guideline 227, 2006
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods:

Test Item:	CHR/H/TERIZ 650 WG; Batch No.: 54191-74; Active ingredients: Mesotrione: 14.15 ± 0.27 % w/w Terbuthylazine: 39.43 ± 0.73 % w/w Isoxaflutole: 9.83 ± 0.26 % w/w according to certificate of analysis
Test Species and Rates:	Based on a non GLP range finding test following rates were tested: see Table 1
Test Design:	The plants were grown until they had reached the 2 to 4 true leaf stage prior to dosing. Test rates were calculated for a water amount of 200 L/ha and were administered onto the plants using laboratory spraying equipment. 24 plants were tested per rate and species. The concentration of the active ingredient in the stock solution was verified analytically. The exposure time was 21 days.
Endpoints:	ER_{10}, ER_{20}, ER_{50} and NOER based on fresh weight; Observation of mortality and phytotoxicity.
Dates of Work:	Pre-application period: January 21, 2016 – February 18, 2016 Application: February 18, 2016 Exposure period: 21 days after application
Test Conditions:	The study was performed in a growth chamber. Pre-application conditions were as follows: Mean temperature was 21.6 °C (16.4 °C to 25.7 °C). Mean humidity was 60% (47% to 87%). Photoperiod: 16 hours light / 8 hours dark. Mean light intensity during the day was 14855 lux (7490 to 18650 lux). Exposure conditions were as follows: Mean temperature was 21.3 °C (16.5 °C to 25.1 °C). Mean humidity was 61% (50% to 86%). Photoperiod: 16 hours light / 8 hours dark. Mean light

intensity during the day was 14377 lux (6010 to 19840 lux).

Table 1. Plant species and tested rates

Species	Rate (g test item/ha)													
	0.152	0.457	1.37	2.38	4.12	7.13	12.3	21.4	37.0	64.2	111	192	333	1000
Brassica napus							x	x	x	x	x	x		
Glycine max					x		x		x		x		x	x
Solanum lycopersicum					x		x		x		x		x	
Beta vulgaris				x	x	x	x	x						
Daucus carota					x		x		x		x		x	
Lactuca sativa	x	x	x		x		x		x					
Cucumis sativus							x		x		x		x	x
Avena sativa									x		x		x	x
Lolium perenne									x		x		x	x
Allium cepa					x		x		x		x		x	

Resluts and discussion:

Results:

Table 2. Summary of effect rates (based on fresh weight)

	NOER	LOER	Statistical		ER_{10}	ER_{20}	ER_{50}	Statistical
	[g test item/ha]		Analysis		[g test item/ha]			Analysis
Brassica napus	< 12.3	12.3	[1]		12.5	28.9	103	[6]
				lower 95%-cl	0.620*	4.71*	64.5	
				upper 95%-cl	28.2	50.1	185	
				r^2 = 0.845				
Glycine max	< 4.12	4.12	[2]		3.76*	17.1	169	[6]
				lower 95%-cl	0.453*	4.34	100	
				upper 95%-cl	11.0	35.8	277	
				r^2 = 0.942				
Solanum lycopersicum	4.12	12.3	[3]		17.3	26.8	52.1	[6]
				lower 95%-cl	7.98	15.9	40.5	
				upper 95%-cl	25.1	35.4	66.4	
				r^2 = 0.957				
Beta vulgaris	2.38	4.12	[1]		3.51	4.77	8.54	[5]
				lower 95%-cl	1.26*	2.32*	6.40	
				upper 95%-cl	5.07	6.37	11.5	
				r^2 = 0.925				
Daucus carota	12.3	37.0	[4]		23.6	44.9	118	[6]
				lower 95%-cl	6.38	18.8	82.9	
				upper 95%-cl	41.6	67.5	163	
				r^2 = 0.949				
Lactuca sativa	1.37	4.12	[3]		1.59	2.73	7.66	[5]
				lower 95%-cl	1.17	2.18	6.74	
				upper 95%-cl	2.01	3.26	8.70	
				r^2 = 0.989				

	NOER	LOER	Statistical		ER_{10}	ER_{20}	ER_{50}	Statistical
	[g test item/ha]		Analysis		[g test item/ha]			Analysis
Cucumis sativus	< 12.3	12.3	[2]		11.9*	47.7	679	[5]
				lower 95%-cl	4.82*	27.5	483	
				upper 95%-cl	21.6	70.4	1072*	
				r^2 = 0.986				
Avena sativa	≥ 1000	> 1000	[3]		n.d.	n.d.	n.d.	
Lolium perenne	111	333	[3]		211**	600**	> 1000	[6]
				lower 95%-cl	n.d.	n.d.	n.d.	
				upper 95%-cl	n.d.	n.d.	n.d.	
				r^2 = 0.897				
Allium cepa	≥ 333	> 333	[4]		n.d.	n.d.	n.d.	

results represent rounded values based on exact data

n.d. not determined due to mathematical reasons

* The ERx-value and/or the confidence limits for the ERx-values are extrapolated

** The ERx-values are with reservation (p(F) = 0.053 > α = 0.05)

[2] multiple comparison Williams t-test, α = 0.05

[3] multiple comparison Dunnett's t-test, α = 0.05

[4] multiple comparison Bonferroni-Welch t-test, α = 0.05

[5] Probit Analysis, cl = confidence limits

[6] Weibull Analysis, cl = confidence limits

Conclusions:

CHR/H/TERIZ 650 WG was tested for effects on the vegetative vigour using ten plant species out of nine different plant families.

The analytical recovery rates of the active ingredients in the stock solution were 100% of the nominal value for Mesotrione, 87% of the nominal value for Isoxaflutole and 108% of the nominal value for Terbuthylazine. In the control solution no test item ingredient was detected.

The most sensitive species in terms of fresh weight were *Beta vulgaris* and *Lactuca sativa* with ER_{50} values of 8.54 g/ha and 7.66 g CHR/H/TERIZ 650 WG/ha, respectively (ER_{20} values of 4.77 and 2.73 g/ha, respectively). They were followed by *Solanum lycopersicum* with an ER_{50} value of 52.1 g CHR/H/TERIZ 650 WG/ha (ER_{20} value of 26.8 g/ha), followed by *Brassica napus* and *Daucus carota* with ER_{50} values of 103 g/ha and 118 g CHR/H/TERIZ 650 WG/ha, respectively (ER_{20} values of 28.9 and 44.9 g/ha, respectively). They were followed by *Glycine max* with an ER_{50} value of 169 g CHR/H/TERIZ 650 WG/ha (ER_{20} value of 17.1 g/ha), which was followed by *Cucumis sativus* with an ER_{50} value of 679 g CHR/H/TERIZ 650 WG/ha (ER_{20} value of 47.7 g/ha). For *Lolium perenne* the ER_{50} value was higher than the highest tested rate of 1000 g/ha, but a NOER value of 111 g CHR/H/TERIZ 650 WG/ha could be determined. The least sensitive species were *Allium cepa* which showed a NOER value of ≥ 333 g CHR/H/TERIZ 650 WG/ha and *Avena sativa* which showed a NOER value of ≥ 1000 g CHR/H/TERIZ 650 WG/ha.

Statistical significant mortality was observed for *Solanum lycopersicum* at 333 g CHR/H/TERIZ 650 WG/ha (38%), for *Beta vulgaris* at 12.3 g CHR/H/TERIZ 650 WG/ha (29%) and for *Daucus carota* at 333 g CHR/H/TERIZ 650 WG/ha (29%).

Clear phytotoxic effects observed were chlorosis (all species except *Avena sativa* and *Lolium perenne*), necrosis (all species except *Avena sativa* and *Lolium perenne*) and growth reduction (all species except *Avena sativa*). Additionally *Brassica napus*, *Glycine max* and *Allium cepa* showed abnormal growth of leaves.

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

No additional studies were performed.

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

No additional studies were performed.

A 2.8 KCP 10.8 Monitoring data

No additional studies were performed.