FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 6821 A

Product name(s): PIORITY

Chemical active substances:

Dimethomorph, 150 g/kg
Dithianon, 350 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: April 2019

MS Finalisation date: February 2022; January 2024

Version history

When	What
October	Updated by Applicant
February 2022	Finalization of the aassessment by zRMS
January 2024	The final Registration Report

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	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: develop-mental 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 arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	CEU	**Grapevine**	F	*Plasmopara viticola*	Foliar Spray	BBCH 55-79	a) 3 b) 3	10-12	a) 1.5 b) 4.5	a) 0.225 dimethomorph + 0.525 dithi-anon b) 0.675 dimethomorph + 1.575 dithi-anon	800-1000	42	-							

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

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

Explanation for column 15 – 21 “Conclusion”

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

Remarks table:

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

9.1.1 Overall conclusions

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)

- Birds

In the Tier I risk assessment, the TERa values were greater than the Annex VI trigger of 10, indicating that PIORITY presents no unacceptable acute risk to birds according to the intended uses. However, the TERlt value for small insectivorous species “Redstart” in grapevine was below the trigger of 5 for Dithianon. A further refinement of the long-term risk was needed. A refinement of the risk was done by refining the DF and PT, and the TER value was above the trigger showing no risk. Therefore, the acute long-term risk to birds after the application of PIORITY according to the GAP is considered acceptable. In addition, no unacceptable acute and long-term risk were obtained in grapevine according to the proposed GAP due to combined exposure.

No risk for birds was identified via drinking water exposure and secondary poisoning for both Dimethomorph and Dithianon following the intended uses of PIORITY on grapevine.

- Mammals

In the Tier I risk assessment, the TERa values were greater than the Annex VI trigger of 10, indicating that PIORITY presents no unacceptable acute risk to mammals according to the intended uses. Howev-er, the TERlt value for small herbivorous mammal "vole” in grapevine was below the trigger of 5 for both active substance. A further refinement of the long-term risk was needed. A refinement of the risk was done by refining the focal species to woodmouse. The TERlt value for this species was above the trigger showing no risk. Therefore, the acute and long-term risk to mammals after the application of PIORITY according to the GAP is considered acceptable. In addition, no unacceptable acute and long-term risk were obtained for the wood mouse (Apodemus sylvaticus) in vineyard according to GAP for combined exposure.

No risk for mammals was identified via drinking water exposure and secondary poisoning for both Dimethomorph and Dithianon following the intended uses of PIORITY on grapevine.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

Regarding Dithianon, most PEC/RAC values taken from the assessment of most aquatic organisms are above the trigger value of 1 in most scenarios for grapevine, indicating that PIORITY poses a potential risk to aquatic organisms. A further refinement and PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW}. Based on the results of the risk assessment at step 4, the following conclusions regarding buffer zones, vegetative buffer strips and nozzles reduction may be drawn:

Grapevine

- D6 ditch and R2 stream scenarios: A 5m no spray buffer zone with 90% of nozzles reduction OR a 10m no spray buffer zone with 50% of nozzles reduction OR a 15m no spray buffer zone are required.
- R1 stream scenario: A 5m no spray buffer zone with 75% of nozzles reduction OR a 10m no spray buffer zone with 50% of nozzles reduction OR a 15m no spray buffer zone are required.
- R3 stream scenario: A 5m no spray buffer zone with 90% of nozzles reduction OR a 10m no spray buffer zone with 50% of nozzles reduction OR a 20m no spray buffer zone are required.
- R4 stream scenario: A 10m vegetative strip/no spray buffer with 50% of nozzles reduction OR a

15m vegetative strip/no spray buffer are required.

The risk to aquatic organisms for the metabolite Phthalaldehyde was assessed as low at FOCUS step 1, step2 and step 3 for the representative uses. The risk to aquatic organisms for the metabolites CL 1017911, Phthalic acid and 1,2-benzenedimethanol were assessed as low at FOCUS step 1 and step2 for the representative uses.

Regarding Dimethomorph, the calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a NOEC for *Oncorhynchus mykiss* of 56 in connection with an assessment factor of 10) in all FOCUS Steps 3 scenarios for the intended use on grapevine. Therefore, no further assessment is necessary.

Regarding the formulated PIORITY, after the risk assessment no unacceptable risk was obtained with the following risk mitigation measures:

- Grapevine late- a 50m no spray buffer zone with 90% of nozzles reduction are required.

*Grapevine - **SPe 3**: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 50 m to surface water bodies with 90% of nozzles reduction.*

Regarding Dithianon, most PEC/RAC values taken from the assessment of most aquatic organisms are above the trigger value of 1 in most scenarios for grapevine, indicating that PIORITY poses a potential risk to aquatic organisms. A further refinement and PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW}.
Based on the results of the risk assessment for dithation at step 4, the following conclusions regarding buffer zones, vegetative buffer strips and nozzles reduction may be drawn:

Grapevine

- ~~D6 ditch and R2 stream scenarios: A 5m no spray buffer zone with 90% of nozzles reduction OR a 10m no spray buffer zone with 50% of nozzles reduction OR a 15m no spray buffer zone are required~~.
- R1 stream scenario: A 5m no spray buffer zone with 75% of nozzles reduction OR a 10m no spray buffer zone with 50% of nozzles reduction OR a 15m no spray buffer zone are required
- ~~R3 stream scenario: A 5m no spray buffer zone with 90% of nozzles reduction OR a 10m no spray buffer zone with 50% of nozzles reduction OR a 20m no spray buffer zone are required.~~
- ~~R4 stream scenario: A 10m vegetative strip/no spray buffer with 50% of nozzles reduction OR a 15m vegetative strip/no spray buffer are required.~~
- D3 ditch scenario : 10m no spray buffer zone with 90% of nozzles reduction OR a 15 m no spray buffer zone with 75 % of nozzles reduction are required or 20m no spray buffer with 50 % of nozzles reduction (relevant for PL)
- D4 stream scenario: 10m no spray buffer zone with 90% of nozzles reduction OR a 15 m no spray buffer zone with 75 % of nozzles reduction are required or 20m no spray buffer with 50 % of nozzles reduction (relevant for PL)

- R1 stream scenario: A 5m no spray buffer zone with 75% of nozzles reduction OR a 10m no spray buffer zone with 50% of nozzles reduction OR a 15m no spray buffer zone are required.
- D3 ditch scenario : 10m no spray buffer zone with 90% of nozzles reduction OR a 15 m no spray buffer zone with 75 % of nozzles reduction are required or 20m no spray buffer with 50 % of nozzles reduction (relevant for PL)
- D4 stream scenario: 10m no spray buffer zone with 90% of nozzles reduction OR a 15 m no spray buffer zone with 75 % of nozzles reduction are required or 20m no spray buffer with 50 % of nozzles reduction

The risk to aquatic organisms for the metabolite Phthalaldehyde was assessed as low at FOCUS step 1, step2 and step 3 for the representative uses. The risk to aquatic organisms for the metabolites CL 1017911, Phthalic acid and 1,2-benzenedimethanol were assessed as low at FOCUS step 1 and step2 for the representative uses.

Regarding Dimethomorph, the calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a NOEC for *Oncorhynchus mykiss* of 56 in connection with an assessment factor of 10) in all FOCUS Steps 3 scenarios for the intended use on grapevine. Therefore, no further assessment is necessary.

The PEC/RAC ratios calculated for surrogate crop scenarios D3 and D4 indicated unacceptable risk at FOCUS Step 3, therefore further assessment with Step 4 values was necessary. The Step 4 refinement showed no unacceptable use when the following risk mitigation measures are considered:

D3: 5 m no spray buffer zone (relevant for PL)

D4: 10 m no spray buffer zone OR 5 m no spray buffer zone + 50% drift reduction by nozzles (relevant for PL)

9.1.1.3 Effects on bees (KCP 10.3.1)

The risk assessment for bees has been done. All the hazard quotients are considerably less than 50, indicating that the active substances pose a low risk to bees. Therefore a low risk to bees is expected from the application of PIORITY at all proposed label rates.

According to EU Reg. 284 /2009 the chronic toxicity test for adult bees, chronic test for larvae should be provided for plant protection product Priority.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

No in-field and off-field risk to non-target arthropods is expected after the application of PIORITY according to the proposed GAP.

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

An application of PIORITY in respect of the GAP should not represent an acute and long term risk to earthworm and the other soil meso/microfauna. The use of PIORITY at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

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

The risk assessment for non-target plants has been done with EU agreed endpoint and the risk to non-target plants for PIORITY is considered to be acceptable when applied according to the proposed use rates.

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

Not relevant for Dithianon and Dimethomorph.

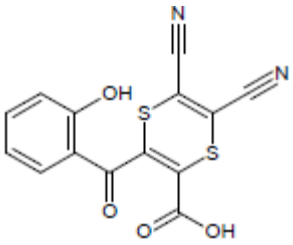
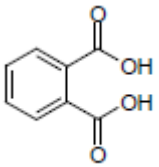
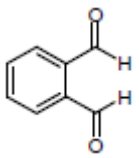
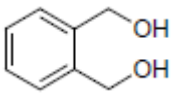
9.1.2 Grouping of intended uses for risk assessment

Risk envelope approach will not be used for this assessment since there is only one intended GAP for the use of PIORITY.

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 PIORITY is indicated in the table.

Table 9.1-2 Metabolites of Dithianon

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
CL 1017911		330.33	Soil: 0.00001% Water: 52.01% Sediment: 3.6% Total system:-	Yes, for water.
Phthalic acid		166.14	Soil: 16 % Water: 0.00001% Sediment: 0.00001% Total system: 38.5%	Yes, for water.
Phthalaldehyde		134.14	Soil: 0.00001% Total system: 11.2%	Yes, for water.
1,2-benzenedimethanol		138.17	Soil: 0.00001% Total system: 20.9%	Yes, for water.

As reported in EFSA *Scientific Report* (2006) 82, 1-69, no metabolites were identified for Dimethomorph active substance.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with Dimethomorph and Dithianon. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of PIORITY were not evaluated as part of the EU assessment of Dimethomorph and Dithianon.

However, the provision of further data on the PIORITY is not considered essential, because endpoints obtained with the active substances are sufficient to evaluate the risk and new studies should not be con-

ducted in regards of animal welfare (EFSA Journal 2009; 7(12):1438).

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

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

Species	Substance	Exposure System	Results	Reference
C. virginiamus	Dithianon	Oral Acute	LD_{50} = 309 mg/kg bw/day	EFSA Journal 2010;8(11):1904
A. platyrhynchos	Dithianon	Oral Acute	LD_{50} > 2000 mg/kg bw/day	EFSA Journal 2010;8(11):1904
LD_{50} (overall geometric mean)[1] [mg a.s./kg b.w.]			**LD_{50} = 786.1 mg/kg bw/day**	
C. virginiamus	Dithianon	Dietary Short-term	LC_{50} > 1198.5 mg/kg bw/d	EFSA Journal 2010;8(11):1904
A. platyrhynchos	Dithianon	Dietary Short-term	LC_{50} > 790 mg/kg bw/d	EFSA Journal 2010;8(11):1904
C. virginiamus	Dithianon	Dietary Reproductive toxicity	**NOEAEL = 22.8 mg/kg bw/d**	EFSA Journal 2010;8(11):1904
Bobwhie quail / Mallard duck	Dimethomorph	Oral Acute	LD_{50} < 2000 mg/kg bw	EFSA Scientific Report (2006) 82, 1-69
Bobwhie quail	FORUM 150 DC (Dimethomorph formulation)	Oral Acute	LD_{50} = 1243 mg prod./kg bw (186 mg a.s./kg bw)	EFSA Scientific Report (2006) 82, 1-69
Bobwhie quail	Dimethomorph	Dietary Short-term	LC_{50} < 5200 ppm (**LD_{50} > 728.3 mg/kg bw/day**)	EFSA Scientific Report (2006) 82, 1-69
Mallard duck	Dimethomorph	Dietary Short-term	LC_{50} < 5200 ppm (LD_{50} > 937.5 mg/kg bw/day)	EFSA Scientific Report (2006) 82, 1-69
Bobwhie quail	Dimethomorph	Reproductive toxicity Long-term	NOEL = 800 ppm (**58.4 mg/kg bw/d**)	EFSA Scientific Report (2006) 82, 1-69
Mallard duck	Dimethomorph	Reproductive toxicity Long-term	NOEL = 800 ppm (78.4 mg/kg bw/d)	EFSA Scientific Report (2006) 82, 1-69

[1]Determination of the geometric mean out of the LD_{50} values of 309 and 2000 mg a.s./kg b.w. of the acute oral toxicity studies (EFSA/2009/1438, 2.4.2).

9.2.1.1 Justification for new endpoints

The EU agreed endpoints are used for the risk assessment. According EFSA Journal 2009; 7(12):1438 it is permissible to use a geometric mean for Dithianon in the acute assessment in case the endpoint of the most sensitive species is not by a factor of 10 below the overall geometric mean. The most sensitive endpoint with an LD_{50} = 309 mg as/kg b.w. in the quail is clearly higher than the 'assessment factor LD_{50}' of 78.6 mg a.s./kg b.w./d. Hence, the LD_{50} (overall geometric mean) = 786.1 mg a.s./kg b.w. is the relevant endpoint to be used for the acute avian risk assessment regarding Dithianon active substance.

9.2.2 Risk assessment for spray applications

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

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

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

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of PIORITY in grapevine

Intended use	**Grapevines**				
Active substance/product	Dithianon				
Application rate (g/ha)	3 x 525				
Acute toxicity (mg/kg bw)	786.1				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard	"Indicator species for screening"	95.3	1.5	75.05	10.5
Reprod. toxicity (mg/kg bw/d)	22.8				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard BBCH ≥ 20	Small insectivorous species "Redstart"	9.9	0.954	4.96	**4.6**
Vineyard BBCH ≥ 40	Small granivorous bird "Finch"	3.4	0.954	1.70	13.4
Vineyard BBCH ≥ 40	Small omnivorous bird "lark"	3.3	0.954	1.65	13.8
Intended use	**Grapevines**				
Active substance/product	Dimethomorph				
Application rate (g/ha)	3 x 225				
Acute toxicity (mg/kg bw)	728.3				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard	"Indicator species for screening"	95.3	1.5	32.16	22.6
Reprod. toxicity (mg/kg bw/d)	58.4				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard	"Indicator species for screening"	38.9	1.8 × 0.53	8.35	7.0

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 9.2-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of PIORITY in grapevine

Intended use	**Grapevines**				
Active substance/product	Dithianon				
Application rate (g/ha)	3 x 525				
Acute toxicity (mg/kg bw)	786.1				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard	"Indicator species for screening" - omnivorous	95.3	1.5	75.05	10.5
Reprod. toxicity (mg/kg bw/d)	22.8				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard	"Indicator species for screening" - omnivorous	38.9	0.954	19.48	**1.17**
Vineyard BBCH ≥ 20	Small insectivorous species "Redstart"	9.9	0.954	4.96	**4.6**
Vineyard BBCH ≥ 40	Small granivorous bird "Finch"	3.4	0.954	1.70	13.4
Vineyard BBCH ≥ 40	Small omnivorous bird "lark"	3.3	0.954	1.65	13.8
Intended use	**Grapevines**				
Active substance/product	Dimethomorph				
Application rate (g/ha)	3 x 225				
Acute toxicity (mg/kg bw)	728.3				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard	"Indicator species for screening"	95.3	1.5	32.16	22.6
Reprod. toxicity (mg/kg bw/d)	58.4				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard	"Indicator species for screening"	38.9	1.8 × 0.53	8.35	7.0

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.

In the Tier I risk assessment, the TER_a values were greater than the Annex VI trigger of 10, indicating that PIORITYpresents no unacceptable acute risk to birds according to the intended uses. However, the TER_{lt} value for small insectivorous species "Redstart" in grapevine was below the trigger of 5 for Dithianon. A further refinement of the long-term risk is needed.

9.2.2.2 Higher-tier risk assessment

In order to refine the risk assessment, the following parameters refined below were considered.

Deposition factor (DF)
PIORITYwill be applied directly to crop. Since grass will be covered by the crop, an interception by the crop has to be taken into account. BBCH stages 55-79 corresponds with the inflorescence emerge, flowering and development of fruits. According to the interception values of FOCUS (2000)[1], for grapevines at growth stage leaf development, an interception factor of 50% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of 0.5 should be applied.

PT value
For "black redstar" a PT mean of 0.28 is ~~proposed~~ obtained. This value is based on the radio tracking part of the study (Brown el al., 2008) submitted in *Dithianon- Additional Report to DAR; Volume 3, Annex B-9: Ecotoxicology October 2006 January 2010* ~~and accepted by the EFSA (*Conclusion on the peer review of the pesticide risk assessment of the active substance dithianon*. EFSA Journal 2010;8(11):1904)~~. The radio tracking part of the study was conducted in France in vineyards during May and June. A 90th percentile **PT value of 0.75** from the vineyard field study submitted is proposed for refinement as worst case. Revised TERs to include the 90th percentile PT values were included in *Final addendum to the Draft Assessment Report (DAR) and Additional Report (October 2010)* and were accepted by EFSA (please, refer to *Conclusion on the peer review of the pesticide risk assessment of the active substance dithianon*. EFSA Journal 2010;8(11):1904). Moreover, this PT value was also accepted by EFSA for long-term risk refinement for "black redstar" in vineyards (please, refer to *Conclusion on the peer review of the pesticide risk assessment of the active substance chlorpyrifos*, EFSA Journal 2011;9(1):1961).

Table 9.2-4: Higher-tier assessment of long-term risk for birds due to the use of PIORITY in grapevine– refined parameters (*) are further described and justified in the text

Intended use	**Grapevine**						
Active substance/product	Dithianon / Dimethomorph 15% + Dithianon 35% WG						
Application rate (g/ha)	3 x 525						
Reprod. toxicity (mg/kg bw/d)	22.8						
TER criterion	5						
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}**
Black Redstart (Phoenicurus ochruros)	50% ground arthropods	0.81	3.5[1] × 0.5[2]	1.8 × 0.53	~~0.28~~ 0.75[3]	~~0.10~~ 0.27	~~17.65~~ 6.59
	50% foliar arthropods	0.81	21.0[1] × 1.0	1.8 × 0.53	~~0.28~~ 0.75[3]	~~1.19~~ 3.19	

[1] FOCUS (2012) "Focus groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202 pp.

	Whole diet	~~1.27~~ 3.46	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1]According Table 1 in Appendix F of EFSA/2009/1438.
[2]Mean deposition factor of 0.4 according to FOCUS 2012.
[3]~~Mean~~ 90th percentile PT determined for black redstar in vineyards (Brown el al., 2008).

zRMS comment:

The risk assessment based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).
The calculations of the acute risk assessment for both active substances were accepted by ZRMS.
In case of the long - risk assessment for Black Redstart for the active subtsance –ditathion the zRMS did not accept the PT value of 0.75 used by the Applicant.
According to EFSA Journal 2010;8(11):1904 the data is not sufficient to reduce this value in vineyard.

The corrected long - term risk assessment is provided below:

Table 9.2-5$_{corr}$:Higher-tier assessment of long-term risk for birds due to the use of PIORITY in grapevine– refined parameters.

Intended use	**Grapevine**						
Active substance/product	Dithianon / Dimethomorph 15% + Dithianon 35% WG						
Application rate (g/ha)	3 x 525						
Reprod. toxicity (mg/kg bw/d)	22.8						
TER criterion	5						
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$_{lt}$**
Black Redstart (Phoenicurus ochruros)	50% ground arthropods	0.81	3.5[1] × 0.5[2]	1.8 × 0.53	1	0.37	**4.95**
	50% foliar arthropods	0.81	21.0[1] × 1.0	1.8 × 0.53	1	4.23	
	Whole diet					4.6	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1]According Table 1 in Appendix F of EFSA/2009/1438.
[2]Mean deposition factor of 0.5 according to FOCUS 2001.

TER$_A$ for both active substances is above trigger of 10 indicating an acceptable risk to birds.
TER$_{LT}$ value for a.s. dithianon is closed to trigger of 5, indicating that the long - term risk assessment for Black Redstart is considered as acceptable by zRMS taking into account that defult values are used for the oter parameter such as : PT.
TER$_{LT}$ value for a.s. dimetomorph is above trigger of 5 indicating acceptable long-term risk for birds.

Risk Assessment for combined exposure

According to the EFSA Journal (2009)[2], the simultaneous exposure of animals to residues of two or more potential toxic substances should be considered in the risk assessment. Therefore, for the assessment of acute effects, a surrogate LD_{50} for the mixture of active substances with known toxicity was derived assuming dose additivity of toxicity. For the calculation, the following equation was used:

$$LD_{50}\left(\text{mix}\right) = \left(\sum_{i} \frac{X\left(\text{a.s}_{i}\right)}{LD_{50}\left(\text{a.s}_{i}\right)} \right)^{-1}$$

With:

$X\ (a.s._i)$ = fraction of each a.s. in the mixture

$LD_{50}\ (a.s._i)$ = acute toxicity value for each a.s.

Acute risks from combined exposure

The active substance content of the formulation PIORITY addressed in this dossier is 15% Dimethomoprh and 35% Dithianon, making up a total of 500 g a.s./Kg product. According to GAP, the maximum application rate is 1.5 kg/ha, therefore, an application rate of 750 g a.s./ha was considered in the assessment.

Table 9.2-4 shows the calculation of the predicted LD_{50} (mix) of Dimethomoprh and Dithianon when mixed in these proportions (step 1 in Appendix B to the EFSA GD 2009).

Table 9.2-6: Avian LD_{50} (mix) for Dimethomoprh and Dithianon when combined as PIORITY (step 1 in EFSA GD 2009, Appendix B)

	Dimethomoprh	Dithianon
Content in the formulation PIORITY	15%	35%
Fraction in the a.s. mixture	0.3000	0.7000
LD_{50} of a.s. [mg/kg bw]	728.3	786.1
Fraction / LD_{50}	0.000412	0.000890
Sum	0.00130239	
1/ sum = predicted LD_{50} (mix)	767.82 mg mix/kg bw	

It is obvious from the comparison of the (low) acute oral toxicity of the active substances, and their relative proportions of the formulated product PIORITY.

[2] European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12): 1438. [139 pp.].

Table 9.2-7: Avian "tox per fraction" for the PIORITY (step 1 in EFSA GD 2009, Appendix B)

	Dimethomoprh	Dithianon	"mix"
Content in the formulation PIORITY	15%	35%	50 %
Fraction in mixture	0.3000	0.7000	1.0
LD_{50} (mg/kg bw)	728.3	786.1	767.82
Tox per fraction	2427.67	1123.00	767.82
Contribution to predicted toxicity	31.63 %	68.37 %	

Dimethomoprh contributes to 31.63% to mixture toxicity, while the Dithianon have an impact on the predicted risk of 68.37 %, therefore, surrogate LD_{50} was used in the acute risk assessment.

Table 9.2-8: First-tier assessment of the acute risk for birds due to the use of PIORITY in grapevine

Intended use	**Grapevine**				
Active substance/product	PIORITY				
Application rate (g/ha)	3 x 750				
LD_{50} (mix) (mg/kg bw)	767.82				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard BBCH ≥ 20	Small insectivorous species "Redstart"	25.7	1.5	28.91	26.6
Vineyard BBCH ≥ 40	Small granivorous bird "Finch"	7.4	1.5	8.33	92.2
Vineyard BBCH ≥ 40	Small omnivorous bird "lark"	7.2	1.5	8.10	94.8

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.

According to reults, no unacceptable acute risk is obtained in grapevine acording to the proposed GAP due to combined exposure.

Regarding chronic risk assessment, the Applicant considers that, according to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment for reproductive effect. Due to differences in evaluated endpoints and the dependency of the derived NOEL of the test design, any calculated TERmix value can only be used for illustrating purposes. Hence, in the case of an unacceptable TERmix, it has to be discussed if the results of the toxicity studies present any evidence for a possible concentration additivity of the effects and risks.

In addition, the combined toxicological effect of these two active substances has not been investigated with regard to repeated dose toxicity. Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profile(s) based on the individual substances.

Despite all of this, the reproductive risk from combined exposure has been performed by the Applicant:

Reproductive risks from combined exposure

Table 9.2-9: Avian NOEL (mix) for Dimethomoprh and Dithianon when combined as PIORITY (step 1 in EFSA GD 2009, Appendix B)

	Dimethomoprh	Dithianon
Content in the formulation PIORITY	15%	35%
Fraction in the a.s. mixture	0.3000	0.7000
NOEL of a.s. [mg/kg bw]	58.4	22.8
Fraction / NOEL	0.005137	0.030702
Sum	0.035838741	
1/ sum = predicted NOEL (mix)	27.90 mg mix/kg bw	

It is obvious from the comparison of the (low) long- term oral toxicity of the active substances, and their relative proportions of the formulated product PIORITY, that any risk of long-term effects would very much be similar to toxicity of both active substances.

Table 9.2-10: Avian "tox per fraction" for the PIORITY (step 1 in EFSA GD 2009, Appendix B)

	Dimethomoprh	Dithianon	"mix"
Content in the formulation PIORITY	15%	35%	50 %
Fraction in mixture	0.3000	0.7000	1.0
NOEL (mg/kg bw)	58.4	22.8	27.90
Tox per fraction	194.67	32.57	30.41
Contribution to predicted toxicity	14.33%	85.67%	

Dimethomoprh contributes to 14.33 % to mixture toxicity, while the Dithianon have an impact on the predicted risk of 85.67 %, therefore, surrogate NOEL was used in the long-term risk assessment.

Table 9.2-11: First-tier assessment of the long-term risk for birds due to the use of PIORITY in grapevine

Intended use	**Grapevine**				
Active substance/product	PIORITY				
Application rate (g/ha)	3 x 750				
NOEL (mix) (mg/kg bw)	27.90				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard BBCH ≥ 20	Small insectivorous species "Redstart"	9.9	1.8 × 0.53	7.08	**3.9**
Vineyard BBCH ≥ 40	Small granivorous bird "Finch"	3.4	1.8 × 0.53	2.43	11.5
Vineyard BBCH ≥ 40	Small omnivorous bird "lark"	3.3	1.8 × 0.53	2.36	11.8

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.

According to reults, no unacceptable long-term risk is obtained in grapevine acording to the proposed GAP except to small insectivorous species "Redstart" where the TERlt value was below the trigger of 5. A further refinement of the long-term risk is needed.

Higher-tier risk assessment

In order to refine the risk assessment, the following parameters refined below were considered. Please, refer to DF and PT refinement in point 9.2.2.2 used for species "Redstar" described above.

Table 9.2-12: Higher-tier assessment of long-term risk for birds due to the use of PIORITY in grapevine– refined parameters (*) are further described and justified in the text

Intended use	**Grapevine**						
Active substance/product	PIORITY						
Application rate (g/ha)	3 x 750						
NOEL (mix) (mg/kg bw)	27.90						
TER criterion	5						
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$_{lt}$**
Black Redstart (Phoenicurus ochruros)	50% ground arthropods	0.81	3.5[1] × 0.5[2]	1.8 × 0.53	~~0.28~~ 0.75[3]	~~0.14~~ 0.38	~~15.11~~ 5.64
	50% foliar arthropods	0.81	21.0[1] × 1.0	1.8 × 0.53	~~0.28~~ 0.75[3]	~~1.70~~ 4.56	
	Whole diet					~~1.85~~ 4.94	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1]According Table 1 in Appendix F of EFSA/2009/1438.
[2]Mean deposition factor of 0.4 according to FOCUS 2012.
[3]~~Mean~~ 90th percentile PT determined for black redstar in vineyards (Brown el al., 2008).

According to reults, no unacceptable long-term risk is obtained in grapevine acording to the proposed GAP due to combined exposure.

zRMS comments:

Table 9.2-13$_{corr}$: Higher-tier assessment of long-term risk for birds due to the use of PIORITY in grapevine- refined parameters (*) are further described and justified in the text

Intended use	**Grapevine**						
Active substance/product	PIORITY						
Application rate (g/ha)	3 x 750						
NOEL (mix) (mg/kg bw)	27.90						
TER criterion	5						
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$_{lt}$**

Black Redstart (Phoenicurus ochruros)	50% ground arthropods	0.81	$3.5^{1} \times 0.5^{2}$	1.8 × 0.53	1	0.507	**4.23**
	50% foliar arthropods	0.81	$21.0^{1} \times 1.0$	1.8 × 0.53	1	6.08	
	Whole diet					6.6	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1]According Table 1 in Appendix F of EFSA/2009/1438.
[2]Mean deposition factor of 0.4 according to FOCUS 2012.
90[th] percentile PT determined for black redstar in vineyards (Brown el al., 2008).

TER_{LT}combitox is below trigger value of 5, indicating that the long-ter risk assessment for Black Redstart needs further refinement at MS s level.

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 PIORITY is 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 3627 L/kg (arithmetic mean N=6, EFSA Journal 2010;8(11):1904), Dithianon belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied

Effective application rate (g/ha)	=	945			
Acute toxicity (mg/kg bw)	=	786.1	quotient	=	1.20
Reprod. toxicity (mg/kg bw/d)	=	22.8	quotient	=	41.45

With a laboratory mean K(f)oc of 430 L/kg (EFSA Scientific Report (2006)82, 1-69), Dimethomorph belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

Effective application rate (g/ha)	=	225			
Acute toxicity (mg/kg bw)	=	728.3	quotient	=	0.56
Reprod. toxicity (mg/kg bw/d)	=	58.4	quotient	=	6.93

zRMS comment:

No specific calculations of exposure and TER are necessary for risk to birds through drinking water (puddle scenario) since the calculated ratios of effective application rate to acute and chronic effect endpoints are below the trigger value of 50 (Dithianon K_{OC} 3627 L/kg and Dimethomorph K_{OC} 430 L/kg).

Risk from bioaccumulation in fish and earthworms is considered acceptable for dithianon exposure.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Dithianon amounts to 3.2 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} of Dimethomorph amounts to 2.63 (*E*) and 2.73 (*Z*), mean value of 2.7, and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

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

Table 9.2-14: Assessment of the risk for earthworm-eating birds due to exposure to Dithianon via bioaccumulation in earthworms (secondary poisoning) for the intended use in grapevine

Parameter	Dithianon	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.59	$PEC_{soil\ twa\ 21d}$ for multiple applications
log P_{ow} / P_{ow}	3.2	EFSA Journal 2010;8(11):1904. The Pow was estimated from the Log Pow, and it value is 1584.89
Koc	3627	Mean (n = 6) EFSA Journal 2010;8(11):1904
foc	0.02	Default
BCF_{worm}	0.27	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.16	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.17	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	22.8	EFSA Journal 2010;8(11):1904.
TER_{lt}	134.44	No risk, TERlt > 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 as a limit value for admissible concentrations of Dithianon in water.

Table 9.2-15: Assessment of the risk for fish-eating birds due to exposure to Dithianon via bioaccumulation in fish (secondary poisoning) for the intended use in grapevine

Parameter	Dithianon	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.00153	$PEC_{sw\ twa\ 21d}$ at Step 1 for multiple applications
BCF_{fish}	28	EFSA Journal 2010;8(11):1904.
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.043	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.007	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	22.8	EFSA Journal 2010;8(11):1904.
TER_{lt}	3347.25	No risk, TERlt > 5

TER values shown in bold fall below the relevant trigger.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant for Dithianon and Dimethomorph.

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

Not relevant for Dithianon and Dimethomorph.

9.2.4 Overall conclusions

In the Tier I risk assessment, the TER_a values were greater than the Annex VI trigger of 10, indicating that PIORITY presents no unacceptable acute risk to birds according to the intended uses. However, the TER_{lt} value for small insectivorous species “Redstart” in grapevine was below the trigger of 5 for Dithianon. A further refinement of the long-term risk was needed. A refinement of the risk was done by refining the DF and PT, and the TER value was above the trigger showing no risk. Therefore, the acute long-term risk to birds after the application of PIORITY according to the GAP is considered acceptable. In addition, no unacceptable acute and long-term risk were obtained in grapevine according to the proposed GAP due to combined exposure.

No risk for birds was identified via drinking water exposure and secondary poisoning for both Dimethomorph and Dithianon following the intended uses of PIORITY on grapevine.

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

Effects on mammals of PIORITY were not evaluated as part of the EU assessment of Dithianon and Dimethomorph. New data submitted with this application are listed in 9.13 and summarised in Section 6

(Mammalian Toxicology) of this report.

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

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

Species	Substance	Exposure System	Results	Reference
Rat	Dithianon	Oral Acute	LD_{50} = > 300 < 500 mg/kg bw/day	EFSA Journal 2010;8(11):1904
Rat	Dithianon	Oral Acute	LD_{50} = 702 mg/kg bw/day	Dithianon ADDENDUM 1 to the Additional Report, 2010
Rat	LD_{50} (geometric mean) [mg a.s./kg b.w.]		**LD_{50} = 458.9 mg/kg bw/day**	
Rabbit	Dithianon	Teratogenicity study	**$NOEAEL_{developmental}$ = 25*** Based on effects on pre- and post implantation losses at 40 mg a.s./kg bw	EFSA Journal 2010;8(11):1904
Rat	Dimethomorph	Oral Acute	**LD_{50} = 3900 mg/kg bw**	EFSA Scientific Report (2006) 82, 1-69
Rat	FORUM 150 DC (Dimethomorph formulation)	Acute	LD_{50} = 900 mg/kg bw = 135 mg a.s./kg bw	EFSA Scientific Report (2006) 82, 1-69
Rat	Dimethomorph	Multi-generation study Long-term	NOAEL 300 ppm **(20 mg/kg bw/d)**	EFSA Scientific Report (2006) 82, 1-69

*Lower endpoint (25 mg a.s./kg bw/d based on prenatal effects in rabbit) derived from developmental studies, from single gavage exposure.

9.3.1.1 Justification for new endpoints

The EU agreed endpoints are used for the risk assessment. The acute oral toxicity of Dithianon has been determined in two studies in rats. It is permissible to derive a geometric mean of the endpoints in the acute dietary risk assessment as different studies exist for one species. The geometric mean is calculated for the two acute oral toxicity endpoints derived from the studies with rats. The value to be used for the risk assessment for wild mammals for dithianon is LD_{50} geometric mean = 458.9 mg a.s./kg b.w.

9.3.2 Risk assessment for spray applications

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

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

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

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of PIORITY in grapevine

Intended use	Grapevine				
Active substance/product	Dithianon				
Application rate (g/ha)	3 x 525				
Acute toxicity (mg/kg bw)	458.9				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole"	40.9	1.5	32.21	14.2
Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph"	8.1	1.5	6.38	71.9
Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew"	5.4	1.5	4.25	107.9
Vineyard Application crop directed BBCH ≥ 40	Small omnivorous mammal "mouse"	5.2	1.5	4.10	112.1
Reprod. toxicity (mg/kg bw/d)	25				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.8 × 0.53	10.87	**2.3**
Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph"	3.3	1.8 × 0.53	1.65	15.1
Vineyard Application crop directed BBCH ≥ 40	Small omnivorous mammal "mouse"	2.3	1.8 × 0.53	1.15	21.7
Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	1.8 × 0.53	0.95	26.3
Intended use	Grapevine				
Active substance/product	Dimethomorph				
Application rate (g/ha)	3 x 225				
Acute toxicity (mg/kg bw)	3900				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard	"Indicator species for screening"	136.4	1.5	46.04	84.7
Reprod. toxicity (mg/kg bw/d)	20				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**

Vineyard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.8 × 0.53	4.66	**4.3**
Vineyard BBCH ≥ 40	Large herbivorous mammal “lagomorph”	3.3	1.8 × 0.53	0.71	28.2
Vineyard Application crop directed BBCH ≥ 40	Small omnivorous mammal “mouse”	2.3	1.8 × 0.53	0.49	40.5
Vineyard BBCH ≥ 20	Small insectivorous mammal “shrew”	1.9	1.8 × 0.53	0.41	49.0

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.

In the Tier I risk assessment, the TER_a values were greater than the Annex VI trigger of 10, indicating that PIORITY presents no unacceptable acute risk to mammals according to the intended uses. However, the TER_{lt} value for small herbivorous mammal "vole” in grapevine was below the trigger of 5 for both active substance. A further refinement of the long-term risk is needed.

zRMS comment:

In the Tier I risk assessment, the TER_a values were greater than the Annex VI trigger of 10, indicating that PIORITY presents no unacceptable acute risk to mammals according to the intended uses.
However, the TER_{lt} value for small herbivorous mammal "vole” in grapevine was below the trigger of 5 **for both active substances.** A further refinement of the long-term risk for vole was indicated.
The applicant provided the higher tier risk assessment presented below.

9.3.2.2 Higher-tier risk assessment

In order to refine the risk assessment, the following parameters refined below were considered.

Identification of focal mammal species

There are many reasons why the risk assessment for vole is considered to be covered through the assessment of other small mammalian species:

- High fecundity and population recuperation of the vole.
- Primary source of food outside crops fields for the vole.
- Necessity of population control measures since the vole is considered a crop pest when high population levels are reached.
- Other agricultural techniques being also means of population control.

In addition, the selection of focal species for the refined risk assessment is based on results of a comprehensive generic field study on focal mammal species in vineyards (Städtler, 2006) submitted in *Dithianon- Additional Report to DAR; Volume 3, Annex B-9: Ecotoxicology October 2006 January 2010*. The study was conducted in France (Burgundy) in five test areas comprising of vineyard area and surrounding area. The life-trapping results of the monitoring study in vineyards clearly establish the wood mouse (*Apodemus sylvaticus*) as the most abundant species overall. Therefore, the focal species selected for the refined risk assessment in grapes is:

- Small omnivorous mammal "mouse": Wood mouse (*Apodemus sylvaticus*)

According to the first-tier risk assessment performed above, no unacceptable long-term risk was obtained for the wood mouse (*Apodemus sylvaticus*) in vineyard according to GAP.

Applicant updated for comments by zRMS-October 2020

Dithianon refinement

DT_{50} and RUD

In the Tier I assessment, the default foliar DT_{50} is 10 days and RUD_{mean} is 54.2 mg/kg for grass+cereals. However, the foliar DT_{50} and RUD_{mean} were refined considering reside decline studies. Four residue decline studies in cereals have been performed by the Applicant in Germany with the formulation Dithianon 70% WG (KCP 10.1.2.1-01 and KCP 10.1.2.1-02). Four applications at 1.5 Kg f.p./ha (1050 g a.s./ha) with 6-9 days of interval were applied for these studies, therefore, proposed GAP is covered. The information used for the determination of the DT_{50} and RUD_m are showed in the table below.

Report/Trial/ country/year	Crop	Appl. rate (g a.s./ha)	BBCH	Analyzed	Residue Dithianon (mg/kg)	Time (days)	RUD (mg/kg)	DT_{50} (days)
Report DPL/84/2019 Trial CT18-1-15DE1 Germany (N), 2020	Winter wheat	4 x 1050	25-32	Whole plant without roots	29.1 29.2 22.4 21.5 12.3 7.50 2.30	0 1 3 5 7 14 21	27.71	5.46
Report DPL/84/2019 Trial CT18-1-15DE2 Germany (N), 2020	Winter wheat	4 x 1050	25-39	Whole plant without roots	22.8 17.7 12.6 12.5 9.21 1.74 1.51	0 1 3 5 7 14 21	21.71	5.36
Report DPL/85/2019 Trial FR058/18-V1 Germany (N), 2020	Winter wheat	4 x 1050	39-69	Whole plant without roots	31.3 22.0 19.8 11.7 10.4 10.9 3.55	0 1 3 5 7 14 21	29.81	6.69
Report DPL/85/2019 Trial FR058/18-V2 Germany (N), 2020	Winter wheat	4 x 1050	37-71	Whole plant without roots	32.8 21.8 19.3 15.1 14.4 13.3 4.73	0 1 3 5 7 14 21	31.24	7.52
						Mean	27.62	6.26

The DT_{50} values were calculated according to the formula:

$DT_{50} = - t \times \ln(2) / \ln (C_{final}/C_{max})$

The estimated DT_{50} from the available residue decline trials are 5.46, 5.36, 6.69 and 7.52 days, clearly below than the default value of 10 days, with a mean DT_{50} of 6.26 days. The estimated RUD values from the available residue decline trials are 27.71, 21.71, 29.81 and 31.24 mg/kg with a RUDm of **27.62** days

Mean values of DT_{50} of 6.26 days and of RUD of 27.62 mg/kg were used for long-term refinement of vole.

MAF and TWA (interval between applications)
In the Tier I, the default twa value used is 0.53. However, since the DT_{50} is lower than 10 days, the 21-d twa value was recalculated considering the mean DT_{50} of 6.26 days and the resulting value is **0.39**, that will be used in the higher-tier assessment.

Considering the application according to the GAP for grapevines, 3 x 525 g a.s./ha with an interval of 10 days, the MAF applied to the risk assessment was 1.8. However, the Applicant wishes to increase the interval between applications from 10 days to 12 days, according to the proposed GAP. Therefore, according to refined DT_{50} value obtained and increasing of interval to 12 days, a MAF_m of **1.33** is obtained and used in the vole refinement.

Table 9.3-3: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of PIORITY in grapevine – refined parameters (*) are further described and justified in the text

Intended use	Grapevine							
Active substance/product	Dithianon							
Application rate (g/ha)	3 x 525							
Reprod. toxicity (mg/kg bw/d)	25							
TER criterion	5							
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m*× DF*** **(mg/kg food)**	**MAF_m* × TWA***	**PT**	**PD**	**DDD_m** **(mg/kg bw/d)**	**TER_{lt}**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	27.62[2] × 0.3[1]	1.33[2] x 0.39[2]	1	1	3.00	8.3

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1] According to Appendix A of EFSA/2009/1438.
[2]RUDm, MAF_m and ftwa value obtained from 4 residue decline trials in cereals performed in Germany (Please, refer to KCP 10.1.2.1-01 and KCP 10.1.2.1-02).

zRMS comment:

Based on an evaluated study at EU by comprehensive generic field study on focal mammal species in vineyards (Städtler, 2006) submitted in *Dithianon - Additional Report to DAR; Volume 3, Annex B-9: Ecotoxicology October 2006 January 2010*, conducted in France (Burgundy) in five test areas comprising of vineyard area and surrounding area, the life-trapping results of the monitoring study in vineyards indicated that the wood mouse (*Apodemus sylvaticus*) was the most abundant species overall. Therefore in EFSA Conclusion 2010 the wood mouse was considered as a focal species .
Based on this recommendation the risk should be provided for wood mouse.
Therefore, the risk should be based on this species.
Additionally, the zRMS evaluated the risk assessment provided by the applicant for vole.
After evaluation of the Report of Kinetic degradation of residue decline in wheat ((Izquierdo J.J., 2021) evaluated by zRMS-PL in ppp Dukes (available on Circa platform) the refined DT_{50} is 8.35 d (90 th percentile) and 6.48 d (mean value) was accepted which are different that value provided by the applicant in the Table above.
It was questioned if the test with so low BBCH 25-39 of cereals (all trials) does not underestimate the results of the test because it is a time when plants grow very fast.
These values were considered not sufficiently reliable.

Therefore, DT_{50} values obtained can be used in the WoE approach only as supportivee information.
The default value of 10 d was used by zRMS in the risk assessment.
In addition for the refinement, the RUD mean value for cereals were used by the applicant
The max value from obtained results should be used.

Table 9.3-4$_{corrected}$: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of PIORITY in grapevine – refined parameters (*) are further described and justified in the text.

Intended use	Grapevine
Active substance/product	Dithianon
Application rate (g/ha)	3 x 525
Reprod. toxicity (mg/kg bw/d)	25
TER criterion	5

Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m*× DF*** **(mg/kg food)**	**MAF_m* × TWA***	**PT**	**PD**	**DDD_m** **(mg/kg bw/d)**	**TER_{lt}**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	32.8 × 0.3[1]	1.6 x 0.53	1	1	5.82	**4.3**

***with 12 d interval**

TER_{LT} for vole is below trigger of 5.
However, based on the information provided in Addendum the risk for wood mouse is sufficient to conclude an acceptable risk for small mammals.

Dimethomorph refinement

Interval between applications
Considering the application according to the GAP for grapevines, 3 x 525 g a.s./ha with an interval of 10 days, the MAF applied to the risk assessment was 1.8. However, if an interval of 12 days is considered (instead of 10 days), the MAF to be applied in the refined risk assessment is **1.6**.

PD
As a further refinement of the risk of vole in grapevines, the PD refinement was considered. A PD refinement is commented by Netherlands[3] and a proposal of refinement is given. The refinement is based on the studies by Rinke (1991) "*Percentage of volume versus number of species: availability and intake of grasses and forbs in microtus arvalis. Folia zoological 40 (2): 143-151*" and by Lüthi, M. *et al* (2010) "*Nutritional ecology of Microtus arvalis* (*Pallas, 1779) in sown wild flower fields and quasi-natural habitats. Revue Suisse de Zoologia 117 (4): 811-828*".
In the study of Rinke (1991) the stomach content of 363 individuals (186 females and 177 males) trapped on five plots of permanent meadow in central Hessia (Germany) were analyzed. The study investigated the vole feeding preferences (mono *vs.* dicot). In the study voles showed a preference for dicots, with the majority of voles (all seasons, sexes, ages) showing > 80% dicot material in stomach contents.

Diet of common voles (%) – Rinke 1991

Season	**Monocotyledons (% volume)**	**Dicotyledonos (% volume)**	**No. of voles**

[3] Evaluation Manual for the authorization of plant protection products according to Regulation (EC) No 1107/2009 Chapter 7, version 2.2; April 2017

Spring	24	76	23
Summer	25	75	152
Autum	48	52	188
Total	36	64	363

In the study of Lüthi et al., 2010 the diet of the common vole in monocot and dicot dominated fields was studied. In the sown wild flower areas vegetation cover was mainly dicot (79%, 81.6% and 79% in the three fields, respectivley) and in the quasi natural habitat the cover was mainly monocots (82.5, 92.5 and 47.5%).

Diet of common voles (%) – Lüthi et al., 2010

Sown wild flower fields	**Field 1**	**Field 2**	**Field 3**	**Average**
Dicots	16.3	31.8	11.2	19.6
Monocots	43.1	36.5	53.3	44.3
Seeds	14.8	16.5	27.0	19.4
Other (roots)	25.8	15.2	8.5	16.6
Natural quasi habitat				
Dicots	17.1	6.2	9.6	11.0
Monocots	67.7	81.9	66.0	71.0
Seeds	6.6	8.4	17.0	10.7
Other (roots)	8.56	3.5	7.4	7.4

Dicot dominated fields: 50% non-grass herbs and 50% grass and cereals

Monocot dominated underground: 25% non-grass herbs and 75% grass and cereals.

The approach is considered appropriate for the refinement of the chronic risk assessmente for vole.

Therefore, for the refinement of the risk in grapevines, a PD of 0.5 for non-grass herbs and 0.5 for grass and cereals will be used.

FIR/bw
For the food category grass and cereals, the FIR/bw value of 1.33, given by EFSA/2009/1438 was used. For the food category non-grass herbs, FIR/bw value was calculated. Default values given by EFSA/2009/1438 were used for the estimation of FIR and a bw value of 25 g for common vole given in EFSA/2009/1439 was used. The resulting values were: FIR = 40.433; FIR/bw = 1.62

Table 9.3-5: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of PIORITY in grapevine – refined parameters (*) are further described and justified in the text

Intended use	Grapevine
Active substance/product	Dimethomorph
Application rate (g/ha)	3 x 225
Reprod. toxicity (mg/kg bw/d)	20
TER criterion	5

Focal species	**Food category, % in diet**	**FIR/bw***	**RUD_m× DF*** **(mg/kg food)**	**MAF_m* × TWA**	**PT**	**PD***	**DDD_m** **(mg/kg bw/d)**	**TER_{lt}**
Common vole	50% grass and	1.33[1]	54.2[1] ×	1.6[2] x	1	0.5	2.06	

(*Microtus arvalis*)	cereals		0.3[1]	0.53				
	50% non-grass herbs	1.62[1]	28.7[1] x 0.3[1]	1.6[2] x 0.53	1	0.5	1.33	
						Total	3.39	5.9

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1] FIR/bw refined accroding to EFSA/2009/1438.
[2] MAF_m with 12 days of interval between applications.

zRMS comment:

The applicant provided the refined risk assessment for a.s.- dimethomorph for vole.
The trigger value of 5 was achieved indicating an acceptable long-term risk assessment for small mammals.

Risk Assessment for combined exposure

According to the EFSA Journal (2009)[4], the simultaneous exposure of animals to residues of two or more potential toxic substances should be considered in the risk assessment. Therefore, for the assessment of acute effects, a surrogate LD_{50} for the mixture of active substances with known toxicity was derived assuming dose additivity of toxicity. For the calculation, the following equation was used:

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

With:

$X\,(a.s._i)$ = fraction of each a.s. in the mixture

$LD_{50}\,(a.s._i)$ = acute toxicity value for each a.s.

Acute risks from combined exposure

The active substance content of the formulation PIORITY addressed in this dossier is 15% Dimethomoprh and 35% Dithianon, making up a total of 500 g a.s./Kg product. According to GAP, the maximum application rate is 1.5 kg/ha, therefore, an application rate of 750 g a.s./ha was considered in the assessment.

Table 9.3-3 shows the calculation of the predicted LD_{50} (mix) of Dimethomorph and Dithianon when mixed in these proportions (step 1 in Appendix B to the EFSA GD 2009).

[4] European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12): 1438. [139 pp.].

Table 9.3-6: Mammalian LD_{50} (mix) for Dimethomorph and Dithianon when combined as PIORITY (step 1 in EFSA GD 2009, Appendix B)

	Dimethomorph	Dithianon
Content in the formulation PIORITY	15%	35%
Fraction in the a.s. mixture	0.3000	0.7000
LD_{50} of a.s. [mg/kg bw]	3900	458.9
Fraction / LD_{50}	0.000077	0.001525
Sum	0.00160231	
1/ sum = predicted LD_{50} (mix)	624.10 mg mix/kg bw	

Table 9.3-7: Mammalian "tox per fraction" for the PIORITY (step 1 in EFSA GD 2009, Appendix B)

	Dimethomorph	Dithianon	"mix"
Content in the formulation PIORITY	15%	35%	50.0 %
Fraction in mixture	0.3000	0.7000	1.0
LD_{50} (mg/kg bw)	3900	458.9	624.10
Tox per fraction	13000.00	655.57	624.10
Contribution to predicted toxicity	4.80%	95.20%	

The tox per fraction is 13000.00 for Dimethomorph and 655.57 for Dithianon. The LD_{50} for Dithianon and suroggate LD_{50} are very similar this indicates that this active substance will contribute to ≥ 90 % to mixture toxicity (95.20%), while the other components of the mixture will only have a marginal impact on the predicted risk. Consequently, the risk assessment can be performed for the most toxic active substance alone. No further considerations according to Steps 2 - 4 are necessary.

Regarding chronic risk assessment, the Applicant considers that, according to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment for reproductive effect. Due to differences in evaluated endpoints and the dependency of the derived NOEL of the test design, any calculated TERmix value can only be used for illustrating purposes. Hence, in the case of an unacceptable TERmix, it has to be discussed if the results of the toxicity studies present any evidence for a possible concentration additivity of the effects and risks.

In addition, the combined toxicological effect of these two active substances has not been investigated with regard to repeated dose toxicity. Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profile(s) based on the individual substances.

Despite all of this, the reproductive risk from combined exposure has been performed by the Applicant:

Reproductive risks from combined exposure

Table 9.3-8: Mammalian NOEL (mix) for Dimethomorph and Dithianon when combined as PIORITY (step 1 in EFSA GD 2009, Appendix B)

	Dimethomorph	Dithianon
Content in the formulation PIORITY	15%	35%
Fraction in the a.s. mixture	0.3000	0.7000
NOEL of a.s. [mg/kg bw]	20	25
Fraction / NOEL	0.015000	0.028000
Sum	0.043	
1/ sum = predicted NOEL (mix)	23.26 mg mix/kg bw	

Table 9.3-9: Mammalian "tox per fraction" for the PIORITY (step 1 in EFSA GD 2009, Appendix B)

	Dimethomorph	Dithianon	"mix"
Content in the formulation PIORITY	15%	35%	50.0 %
Fraction in mixture	0.3000	0.7000	1.0
NOEL (mg/kg bw)	20	25	23.26
Tox per fraction	66.67	35.71	23.26
Contribution to predicted toxicity	34.88%	65.12%	

Dimethomoprh contributes to 34.88 % to mixture toxicity, while the Dithianon have an impact on the predicted risk of 65.12 %, therefore, surrogate NOEL was used in the long-term risk assessment.

Table 9.3-10: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of PIORITY in grapevine

Intended use	**Grapevine**				
Active substance/product	PIORITY				
Application rate (g/ha)	3 x 750				
NOEL (mix) (mg/kg bw/d)	23.26				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.8 × 0.53	15.53	**1.5**
Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph"	3.3	1.8 × 0.53	2.36	9.9
Vineyard Application crop directed BBCH ≥ 40	Small omnivorous mammal "mouse"	2.3	1.8 × 0.53	1.65	14.1
Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	1.8 × 0.53	1.36	17.1

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

According to reults, no unacceptable long-term risk is obtained in grapevine for combined exposure acording to the proposed GAP, except to the for small herbivorous mammal "vole" where the TERlt value was below the trigger of 5. A further refinement of the long-term risk is needed.

Higher-tier risk assessment

In order to refine the risk assessment. Please, refer to the identification of focal mammal species refinement in point 9.3.2.2 used for vole performed above. Since no unacceptable long-term risk was obtained for the wood mouse (*Apodemus sylvaticus*) in vineyard according to GAP for combined exposure, no further refinement will be needed.

Applicant updated for comments by zRMS-October 2020

Different approaches are proposed by the Applicant below:

Approach 1. Uncertainity analysis and Weight of Evidence

According to *Bullet Points: Ecotoxicology - Combination toxicology Article 43* (November, 2017):

"For higher Tier refinements, there are various approaches by the MS, most of whom would rely on a WoE approach if no agreed methods/ guidance are available; some MS would exhaust single a.s. refinements as a first step for the refined combitox assessment."

The Applicant wishes to insist that due to the dependency of NOEC values from experimental dose-spacing and due to the diversity of biological endpoints in long-term/chronic toxicity tests, a calculated NOEC(mix) is unlikely to constitute a reliable measure of toxicity. Against that background, the calculated TER(mix) for a long-term/chronic risk is only applied in the assessment in combination with additional considerations on its possible relevance in terms of actual risk. Although a long-term TERlt of 1.5 for the vole is bellow the trigger of 5, a risk from combined effects of dimethomorph and dithianon can be considered low. For explanation, see the uncertainity analysis below

Combination toxicity is calculated assuming additive toxicity, which is considered a worst case. A long-term TERlt of 1.5 for the vole is based on TERLT values that were derived from a generally robust assessment. Default RUD values were used, although they might have been lower under natural conditions as indicated in the core document. No biological parameters like PD and PT were changed. Further, the DT50 is considered to be quite conservative.

In conclusion, the combined risk assessment for small herbivorous mammals "vole" results in a long-term TERlt value that is below the trigger value of 5, indicating an unacceptable long-term risk to small herbivorous mammals from the summation of the two active substances dimethomorph and dithianon. However, the uncertainity analysis has shown that a long-term risk from the combined effects of the active substances can be acceptable. The application of PIORITY according to the submitted GAP demonstrated a safe risk to mammals under natural conditions.

In addition to this, as it was demonstrated above, the long-term risk for vole was refined for each substance separately and the TERlt values for each actives were above the trigger of 5 showing no unacceptable risk for vole.

In addition, the Applicant wishes to insist that, the selection of focal species *Apodemus sylvaticus* for the refined risk assessment is based on results of a comprehensive generic field study on focal mammal species in vineyards (Städtler, 2006) submitted in *Dithianon- Additional Report to DAR; Volume 3, Annex B-9: Ecotoxicology October 2006 January 2010*.

Moreover, the Applicant wished to insist that vole if not a focal species for the risk assessment based on:
a) the results of a comprehensive generic field study on focal mammal species in vineyards (Städtler, 2006) submitted in *Dithianon- Additional Report to DAR; Volume 3, Annex B-9: Ecotoxicology October 2006 January 2010*.
b) according to *Fluazifop-P Confirmatory data_Addendum Vol3 B9 Revised Oct 2014*, there are many reports from the literature that the optimum or prime habitat‘ of common voles is undisturbed grassland or set-aside at a vegetation height of minimum 20 cm (De Jonge and Dienske, 1979; Delattre et al., 1996; Butet and Leroux, 2001; Giraudoux et al., 1994; Gorman and Reynolds, 1993) or perennial crops like alfalfa (Truszkowski, 1982). The preference for primary habitats is underlined by the findings of Briner et al. (2005), who demonstrated by using automatic radio tracking, that *M. arvalis* developed high population densities containing 90% of the total home range in wild flower strips neighbouring crop fields, but hardly ever entered the nearby crops, even when those were highly palatable. Also, Koks et al. (2007) showed that vole abundance was twice as high in set aside land and in high and dense vegetation than in neighbouring non fallow habitat types like plantations or cereals.

Therefore, it can be stated that

- When local population densities are low, Common voles are prone to spend much less time in crop fields, which only serve as transient habitats.

- Secondary populations of the Common vole in-field (as opposed to the primary population in the margins) are also of little to no importance for the survival of the local populations, since harvest and ploughing will destroy their home range habitat at least once a year.

Since this species is so prolific, it can additionally be stated that a slight reduction in the growth potential of secondary populations in field crops will usually also be of little to no importance for the population of local predator species.

Therefore, it is may be more appropriate to consider the other small mammals, such as the wood mouse (*Apodemus sylvaticus*) and common shrew (*Sorex araneus*), as relevant focal species in crop habitats. The risk assessment is considered to be covered through the assessment of other small mammalian species for the following reasons:

- High fecundity and population recuperation of the vole ;
- Primary source of food outside crops fields for the vole ;
- Necessity of population control measures since the vole is considered a crop pest when high population levels are reached ;
- Other agricultural techniques being also means of population control

zRMS comment:

We agree that based on the results of the generic field study on focal mammal species in vineyards (Städtler, 2006) submitted in *Dithianon- Additional Report to DAR; Volume 3, Annex B-9: Ecotoxicology October 2006 January 2010 indicated wood mouse as the focal species for vine.*
Based on this assumption the risk for small herbivores mammal based on wood mouse is considered acceptable.

Approach 2. Reduction in applications. Assessment of combined toxicity by step wise approach (TERmix)

Firstly, a reduction in number of application from 3 to 1 is proposed by the Applicant. Higher-tier refinement for actives presented in updated is performed below with 1 application:

Table 9.3-11: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of PIORITY in grapevine – refined parameters (*) are further described and justified in the text

Intended use	Grapevine							
Active substance/product	Dithianon							
Application rate (g/ha)	1 x 525							
Reprod. toxicity (mg/kg bw/d)	25							
TER criterion	5							
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m*× DF* (mg/kg food)**	**MAF_m* × TWA***	**PT**	**PD**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	27.62[2] × 0.3[1]	1.0 x 0.39[2]	1	1	2.26	11.1

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1] According to Appendix A of EFSA/2009/1438.
[2]RUDm and ftwa value obtained from 4 residue decline trials in cereals performed in Germany (Please, refer to KCP 10.1.2.1-01 and KCP 10.1.2.1-02).

Table 9.3-12corr: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of PIORITY in grapevine – refined parameters

Intended use	Grapevine							
Active substance/product	Dithianon							
Application rate (g/ha)	1 x 525							
Reprod. toxicity (mg/kg bw/d)	25							
TER criterion	5							
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_{max}*× DF* (mg/kg food)**	**MAF_m* × TWA***	**PT**	**PD**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	32.8 × 0.3[1]	1x 0.53	1	1	3.64	6.86

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1] According to Appendix A of EFSA/2009/1438.
[2]RUD and ftwa value obtained from 4 residue decline trials in cereals performed in Germany (Please, refer to KCP 10.1.2.1-01 and KCP 10.1.2.1-02).

Table 9.3-13: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of PIORITY in grapevine – refined parameters (*) are further described and justified in the text

Intended use	Grapevine

Active substance/product		Dimethomorph						
Application rate (g/ha)		1 x 225						
Reprod. toxicity (mg/kg bw/d)		20						
TER criterion		5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD$_m$× DF* (mg/kg food)**	**MAF$_m$* × TWA**	**PT**	**PD***	**DDD$_m$ (mg/kg bw/d)**	**TER$_{lt}$**
Common vole (*Microtus arvalis*)	50% grass and cereals	1.33[1]	54.2[1] × 0.3[1]	1.0 x 0.53	1	0.5	1.29	
	50% non-grass herbs	1.62[1]	28.7[1] x 0.3[1]	1.0 x 0.53	1	0.5	0.83	
						Total	2.12	9.4

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1] FIR/bw refined accroding to EFSA/2009/1438.

The TER_{lt} values obtained have been considered for the step-wise approach performed below.

An assessment of combined toxicity of the active substances present in PIORITY has been made according to current EFSA RMS comment:
Guidance. When a product contains more than one active substance, an additional assessment on combined toxicity risk has to be presented. It is considered that a quantitative toxicity risk assessment according to concentration addition is not needed if one of the following points applies:

- The risk assessment for all active substances in the product passes with a high margin of safety.
- One active substance clearly drives the risk assessment.

These conditions are assessed following a step-wise approach.

1st step: Margin of safety

Condition: all TER values are >Trigger × n

Where:
n = number active substances in the mixture

2nd step: Risk per fraction

Condition: One a.s. contributes to ≥90% of the predicted combined toxicity of the product.

Assessment: The contribution of each individual a.s. to the combined toxicity (risk per fraction, rpf) is estimated based on the following equation:

$$rpf_{a.s.1} = 1/TER_{a.s.1} / (1/TER_{a.s.1} + 1/TER_{a.s.2})$$

The estimation is based on TER values from the same refinement level to assure comparability.

3rd step: TER_{MIX} calculation

Condition: The combined toxicity is acceptable if $TER_{MIX} \geq 10$ (acute) or ≥ 5 (long-term)
Assessment: The combined toxicity risk (TER_{MIX}) with concentration-addition is estimated based on the following equation:

$$TER_{mix} = 1/(1/TER_{a.s.1} + 1/TER_{a.s.2})$$

Table 9.3-14: Combined toxicity assessment – mammals

Intended use	Grapevine					
Active sub-stance/product	Dimethomorph 15% + Dithianon 35% WG (PIORITY)					
Application rate (Kg/ha)	1.5					
Focal species	**TER values**		**Trigger**	**1st step (all TER ≥trigger × n)**	**2nd step (Rpfmax)**	**3rd step (TER_{MIX})**
	DIM	**DITH**				
Common vole (*Microtus arvalis*)	9.4	~~11.1~~ 6.86	5	No	No 0.54 (DIM) 0.46 (DITH)	~~5.1~~ 4.16

Applying refined risk assessment the calculated TER value do achieve the acceptability criterion the acceptability criterion TER ≥ 5 for long-term effects on mammals. Therefore, no further combined toxicity risk assessment is required.

zRMS comment:

Based on the information provided in the Addendum Dithianon- Additional Report to DAR; Volume 3, Annex B-9: Ecotoxicology October 2006 January 2010 wood mouse as the focal species for vine. Therefore, the TER_{mix} was provided for this species and for 3 applications.

The combitox long-term for wood mouse.

Intended use	Grapevine		
Active sub-stance/product	Dimethomorph 15% + Dithianon 35% WG (PIORITY)		
Application rate (Kg/ha)	1.5		
Focal species	**TER values**		TERmix
	DIM	**DITH**	
Wood mouse	40.5	21.7	14.28
Rabbit	15.1	28.7	10

The combitox long-term risk assessment is considered as acceptable for small mammal wood mouse and rabbit.

9.3.2.3 Drinking water exposure

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

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorp-

tive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 3627 L/kg (arithmetic mean N=6, EFSA Journal 2010;8(11):1904), Dithianon belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

Effective application rate (g/ha)	=	945			
Acute toxicity (mg/kg bw)	=	458.9	quotient	=	2.06
Reprod. toxicity (mg/kg bw/d)	=	25	quotient	=	37.80

With a laboratory mean K(f)oc of 430 L/kg (EFSA Scientific Report (2006)82, 1-69), Dimethomorph belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

Effective application rate (g/ha)	=	405			
Acute toxicity (mg/kg bw)	=	3900	quotient	=	0.10
Reprod. toxicity (mg/kg bw/d)	=	20	quotient	=	20.25

zRMS comment:

No specific calculations of exposure and TER are necessary for risk to birds through drinking water (puddle scenario) since the calculated ratios of effective application rate to acute and chronic effect endpoints are below the trigger value of 50 (Dithianon K_{OC} 3627 L/kg and Dimethomorph K_{OC} 430 L/kg).

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of Dithianon amounts to 3.2 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} of Dimethomorph amounts to 2.63 (*E*) and 2.73 (*Z*), mean value of 2.7, and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

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

Table 9.3-15: Assessment of the risk for earthworm-eating mammals due to exposure to Dithianon via bioaccumulation in earthworms (secondary poisoning) for the intended use in grapevine

Parameter	Dithianon	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.59	$PEC_{soil\ twa\ 21d}$ for multiple applications
log P_{ow} / P_{ow}	3.2	EFSA Journal 2010;8(11):1904. The Pow was estimated from the Log Pow, and it value is 1584.89
Koc	3627	Mean (n = 6) EFSA Journal

Parameter	Dithianon	comments
		2010;8(11):1904
foc	0.02	Default
BCF_{worm}	0.27	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.16	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.21	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	25	EFSA Journal 2010;8(11):1904.
TER_{lt}	120.92	No risk, TERlt > 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 predicted concentrations in surface water for aquatic organisms as a limit value for admissible concentrations of Dithianon in water.

Table 9.3-16: Assessment of the risk for fish-eating mammals due to exposure to Dithianon via bioaccumulation in fish (secondary poisoning) for the intended use in grapevine

Parameter	Dithianon	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.00153	$PEC_{sw\ twa\ 21d}$ at Step 1 for multiple applications
BCF_{fish}	28	EFSA Journal 2010;8(11):1904.
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.043	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.006	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	25	EFSA Journal 2010;8(11):1904.
TER_{lt}	4109.63	No risk, TERlt > 5

TER values shown in bold fall below the relevant trigger.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant for Dithianon and Dimethomorph.

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

Not relevant for Dithianon and Dimethomorph.

9.3.4 Overall conclusions

In the Tier I risk assessment, the TER_a values were greater than the Annex VI trigger of 10, indicating that PIORITY presents no unacceptable acute risk to mammals according to the intended uses. However, the TER_{lt} value for small herbivorous mammal "vole" in grapevine was below the trigger of 5 for both

active substance. A further refinement of the long-term risk was needed. A refinement of the risk was done by refining the focal species to woodmouse. The TERlt value for this species was above the trigger showing no risk. Therefore, the acute and long-term risk to mammals after the application of PIORITY according to the GAP is considered acceptable. In addition, no unacceptable acute and long-term risk were obtained for the wood mouse (*Apodemus sylvaticus*) in vineyard according to GAP for combined exposure.

No risk for mammals was identified via drinking water exposure and secondary poisoning for both Dimethomorph and Dithianon following the intended uses of PIORITY on grapevine.

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

Not relevant for Dithianon and Dimethomorph.

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

Effects on aquatic organisms of PIORITY were not evaluated as part of the EU assessment of Dithianon and Dimethomorph. New data submitted with this application are listed in 9.13 and summarised in Appendix 2.

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

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Dithianon and Dimethomorph / and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Fish				
Ictalurus punctatus	Dithianon	96 h, s	LC_{50} = 40 µg a.s./L $_{nom}$	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Dithianon	96 h, s	LC_{50} = 70 µg a.s./L $_{nom}$	EFSA Journal 2010;8(11):1904
Lepomis macrochirus	Dithianon	96 h, ss	LC_{50} = 36 µg a.s./L $_{nom}$	EFSA Journal 2010;8(11):1904
Carassius auratus	Dithianon	96 h, s	LC_{50} = 47.5 µg a.s./L $_{im}$	EFSA Journal 2010;8(11):1904
Gasterosteus aculeatus	Dithianon	96 h, s	LC_{50} = 27.3 µg a.s./L $_{in}$	EFSA Journal 2010;8(11):1904
Brachydanio rerio	Dithianon	96 h, s	LC_{50} = 47.8 µg a.s./L $_{im}$	EFSA Journal 2010;8(11):1904
Brachydanio rerio	Dithianon	96 h, s	LC_{50} = 50.8 µg a.s./L $_{im}$	EFSA Journal 2010;8(11):1904

Species	Substance	Exposure System	Results	Reference
Oryzias latipes	Dithianon	96 h, s	LC_{50} = 41.6 µg a.s./L $_{im}$	EFSA Journal 2010;8(11):1904
Ictalurus punctatus	Dithianon	96 h, s	**LC_{50} = 14.3 µg a.s./L $_{im}$**	EFSA Journal 2010;8(11):1904
Cyprinus carpio	Dithianon	96 h, s	LC_{50} = 59.6 µg a.s./L $_{im}$	EFSA Journal 2010;8(11):1904
Pimephales promelas	Dithianon	96 h, s	LC_{50} = 53.6 µg a.s./L $_{im}$	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Dithianon	96 h, s	LC_{50} = 44 µg a.s./L $_{nom}$	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Dithianon	96 h, s	LC_{50} = 30 µg a.s./L $_{im}$	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Dithianon	Species Sensitivity Distribution (SSD)	HC_5 = 19.4 µg/L	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	CL 1017911	96 h, s	**LC_{50} = 3260 µg a.s./L**	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Delan 70 WG (BAS 216 03 F, Dithianon formulation)	96 h, s	LC_{50} = 23 µg a.s./L	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Phthaldialdehyde	96 h, s	**LC_{50} = 83 µg a.s./L mm**	Addendum to DAR – Vol3, B9 - June 2014
Oncorhynchus mykiss	1,2-benzenedimetha-nol	96 h, s	**LC_{50} > 100000 µg a.s./L nom**	Addendum to DAR – Vol3, B9 - June 2014
Oncorhynchus mykiss	Phthalic acid	96 h, s	**LC_{50} > 100000 µg a.s./L nom**	EFSA conclusions on folpet, re-issued 2009
Oncorhynchus mykiss	Dithianon	79 d, ss	NOEC = 3.9 µg a.s./L $_{mm}$	EFSA Journal 2010;8(11):1904
Gasterosteus aculeatus	Dithianon	28 d, s	NOEC = 8.3 µg a.s./L $_{mm}$	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Dithianon	21 d, f	NOEC = 4 µg a.s./L $_{nom}$	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Dithianon	21 d, f	NOEC = 2.6 µg a.s./L $_{im}$	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Dithianon	21 d, f	NOEC = 0.625 µg a.s./L $_{nom}$	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Dithianon	21 d, f	**NOEC = 0.46 µg a.s./L $_{im}$**	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Dithianon	90 d, ss	NOEC = 4.7 µg a.s./L $_{mm}$	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Delan 70 WG (BAS 216 03 F, Dithianon formulation)	28 d, ss	NOEC = 2.2 µg a.s./L	EFSA Journal 2010;8(11):1904
Oncorhynchus mykiss	Delan 70 WG (BAS 216 03 F, Dithianon formulation)	28 d, f	NOEC < 0.43 µg a.s./L	EFSA Journal 2010;8(11):1904

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	Dimethomorph	96 h, s	**LC_{50} = 3.4 mg a.s./L mm**	EFSA Scientific Report (2006) 82, 1-69
Oncorhynchus mykiss	Dimethomorph	60 d, ELS, f	**NOEC = 0.056 mg a.s./L_{nom}**	EFSA Scientific Report (2006) 82, 1-69
Oncorhynchus mykiss	Forum (CYD 15107, Dimethomorph formulation)	96 h, s	LC_{50} = 2.64 mg a.s./L_{nom}	EFSA Scientific Report (2006) 82, 1-69
Oncorhynchus mykiss	Forum (CYD 15107, Dimethomorph formulation)	28 d, f	NOEC = 0.07 mg a.s./L_{nm}	EFSA Scientific Report (2006) 82, 1-69
Invertebrates				
Daphnia magna	Dithianon	48 h, s	**EC_{50} = 260 µg a.s./L mm**	EFSA Journal 2010;8(11):1904
Daphnia magna	Dithianon	21 d, ss	NOEC = 60 µg a.s./L nom	EFSA Journal 2010;8(11):1904
Daphnia magna	Dithianon	21 d, ss	NOEC = 100 nom µg a.s./L im	EFSA Journal 2010;8(11):1904
Daphnia magna	Dithianon	21 d, ss	**NOEC = 59.5 µg a.s./L im**	EFSA Journal 2010;8(11):1904
Daphnia magna	Delan 70 WG (BAS 216 03 F, Dithianon formulation)	48 h, s	NOEC = 110 µg a.s./L im	EFSA Journal 2010;8(11):1904
Daphnia magna	CL 1017911	48 h, s	**EC_{50} = 45600 µg a.s./L**	EFSA Journal 2010;8(11):1904
Daphnia magna	Phthaldialdehyde	48 h, s	**EC_{50} = 136 µg a.s./L nom**	Addendum to DAR – Vol3, B9 - June 2014
Daphnia magna	1,2-benzenedimetha-nol	48 h, s	**EC_{50} > 100000 µg a.s./L nom**	Addendum to DAR – Vol3, B9 - June 2014
Daphnia magna	Phthalic acid	48 h, s	**EC_{50} > 100000 µg a.s./L nom**	EFSA conclusions on folpet, re-issued 2009
Daphnia magna	Dimethomorph	48 h, s	EC_{50} > 10.6 mg a.s./L mm	EFSA Scientific Report (2006) 82, 1-69
Mysidopsis bahia	Dimethomorph	96 h, f	EC_{50} = 7.9 mg a.s./L mm	EFSA Scientific Report (2006) 82, 1-69
Crassostrea virginica	Dimethomorph	96 h, f	**EC_{50} = 4.4 mg a.s./L mm**	EFSA Scientific Report (2006) 82, 1-69
Daphnia magna	Dimethomorph	22 d, ss	**NOEC = 0.1 mg a.s./L nom**	DAR Dimethomorph, 2004
Sed. dwell. insects				
Chironomus riparius	Dithianon	28 d, s	**NOEC = 125 µg a.s./L nom**	EFSA Journal 2010;8(11):1904

Species	Substance	Exposure System	Results	Reference
Chironomus riparius	Dimethomorph	28 d, s	**NOEC = 4.4 mg a.s./L****	DAR Dimethomorph, 2004
Algae				
Selenastrum capricornutum	Dithianon	72 h, s	**E_bC_{50} = 90 µg a.s./L $_{im}$**	EFSA Journal 2010;8(11):1904
Selenastrum capricornutum	Dithianon	72 h, s	NOEC = 25 µg a.s./L_{im}	EFSA Journal 2010;8(11):1904
Selenastrum capricornutum	Dithianon	72 h, s	NOEC = 140 µg a.s./L_{nom}	EFSA Journal 2010;8(11):1904
Selenastrum capricornutum	Delan 70 WG (BAS 216 03 F, Dithianon formulation)	72 h, s	E_bC_{50} = 64 µg a.s./L	EFSA Journal 2010;8(11):1904
Selenastrum capricornutum	Delan 70 WG (BAS 216 03 F, Dithianon formulation)	72 h, s	NOEC = 10 µg a.s./L	EFSA Journal 2010;8(11):1904
Pseudokirchneriella subcapitata	CL 1017911	72 h, s	**E_bC_{50} = 1970 µg a.s./L E_rC_{50} = 4340 µg a.s./L**	EFSA Journal 2010;8(11):1904
Pseudokirchneriella subcapitata	Phthalic acid	72 h, s	**EC_{50} > 100000 µg a.s./L nom**	EFSA conclusions on folpet, re-issued 2009
Scenedesmus subspicatus	Dimethomorph	72 h, s	**EC_{50} = 24.4 mg a.s./L $_{nom}$**	DAR Dimethomorph, 2004
Scenedesmus subspicatus	Forum (CYD 15107, Dimethomorph formulation)	72 h, s	EC_{50} = 3.74 mg a.s./L	DAR Dimethomorph, 2004
Higher-tier studies (micro- or mesocosms studies)				
O. mykiss *Zooplankton*	Delan 70 WG (BAS 216 03 F, Dithianon formulation)		LC_{50} = 13 µg a.s./L LC_{50} > 130 µg a.s./L NOEC = 4.3 µg a.s./L NOEC = 130 µg a.s./L	EFSA Journal 2010;8(11):1904

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

**As stated in EFSA *Scientific Report*, Dimethomorph was detected in sediment at amounts up to 66% one day after application. The effect on sediment dwelling organisms was addressed with a study on *Chironomus riparius*. No effects were observed at the highest test concentration, 4.4 mg/L and it can be concluded that *Chironomus* will be protected by risk mitigation measures needed to protect fish.

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

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	PIORITY	96 h, ss	LC_{50} = 0.0256 mg f.p./L^{nom}	KCP 10.2.1-01 xxxxxxx 2019 W/82/18

Species	Substance	Exposure System	Results	Reference
Daphnia magna	PIORITY	48 h, ss	EC_{50} = 0.649 mg f.p./L^{nom}	KCP 10.2.1-02 Turek, T. 2018 W/84/18
Pseudokirchneriella subcapitata	PIORITY	72 h, s	**E_rC_{50} = 0.717 mg f.p./L^{nom}** E_yC_{50} = 0.149 mg f.p./L^{nom}	KCP 10.2.1-03 Turek, T. 2018 W/83/18
Lemna gibba	PIORITY	7-day, ss	Frond number E_rC_{50} = 81.24 mg f.p./L^{nom} E_yC_{50} = 4.03 mg f.p./L^{nom} Dry weight **E_rC_{50} = 42.76 mg f.p./L^{nom}** E_yC_{50} = 3.65 mg f.p./L^{nom}	KCP 10.2.1-04 Turek, T. 2019 W/85/18
Higher-tier studies (micro- or mesocosm studies)				
None				

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

The used endpoints are the EU agreed ones, except for formulation, corresponding to data proper to PIORITY formulation.

9.5.2 Risk assessment

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

The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for PIORITY for each organism group for the use of PIORITY in late grapevine (single/multiple application) (worst case)

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Lemna gibba***
Endpoint		LC_{50}	EC_{50}	E_rC_{50}	E_rC_{50}

Group			**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic macro-phytes**
(µg/L)			25.6	649	717	42760
AF			100	100	10	10
RAC (µg/L)			0.256	6.49	71.7	4276
Nozzzles	**Distance (m)**	**PEC $_{gl-max}$ (µg/L)**				
None	3m	40.100/103.500	**156.64/404.30**	**6.18/15.95**	0.56/**1.44**	0.01/0.02
90%	3m	4.010/10.350	**15.66/40.43**	0.62/**1.59**	0.06/0.14	-/-
None	20m	2.100/5.100	**8.20/19.92**	-/0.79	-/-	-/-
90%	20m	0.210/0.510	0.82/**1.99**	-/-	-/-	-/-
None	40m	0.700/1.650	**2.73/6.45**	-/-	-/-	-/-
75%	40m	0.175/0.413	0.68/**1.61**	-/-	-/-	-/-
None	50m	0.500/1.200	**1.95/4.69**	-/-	-/-	-/-
50%	50m	0.250/0.600	0.98/**2.34**	-/-	-/-	-/-
90%	50m	-/0.120	-/0.47	-/-	-/-	-/-

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

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 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Dithianon for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of PIORITY in late grapevine (single/multiple application) (worst case)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**
Test species		***Ictalurus punctatus***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Selenastrum capricornutum***	***Chironomus riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC
(µg/L)		14.3	0.46	260	59.5	90	125
AF		100	10	100	10	10	10
RAC (µg/L)		0.143	0.046	2.6	5.95	9	12.5
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**						
Step 1							
	47.45/47.45	**331.818/331.818**	**1,031.522/1,031.522**	**18.250/18.250**	**7.975/7.975**	**5.272/5.272**	**3.796/3.796**
Step 2							
S-Europe	14.05/12.20	**98.252/85.315**	**305.435/265.217**	**5.404/4.692**	**2.361/2.050**	**1.561/1.356**	**1.124**/0.976
N-Europe							
Step 3							
D3[#]/ditch	19.220/13.680	**134.406/ 95.664**	**417.826/ 297.391**	**7.392/ 5.262**	**3.230/ 2.299**	**2.136/ 1.520**	**1.538/ 1.094**
D4[#]/pond	0.860/0.626	**6.014/ 4.378**	**18.696/ 13.609**	0.331/ 0.241	0.145/ 0.105	0.096/ 0.070	0.069/ 0.050
D4[#]/stream	19.270/13.770	**134.755/ 96.294**	**418.913/ 299.348**	**7.412/ 5.296**	**3.239/ 2.314**	**2.141/ 1.530**	**1.542/ 1.102**
D6/ditch	8.954/7.693	**62.615/53.797**	**194.652/167.239**	**3.444/2.959**	**1.505/1.293**	0.995/0.855	0.716/0.615
R1/pond	0.321/0.269	**2.245/1.881**	**6.978/5.848**	0.123/0.103	0.054/0.045	0.036/0.030	0.026/0.022
R1/stream	6.594/5.621	**46.112/39.308**	**143.348/122.196**	**2.536/2.162**	**1.108/0.945**	0.733/0.625	0.528/0.450

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
R2/stream	8.828/7.524	**61.734/52.615**	**191.913/163.565**	**3.395/2.894**	**1.484/1.265**	0.981/0.836	0.706/0.602
R3/stream	9.280/7.942	**64.895/55.538**	**201.739/172.652**	**3.569/3.055**	**1.560/1.335**	**1.031**/0.882	0.742/0.635
R4/stream	6.483/5.634	**45.336/39.399**	**140.935/122.478**	**2.493/2.167**	**1.090**/0.947	0.720/0.626	0.519/0.451

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
[#] Calculation done for surrogate crop - pome/stone fruits, late application.

Metabolites of Dithianon

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CL 1017911 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PIORITY in late grapevine (single/multiple application) (worst case)

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint (µg/L)		LC_{50} 3260	EC_{50} 45600	E_bC_{50} 1970
AF		100	100	10
RAC (µg/L)		32.6	456	197
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	113.36/340.09	**3.477/10.432**	0.249/0.746	0.575/**1.726**
Step 2				
N-Europe	11.81/18.05	0.362/0.554	0.026/0.040	0.060/0.092
S-Europe	18.25/29.54	0.560/0.906	0.040/0.065	0.0930/0.150

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

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Phthalic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PIORITY in late grapevine (single/multiple application) (worst case)

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint (µg/L)		LC_{50} >100000	EC_{50} >100000	E_bC_{50} >100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	55.74/167.21	0.056/0.167	0.005/0.009	0.006/0.017
Step 2				
N-Europe	4.89/8.67	0.005/0.009	0.005/0.009	<0.001/0.001
S-Europe	7.26/12.82	0.007/0.013	0.007/0.013	0.001/0.001

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

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Phthalaldehyde for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of PIORITY in late grapevine (single/multiple application) (worst case)

Group		**Fish acute**	**Inverteb. acute**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***
Endpoint		LC_{50}	EC_{50}
(µg/L)		83	136
AF		100	100
RAC (µg/L)		0.83	1.36
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**		
Step 1			
	9.47/28.41	**11.410/34.229**	**6.963/20.890**
Step 2			
N-Europe	0.71/1.05	0.855/**1.265**	0.522/0.772
S-Europe	1.18/2.01	**1.422/1.422**	0.868/0.868
Step 3			
D3[#]/ ditch	0.385/0.305	0.464/ 0.367	0.283/ 0.224
D4[#]/ pond	0.024/0.018	0.029/ -	0.018/ -
D4[#]/ stream	0.200/0.148	0.241/ 0.178	0.147/ 0.109
D6/ditch	0.167/0.212	0.201/0.255	0.123/0.156
R1/pond	0.009/0.008	0.011/0.010	0.007/0.006
R1/stream	0.057/0.048	0.069/0.058	0.042/0.035
R2/stream	0.055/0.049	0.066/0.059	0.040/0.036
R3/stream	0.123/0.144	0.148/0.173	0.090/0.106
R4/stream	0.043/0.060	0.052/0.072	0.032/0.044

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

Calculation done for surrogate crop - pome/stone fruits, late application.

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 1,2-benzenedimethanol for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PIORITY in late grapevine (single/multiple application) (worst case)

Group		**Fish acute**	**Inverteb. acute**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***
Endpoint		LC_{50}	EC_{50}
(µg/L)		>100000	>100000
AF		100	100
RAC (µg/L)		1000	1000
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**		
Step 1			

Group		**Fish acute**	**Inverteb. acute**
	18.20/54.60	0.018/0.055	0.018/0.055
Step 2			
N-Europe	1.80/2.70	0.002/0.003	0.002/0.003
S-Europe	2.83/4.54	0.003/0.005	0.003/0.005

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

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Dimethomorph for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of PIORITY in late grapevine (single/multiple application) (worst case)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**		**Sed. dwell. prolonged**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Crassostrea virginica***	***Daphnia magna***	***Scenedesmus subspicatus***		***Chironomus riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}		NOEC
(µg/L)		3400	56	4400	100	3700		4400
AF		100	10	100	10	10		10
RAC (µg/L)		34	5.6	44	10	370		440
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**						**PEC $_{gl\text{-}max}$ (µg/kg)**	
Step 1								
	54.12/162.37	**1.592/4.776**	**9.664/28.995**	**1.230/3.690**	**5.412/16.237**	0.146/0.439	215.39/646.16	0.490/1.469
Step 2								
N-Europe	7.88/19.75	0.232/0.581	**1.407/3.527**	0.179/0.449	0.788/1.975	0.021/0.053	30.97/77.90	0.070/0.177
S-Europe	11.54/29.51	0.339/0.339	**2.061/2.061**	0.262/0.262	**1.154/1.154**	0.031/0.031	46.32/118.81	0.026/0.067
Step 3								
D3[#]/ ditch	8.264/5.895	0.243/ 0.173	**1.476/ 1.053**	0.188/ 0.134	0.826/ 0.590	0.022/ 0.016	4.837/6.032	0.011/ 0.014
D4[#]/ pond	0.370/1.412	0.011/ 0.042	0.066/ 0.252	0.008/ 0.032	0.037/ 0.141	0.001/ 0.004	2.036/8.861	0.005/ 0.020
D4[#]/ stream	8.282/5.922	0.244/ 0.174	**1.479/ 1.058**	0.188/ 0.135	0.828/ 0.592	0.022/ 0.016	1.435/3.450	0.003/ 0.008
D6/ditch	3.837/4.069	-/-	0.685/0.727	-/-	0.384/0.407	-/-	2.391/7.682	-/-
R1/pond	0.138/0.314	-/-	0.025/0.056	-/-	0.014/0.031	-/-	0.553/1.284	-/-
R1/stream	2.826/3.567	-/-	0.505/0.637	-/-	0.283/0.357	-/-	0.950/1.851	-/-

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**		**Sed. dwell. prolonged**
R2/stream	3.783/3.225	-/-	0.676/0.576	-/-	0.378/0.323	-/-	0.771/1.763	-/-
R3/stream	3.977/3.404	-/-	0.710/0.608	-/-	0.398/0.340	-/-	1.782/1.705	-/-
R4/stream	2.778/3.240	-/-	0.496/0.579	-/-	0.278/0.324	-/-	0.423/2.692	-/-

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
Calculation done for surrogate crop - pome/stone fruits, late application.

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Dimethomorph for each organism group based on FOCUS Steps 4 calculations for the use of PIORITY in late pome/ stone fruits as a surrogate crop to grapevine (single/multiple application) (worst case)

Intended use		Grapevine							
Active substance		Dimetomorph							
Application rate (g/ha)		3 x 225							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch#	5.576/4.038	2.492 / -	-	-	-	-	-	-
50 %		2.788/ -	-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream#	6.463/4.668	2.888 / -	-	-	-	-	-	-
50 %		3.231/ -	-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
RAC									
5.6		**PEC/RAC**							
None	D3 ditch#	0.996/ 0.721	0.445/ -	-	-	-	-	-	-
50 %		0.498/ -	-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream#	**1.154**/ 0.834	0.516/ -	-	-	-	-	-	-
50 %		0.577/ -	-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-

Dimethomorph:
For the intended use on grapevine, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a NOEC for *Oncorhynchus mykiss* of 56 in connection with an assessment factor of 10) in all FOCUS Steps 3 scenarios relevant for grapevine. The PEC/RAC ratios calculated for surrogate crop scenarios D3 and D4 indicated unacceptable risk at FOCUS Step 3, therefore further assessment with Step 4 values was necessary. The Step 4 refinement showed no unacceptable use when the following risk mitigation measures are considered:
D3: 5 m no spray buffer zone
D4: 10 m no spray buffer zone OR 5 m no spray buffer zone + 50% drift reduction by nozzles

Dithianon metabolites:
For the intended use on grapevine, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a LC_{50} for *Oncorhynchus mykiss* of 3260, more than 100000, 83 and more than 100000 in connection with an assessment factor of 100, for CL 1017911, Phthalic acid, Phthalaldehyde and 1,2-benzenedimethanol, respectively) in all FOCUS Steps 2-3 scenarios. Therefore, no further assessment is necessary.

Dithianon:
For the intended use on grapevine, calculated PEC/RAC ratios did not indicate an acceptable risk for all aquatic organisms except *Chironomus riparius* in several FOCUS Steps 1 3 scenarios. Therefore, further refinement and PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and are presented below.

Fish. Higher tier risk assessment (refinement of the risk assessment)

According to the *Conclusion on the peer review of the pesticide risk assessment of the active substance dithianon*, the use of the proposed Species Sensitivity Distribution (SSD) approach based on the LC_{50} is more appropriate for the acute risk assessment. Therefore for the refinement of the risk assessment, the median HC_5 of 19.4 µg/L was used with an assessment factor of 10. The RAC obtained was of **1.94 µg/L**.

For the chronic risk assessment for fish, the endpoint (i.e. NOEC of 3.9 µg a.s./L) from the 79-days semi-static test on *O. mykiss* was considered more appropriate by EFSA because pulsed exposure was covered in such a study. Given the mid-range sensitivity of rainbow trout, EFSA agreed that the acute data from 10 species could be used as a weight of evidence for reducing the Annex VI trigger of 10. An assessment factor of 3 was derived from the relative sensitivity of rainbow trout (LC_{50} = 44 µg a.s./L) compared to the most sensitive species (LC_{50} = 14.3 µg a.s./L). This assessment factor was considered sufficient to cover the inter-species variability. The RAC obtained was of **1.30 µg/L**.

Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies

Table 9.5-11: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Dithianon based on FOCUS Step 4 calculations and refined toxicity data for fish (based on HC_5 acute toxicity endpoint) with mitigation of spray drift and run-off for the use of PIORITY in late grapevine (single/multiple application) (worst case)

Intended use		Grapevine							
Active substance		Dithianon							
Application rate (g/ha)		3 x 525							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch[#]	12.970/9.373	5.794/4.367	2.925/2.164	1.787/1.261	-	-	-	-
50 %		6.485/4.684	2.897/2.182	1.462/1.082	0.893/0.630	-	-	-	-
75 %		3.241/2.342	1.448/1.091	0.731/0.541	-	-	-	-	-
90 %		1.296/0.936	0.579/0.436	-	-	-	-	-	-
None	D4 stream[#]	15.040/10.860	6.717/5.059	3.391/2.507	2.072/1.461	-	-	-	-
50 %		7.515/5.428	3.356/2.528	1.695/1.253	1.03/0.730	-	-	-	-
75 %		3.756/2.713	1.678/1.264	0.847/0.626	-	-	-	-	-
90 %		1.502/1.085	0.671/0.505	-	-	-	-	-	-
None	D6 ditch	5.414/4.641	1.961/1.659	1.065/0.895	-	-	-	-	-
50 %		2.707/2.320	0.981/0.8296	-	-	-	-	-	-
75 %		1.353/1.160	-	-	-	-	-	-	-
90 %		0.541/-	-	-	-	-	-	-	-
None	R1 stream	4.805/4.079	1.740/1.459	0.945/0.917	-	4.805/4.079	1.740/1.458	0.945/0.786	0.610/0.505
50 %		2.402/2.040	0.870/0.917	-	-	2.402/2.039	0.870/0.729	-	-
75 %		1.201/1.020	-	-	-	1.201/1.020	-	-	-
90 %		-	-	-	-	-	-	-	-

Intended use		Grapevine							
Active substance		Dithianon							
Application rate (g/ha)		3 x 525							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	R2 stream	6.433/5.460	2.329/1.952	1.266/1.053	-	6.433/5.460	2.329/1.952	1.266/1.053	0.817/0.676
50 %		3.216/2.730	1.165/0.976	-	-	3.216/2.730	1.165/0.976	-	-
75 %		1.608/1.365	-	-	-	1.608/1.365	-	-	-
90 %		0.643/0.546	-	-	-	0.643/0.546	-	-	-
None	R3 stream	6.762/5.763	2.449/2.061	1.331/1.111	0.859/-	6.762/5.763	2.449/2.060	1.331/1.111	0.859/0.713
50 %		3.380/2.882	1.224/1.031	-	-	3.380/2.881	1.224/1.030	-	-
75 %		1.690/1.441	-	-	-	1.690/1.441	-	-	-
90 %		0.767/0.718	-	-	-	0.676/0.577	-	-	-
None	R4 stream	4.724/4.089	1.711/2.097	0.930/2.097	-/2.097	4.724/4.0808	1.711/1.462	0.930/0.788	0.600/0.506
50 %		2.362/2.097	0.855/2.097	-/2.097	-	2.362/2.044	0.855/0.950	-	-
75 %		1.181/2.097	-	-	-	1.181/1.365	-	-	-
90 %		-/2.097	-	-	-	-/1.365	-	-	-
RAC (µg/L) 1.94		**PEC/RAC ratio**							
None	D3 ditch[#]	**6.686/ 4.831**	**2.987/ 2.251**	**1.508**/ 1.115	0.921/ 0.650	-	-	-	-
50 %		**3.343/ 2.414**	**1.493/ 1.125**	0.754/ 0.558	0.460/ 0.325	-	-	-	-
75 %		**1.671/ 1.207**	0.746/ 0.562	0.377/ 0.279	-/ -	-	-	-	-
90 %		0.668/ 0.482	0.298/ 0.225	-/ -!	-/ -	-	-	-	-
None	D4 stream[#]	7.753/ 5.598	**3.462/ 2.608**	**1.748**/ 1.292	**1.068**/ 0.753	-	-	-	-

Intended use		Grapevine							
Active substance		Dithianon							
Application rate (g/ha)		3 x 525							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50 %		3.874/ 2.798	**1.730/ 1.303**	0.874/ 0.646	0.531/ 0.376	-	-	-	-
75 %		1.936/ 1.398	0.865/ 0.652	0.437/ 0.323	-/ -	-	-	-	-
90 %		0.774/ 0.559	0.346/ 0.260	-/ -	-/ -	-	-	-	-
None	D6 ditch	**2.791/2.392**	**1.011**/0.855	0.549/0.461	-/-	-/-	-/-	-/-	-/-
50 %		**1.395/1.196**	0.506/0.428	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.697/0.598	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	**2.477/2.103**	0.897/0.752	-/-	-/-	**2.477/2.103**	0.897/0.752	0.487/0.405	-/-
50 %		**1.238/1.052**	-/-	-/-	-/-	**1.238/1.051**	-/-	-/-	-/-
75 %		0.619/0.526	-/-	-/-	-/-	0.619/0.526	-/-	-/-	-/-
None	R2 stream	**3.316/2.814**	**1.201/1.006**	0.653/0.543	-/-	**3.316/2.814**	**1.201/1.006**	0.653/0.543	-/-
50 %		**1.658/1.407**	0.601/0.503	-/-	-/-	**1.658/1.407**	0.601/0.503	-/-	-/-
75 %		0.829/0.704	-/-	-/-	-/-	0.829/0.704	-/-	-/-	-/-
None	R3 stream	**3.486/2.971**	**1.262/1.062**	0.686/0.573	-/-	**3.486/2.971**	**1.262/1.062**	0.686/0.573	-/-
50 %		**1.742/1.486**	0.631/0.531	-/-	-/-	**1.742/1.485**	0.631/0.531	-/-	-/-
75 %		0.871/0.743	-/-	-/-	-/-	0.871/0.743	-/-	-/-	-/-
None	R4 stream	**2.435/2.108**	0.882/**1.081**	0.479/**1.081**	-/**1.081**	**2.435/2.104**	0.882/0.754	-/-	-/-
50 %		**1.218/1.081**	0.441/**1.081**	-/**1.081**	-/-	**1.218/1.054**	-/-	-/-	-/-
75 %		0.609/**1.081**	-/-	-/-	-/-	0.609/0.704	-/-	-/-	-/-
90 %		-/**1.081**	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Grapevine							
Active substance		Dithianon							
Application rate (g/ha)		3 x 525							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
RAC (µg/L)									
1.3		**PEC/RAC ratio**							
None	D3 ditch[#]	**9.98/7.21**	**4.46/3.36**	**2.25/1.66**	**1.37/0.97**				
50 %		**4.99/3.60**	**2.23/1.68**	1.12/0.03	0.69/0.48				
75 %		**2.49/1.80**	**1.11/0.84**	0.56/0.42	-				
90 %		**1.00/0.72**	0.45/0.34	-	-				
None	D4 stream[#]	**11.57/8.35**	**5.17/3.89**	**2.61/1.93**	**1.59/1.12**				
50 %		**5.78/4.18**	**2.58/1.94**	**1.30**/0.96	0.79/0.56				
75 %		**2.89/2.09**	**1.29/0.97**	0.65/0.48	-				
90 %		**1.16/0.83**	0.52/0.39	-	-				
None	D6 ditch	**4.165/3.570**	**1.508/1.276**	0.819/0.688	-/-	-/-	-/-	-/-	-/-
50 %		**2.082/1.785**	0.755/0.638	-/-	-/-	-/-	-/-	-/-	-/-
75 %		**1.041**/0.892	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.416/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	**3.696/3.138**	**1.338/1.122**	0.727/0.705	-/-	**3.696/3.138**	**1.338/1.122**	0.727/0.605	-/-
50 %		**1.848/1.569**	0.669/0.705	-/-	-/-	**1.848/1.568**	0.669/0.561	-/-	-/-
75 %		0.924/0.785	-/-	-/-	-/-	0.924/0.785	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	**4.948/4.200**	**1.792/1.502**	0.974/0.810	-/-	**4.948/4.200**	**1.792/1.502**	0.974/0.810	-/-

Intended use		Grapevine							
Active substance		Dithianon							
Application rate (g/ha)		3 x 525							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50 %		**2.474/2.100**	0.896/0.751	-/-	-/-	**2.474/2.100**	0.896/0.751	-/-	-/-
75 %		**1.237/1.050**	-/-	-/-	-/-	**1.237/1.050**	-/-	-/-	-/-
90 %		0.495/0.420	-/-	-/-	-/-	0.495/0.420	-/-	-/-	-/-
None	R3 stream	**5.202/4.433**	**1.884/1.585**	**1.024**/0.855	0.661/-	**5.202/4.433**	**1.884/1.585**	**1.024**/0.855	0.661/0.548
50 %		**2.600/2.217**	0.942/0.793	-/-	-/-	**2.600/2.216**	0.942/0.792	-/-	-/-
75 %		**1.300/1.108**	-/-	-/-	-/-	**1.300/1.108**	-/-	-/-	-/-
90 %		0.590/0.552	-/-	-/-	-/-	0.520/0.444	-/-	-/-	-/-
None	R4 stream	**3.634/3.145**	**1.316/1.613**	0.715/**1.613**	-/**1.613**	**3.634/3.139**	**1.316/1.125**	0.715/0.606	-/-
50 %		**1.817/1.613**	0.658/**1.613**	-/**1.613**	-/-	**1.817/1.572**	0.658/0.731	-/-	-/-
75 %		0.908/**1.613**	-/-	-/-	-/-	0.908/**1.050**	-/-	-/-	-/-
90 %		-/**1.613**	-/-	-/-	-/-	-/**1.050**	-/-	-/-	-/-
RAC (µg/L)		**PEC/RAC ratio**							
2.6									
None	D6 ditch	**2.082/1.785**	0.754/0.638	-/-	-/-	-/-	-/-	-/-	-/-
50 %		**1.041**/0.892	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.520/0.446	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	**1.848/1.569**	0.669/0.561	-/-	-/-	**1.848/1.569**	0.669/0.561	-/-	-/-
50 %		0.924/0.785	-/-	-/-	-/-	0.924/0.784	-/-	-/-	-/-
None	R2 stream	**2.474/2.100**	0.896/0.751	-/-	-/-	**2.474/2.100**	0.896/0.751	-/-	-/-

Intended use		Grapevine							
Active substance		Dithianon							
Application rate (g/ha)		3 x 525							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50 %		**1.237/1.050**	-/-	-/-	-/-	**1.237/1.050**	-/-	-/-	-/-
75 %		0.618/0.525	-/-	-/-	-/-	0.618/0.525	-/-	-/-	-/-
None	R3 stream	**2.601/2.217**	0.942/0.793	-/-	-/-	**2.601/2.217**	0.942/0.792	-/-	-/-
50 %		**1.300/1.108**	-/-	-/-	-/-	**1.300/1.108**	-/-	-/-	-/-
75 %		0.650/0.554	-/-	-/-	-/-	0.650/0.554	-/-	-/-	-/-
None	R4 stream	**1.817/1.573**	0.658/0.807	-/-	-/-	**1.817/1.570**	0.658/0.562	-/-	-/-
50 %		0.908/0.807	-/-	-/-	-/-	0.908/0.786	-/-	-/-	-/-
RAC (µg/L) 5.95		**PEC/RAC ratio**							
None	D6 ditch	0.910/0.780	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.808/0.686	-/-	-/-	-/-	0.808/0.686	-/-	-/-	-/-
None	R2 stream	**1.081**/0.918	0.391/-	-/-	-/-	**1.081**/0.918	0.391/-	-/-	-/-
50 %		0.541/-	-/-	-/-	-/-	0.541/-	-/-	-/-	-/-
None	R3 stream	**1.136**/0.969	0.412/-	-/-	-/-	**1.136**/0.969	0.412/-	-/-	-/-
50 %		0.568/-	-/-	-/-	-/-	0.568/-	-/-	-/-	-/-
None	R4 stream	0.794/0.687	-/-	-/-	-/-	0.794/0.686	-/-	-/-	-/-
RAC (µg/L) 9.00		**PEC/RAC ratio**							
None	D6 ditch	0.602/0.516	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Grapevine							
Active substance		Dithianon							
Application rate (g/ha)		3 x 525							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	R1 stream	0.534/0.453	-/-	-/-	-/-	0.534/0.453	-/-	-/-	-/-
None	R2 stream	0.715/0.607	-/-	-/-	-/-	0.715/0.607	-/-	-/-	-/-
None	R3 stream	0.751/0.640	-/-	-/-	-/-	0.751/0.640	-/-	-/-	-/-
None	R4 stream	0.525/0.454	-/-	-/-	-/-	0.525/0.453	-/-	-/-	-/-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.
*The value used for reduction in run-off volume, run-off flux, erosion mass and erosion flux was 0.4, according to the Austrian Environmental Agency AGES.
**The value used for reduction in run-off volume and run-off flux was 0.7, and the value used for reduction in erosion mass and erosion flux was 0.9, according to the Austrian Environmental Agency AGES.
[#] Calculation done for surrogate crop - pome/stone fruits, late application.

Risk assessment for the combinations of a.s. in the formulation

Following the dilution and spraying of the formulated product, much of the formulation constituents are likely to be lost by volatilisation. Therefore, shortly after application of a formulated product, aquatic organisms are mainly exposed to the active substance present in the formulation. In addition, as demonstrated in the short-term studies here above there are no indications for interactions of the active substances (no synergisms or additional toxicity occurs due to the co-formulants) given that the formulation does not cause an (unexpected) increased toxicity compared to the active substances. An evaluation of the risk posed by the intact formulation is therefore relevant only for the acute/short-term assessment. The long-term risk was assessed considering data for the active substances in the formulation and no chronic combined risk assessment has been performed.

According to the new EFSA Scientific Opinion (EFSA, 2013) measured and calculated mixture toxicity should be compared to determine synergistic, additive or antagonistic effects of the formulation. In the following the concentration addition (CA) model is used as proposed by EFSA.

To determine the respective formulation effect, EFSA proposed to calculate the model deviation ratio (MDR), which divides the calculated mixture toxicity ($LC_{50}/EC_{50\ mix\text{-}CA}$) by the measured mixture toxicity ($LC_{50}/EC_{50\ PIORITY}$). Ecotoxicity studies are biological test systems which underlie a certain natural biological variability when repeating a study. Hence, a threshold has to be defined when an increased/decreased mixture toxicity effect cannot be seen as only additive any longer. EFSA proposes a factor of 5, *i.e.* if the MDR is between 0.2 and 5 the observed and calculated mixture toxicities are considered in agreement.

Active susbtance / species	**Test system**	**Endpoint (mg a.s./L)**
Dimethomorph		
Oncorhynchus mykiss	LC_{50} 96h	3.4
Crassostrea virginica	EC_{50} 48h	4.4
Scenedesmus subspicatus	E_bC_{50} 72h	3.7
Dithianon		
Ictalurus punctatus	LC_{50} 96h	0.0143
Daphnia magna	EC_{50} 48h	0.26
Selenastrum capricornutum	E_bC_{50} 72h	0.09

The calculated MDR values are between 0.2 and 5 for each organism (see Table 9.5-12), indicating that the formulation does not cause an (unexpected) increased toxicity compared to the active substances for these organisms. No synergisms or additional toxicity occurs due to the co-formulants

Table 9.5-10: Summary of results obtained in the studies with the formulated product PIORITY and comparison of calculated and measured mixture toxicity

Test species	**Endpoint & Test system**	**LC_{50} / EC_{50} [mg/L]**			
		Measured toxicity of PIORITY ($LC_{50\ PIORITY}$ or $EC_{50\ PIORITY}$) (mg/L)	**Measured toxicity of PIORITY (converted to be a.i. based) ($LC_{50\ PIORITY}$ or $EC_{50\ PIORITY}$) (mg a.s./L)**	**Calculated mixture toxicity[a] $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$**	**Model deviation ratio (MDR = $EC_{50\ mix\text{-}CA}$ / $EC_{50\ PIORITY}$)**
Fish	LC_{50}, acute, 96 h	0.0256	0.013	0.020	1.593
Aq. Invertebrates	EC_{50}, acute, 48 h	0.649	0.325	0.362	1.116
Algae	E_yC_{50}, 72 h	0.149	0.075	0.127	1.708

[a] The mixture toxicity of the formulation was re-calculated based on the nominal contents of Dimethomorph (150 g/Kg) and Dithianon (350 g/Kg) within the formulation.

The calculated factors fall outside 0.8-1.2 for each organism (see Table 9.5-13), indicating that the mixture composition in the formulation study giving the measured mixture toxicity is not similar to the mixture composition at the PEC_{mix}.

Table 9.5-11: Comparison of mixture composition in the formulation study (giving the measured mixture toxicity) and mixture composition at the PEC_{mix}

Test species	Endpoint & Test system	LC_{50} / EC_{50} [mg/L]		
		Calculated mixture toxicity (a.s. in PIORITY) $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$	Calculated mixture toxicity (a.s. in PEC_{mix})[b] $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$ at higher exposure tier	Factors ($EC_{50\ mix\text{-}CA}$ (a.s. in PIORITY)/$EC_{50\ mix\text{-}CA}$ (a.s. in PEC_{mix})) at lower exposure tier
Fish	LC_{50}, acute, 96 h	0.020	0.080	0.254
Aq. Invertebrates	EC_{50}, acute, 48 h	0.362	1.165	0.311
Algae	E_yC_{50}, 72 h	0.127	0.463	0.275

[a] The mixture toxicity of the formulation was re-calculated based on the nominal contents of Dimethomorph (150 g/Kg) and Dithianon (350 g/Kg) within the formulation.

[b] The mixture toxicity of the formulation was re-calculated based on the mixture composition at the PEC_{mix} for Dimethomorph (0.004069 mg/L at Step 3 for D6 ditch scenario) and Dithianon (0.000859 mg/L at Step 4 for R3 stream scenario with 20m vegetative strip/no spray buffer).

Regarding fish, aquatic invertebrates and algae, the risk assessments based on single-substance toxicity data for Dimethomoprh and Dithianon respectively are sufficient given that they were identified as the drivers of the mixture toxicity since the formulation toxicity – endpoint recalculated to each active substance concentrations –comes for 90 % (of more) from the toxicity per fraction of a single a.s. (TUi) (see Table 9.5-14).

Table 9.5-12: Comparison of calculated mixture toxicity and toxicity per fraction of a single a.s.

Test species	Endpoint & Test system	LC_{50} / EC_{50} [mg/L]		
		Calculated mixture toxicity (a.s. in PIORITY) $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$	Calculated toxicity per fraction of PIORITY (based on each a.s.) ($1/TU_i$)[a]	Deviation from mixture toxicity ($1-EC_{x\ mix\text{-}CA}$ x ($1/EC_{x\ mix\text{-}CA}$ - TU_i)) [%]
Fish	LC_{50}, acute, 96 h	0.020	Dimethomorph: 11.333 Dithianon: 0.020	Dimethomorph: 0.2% **Dithianon: 99.82%**
Aq. Invertebrates	EC_{50}, acute, 48 h	0.362	Dimethomorph: 14.667 Dithianon: 0.371	Dimethomorph: 2.5% **Dithianon: 97.53%**
Algae	E_yC_{50}, 72 h	0.127	Dimethomorph: 12.333 Dithianon: 0.129	Dimethomorph: 1.0% Di**thianon: 99.0%**

[a] TUi is defined as the concentration of the i^{th} a.s. at the $EC_{50\ PIORITY}$ (re-caculated to the sum of a.s.) divided by the respective single-substance toxicity ($EC_{50\ a.s.}$). This is calculated based on the nominal contents of Dimethomorph (150 g/Kg) and Dithianon (350 g/Kg) within the formulation.

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for fish aquatic invertebrates and *algae*.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (ECxPIORITY) and a.s. (ECxa.s.):	Please refer to tables 9.5-1, 9.5-2 and 9.5-3	Go to 2

2	Check the plausibility of the measured formulation toxicity (ECxPIORITY) against the calculated mixture toxicity ECxmix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (ECxPIORITY) by means of the model deviation ratio (MDR = ECxmix-CA/ECxPIORITY).	MDR = 0.2–5 (CA approximately holds for the mixture)	Please refer to table 9.5-12	Go to 3
3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxPIORITY) 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 ECxPIORITY 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 ECxmix-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).	ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix) is <0.8 or >1.2	Please refer to table 9.5-13	Go to 5
5	Check whether one mixture component clearly drives the toxicity if considering the measured mixture toxicity (ECx PIORITY), 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)?	>=90% for one a.s.	Please refer to table 9.5-14	Go to 6
6	Conduct a RA based on single-substance toxicity data (ECx a.s.) for the identified 'driver' of mixture toxicity, with the exposure-toxicity ratio (ETRa.s.) being defined as the PECa.s. divided by the measured ECx a.s. and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	Covered by active substance assessment		**Low risk**

9.5.3 Overall conclusions

Regarding Dithianon, most PEC/RAC values taken from the assessment of most aquatic organisms are above the trigger value of 1 in most scenarios for grapevine, indicating that PIORITY poses a potential risk to aquatic organisms. A further refinement and PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW}. Based on the results of the risk assessment at step 4, the following conclusions regarding

buffer zones, vegetative buffer strips and nozzles reduction may be drawn:

Grapevine

- D6 ditch and R2 stream scenarios: A 5m no spray buffer zone with 90% of nozzles reduction OR a 10m no spray buffer zone with 50% of nozzles reduction OR a 15m no spray buffer zone are required.
- R1 stream scenario: A 5m no spray buffer zone with 75% of nozzles reduction OR a 10m no spray buffer zone with 50% of nozzles reduction OR a 15m no spray buffer zone are required.
- R3 stream scenario: A 5m no spray buffer zone with 90% of nozzles reduction OR a 10m no spray buffer zone with 50% of nozzles reduction OR a 20m no spray buffer zone are required.
- R4 stream scenario: A 10m vegetative strip/no spray buffer with 50% of nozzles reduction OR a 15m vegetative strip/no spray buffer are required.
- D3 ditch scenario : 10m no spray buffer zone with 90% of nozzles reduction OR a 15 m no spray buffer zone with 75 % of nozzles reduction are required or 20m no spray buffer with 50 % of nozzles reduction
- D4 stream scenario: 10m no spray buffer zone with 90% of nozzles reduction OR a 15 m no spray buffer zone with 75 % of nozzles reduction are required or 20m no spray buffer with 50 % of nozzles reduction

The mitigation measures required for surrogate pome/ stone fruits scenarios D3 ditch and D4 stream are covered by the mitigation measures required for grapevine scenarios.

The risk to aquatic organisms for the metabolite Phthalaldehyde was assessed as low at FOCUS step 1, step2 and step 3 for the representative uses. The risk to aquatic organisms for the metabolites CL 1017911, Phthalic acid and 1,2-benzenedimethanol were assessed as low at FOCUS step 1 and step2 for the representative uses.

Regarding Dimethomorph, the calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a NOEC for *Oncorhynchus mykiss* of 56 in connection with an assessment factor of 10) in all FOCUS Steps 3 scenarios for the intended use on grapevine. Therefore, no further assessment is necessary.

Regarding the formulated PIORITY, after the risk assessment no unacceptable risk was obtained with the following risk mitigation measures:

- Grapevine late- a 50m no spray buffer zone with 90% of nozzles reduction are required.

*Grapevine - **SPe 3**: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 50 m to surface water bodies with 90% of nozzles reduction.*

zRMS comment:

Regarding Dithianon, most PEC/RAC values taken from the assessment of most aquatic organisms are above the trigger value of 1 in most scenarios for grapevine, indicating that PIORITY poses a potential risk to aquatic organisms. A further refinement and PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW}.
Based on the results of the risk assessment for dithation at step 4, the following conclusions regarding buffer zones, vegetative buffer strips and nozzles reduction may be drawn:

Grapevine

- D6 ditch and R2 stream scenarios: A 5m no spray buffer zone with 90% of nozzles reduction OR a 10m no spray buffer zone with 50% of nozzles reduction OR a 15m no spray buffer zone are required.
- R1 stream scenario: A 5m no spray buffer zone with 75% of nozzles reduction OR a 10m no

spray buffer zone with 50% of nozzles reduction OR a 15m no spray buffer zone are required

- R3 stream scenario: A 5m no spray buffer zone with 90% of nozzles reduction OR a 10m no spray buffer zone with 50% of nozzles reduction OR a 20m no spray buffer zone are required.
- R4 stream scenario: A 10m vegetative strip/no spray buffer with 50% of nozzles reduction OR a 15m vegetative strip/no spray buffer are required.
- D3 ditch scenario : 10m no spray buffer zone with 90% of nozzles reduction OR a 15 m no spray buffer zone with 75 % of nozzles reduction are required or 20m no spray buffer with 50 % of nozzles reduction (relevant for PL)
- D4 stream scenario: 10m no spray buffer zone with 90% of nozzles reduction OR a 15 m no spray buffer zone with 75 % of nozzles reduction are required or 20m no spray buffer with 50 % of nozzles reduction (relevant for PL)

The risk to aquatic organisms for the metabolite Phthalaldehyde was assessed as low at FOCUS step 1, step2 and step 3 for the representative uses. The risk to aquatic organisms for the metabolites CL 1017911, Phthalic acid and 1,2-benzenedimethanol were assessed as low at FOCUS step 1 and step2 for the representative uses.
Regarding Dimethomorph, the calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a NOEC for *Oncorhynchus mykiss* of 56 in connection with an assessment factor of 10) in all FOCUS Steps 3 scenarios for the intended use on grapevine. Therefore, no further assessment is necessary.
The PEC/RAC ratios calculated for surrogate crop scenarios D3 and D4 indicated unacceptable risk at FOCUS Step 3, therefore further assessment with Step 4 values was necessary. The Step 4 refinement showed no unacceptable use when the following risk mitigation measures are considered:
D3: 5 m no spray buffer zone 9 relevant for PL)
D4: 10 m no spray buffer zone OR 5 m no spray buffer zone + 50% drift reduction by nozzles (relevant for PL)

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

Effects on bees of PIORITY were not evaluated as part of the EU assessment of Dithianon and Dimethomorph. New data submitted with this application are listed in 9.13 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: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Dithianon	Oral	**LD_{50} > 25.4 µg a.s./bee**	EFSA Journal 2010;8(11):1904
Apis mellifera	Dithianon	Contact	**LD_{50} > 100 µg a.s./bee**	EFSA Journal 2010;8(11):1904

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Delan 70 WG (BAS 216 03 F, Dithianon formulation)*	Oral	LD_{50} > 91.77* µg a.s./bee	EFSA Journal 2010;8(11):1904
Apis mellifera	Delan 70 WG (BAS 216 03 F, Dithianon formulation)*	Contact	LD_{50} > 100* µg a.s./bee	EFSA Journal 2010;8(11):1904
Apis mellifera	Dimethomorph	Oral	**LD_{50} > 32.4 µg/bee**	EFSA Scientific Report (2006) 82, 1-69
Apis mellifera	Dimethomorph	Contact	**LD_{50} > 102 µg/bee**	EFSA Scientific Report (2006) 82, 1-69
Apis mellifera	CME 151 (WL 127 294, Dimethomorph formulation)	Oral	LD_{50} > 100 µg f.p./bee	EFSA Scientific Report (2006) 82, 1-69
Apis mellifera	CME 151 (WL 127 294, Dimethomorph formulation)	Contact	LD_{50} > 100 µg f.p./bee	EFSA Scientific Report (2006) 82, 1-69
Apis mellifera	AC 336379 (SF 070460, Dimethomorph formulation)	Oral	LD_{50} > 74.4 µg f.p./bee	EFSA Scientific Report (2006) 82, 1-69
Apis mellifera	AC 336379 (SF 070460, Dimethomorph formulation)	Contact	LD_{50} > 100 µg f.p./bee	EFSA Scientific Report (2006) 82, 1-69
Apis mellifera	PIORITY	Oral, 48h	LD_{50} > 400 µg f.p./bee (>57.04 µg dimetomorph/bee + >140.76 µg dithianon/bee)	KCP 10.3.1.1.1 Lemańska, N. 2018 B/45/17
Apis mellifera	PIORITY	Contact, 48h	LD_{50} > 400 µg f.p./bee (>57.04 µg dimetomorph/bee + >140.76 µg dithianon/bee)	KCP 10.3.1.1.2 Lemańska, N. 2018 B/46/17
Higher-tier studies (tunnel test, field studies)				
None				

*based on the content of the active substance in the product (nominal)

9.6.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones, except for formulation, corresponding to data proper to PIORITY formulation.

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: First-tier assessment of the risk for bees due to the use of PIORITY in grapevine

Intended use	Grapevine		
Active substance	Dithianon		
Application rate (g/ha)	3 x 525		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>25.4	525	<20.67
Contact toxicity	>100		<5.25
Intended use	Grapevine		
Active substance	Dimethomorph		
Application rate (g/ha)	3 x 225		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>32.4	225	<6.94
Contact toxicity	>102		<2.21
Intended use	Grapevine		
Active substance	PIORITY		
Application rate (g/ha)	3 x 1500		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>400	1500	<3.75
Contact toxicity	>400		<3.75

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

zRMS comments:

Studies on the toxicity to bees have been carried out with dithianon and dimetomorph. Full details of these studies are provided in the respective EU RAR and related documents.
Effects on bees of Priority were not evaluated as part of the EU assessment of metazachlor and clomazon.
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).
Therefore, the risk assessment has been conducted according to EPPO/OEPP (2003) Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)).
Based on the acute risk assessment with the consideration SANCO/10329/2002 rev.2 (final), October 17, 2002), HQ values for adult bees from exposure of Priority and their active substances are< 50, indicating un acceptable risk to adult bees.

According to EU Reg. 284 /2009 the chronic toxicity test for adult bees, chronic test for larvae should be provided for plant protection product.

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

Not relevant.

9.6.3 Effects on bumble bees

Not required.

9.6.4 Effects on solitary bees

Not required.

9.6.5 Overall conclusions

The risk assessment for bees has been done. All the hazard quotients are considerably less than 50, indicating that the active substances pose a low risk to bees. Therefore a low risk to bees is expected from the application of PIORITY at all proposed label rates.

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

Effects on non-target arthropods of PIORITY were not evaluated as part of the EU assessment of Dithianon and Dimethomorph. New data submitted with this application are listed in 9.13 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 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	Delan 70 WG (Dithianon formulation)	Laboratory test glass plates (2D)	LR_{50} > 0.96 kg/ha	EFSA Journal 2010;8(11):1904
Typhlodromus pyri (protonymphs)	Delan 70 WG (Dithianon formulation)	Laboratory test glass plates (2D)	LR_{50} > 6 kg/ha (> 4.2 kg a.s./ha)	EFSA Journal 2010;8(11):1904
Aphidius rhopalosiphi	Delan 70 WG (Dithianon formulation)	Laboratory test glass plates (2D)	LR_{50} > 6 kg/ha (> 4.2 kg a.s./ha)	EFSA Journal 2010;8(11):1904

Species	Substance	Exposure System	Results	Reference
Aphidius rhopalosiphi (adults)	Delan 70 WG (Dithianon formulation)	Extended laboratory test barley plants (3D)	LR_{50} > 3.02 kg Delan 70 WG/ha (equivalent to 2.114 kg a.s./ha) ER_{50} > 2.076 kgDelan 70 WG/ha (equivalent to 1.453 kg a.s./ha)	EFSA Journal 2010;8(11):1904
Aphidius rhopalosiphi (adults)	Delan 70 WG (Dithianon formulation)	Aged-residue test Natural substrate barley plants (3D)	Mortality at 4 kg/ha (equivalent to 2.8 kg a.s./ha): 47 % at 0 DAT 0 % at 7 DAT Mortality at 6 kg/ha (equivalent to 4.2 kg a.s./ha): 80 % at 0 DAT 0 % at 7 DAT Effects sublethal at 4 kg/ha (equivalent to 2.8 kg a.s./ha): 47 % at 0 DAT: 50 % at 0 DAT -47 % at 7 DAT Effects sublethal at 6 kg/ha (equivalent to 4.2 kg a.s./ha):: - % at 0 DAT -41 % at 7 DAT	EFSA Journal 2010;8(11):1904
Chrysoperla Carnea	Delan 70 WG (Dithianon formulation)	Extended laboratory test Natural substrate bean plants (2D)	Mortality: 10 % at 0.8 kg/ha 25 % at 2.4 kg/ha 4 % at 4.8 kg/ha 11 % at 6.0 kg/ha LR_{50} > 6.0 kg Delan 70 WG/ha (equivalent to > 4.2 kg a.s./ha) Red. of fecundity: No effects at 0.8 kg/ha No effects at 2.4 kg/ha No effects at 4.8 kg/ha No effects at 6.0 kg/ha	EFSA Journal 2010;8(11):1904
Pardosa spp.	Delan 70 WG (Dithianon formulation)	Extended laboratory test Natural substrate Direct application	Mortality: 0.0 % at 0.8 kg/ha -3.0 % at 2.4 kg/ha 6.0 % at 6.0 kg/ha Effects sublethal: 0.0 % at 0.8 kg/ha 8.0 % at 2.4 kg/ha 2.0 % at 6.0 kg/ha	EFSA Journal 2010;8(11):1904

Species	Substance	Exposure System	Results	Reference
Phytoseiulus Persimilis (Protonymphs)	Forum (CYA 15107, Dimethomorph formulation)	Laboratory test 8 d Leaf discs of *Phaseolus vulgaris* L. (2D)	Mortality at 115 g Dimethomorph /ha: 0 % Sublethal effects at 115 g Dimethomorph /ha: 0 % (fertility)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Trichogramma Cacoeciae (Imagines)	Forum (CYA 15107, Dimethomorph formulation)	Laboratory test 7 d Glass plates (2D)	Mortality at 115 g Dimethomorph /ha: 0 % Sublethal effects at 115 g Dimethomorph /ha: 8 % (paratisation capacity)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Trichogramma Cacoeciae (Imagines)	SF 07460 (Dimethomorph formulation)	Extended laboratory test 5 d Vine plants (3D)	Mortality at 360 g Dimethomorph /ha: 0 % Sublethal effects at 360 g Dimethomorph /ha: + 14 % (paratisation capacity)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Trichogramma Cacoeciae (Imagines)	SF 07460 (Dimethomorph formulation)	Extended laboratory test 5 d Vine plants (3D)	Mortality at 3 x 360 g Dimethomorph /ha: 0 % Sublethal effects at 3 x 360 g Dimethomorph /ha: + 4 % (paratisation capacity)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Trichogramma Cacoeciae (Imagines)	SF 07460 (Dimethomorph formulation)	Extended laboratory test 5 d Vine plants (3D)	Mortality at 6 x 360 g Dimethomorph /ha: 0 % Sublethal effects at 6 x 360 g Dimethomorph /ha: 6 % (paratisation capacity)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Pardosa spp. (adult)	Forum (CYA 15107, Dimethomorph formulation)	Laboratory test 14 d Quartz sand (2D)	Mortality at 300 g Dimethomorph /ha: 0 % Sublethal effects at 300 g Dimethomorph /ha: 0 % (food uptake)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Pardosa spp. (adult)	Forum (CYA 15107, Dimethomorph formulation)	Laboratory test 14 d Quartz sand (2D)	Mortality at 600 g Dimethomorph /ha: 0 % Sublethal effects at 600 g Dimethomorph /ha: 0 % (food uptake)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004

Species	Substance	Exposure System	Results	Reference
Pardosa spp. (adult)	SF 07460 (Dimethomorph formulation)	Extended laboratory test 16 d Loam soil LUFA 2.1 (2D)	Mortality at 6 x 72 g Dimethomorph /ha: 3 % Sublethal effects at 6 x 72 g Dimethomorph /ha: 0 % (food uptake)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Pardosa spp. (adult)	SF 07460 (Dimethomorph formulation)	Extended laboratory test 16 d Loam soil LUFA 2.1 (2D)	Mortality at 6 x 300 g Dimethomorph /ha: 15 % Sublethal effects at 6 x 300 g Dimethomorph /ha: 5 % (food uptake)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Typhlodromus pyri (protonymphs)	Forum (CYA 15107, Dimethomorph formulation)	Extended laboratory test 2D	Mortality at 115 g Dimethomorph /ha: 23 %	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Typhlodromus pyri (protonymphs)	BAS 550 02 F (Dimethomorph formulation)	Extended laboratory test 14 d Leaf discs of *Phaseolus vulgaris* (2D)	LR_{50} > 1800 g a.s./ha ER_{50} >1800 g a.s./ha	EFSA Scientific Report (2006) 82, 1-69 and Addendum Dimethomorph, May 2005
Aphidius rhopalosiphi (adults)	BAS 550 02 F (Dimethomorph formulation)	Extended laboratory test 11 d Barley plants (3D)	LR_{50} > 1800 g a.s./ha ER_{50} >1800 g a.s./ha	EFSA Scientific Report (2006) 82, 1-69 and Addendum Dimethomorph, May 2005
Field or semi-field tests				
Typhlodromus pyri	Forum (CYA 15107, Dimethomorph formulation)	Grapes 104 d	1st final counting 7 days after 6 applications: 25.6 % (effetcs in comparison to untreated control) 2nd final counting 28 days after 6 applications: 14.9 % (effetcs in comparison to untreated control)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Typhlodromus pyri (protonymphs)	Forum (CYA 15107, Dimethomorph formulation)	Grapes 91 d	1st final counting 7 days after 6 applications: 14.8 % (effetcs in comparison to untreated control) 2nd final counting 28 days after 6 applications: 2.3 % (effetcs in comparison to untreated control)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	Forum (CYA 15107, Dimethomorph formulation)	Grapes 97 d	1st final counting 7 days after 6 applications: 9.8 % (effetcs in comparison to untreated control) 26.7 % (effects in comparison to water treated control) 2nd final counting 28 days after 6 applications: 7.0 % (effetcs in comparison to untreated control) 47.0 % (effects in comparison to water treated control)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Typhlodromus pyri (protonymphs)	PIORITY	Extended laboratory test, bean leaves	**LR_{50} > 8.6 Kg f.p./ha (equivalent to >1226.4 g dimetomorph/ha + >3026.3 g dithianon/ha)** **ER_{50} > 8.6 Kg f.p./ha (equivalent to >1226.4 g dimetomorph/ha + >3026.3 g dithianon/ha)**	KCP 10.3.2.2-01 Lemańska, N. 2018 B/48/17
Aphidius rhopalosiphi (adults)	PIORITY	Extended study, barley plants	LR_{50} > 17.2 Kg f.p./ha (equivalent to >2.5 Kg dimetomorph/ha + >6.1 Kg dithianon/ha) **ER_{50} = 10.6 Kg f.p./ha (equivalent to 1.5 Kg dimetomorph/ha + 3.7 Kg dithianon/ha**)	KCP 10.3.2.2-02 Lemańska, N. 2018 B/47/17

9.7.1.1 Justification for new endpoints

The used endpoints are corresponding to data proper to PIORITY formulation.

In Dimethomorph DAR and the following Addenda, as well as in EFSA Scientific Report (2006) 82, 1-69, laboratory and extended laboratory studies are available. The originally submitted arthropod test data in the DAR were not sufficient for a quantitative risk assessment neither for the in-field nor for the off-field situation. In order to perform HQ calculation, two dose/response tests with *Aphidius rhopalosiphi* and *Typhlodromus pyri* on natural substrate were carried out, thus skipping Tier 1 of the ESCORT 2 assessment scheme. The results of both tests confirm a relatively low toxicity of Dimethomorph to arthropods (see Table 9.7-1.)

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

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of PIORITY in grapevine

Intended use	Grapevine		
Active substance/product	PIORITY		
Application rate (g/ha)	3 x 1500 g f.p./ha		
MAF	2.3 (foliar)		
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	>8600 g f.p./ha	3450 g f.p./ha	yes
Aphidius rhopalosiphi	10600 g f.p./ha		yes
Intended use	Grapevine		
Active substance/product	PIORITY		
Application rate (g/ha)	3 x 1500 f.p./ha (750** g f.p./ha)		
MAF	2.7 (soil)		
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	>8600 g f.p./ha	2025 g f.p./ha	yes
Aphidius rhopalosiphi	10600 g f.p./ha		yes

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

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

**rate with a 50% of interception.at BBCH 55-79. According to the interception values of FOCUS (2012).

9.7.2.2 Risk assessment for off-field exposure

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of PIORITY in grapevine

Intended use	Grapevine				
Active substance/product	PIORITY				
Application rate (g/ha)	3 x 1500 g f.p./ha				
MAF	2.3 (foliar)				
vdf	10 (2D) / 1 (3D), 5 (2D)*				
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	>8600 g f.p./ha	6.90	23.81 47.62	5	Yes yes
Aphidius rhopalosiphi	10600 g f.p./ha		238.05 476.1	5	Yes yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

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

*according to recommendation given in Central Zone

zRMS comments:
The risk assessment for in – field and off-field non - target arthropods was considered acceptable by zRMS.
The PER in -field and PER -off field for two indicator species was lower than rate with ≤ 50 % effect for the product Priority, indicating low risk for off-non-target arthropods.

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

No in-field and off-field risk to non-target arthropods is expected after the application of PIORITY according to the proposed GAP.

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 Dithianon and Dimethomorph. 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 PIORITY were not evaluated as part of the EU assessment of Dithianon and Dimethomorph. New data submitted with this application are listed in 9.13 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 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Dithianon	Acute 14 d	LC_{50} = 578.4 mg a.s./kg d.w.soil (mg a.s/ha) **LC_{50corr} = 289.2[1)] mg a.s./kg d.w.soil**	EFSA Journal 2010;8(11):1904

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Dithianon	Chronic 56 d	NOEC = 48 mg a.s./kg d.w.soil (mg a.s/ha) **$NOEC_{corr}$ = 24 mg a.s./kg d.w.soil (mg a.s/ha)***	EFSA Journal 2010;8(11):1904
Eisenia fetida	DELAN 70 WG (BAS 216 03 F, Dithianon formulation)	Acute 14-d toxicity test	LC_{50} > 700 mg a.s./kg soil dry weight LC_{50corr} > 350 mg a.s./kg soil dry weight*	EFSA Journal 2010;8(11):1904
Eisenia fetida	DELAN 70 WG (BAS 216 03 F, Dithianon formulation)	Chronic 56-d repro test (artificial substrate)	NOEC 22.3 mg a.s./kg soil dry weight (NOEC 56 mg a.s./kg soil dry weight, refined calculation based on the actual amount of soil dry weight per test vessel) $NOEC_{corr}$ = 11.15 1) mg a.s./kg soil dry weight ($NOEC_{corr}$ 28 mg a.s./kg soil dry weight, refined calculation based on the actual amount of soil dry weight per test vessel)	EFSA Journal 2010;8(11):1904
Eisenia fetida	DELAN 70 WG (BAS 216 03 F, Dithianon formulation)	Chronic 56-d repro test (field soil)	NOEC 3.7 a.s./kg soil dry weight (NOEC 9.3 mg a.s./kg soil dry weight, refined calculation based on the actual amount of soil dry weight per test vessel)	EFSA Journal 2010;8(11):1904
Eisenia fetida	Dimethomorph	14 d, acute	LC_{50} > 1000 mg/kg **$LC_{50,corr}$ > 500 mg/kg***	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Eisenia fetida	Dimethomorph	8 weeks (56 d), chronic	NOEC = 120 mg/kg **$NOEC_{corr}$ = 60 mg/kg***	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
Eisenia fetida	Forum (CYD 15107, Dimethomorph formulation)	14 d, acute	LC_{50} = 1326 mg/kg **(corresponding to 99.5 mg a.s./kg*)**	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Forum (BAS 550 09 F, Dimethomorph formulation)	Mixed into substrate 56 d, chronic 5 % peat content	LC_{50} = 92.20 mg/kg dw **(corresponding to 6.4 mg a.s./kg*)**	EFSA Scientific Report (2006) 82, 1-69 and addendum Dimethomorph, April 2006
Eisenia fetida	PIORITY	56 d, chronic	NOEC = 320 mg f.p./kg dw soil (equivalent to 45.6 mg dimetomorph/kg dw soil + 112.6 mg dithianon/kg dw soil) $EC_{10=}$ 226 mg f.p./kg dw soil (equivalent to 32.3 mg dimetomorph/kg dw soil + 79.7 mg dithianon/kg dw soil) **$EC_{10corr=}$ 113 mg f.p./kg dw soil (equivalent to 16 mg dimetomorph/kg dw soil + 40 mg dithianon/kg dw soil)**	KCP 10.4.1.1 Weronika, D. 2018 G/81/18
Folsomia candida	PIORITY	28 d, chronic	NOEC = 320 mg f.p./kg dw soil (equivalent to 45.6 mg dimetomorph/kg dw soil + 112.6 mg dithianon/kg dw soil) **NOECcorr = 160 mg f.p./kg dw soil (equivalent to 22.8 mg dimetomorph/kg dw soil + 56.3 mg dithianon/kg dw soil)** $EC_{10=}$ 460.8 mg f.p./kg dw soil (equivalent to 65.7 mg dimetomorph/kg dw soil + 162.2 mg dithianon/kg dw soil)	KCP 10.4.2.1-01 Weronika, D. 2018 G/80/18
Field studies				
None				
Litter bag test				
As stated in EFSA Scientific Report for Dimethomorph (EFSA Scientific Report (2006) 82, 1-69), a litter bag study using 3 applications of 1.2 kg a.s./ha with 6 and 10 days interval did not reveal any significant effect on the breakdown of leaf material.				

In bold, value used for the risk assessment

*Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002 since log P_{ow} > 2.

9.8.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones, except for formulation, corresponding to data proper to PIORITY formulation.

Regarding the Dithianon metabolite Phthalic acid, according to *Final addendum to the Draft Assessment Report (DAR) and Additional Report* (October, 2010) : "*it is a metabolite which may occur to some extent in soil following 15 days of continuous irradiation in laboratory soil photolysis. However, no specific studies have been performed for this degradation product as it is known from literature and from EFSA conclusions to be of low ecotoxicological relevance*". Therefore, the Applicant considers that any risk assessment will be needed for this metabolite.

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 need to be considered for Dimethomorph.

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of PIORITY in grapevine

Intended use	Grapevine		
Acute effects on earthworms			
Product/active substance	**LC_{50} * (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Dithianon	289.2	0.707	409.05
Dimethomorph	500	0.363	1377.41
Dimethomorph	99.5	0.363	274.10
Chronic effects on earthworms			
Product/active substance	**NOEC or EC_{10} * (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Dithianon	24	0.707	33.95
Dimethomorph	60	0.363	165.29
Dimethomorph	6.4	0.363	17.63
PIORITY	113	2.4	47.08
PIORITY**	39.9	0.707	56.44
PIORITY***	16.2	0.363	44.63
Chronic effects on other soil macro- and mesofauna			
Product/active substance	**NOEC * (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**

PIORITY	160	2.4	66.67
PIORITY**	56.3	0.707	79.63
PIORITY***	22.8	0.363	62.81

TER values shown in bold fall below the relevant trigger.
* endopint corrected.
** endpoint expressed as mg dithianon/kg dw soil from PIORITY study.
*** endpoint expressed as mg dimetomorph/kg dw soil from PIORITY study.

Chronic studies with PIORITY on earthworms and collembolan were submitted by the Applicant and no unacceptable risk was obtained after the risk assessment. Moreover, the risk assessment for NTA with the formulation was acceptable for indicator species and including with endpoints from Monograph for the ground dwelling arthropod *Pardosa* sp for both active substances. Therefore, the Applicant considers that an acceptable risk to *Hypoaspis aculeifer* for formulation PIORITY can be concluded on the basis that low risks to earthworms and other soil macro-organisms, and ground dwelling arthropod with formulation were concluded.

Therefore, it is expected that chronic toxicity on *Hypoaspis* will result from prolonged exposure and the formulation is not expected to remain intact in the environment.

ZRMS comments:

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate).
The TER_{LT} values are above trigger value of 5, indicating an acceptable risk for earthworm and other soil – macro-organism for proposed use of both active substances , their metabolites and ppp Priority.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

An application of PIORITY in respect of the GAP should not represent an acute and long term risk to earthworm and the other soil meso/microfauna.

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

Effects on soil microorganisms of PIORITY were not evaluated as part of the EU assessment of Dithianon and Dimethomorph. New data submitted with this application are listed in 9.13 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: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	DELAN 70 WG (BAS 216 03 F, Dithianon formulation)	28 d, aerobic soil type	+5.4 % effect at day 28 at 26.71 mg a.s./kg d.w.soil (eq. 14 kg Dithianon/ha)	EFSA Journal 2010;8(11):1904
C-mineralisation	DELAN 70 WG (BAS 216 03 F)	28 d, aerobic soil type	-9.5 % effect at day 28 at 26.71 mg a.s./kg d.w.soil (eq. 14 kg Dithianon/ha)	EFSA Journal 2010;8(11):1904
N-mineralisation	Forum (CYA 15107, Dimethomorph formulation)	28 d, aerobic Loamy sand and sandy silt	No effect up to 40 L prod./ha (corresponding to 6 kg Dimethomorph/ha, equivalent to 8 mg a.s./kg d.w.soil*)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
C-mineralisation	Forum (CYA 15107, Dimethomorph formulation)	56 d, aerobic loamy sand and sandy silt	No effect up to 40 L prod./ha (corresponding to 6 kg Dimethomorph/ha, equivalent to 8 mg a.s./kg d.w.soil*)	EFSA Scientific Report (2006) 82, 1-69 and DAR Dimethomorph, 2004
N-mineralisation	PIORITY	28 d, aerobic soil type	-24.7% of effects at 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil) -18.3% of effects at 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil)	KCP 10.5.1 Weronika, D. 2018 G/78/18
C-mineralisation	PIORITY	28 d, aerobic soil type	+5.7% of effects at 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil) +6.0% of effects at 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil)	KCP 10.5.2 Weronika, D. 2018 G/79/18

*calculation based on a bulk density of 1.5 g/cm^3 and a soil mixing depth of 5 cm

9.9.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones, except for formulation, corresponding to data proper to PIORITY formulation.

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: Assessment of the risk for effects on soil micro-organisms due to the use of PIORITY in grapevine

Intended use	Grapevine		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Dithianon	26.71 (at 28 d)	0.707	yes
Dimethomorph	8 (at 28 d)	0.363	yes
PIORITY	104.0 (at 28 d)	2.4	yes
PIORITY*	36.60 (at 28 d)	0.707	yes
PIORITY**	14.83 (at 28 d)	0.363	yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Dithianon	26.71 (at 28 d)	0.707	yes
Dimethomorph	8 (at 56 d)	0.363	yes
PIORITY	104.0 (at 28 d)	2.4	yes
PIORITY*	36.60 (at 28 d)	0.707	yes
PIORITY**	14.83 (at 28 d)	0.363	yes

*endpoint expressed as mg dithianon/kg dw soil from PIORITY study.
** endpoint expressed as mg dimetomorph/kg dw soil from PIORITY study.

zRMS comments:
The risk assessment for soil micro-organism after exposure of ppp Priority, has been accepted by the ZRMS.
In the same time, the risk assessment was provided by the both active substances and was considered acceptable by ZRMS.
The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PEC soil for the maximum application rate of active substances and and plant protection product Priority.
These results indicate that the risk to non-target soil micro-organisms is acceptable following use of Priority according to the proposed use pattern.

9.9.3 Overall conclusions

The use of PIORITY at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

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

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with Dithianon and Dimethomorph. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of PIORITY were not evaluated as part of the EU assessment of Dithianon and Dimethomorph. New data submitted with this application are listed in 9.13 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 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
Allium cepa *Avena sativa* *Beta vulgaris* *Raphanus sativus* *Glycine max* *Lactuca sativa* *Zea Mays*	DELAN 70 WG (BAS 216 03 F, Dithianon formulation)	21 d Pre-emergence application	ER_{50}> 6 kg f.p./ha (>4.2 kg a.s./ha)	EFSA Journal 2010;8(11):1904
Allium cepa *Avena sativa* *Beta vulgaris* *Raphanus sativus* *Glycine max* *Lactuca sativa* *Zea Mays*	DELAN 70 WG (BAS 216 03 F, Dithianon formulation)	21 d Post-emergence application	ER_{50}> 6 kg f.p./ha (>4.2 kg a.s./ha)	EFSA Journal 2010;8(11):1904
Avena sativa, *Allium cepa,* *Lactuca sativa,* *Raphanus sativus,* *Glycine max,* *Beta vulgaris,* *Zea Mays*	Forum (CYA 15107, Dimethomorph formulation)	Seedling emergence	Not effects at rates of 0.6 kg a.s./ha and 1.8 kg a.s/ha	DAR, Vol.3, 2004; EFSA Scientific Report (2006) 82, 1-69
Avena sativa, *Allium cepa,* *Lactuca sativa,* *Raphanus sativus,* *Glycine max,* *Beta vulgaris,* *Zea Mays*	Forum (CYA 15107, Dimethomorph formulation)	Vegetative vigour	Not effects at rates of 0.6 kg a.s./ha and 1.8 kg a.s/ha	DAR, Vol.3, 2004; EFSA Scientific Report (2006) 82, 1-69

Species	Substance	Exposure System	Results	Reference
Sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, pea *(Pisum sativum)*, carrot *(Daucus carota)*, onion *(Allium cepa)* and oats *(Avena sativa)*	PIORITY	Seedling emergence	ER_{50}> 4680 g f.p./ha (equivalent to 667.4 g dimetomorph/ha + 1646.9 g dithianon/ha)	KCP 10.6.2-01 Weronika, D. 2018 G/75/18
Sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, pea *(Pisum sativum)*, carrot *(Daucus carota)*, onion *(Allium cepa)* and oats *(Avena sativa)*	PIORITY	Vegetative vigour	ER_{50}> 4680 g f.p./ha (equivalent to 667.4 g dimetomorph/ha + 1646.9 g dithianon/ha)	KCP 10.6.2-02 Weronika, D. 2018 G/77/18

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones, except for formulation, corresponding to data proper to PIORITY formulation.

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: Assessment of the risk for non-target plants due to the use of PIORITY in grapevine (Dithianon)

Intended use	Grapevines
Active substance/product	Dithianon / PIORITY
Application rate (g/ha)	2 x 525
MAF	2.3

Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Avena sativa, Allium cepa, Lactuca sativa, Raphanus sativus, Glycine max, Beta vulgaris and Zea Mays	>42000	6.90	83.32	>50.41

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

Table 9.10-3: Assessment of the risk for non-target plants due to the use of PIORITY in grapevine (Dimethomorph)

Intended use	Grapevines
Active substance/product	Dimethomorph / PIORITY
Application rate (g/ha)	3 x 225
MAF	2.3

Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Avena sativa, Allium cepa, Lactuca sativa, Raphanus sativus, Glycine max, Beta vulgaris and Zea Mays	1800	6.90	35.71	50.41

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

Table 9.10-4: Assessment of the risk for non-target plants due to the use of PIORITY in grapevine

Intended use	Grapevines
Active substance/product	PIORITY
Application rate (g/ha)	3 x 1500 g f.p./ha
MAF	2.3

Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Helianthus annuus, Brassica oleracea var. capitata, Pisum sativum, Daucus carota, Allium cepa and *Avena sativa*	>4680 g f.p./ha	6.90	238.05	>19.66

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

zRMS comments:

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002).
The risk assessment for non – target plants after exposure to Priority taking inoto account the max application rate of 3 x1500 g product/ha and ER_{50} value of >4680 g product/ha, has been accepted by zRMS.
No mitigation measures are required.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

The risk assessment for non-target plants has been done with EU agreed endpoint and the risk to non-target plants for PIORITY is considered to be acceptable when applied according to the proposed use rates.

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

Not relevant for Dithianon and Dimethomorph.

9.12 Monitoring data (KCP 10.8)

Not relevant for Dithianon and Dimethomorph.

9.13 Classification and Labelling

	Dimethomorph 15% Dithianon 35% WG	
Common Name	PIORITY	
Classification and proposed labelling		
With regard to ecotoxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Code(s) for hazard pictogram(s): Signal word: Hazard statement(s): Precautionary statement:	Aquatic Acute Category 1 Aquatic Chronic Category 1 GHS09 Warning H 400, H410 ~~P273,~~ P391, P501

Dithianon is classified as Aquatic Acute Category 1 and Aquatic Chronic Category 1 (M = 1).
Dimethomorph 15% + Dithianon 35% WG contains 1 × 35.71 ≥ 25% [M × Acute 1 ≥ 25% or M × Chronic 1 ≥ 25%] of this active substance, therefore hazard statement H400 and H410, with pictogram GHS09

and signal word “Warning” is proposed.

Grapevine **SPe 3**: To protect aquatic organisms respect an unsprayed buffer zone of 50 m to surface water bodies with 90% of nozzles reduction.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 1.2.1-01	Kull, S.	2019	Residue study (Decline) in cereals following four sequential applications with Dithianon 70% WG in Germany 2018 – field part CT18-1-15 CropTrials GmbH GLP Unpublished	N	Sharda Cropchem Limited
KCP 1.2.1-02	Rump, K.	2020	Determination of residues at decline of Dithianon in Winter Wheat, following four broadcast applications of DITHIANON 70% WG, under open field conditions Germany - Season 2018 FRS 058/18 Field Research Support GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-01	xxxxxxx	2019	Dimethomorph 15% + Dithianon 35% WG Rainbow trout, Acute toxicity test Report No. W/82/18 xxxxxxxx GLP Unpublished	Y	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1-02	Turek, T.	2018	Dimethomorph 15% + Dithianon 35% WG *Daphnia magna*, acute immobilisation test Report No. W/84/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-03	Turek, T.	2018	Dimethomorph 15% + Dithianon 35% WG *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*) Growth inhibition test Report No. W/83/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-04	Turek, T.	2019	Dimethomorph 15% + Dithianon 35% WG *Lemna gibba* CPCC 310, Growth inhibition test Report No. W/85/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3..1.1.1	Lemańska, N.	2018	Dimethomorph 15% + Dithianon 35% WG Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test Report No. B/45/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3..1.1.2	Lemańska, N.	2018	Dimethomorph 15% + Dithianon 35% WG Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test Report No. B/46/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.2.2-01	Lemańska, N.	2019	An extended laboratory test for evaluating the effects of Dimethomorph 15% + Dithianon 35% WG on the predatory mite, *Typhlodromus pyri* (Sch.) Report No. B/48/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-02	Lemańska, N.	2018	An extended laboratory test for evaluating the effects of Dimethomorph 15% + Dithianon 35% WG on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani Perez) Report No. B/47/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.1.1	Weronika, D.	2018	Dimethomorph 15% + Dithianon 35% WG Earthworm Reproduction Test (*Eisenia andrei*) Report No. G/81/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-01	Weronika, D.	2018	Dimethomorph 15% + Dithianon 35% WG Collembolan (*Folsomia candida*) Reproduction Test Report No. G/80/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.5.1	Weronika, D.	2018	Dimethomorph 15% + Dithianon 35% WG Soil Microorganisms: Nitrogen Transformation Test Report No. G/78/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited

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 10.5.2	Weronika, D.	2018	Dimethomorph 15% + Dithianon 35% WG Soil Microorganisms: Carbon Transformation Test Report No. G/79/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-01	Weronika, D.	2018	Dimethomorph 15% + Dithianon 35% WG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Report No. G/75/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-02	Weronika, D.	2018	Dimethomorph 15% + Dithianon 35% WG Terrestrial Plant Test: Vegetative Vigour Test Report No. G/77/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

Please refer to section B6.

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

Comments of zRMS: The study previously assessed by zRMS –PL in ppp Duke (Sharda company),

Residue Section: Study is accepted and valid with regard to storage stability data. The analytical method used is acceptable.
LOQ = 0.01 mg/kg
Fate Section: The kinetic analysis was submitted by the applicant and was considered as acceptable.

Trial	DT_{50} (d)	DT_{90} (d)	χ^2 (%)	MODEL
CT18-1-15DE1	6.65	22.1	8.16	SFO
CT18-1-15DE2	5.0	16.6	9.05	

Reference: KCP 10.1.2.1-01

Report Residue study (decline) in cereals following four sequential applications with Dithianon 70% WG in Germany 2018. Field trial CT18-1-15, Analytical phase report DPL-84-2019

Guideline(s): Yes
Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2019 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414, SANCO/3029/99 rev.4, 11/07/2000
Guidance document on pesticide residue and analytical methods, SANCO/825/00 rev. 8.1, 16/11/2010
OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)
EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97,

rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials
The Principles of Good Laboratory Practice, ChemG 25.07.1994, § 19, Annex 1 (BGBL 21, I, 2001, p. 843-855)
OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999)
20, Paris 2002
The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002
The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9

Deviations: Trial CT18-1-15DE1
Deviation dated 03.05.2018: Application C was performed after a 9 days interval instead of a 7 days interval due to unfavourable weather conditions.
Deviation dated 16.05.2018: The crop development was slower than expected. The crop stage at application timing D was BBCH 32 instead of BBCH 39.

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of two trials were conducted in cereals in Central Europe (Germany) to determine the magnitude of residues at decline of Dithianon in or on raw agricultural commodities (RAC).

The decline trials were carried out on open field in North and South Germany. Two plots were measured out in winter wheat for each trial: one untreated control plot and one treated plot. Plot 2 was treated four times with the test item Dithianon 70% WG with the rate of 1.5 kg/ha. The spray interval was 6-9 days. The used water volume was 200-300 L/ha. The first application was performed at crop stage BBCH 25-27, the last application at crop stage BBCH 32-39.

Specimens of the raw agricultural commodity whole plant without roots were collected at the day of the last application and 1, 3, 5, 7, 14 and 21 days after the last application.

The residues of Dithianon were extracted according to the multi-residue A-QuEChERS method and quantification was performed by using LC-MS/MS detection.

The caracteristics ot the analytical method was as follows:

Extraction

5 g of homogeneized sample was weighted into a 50 mL centrifugue tube, 10 mL of water (HPLC purity grade) and 10 mL of acidified with 1% of HCOOH acetonitroile was added. Next, to the sample was added internal standard solution (10 µL/1 g of sample). The mixture was shaken vigorously by hand for one minute, then was added 4 mg $MgSO_4$ and 1 g NaCl, shaken for 1 min and centrifugued at 4700 rpm for 10 min for phase separation. After that, extract was fileterd through a membrane filter and the final wxtract was directly employed for LC-MS/MS analysis. Quantification was performed using internal standard method.

Fortification and control samples

5 g of the homogeneized untreated sample were weighted into a 50 mL centrifugue tube. Appropriate active substance standard solution was added and the sample was extracted.

Fortification level	Amount of standard solution 1.1 added [µl]	Amount of standard solution 1.2 added [µl]
Matrix blank	-	-
PK 0.010 mg/kg	-	50
PK 0.10 mg/kg	50	-

Preparation of solutions

Analytical standard solutions

Name of analytical standard	Amount [mg]	Flask volume [ml]	Final concentration [µg/ml]	Solvent used
Dithianon	10.0	10	1000	acetonitrile containing 0.4 % CH_3COOH
Dithianon - D_4	5.00	10	500	acetonitrile containing 0.4 % CH_3COOH

Name of intermediate standard solution	Name of analytical standard	Volume of stock solution standard [µl]	Flask volume [ml]	Final concentration [µg/ml]
Intermediate solution (1.2)	Dithianon	10.0	10.0	1.00
Intermediate solution (1.1)	Dithianon	100	10.0	10.0
Intermediate solution (1.3)	Dithianon D_4	200	10.0	10.0

Calibration working solutions

Calibration level	Amount of 1.1 solution added [µl]	Amount of 1.2 solution added [µl]	Amount of 1.3 internal solution added [µl]
Cal blank	-	-	50.0
Cal 1 ppb	-	5	50.0
Cal 2 ppb	-	10	50.0
Cal 5 ppb	-	25	50.0
Cal 10 ppb	-	50	50.0
Cal 100 ppb	50	-	50.0
Cal 250 ppb	125	-	50.0
Cal 500 ppb	250	-	50.0

Analysis

The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.

Results:

No residue above the LOQ were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 1: Summary of the KCP 10.1.2.1-01 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Dithianon	PHI (days) (d)	Details on trial (e)
CT18-1-15DE1/ Germany / CEU / 2018	Cereal/ Winter wheat	1) 08/10/2017 2) - 3) 24/05/2018	103 1.5 106 5.6 104 0.1 102 3.0	200 200 200 200	0.05 1 0.05 3 0.05 2 0.05 1	11/04/2018 18/04/2018 27/04/2018 03/05/2018	BBCH 25-27 BBCH 30 BBCH 32 BBCH 32	Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root)	29.1 29.2 22.4 21.5 12.3 7.50 2.30	0 1 3 5 7 14 21	Analytical phase report: DPL-84-2019 LOD = 0.003 mg/kg LOQ = 0.01 mg/kg Time between harvest and extraction: 405 d
CT18-1-15DE1/ Germany / CEU / 2018	Cereal/ Winter wheat	1) 20/10/2017 2) - 3) 24/05/2018	104 0.1 100 6.0 105 7.1 102 9.8	300 300 300 300	0.03 5 0.03 4 0.03 5 0.03 4	12/04/2018 19/04/2018 26/04/2018 03/05/2018	BBCH 25 BBCH 32 BBCH 32 BBCH 39	Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root)	22.8 17.7 12.6 12.5 9.21 1.74 1.51	0 1 3 5 7 14 21	Analytical phase report: DPL-84-2019 LOD = 0.003 mg/kg LOQ = 0.01 mg/kg Time between harvest and extraction: 405 d

(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

KINETIC REPORT ON KULL, S. (2019). Residue study (Decline) in cereals following four sequential applications with Dithianon 70% WG in Germany 2018 – field part. Report Number CT18-1-15 Ehlbeek 2, 30938 Burgwedel, Germany, using Cake v3.4.

Author
Juan J. Izquierdo, November 2021
Sharda Cropchem España S.L.

Summary

During the growing season of 2018, a total of two trials were conducted in cereals in Central Europe (Germany) to determine the magnitude of residues at decline of Dithianon in or on raw agricultural commodities (RAC).

The decline trials were carried out on open field in North and South Germany. Two plots were measured out in winter wheat for each trial: one untreated control plot and one treated plot. Plot 2 was treated four times with the test item Dithianon 70% WG with the rate of 1.5 kg/ha. The spray interval was 6-9 days. The used water volume was 200-300 L/ha. The first application was performed at crop stage BBCH 25-27, the last application at crop stage BBCH 32-39.

Specimens of the raw agricultural commodity whole plant without roots were collected at the day of the last application and 1, 3, 5, 7, 14 and 21 days after the last application.

The residues of Dithianon were extracted according to the multi-residue A-QuEChERS method and quantification was performed by using LC-MS/MS detection.

Residue analysis

The analytical phase was conducted at the SGS Polska Sp.z.o.o. facility located in Poland The Limit of Quantification (LOQ) required was 0.01mg/kg for Dithianon.

Summary of the trials

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Water (l/ha)	g a.s./hl	Dates of treatment or no. of treat-ments and last date (c)	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg): Dithianon	PHI (days) (d)	Details on trial (e)
CT18-1-15DE1/ Germany / CEU / 2018	Cereal/ Winter wheat	1) 08/10/2017 2) - 3) 24/05/2018	1031.5 1065.6 1040.1 1023.0	200 200 200 200	0.051 0.053 0.052 0.051	11/04/2018 18/04/2018 27/04/2018 03/05/2018	BBCH 25-27 BBCH 30 BBCH 32 BBCH 32	Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root)	29.1 29.2 22.4 21.5 12.3 7.50 2.30	0 1 3 5 7 14 21	Analytical phase report: DPL-84-2019 LOD = 0.003 mg/kg LOQ = 0.01 mg/kg Time between harvest and extraction: 405 d
CT18-1-15DE1/ Germany / CEU / 2018	Cereal/ Winter wheat	1) 20/10/2017 2) - 3) 24/05/2018	1040.1 1006.0 1057.1 1029.8	300 300 300 300	0.035 0.034 0.035 0.034	12/04/2018 19/04/2018 26/04/2018 03/05/2018	BBCH 25 BBCH 32 BBCH 32 BBCH 39	Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root)	22.8 17.7 12.6 12.5 9.21 1.74 1.51	0 1 3 5 7 14 21	Analytical phase report: DPL-84-2019 LOD = 0.003 mg/kg LOQ = 0.01 mg/kg Time between harvest and extraction: 405 d

(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

The half life calculations have been done using Cake v 3.4. Below the calculated DT_{50} and DT_{90} for the trials.

Trial	DT_{50} (d)	DT_{90} (d)	χ^2 (%)	MODEL
CT18-1-15DE1	6.65	22.1	8.16	SFO
CT18-1-15DE2	5.0	16.6	9.05	

In the next tables and figures are given the data and the summary of the graphics used for half life modelling. The modelling has been done without any improvement, using the data as such (Detailed Cake v3.4 reports will be sent separately).

Table 1: Data used for modelling

Time (d)	Dithianon residue (mg/kg)	
	CT18-1-15DE1	CT18-1-15DE2
0	29.1	22.8
1	29.2	17.7
3	22.4	12.3
5	21.5	12.5
7	12.3	9.21
14	7.50	1.74
21	2.30	1.51

Trial CT18-1-15DE1

Estimated Values:

Parameter	Value	s	Prob. > t	Lower (90%) CI	Upper (90%) CI	Lower (95%) CI	Upper (95%) CI
Parent_0	30.84	1.569	N/A	27.68	34	26.81	34.88
k_Parent	0.1042	0.01359	3.01E-004	0.07679	0.1316	0.06924	0.139

Sum of Squared Residuals: 23.24

χ^2

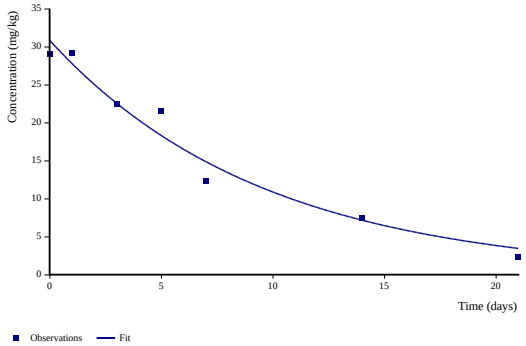
Parameter	Error %	Degrees of Freedom
All data	8.16	5
Parent	8.16	5

Decay Times:

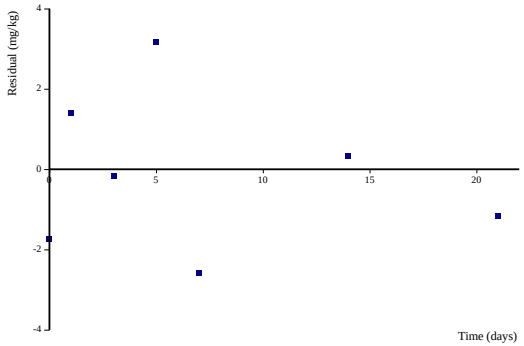
Compartment	DT50 (hours)	DT90 (hours)
Parent	6.65	22.1

Graphical Summary:

Observations and Fitted Model:



Residuals:



Trial CT18-1-15DE2

Estimated Values:

Parameter	Value	s	Prob. > t	Lower (90%) CI	Upper (90%) CI	Lower (95%) CI	Upper (95%) CI
Parent_0	21.68	1.16	N/A	19.34	24.02	18.7	24.66
k_Parent	0.1386	0.01791	2.88E-004	0.1025	0.1747	0.09257	0.185

Sum of Squared Residuals: 11.27

χ^2

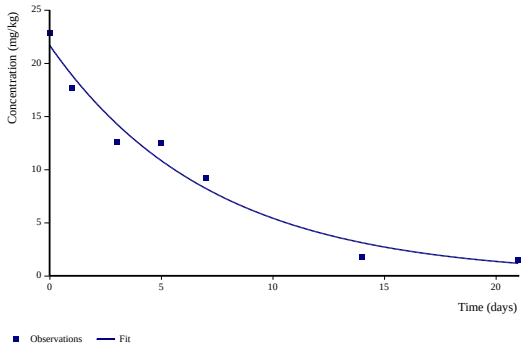
Parameter	Error %	Degrees of Freedom
All data	9.05	5
Parent	9.05	5

Decay Times:

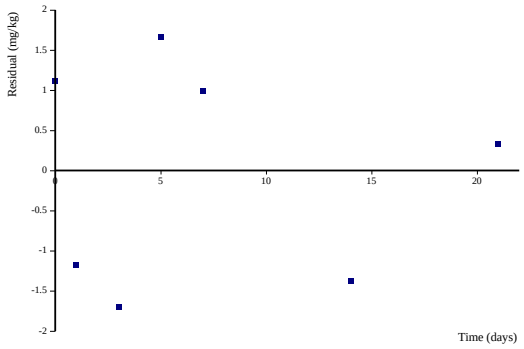
Compartment	DT50 (hours)	DT90 (hours)
Parent	5	16.6

Graphical Summary:

Observations and Fitted Model:



Residuals:



Agreed endpoits:

Trial	DT_{50} (d)	DT_{90} (d)	χ^2 (%)	MODEL
CT18-1-15DE1	6.65	22.1	8.16	SFO
CT18-1-15DE2	5.0	16.6	9.05	

Trial	DT_{50} (d)	DT_{90} (d)	χ^2 (%)	MODEL
FRS058/18-V1	5.92	19.7	15.9	SFO
FRS058/18-V2	8.35	27.8	15.2	

zRMS comment:

The DT_{50} is not considered in the risk assessment
Residue Section: Study is accepted and valid with regard to storage stability data. The analytical method used is acceptable.
LOQ = 0.01 mg/kg
Fate Section: The kinetic analysis was submitted by the applicant and was considered as acceptable.

Results:

Trial	DT_{50} (d)	DT_{90} (d)	χ^2 (%)	MODEL
FRS058/18-V1	5.92	19.7	15.9	SFO
FRS058/18-V2	8.35	27.8	15.2	

Reference: KCP 10.1.2.1-02

Report Determination of residues at decline of dithianon in winter wheat, following four broadcast applications of Dithianon 70% WG, under open field conditions Germany - season 2018. Field trial FRS 058/18, Analytical phase report DPL-85-2019

Guideline(s): Yes
Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2019 concerning the placing of plant protection products on the market and re-pealing Council Directives 79/117/EEC and 91/414/EEC
Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414, SANCO/3029/99 rev.4, 11/07/2000
Guidance document on pesticide residue and analytical methods, SANCO/825/00 rev. 8.1, 16/11/2010
OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)
EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials
The Principles of Good Laboratory Practice, ChemG 25.07.1994, § 19, Annex 1 (BGBL 21, I, 2001, p. 843-855)
OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999)
20, Paris 2002
The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002
The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of two trials were conducted in cereals in Central Europe (Germany) to determine the magnitude of residues

at decline of Dithianon in or on raw agricultural commodities (RAC).

The decline trials were carried out on open field in Germany. Two plots were measured out in winter wheat for each trial: one untreated control plot and one treated plot. Plot 2 was treated four times with the test item Dithianon 70% WG with the rate of 1.5 kg/ha. The spray interval was 6-7 days. The used water volume was 200-300 L/ha. The first application was performed at crop stage BBCH 25-30, the last application at crop stage BBCH 39.

Specimens of the raw agricultural commodity whole plant without roots were collected at the day of the last application and 1, 3, 5, 7, 14 and 21 days after the last application.

The residues of Dithianon were extracted according to the multi-residue A-QuEChERS method and quantification was performed by using LC-MS/MS detection.

The caracteristics ot the analytical method was as follows:

Extraction

5 g of homogeneized sample was weighted into a 50 mL centrifugue tube, 10 mL of water (HPLC purity grade) and 10 mL of acidified with 1% of HCOOH acetonitroile was added. Next, to the sample was added internal standard solution (10 µL/1 g of sample). The mixture was shaken vigorously by hand for one minute, then was added 4 mg $MgSO_4$ and 1 g NaCl, shaken for 1 min and centrifugued at 4700 rpm for 10 min for phase separation. After that, extract was fileterd through a membrane filter and the final wxtract was directly employed for LC-MS/MS analysis. Quantification was performed using internal standard method.

Fortification and control samples

5 g of the homogeneized untreated sample were weighted into a 50 mL centrifugue tube. Appropriate active substance standard solution was added and the sample was extracted.

Fortification level	Amount of standard solution 1.1 added [µl]	Amount of standard solution 1.2 added [µl]
Matrix blank	-	-
PK 0.010 mg/kg	-	50
PK 0.10 mg/kg	50	-

Preparation of solutions

Analytical standard solutions

Name of analytical standard	Amount [mg]	Flask volume [ml]	Final concentration [µg/ml]	Solvent used
Dithianon	10.0	10	1000	acetonitrile containing 0.4 % CH_3COOH
Dithianon - D_4	5.00	10	500	acetonitrile containing 0.4 % CH_3COOH

Name of intermediate standard solution	Name of analytical standard	Volume of stock solution standard [µl]	Flask volume [ml]	Final concentration [µg/ml]
Intermediate solution (1.2)	Dithianon	10.0	10.0	1.00
Intermediate solution (1.1)	Dithianon	100	10.0	10.0
Intermediate solution (1.3)	Dithianon D_4	200	10.0	10.0

Calibration working solutions

Calibration level	Amount of 1.1 solution added [µl]	Amount of 1.2 solution added [µl]	Amount of 1.3 internal solution added [µl]
Cal blank	-	-	50.0
Cal 1 ppb	-	5	50.0
Cal 2 ppb	-	10	50.0
Cal 5 ppb	-	25	50.0
Cal 10 ppb	-	50	50.0
Cal 100 ppb	50	-	50.0
Cal 250 ppb	125	-	50.0
Cal 500 ppb	250	-	50.0

Analysis

The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.

Results:

No residue above the LOQ were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 2: Summary of the KCP 10.1.2.1-02 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Dithianon	PHI (days) (d)	Details on trial (e)
FRS058/ 18-V1/ Germany / CEU / 2018	Winter wheat/ Barny	1) 18/10/2017 2) May/June 3) 05/06/2018	1032.5 1023.8 1023.8 1058.7	200 200 200 200	0.052 0.051 0.051 0.053	24/04/2018 02/05/2018 09/05/2018 15/05/2018	BBCH 30-31 BBCH 31 BBCH 37 BBCH 39	Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root)	31.3 22.0 19.8 11.7 10.4 10.9 3.55	0 1 3 5 7 14 21	Analytical phase report: DPL-85-2019 LOD = 0.003 mg/kg LOQ = 0.01 mg/kg Time between harvest and extraction: 396 d
FRS058/ 18-V2/ Germany / CEU / 2018	Winter wheat/ Ritmo	1) 17/10/2017 2) May/June 3) 05/06/2018	1084.7 1080.5 1032.2 1041.3	300 300 300 300	0.036 0.036 0.034 0.035	12/04/2018 19/04/2018 26/04/2018 03/05/2018	BBCH 25 BBCH 32 BBCH 32 BBCH 39	Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root)	32.8 21.8 19.3 15.1 14.4 13.3 4.73	0 1 3 5 7 14 21	Analytical phase report: DPL-85-2019 LOD = 0.003 mg/kg LOQ = 0.01 mg/kg Time between harvest and extraction: 396 d

(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

KINETIC REPORT ON Rump, K. (2020). Determination of residues at decline of Dithianon in Winter Wheat, following four broadcast applications of DITHIANON 70% WG, under open field conditions Germany - Season 2018. Report Number FRS 058/18 Field Research Support, Max-Planck-Straße 5, D-31515 Wunstorf, Germany, using Cake v3.4.

Author
Juan J. Izquierdo, November 2021
Sharda Cropchem España S.L.

Summary

During the growing season of 2018, a total of two trials were conducted in cereals in Central Europe (Germany) to determine the magnitude of residues at decline of Dithianon in or on raw agricultural commodities (RAC).

The decline trials were carried out on open field in Germany. Two plots were measured out in winter wheat for each trial: one untreated control plot and one treated plot. Plot 2 was treated four times with the test item Dithianon 70% WG with the rate of 1.5 kg/ha. The spray interval was 6-7 days. The used water volume was 200-300 L/ha. The first application was performed at crop stage BBCH 25-30, the last application at crop stage BBCH 39.

Specimens of the raw agricultural commodity whole plant without roots were collected at the day of the last application and 1, 3, 5, 7, 14 and 21 days after the last application.

The residues of Dithianon were extracted according to the multi-residue A-QuEChERS method and quantification was performed by using LC-MS/MS detection.

Residue analysis

The analytical phase was conducted at the SGS Polska Sp.z.o.o. facility located in Poland The Limit of Quantification (LOQ) required was 0.01mg/kg for Dithianon.

Summary of the trials

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treat-ments and last date (c)	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg): Dithianon	PHI (days) (d)	Details on trial (e)
FRS058/18-V1/ Germany / CEU / 2018	Winter wheat/ Barny	1) 18/10/2017 2) May/June 3) 05/06/2018	1032.5 1023.8 1023.8 1058.7	200 200 200 200	0.052 0.051 0.051 0.053	24/04/2018 02/05/2018 09/05/2018 15/05/2018	BBCH 30-31 BBCH 31 BBCH 37 BBCH 39	Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root)	31.3 22.0 19.8 11.7 10.4 10.9 3.55	0 1 3 5 7 14 21	Analytical phase report: DPL-85-2019 LOD = 0.003 mg/kg LOQ = 0.01 mg/kg Time between harvest and extraction: 396 d
FRS058/18-V2/ Germany / CEU / 2018	Winter wheat/ Ritmo	1) 17/10/2017 2) May/June 3) 05/06/2018	1084.7 1080.5 1032.2 1041.3	300 300 300 300	0.036 0.036 0.034 0.035	12/04/2018 19/04/2018 26/04/2018 03/05/2018	BBCH 25 BBCH 32 BBCH 32 BBCH 39	Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root) Cereals (whole plant without root)	32.8 21.8 19.3 15.1 14.4 13.3 4.73	0 1 3 5 7 14 21	Analytical phase report: DPL-85-2019 LOD = 0.003 mg/kg LOQ = 0.01 mg/kg Time between harvest and extraction: 396 d

(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

The half life calculations have been done using Cake v 3.4. Below the calculated DT_{50} and DT_{90} for the trials.

Trial	DT_{50} (d)	DT_{90} (d)	χ^2 (%)	MODEL
FRS058/18-V1	5.92	19.7	15.9	SFO
FRS058/18-V2				

The first order kinetic results are in the limit of the χ^2 and no reliable calculation has been obtained in the other models, since the statistics failed. In the next tables and figures are given the data and the summary of the graphics used for half life modelling. The modelling has been done without any improvement, using the data as such (Detailed Cake v3.4 reports will be sent separately).

Table 1: Data used for modelling

Time (d)	Dithianon residue (mg/kg)	
	FRS058/18-V1	FRS058/18-V2
0	31.3	32.8
1	22.0	21.8
3	19.8	19.3
5	11.7	15.1
7	10.4	14.4
14	10.9	13.3
21	3.55	4.73

Trial FRS058/18-V1

Estimated Values:

Parameter	Value	s	Prob. > t	Lower (90%) CI	Upper (90%) CI	Lower (95%) CI	Upper (95%) CI
Parent_0	27.62	2.773	N/A	22.04	33.21	20.5	34.75
k_Parent	0.1172	0.02938	0.005225	0.05797	0.1764	0.04164	0.193

Sum of Squared Residuals: 69.03

χ^2

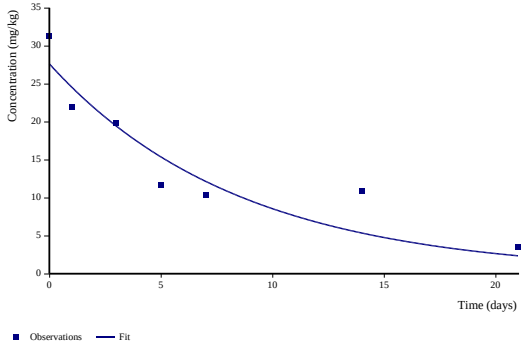
Parameter	Error %	Degrees of Freedom
All data	15.9	5
Parent	15.9	5

Decay Times:

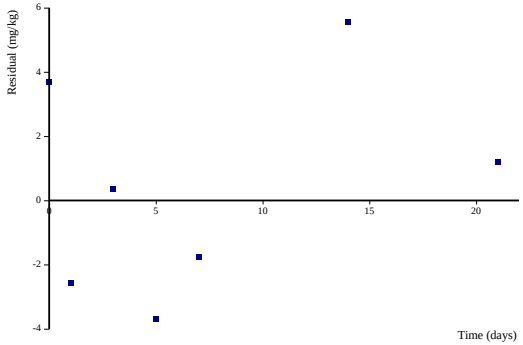
Compartment	DT50 (hours)	DT90 (hours)
Parent	5.92	19.7

Graphical Summary:

Observations and Fitted Model:



Residuals:



Trial FRS058/18-V2

Estimated Values:

Parameter	Value	s	Prob. > t	Lower (90%) CI	Upper (90%) CI	Lower (95%) CI	Upper (95%) CI
Parent_0	27.28	2.727	N/A	21.79	32.78	20.27	34.3
k_Parent	0.08297	0.02259	0.007195	0.03746	0.1285	0.02491	0.141

Sum of Squared Residuals: 77.21

χ^2

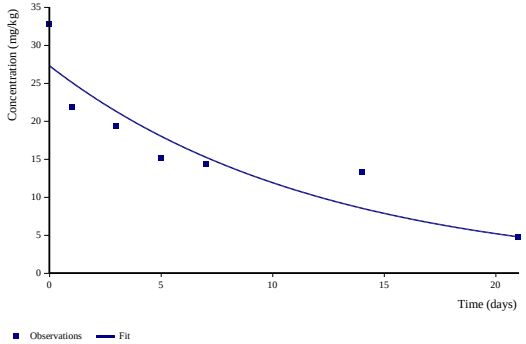
Parameter	Error %	Degrees of Freedom
All data	15.2	5
Parent	15.2	5

Decay Times:

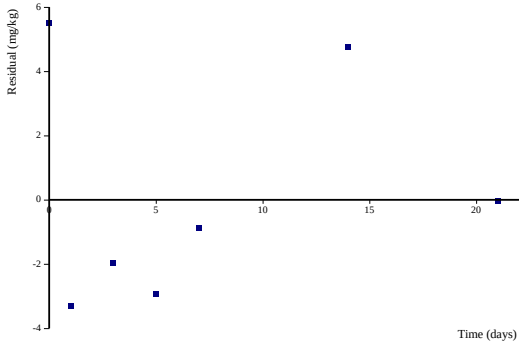
Compartment	DT50 (hours)	DT90 (hours)
Parent	8.35	27.8

Graphical Summary:

Observations and Fitted Model:



Residuals:



Results:

Trial	DT_{50} (d)	DT_{90} (d)	χ^2 (%)	MODEL
FRS058/18-V1	5.92	19.7	15.9	SFO
FRS058/18-V2	8.35	27.8	15.2	

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

A 2.2 KCP 10.2 Effects on aquatic organisms

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

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. - the mortality in the control was 0% at exposure termination (should not exceed 10% or 1 fish if less than 10 fish are used); - dissolved oxygen concentrations were within the range of 91 – 99% of air saturation value (obligatory above 60% of air saturation value). **Agreed endpoints:** The LC_{50}/96 h =0.0256 mg/L (nominal test item concentration). The LOEC/96 h =0.025 mg/L and the NOEC/96 h value is 0.013 mg/L (nominal test item concentration).

Reference:	KCP 10.2.1 - 01
Report	"Dimethomorph 15% + Dithianon 35% WG: Rainbow trout, Acute toxicity test". xxxxxx, 2019, W/82/18, xxxxxxxxxxx
Guideline(s):	Yes, OECD Guideline No. 203 (1992)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Yes

Materials and methods

Test item:

Description:	Dimethomorph 15% + Dithianon 35% WG
Production batch:	SCL – 78352
A.i. content:	dimethomorph 14.26% (w/w); dithianon 35.19% (w/w)

Test system:

Species:	Rainbow trout (*Oncorhynchus mykiss*)
Strain:	-
Age:	Approximately 5.5 months
Average weight:	1.05 g ± 0.15 g
Average length:	4.94 cm ± 0.39 cm
Source:	'The Culture of Salmonidae Fish in Zawoja', Poland.
Acclimation period:	12 days
Diet:	During the adaptation the fish were fed with standard granulated fish food in the amount of 2% of their aver-

age body weight per day (standard dry food, Aller Aqua, Denmark). Feeding of the fish was terminated 24 h before exposure initiation.

Experimental conditions:

Temperature:	13.6 – 14.2°C
Dissolved O_2:	95 – 99 % ASV
Hardness:	-
pH:	7.31 – 7.91
Light and photoperiod:	12h light and 12h dark.
Loading:	0.74 g/L (10 L, seven fish in each aquarium).
Test procedure:	Semi-static system with daily renewal (96 h of exposure), one replicate of each test item concentration and control.

Experimental period: 96h

Test design and treatment

Semi-static system (96 hours, renewal every 24 hours, one replicate of seven fish for each test item concentration and the control).
The following test item concentrations were used for exposure: 0.1, 0.05, 0.025, 0.013, 0.0063 mg/L plus control. The fish were observed for intoxication symptoms (loss of balance, nontypical swimming, respiratory problems and pigmentation changes) and for mortality after 3, 6, 24, 48, 72 and 96 h of exposure.
The concentrations of dimethomorph and dithianon were chemically analyzed with a validated liquid chromatographic method with DAD detection. At the first renewal, the analysed concentration of dithianon was below LoD in the test item concentrations of 0.0063 and 0.013 mg/L. At the second renewal, the analysed concentration of dithianon was below LoD in the test item concentrations of 0.0063 mg/L and analysed concentration of dithianon was below LoQ in the test item concentrations of 0.013, 0.025, 0.05 mg/L. At the third renewal, the analysed concentration of dithianon was below LoD in the test item concentrations of 0.0063 mg/L and analysed concentration of dithianon was below LoQ in the test item concentration of 0.0130 mg/L. At exposure termination, the analysed concentration of dithianon was below LoD in the test item concentration of 0.0063 mg/L and below LoQ in the test item concentrations of 0.0130, 0.025 mg/L.
Therefore, the concentrations of dimethomorph were stable during 24 h under test conditions and the concentrations of dithianon were not stable during 24 h under test conditions.
The endpoint values were determined based on the nominal test item concentrations, nominal concentrations of dimethomorph, nominal concentrations of dithianon, geometric means of determined concentrations of dithianon.

Results

Table 4. Recovery and precision for dithianon in the fortified samples (n = 5)

Nominal concentration [mg/L]	Determined concentration of dithianon in replicates [mg/L]					Average [mg/L]	Recovery [%]	SD [mg/L]	RSD [%]
	1	2	3	4	5				
control	0.000000	0.000000	--	--	--	0.000000	--	0.000	--
0.001	0.00093	0.00100	0.00091	0.00099	0.00092	0.00095	94.9	0.00004	4.2
1.000	0.8360	0.9768	0.8321	0.9767	0.8353	0.8914	89.1	0.0779	8.7

LoQ = 0.001 mg/L
LoD = 0.0003 mg/L
SD – standard deviation
RSD – relative standard deviation

Table 20. Concentration and stability of dimethomorph – definitive test

Nominal test item concentration [mg/L]	Control	0.0063	0.013	0.025	0.05	0.1	Day of sampling
Nominal concentration of dimethomorph [mg/L]	---	0.000898	0.00185	0.00357	0.00713	0.0143	
Average determined concentration (n=3) of dimethomorph [mg/L]	<LoD	<LoD	<LoQ	<LoQ	0.00643	0.0121	day 0 fresh
% of nominal concentration	---	---	---	---	90.1	85.0	
Average determined concentration (n=3) of dimethomorph [mg/L]	<LoD	<LoD	<LoQ	<LoQ	0.00611	0.0134	day 1 old
% of nominal concentration	---	---	---	---	85.7	94.0	
Average determined concentration (n=3) of dimethomorph [mg/L]	<LoD	<LoD	<LoQ	<LoQ	0.00625	0.0123	day 1 fresh
% of nominal concentration	---	---	---	---	87.7	86.2	
Average determined concentration (n=3) of dimethomorph [mg/L]	<LoD	<LoD	<LoQ	<LoQ	0.00588	0.0133	day 2 old
% of nominal concentration	---	---	---	---	82.5	93.1	
Average determined concentration (n=3) of dimethomorph [mg/L]	<LoD	<LoD	<LoQ	<LoQ	0.00646	---	day 2 fresh
% of nominal concentration	---	---	---	---	90.7	---	
Average determined concentration (n=3) of dimethomorph [mg/L]	<LoD	<LoD	<LoQ	<LoQ	0.00698	---	day 3 old
% of nominal concentration	---	---	---	---	97.9	---	

Table 20 - continuation. Concentration and stability of dimethomorph – definitive test

Nominal test item concentration [mg/L]	Control	0.0063	0.013	0.025	0.05	0.1	Day of sampling
Nominal concentration of dimethomorph [mg/L]	---	0.000898	0.00185	0.00357	0.00713	0.0143	
Average determined concentration (n=3) of dimethomorph [mg/L]	<LoD	<LoD	<LoQ	<LoQ	---	---	day 3 fresh
% of nominal concentration	---	---	---	---	---	---	
Average determined concentration (n=3) of dimethomorph [mg/L]	<LoD	<LoD	<LoQ	<LoQ	---	---	day 4 old
% of nominal concentration	---	---	---	---	---	---	

LoQ = 0.005 mg/L
LoD = 0.001 mg/L
(---) no value/not calculated

Table 21. Concentration and stability of dithianon – definitive test

Nominal test item concentration [mg/L]	Control	0.0063	0.013	0.025	0.05	0.1	Day of sampling
Nominal concentration of dithianon [mg/L]	---	0.00222	0.00457	0.0088	0.0176	0.0352	
Geometric mean of determined concentration of dithianon * [mg/L]	---	0.0008	0.0014	0.0027	0.0045	0.0088	
Average determined concentration (n=3) of dithianon [mg/L]	<LoD	0.00195	0.00481	0.00959	0.0148	0.0307	day 0 fresh
% of nominal concentration	---	88.1	105.2	109.0	83.0	87.1	
Average determined concentration (n=3) of dithianon [mg/L]	<LoD	<LoD	<LoD	0.00136	0.00223	0.00390	day 1 old
% of nominal concentration	---	---	---	15.4	12.6	11.1	
Average determined concentration (n=3) of dithianon [mg/L]	<LoD	0.00181	0.00386	0.00818	0.0153	0.0285	day 1 fresh
% of nominal concentration	---	81.7	84.3	93.0	86.8	81.1	
Average determined concentration (n=3) of dithianon [mg/L]	<LoD	<LoD	<LoQ	<LoQ	<LoQ	0.0016	day 2 old
% of nominal concentration	---	---	---	---	---	4.5	
Average determined concentration (n=3) of dithianon [mg/L]	<LoD	0.00230	0.00413	0.00864	0.0143	---	day 2 fresh
% of nominal concentration	---	103.8	90.3	98.2	81.3	---	
Average determined concentration (n=3) of dithianon [mg/L]	<LoD	<LoD	<LoQ	0.00116	0.00176	---	day 3 old
% of nominal concentration	---	---	---	13.2	10.0	---	

Table 21 – continuation. Concentration and stability of dithianon – definitive test

Nominal test item concentration [mg/L]	Control	0.0063	0.013	0.025	0.05	0.1	
Nominal concentration of dithianon [mg/L]	---	0.00222	0.00457	0.0088	0.0176	0.0352	Day of sampling
Geometric mean of determined concentration of dithianon * [mg/L]	---	0.0008	0.0014	0.0027	0.0045	0.0088	
Average determined concentration (n=3) of dithianon [mg/L]	<LoD	0.00193	0.00432	0.00878	---	---	day 3 fresh
% of nominal concentration	---	87.2	94.5	99.8	---	---	
Average determined concentration (n=3) of dithianon [mg/L]	<LoD	<LoD	<LoQ	<LoQ	---	---	day 4 old
% of nominal concentration	---	---	---	---	---	---	

LoQ = 0.001 mg/L
LoD = 0.0003 mg/L
(---) no value/not calculated
*Geometric mean was calculated according to the formula given in Annex 2 – Formula for calculating geometric mean exposure concentration [13]

In the control and in the test item concentrations of 0.0063 and 0.013 mg/L neither mortality of fish nor symptoms of intoxication were observed during exposure (i.e. after 3, 6, 24, 48, 72 and 96 h of exposure).
In the test item concentration of 0.025 mg/L, nontypical swimming and respiratory problems for one fish was observed after 24 h of exposure. After 48 h of exposure, nontypical swimming and respiratory problems for three fish were observed. After 72 h of exposure, nontypical swimming for three fish and respiratory problems for all fish were observed. After 96 h of exposure, three fish were dead, loss of balance for one fish, nontypical swimming for two fish and respiratory problems for four fish were observed.
In the test item concentration of 0.05 mg/L, respiratory problems for two fish, was observed after 24 h of exposure. After 48 h of exposure, four fish were dead, loss of balance for one fish, nontypical swimming and respiratory problems for three fish were observed. After 72 h of exposure all fish were dead.
In the test item concentration of 0.1 mg/L, respiratory problems for all fish were observed after 3 and 6 h of exposure. After 24 h of exposure, five fish were dead, loss of balance, nontypical swimming and respiratory problems for two fish were observed. After 48 h of exposure, all fish were dead.

The endpoint values determined on the basis of the nominal test item concentrations and mortality of fish are given below:

The LC50/96 h values is 0.0256 mg/L.
The LOEC/96 h value is 0.025 mg/L.
The NOEC/96 h value is 0.013 mg/L.

The endpoint values determined on the basis of the nominal concentrations of dimethomorph and mortality of fish:

The LC50/96 h value is 0.00367 mg/L.
The LOEC/96 h value is 0.00357 mg/L.
The NOEC/96 h value is 0.00185 mg/L.

The endpoint values determined on the basis of the nominal concentrations of dithianon and mortality of fish:

The LC50/96 h value is 0.00903 mg/L.
The LOEC/96 h value is 0.0088 mg/L.
The NOEC/96 h value is 0.00457 mg/L.

The endpoint values determined on the basis of geometric means of determined concentrations of dithianon and mortality of fish:

The LC50/96 h value is 0.0028 mg/L.
The LOEC/96 h value is 0.0027 mg/L.
The NOEC/96 h value is 0.0014 mg/L.

Conclusion
The LC_{50}/96 h value is 0.0256 mg/L (nominal test item concentration).

The LOEC/96 h value is 0.025 mg/L and the NOEC/96 h value is 0.013 mg/L (nominal test item concentration).

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • The immobilization of *Daphnia magna* in the control was 0% (criterion: not more than 10%). • The dissolved oxygen concentrations in the test vessels were within the range of 8.3 – 8.9 mg/L (criterion: not less than 3 mg/L). **Agreed endpoints:** EC_{50}/48 h =0.649 mg/L (95% confidence interval 0.486 – 0.866). The EC_{20}/48 h =0.256 mg/L (95% confidence interval 0.175 – 0.374). The EC_{10}/48 h =0.157 mg/L (95% confidence interval 0.098 – 0.251).

Reference:	KCP 10.2.1-02
Report	"Dimethomorph 15% + Dithianon 35% WG. *Daphnia magna*, Acute Immobilisation Test", Tina Turek (2018), Report No. W/84/18. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	OECD Guideline No. 202 (2004)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

Immobilisation of Daphnia magna exposed to the test item Dimethomorph 15% + Dithianon 35% WG was investigated during a 48-hours semi-static test with a renewal after 24 h of exposure. The test was performed in glass beakers of 150 mL capacity, containing 100 mL of either the test item concentration or the control per replicate. The following test item concentrations were used: 20, 10, 5.0, 2.5, 1.25, 0.63, 0.31, 0.16, 0.078 mg/L plus the control. Four replicates per treatment and the control with five daphnids per replicate were used. The *Daphnia magna* were observed for immobilization after 24 and 48 hours of exposure.

The concentration of Dimethomorph & Dithianon was chemically determined using a validated chromatographic method.

In spent samples, the determined concentrations of dimethomorph were in the range of 79.0 – 97.9% of the nominal concentration and the determined concentrations of dithianon were in the range of 9.9 – 107.0% of the nominal concentration. Therefore, the concentrations of dimethomorph and dithianon were not stable under test conditions.

Results

Preliminary test
In the preliminary test, the test item concentrations of 100, 10, 1.0 and 0.1 mg/L and the control (0.0 mg/L) were used.
After 24 and 48 hours of the exposure, in the test item concentrations of 0.1, 1.0, 10 and 100 mg/L, the immobilisation of Daphnia magna was 5, 75, 90 and 100%, respectively.

Definitive test
In the definitive test *Daphnia magna* was exposed to the test item concentration of 20, 10, 5.0, 2.5, 1.25, 0.63, 0.31, 0.16, 0.078 mg/L plus the control for 48 hours in a semi-static system. The results are summarized in the table below.

Table 10.2.1-01.1 Immobilization of *Daphnia magna*, definitive test

Nominal test item concentration [mg/L]	Number of *Daphnia magna*	Number of immobilized *Daphnia magna*								Total of immobilized *Daphnia magna* [%]	
		24 h				48 h					
		Replicates									
		A	B	C	D	A	B	C	D	24 h	48 h
Control (0.0)	20	0	0	0	0	0	0	0	0	0	0
0.078	20	0	0	0	0	1	0	0	0	0	5
0.16	20	0	0	1	0	0	0	1	0	5	5
0.31	20	1	0	1	2	1	0	2	2	20	25
0.63	20	1	2	1	1	2	3	2	3	25	50
1.25	20	0	3	1	2	3	5	4	4	30	80
2.5	20	3	1	3	1	5	3	5	4	40	85
5.0	20	3	2	2	2	5	5	5	4	45	95
10	20	3	3	3	1	5	5	5	5	50	100
20	20	4	4	3	3	5	5	5	5	70	100

Validity criteria

In the definitive test, the following validity criteria specified in the OECD Guideline No. 202 (2004) were met:

- The immobilization of *Daphnia magna* in the control was 0% (criterion: not more than 10%).
- The dissolved oxygen concentrations in the test vessels were within the range of 8.3 – 8.9 mg/L (criterion: not less than 3 mg/L).

Conclusion

The endpoint values determined based on nominal test item concentration:
The median concentration causing 50% immobilisation of Daphnia magna after 24 h of exposure, i.e. the EC_{50}/24 h value is 5.906 mg/L (95% confidence interval 3.071 – 11.360). The EC_{20}/24 h value is 0.651 mg/L (95% confidence interval 0.335 – 1.263). The EC_{10}/24 h value is 0.205 mg/L (95% confidence interval 0.080 – 0.525).

The median concentration causing 50% immobilisation of Daphnia magna after 48 h of exposure, i.e. the EC_{50}/48 h value is 0.649 mg/L (95% confidence interval 0.486 – 0.866). The EC_{20}/48 h value is 0.256 mg/L (95% confidence interval 0.175 – 0.374). The EC_{10}/48 h value is 0.157 mg/L (95% confidence interval 0.098 – 0.251).

The data on immobilisation of the Daphnia magna at exposure termination were analyzed using Step-down Cochran-Armitage Test Procedure, which showed a significant difference between the nominal test

item concentrations in the range of 0.31 – 20 mg/L and the control. Therefore, the LOEC/48 h value is 0.31 mg/L and the NOEC/48 h value 0.16 mg/L.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • the biomass in the control increased by a factor of 209.1 within the 72-hour test period (criterion: at least a 16-fold growth). • The coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 1.5% (criterion: it must not exceed 7%). • The mean coefficient of variation for the section-by-section growth rate in the control culture was 18.6% (criterion: it must not exceed 35%). **Agreed endpoints:** The endpoint values based on the nominal test item concentrations: ErC_{50}/72 h value is 0.717 mg/L (95% confidence interval: 0.660 – 0.783). EyC50/72 h value is 0.149 mg/L (95% confidence interval:0.120 – 0.185). LOEC/72 h value for growth rate and yield is lower than or equal to 0.012 mg/L. NOEC/72 h value for growth rate and yield is lower than 0.012 mg/L. The endpoint values based on the nominal concentrations of dimethomorph: ErC50/72 h value is 0.1022 mg/L (95% confidence interval: 0.0941 – 0.1117). EyC50/72 h value is 0.0212 mg/L (95% confidence interval: 0.0171 – 0.0264). LOEC/72 h value for growth rate and yield is lower than or equal to 0.0017 mg/L. NOEC/72 h value for growth rate and yield is lower than 0.0017 mg/L. The endpoint values based on the nominal concentrations of dithianon: ErC50/72 h value is 0.2522 mg/L (95% confidence interval:0.2322 – 0.2757). EyC50/72 h value is 0.0523 mg/L (95% confidence interval: 0.0421 – 0.0651) LOEC/72 h value for growth rate and yield is lower than or equal to 0.0042 mg/L. NOEC/72 h value for growth rate and yield is lower than 0.0042 mg/L. The endpoint values based on geometric means of determined concentrations of dimethomorph: ErC50/72 h value is 0.0869 mg/L (95% confidence interval:0.0800 – 0.0949). EyC50/72 h value is 0.0166 mg/L (95% confidence interval: 0.0131 – 0.0210). LOEC/72 h value for growth rate and yield is lower than or equal to 0.0025 mg/L. NOEC/72 h value for growth rate and yield is lower than 0.0025 mg/L. The endpoint values based on geometric means of determined concentrations of dithianon: ErC50/72 h = 0.08896 mg/L (95% confidence interval:0.07629 – 0.10509). EyC50/72 h value =0.00651 mg/L (95% confidence interval: 0.00479 – 0.00907). LOEC/72 h value for growth rate and yield is lower than or equal to 0.00054mg/L. NOEC/72 h value for growth rate and yield is lower than 0.00054 mg/L.

Reference:	KCP 10.2.1-03
Report	"Dimethomorph 15% + Dithianon 35% WG. *Pseudokirchneriella subcapitata* SAG 61.81 Growth Inhibition Test", Tina Turek (2018), Report No. W/83/18. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	OECD Guideline No. 201 (2006)
Deviations:	No.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

The growth of the green algae *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*) exposed to the test item, Dimethomorph 15% + Dithianon 35% WG, was investigated during a 72-hour test. The test was performed in glass flasks with a capacity of 250 mL containing 100 mL of either the test item concentration or the control per replicate. The initial density of the algae was 1 x 104 cells/mL. The following test item concentrations were used: 1.0, 0.33, 0.11, 0.037, 0.012 mg/L plus the control. For exposure, three replicates were used for each test item concentration, whereas six replicates for control. Three replicates were used for each test item concentration, whereas six replicates were used for control.

The concentrations of dimethomorph and dithianon were determined using a validated liquid chromate graphic method. Samples of each test item concentration and the control collected at exposure initiation, after 24, 48 and 72 h of exposure were chemically analysed.

At exposure initiation, in the test item concentrations of 0.012 and 0.037 mg/L, the analysed concentrations of dimethomorph were below LoQ. In the test item concentrations in the range of 0.11 –1.0 mg/L, the determined concentrations of dimethomorph were in the range of 87.1 – 94.4% of the nominal concentration. In the all test item concentrations, the eternined concentrations of dithianon were in the range of 85.5 – 101.8% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly.

After 24 h of exposure, in the test item concentrations of 0.012 and 0.037 mg/L, the analysed concentrations of dimethomorph were below LoQ. In the test item concentrations in the range of 0.11 – 1.0 mg/L, the determined concentrations of dimethomorph were in the range of 82.7 – 99.8% of the nominal concentration. In the test item concentrations of 0.012 and 0.037 mg/L, the analysed concentrations of dithianon were below LoQ. In the test item concentrations in the range of 0.11 – 1.0 mg/L, the determined concentrations of dithianon were in the range of 31.8 – 49.4% of the nominal concentration.

After 48 h of exposure, in the test item concentrations of 0.012 and 0.037 mg/L, the analysed concentrations of dimethomorph were below LoQ. In the test item concentrations in the range of 0.11 – 1.0 mg/L, the determined concentrations of dimethomorph were in the range of 79.2 – 85.6% of the nominal concentration. In the test item concentration of 0.012 mg/L, the analysed concentration of dithianon was below LoD and in the test item concentration of 0.037 mg/L, the analysed concentration of dithianon was below LoQ. In the test item concentrations in the range of 0.11 – 1.0 mg/L, the determined concentrations of dithianon were in the range of 2.8 – 45.9% of the nominal concentration At exposure termination, in the test item concentrations of 0.012 and 0.037 mg/L, the analysed concentrations of dimethomorph were below LoQ. In the test item concentrations in the range of 0.11 – 1.0 mg/L, the determined concentrations of dimethomorph were in the range of 78.6 – 81.2% of the nominal concentration. In the test item concentrations of 0.012 and 0.037 mg/L, the analysed concentrations of dithianon were below LoD and in the

test item concentration of 0.11 mg/L, the analysed concentration of dithianon was below LoQ. In the test item concentrations of 0.33 and 1.0 mg/L, the determined concentrations of dithianon were 1.8 and 21.1% of the nominal concentration, respectively.

Since the concentrations of dimethomorph and dithianon were below 80% of the nominal concentration, it can be concluded that the concentrations of dimethomorph and dithianon were not stable under test conditions.

The endpoint values were determined based on the nominal test item concentrations, nominal concentrations of dimethomorph and dithianon, geometric means of determined concentrations of dimethomorph and geometric means of determined concentrations of dithianon.

Results

Preliminary test (non–GLP)
The test was performed using five test item concentrations:100, 10, 1.0, 0.1, and 0.01 mg/L plus the control. The inhibition of growth rate and yield estimated in comparison to the control after 72 hours of exposure are given in the table below.

Table 10.2.1-02.1 Growth rate and yield inhibition, first preliminary test (non-GLP)

Nominal test item concentration [mg/L]	% inhibition after 72 h of exposure (growth rate)	% inhibition after 72 h of exposure (yield)
Control	0.00	0.00
0.01	-0.29*	-0.68*
0.1	9.30	38.25
1	78.73	98.56
10	88.67	99.33
100	110.49*	100.30**

*calculated inhibition values are lower than 0%, what means that the algal cell density at exposure termination is higher than the algal cell density in the control.
**calculated inhibition values are higher than 100%, what means that the algal cell density at observation during exposure is lower than the algal cell density at exposure initiation.

Definitive test
In the definitive test, the algae, *Pseudokirchneriella subcapitata*, with an initial cell density of 1 x 10^4 cells/mL were exposed to the test item concentrations: 1.0, 0.33, 0.11, 0.037, 0.012 mg/L plus the control. The results are summarized in the table below.

Table 10.2.1-02.2 Inhibition of growth rate and yield, definitive test

Nominal test item concentration [mg/L]	% inhibition after 72 h of exposure (growth rate)	% inhibition after 72 h of exposure (yield)
Control	0.00	0.00
0.012	4.8	21.8
0.037	5.0	22.4
0.11	6.1	27.9
0.33	24.6	73.1
1.0	61.6	96.7

Validity criteria

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

- the biomass in the control increased by a factor of 209.1 within the 72-hour test period (criterion: at least a 16-fold growth).
- The coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 1.5% (criterion: it must not exceed 7%).

- The mean coefficient of variation for the section-by-section growth rate in the control culture was 18.6% (criterion: it must not exceed 35%).

Conclusion

The endpoint values were determined on the basis of the nominal test item concentrations, nominal concentrations of dimethomorph and dithianon, geometric means of determined concentrations of dimethomorph and geometric means of determined concentrations of dithianon [1, 8]. The E_rC_x and the E_yC_x values were calculated with the probit method. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were determined on the basis of the results of statistical analyses.

The endpoint values determined based on the nominal test item concentrations:
The concentration causing a 50% inhibition of the average specific growth rate of *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*), i.e. the E_rC_{50}/72 h value is 0.717 mg/L (95% confidence interval: 0.660 – 0.783). The E_rC_{20}/72 h value is 0.265 mg/L (95% confidence interval: 0.230 – 0.297). The ErC10/72 h value is 0.157 mg/L (95% confidence interval: 0.129 – 0.185).

Statistical tests based on the growth rate data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure which showed significant difference between all nominal test item concentrations and the control.

The lowest test item concentration causing an effect on growth rate inhibition LOEC/72 h value is lower than or equal to 0.012 mg/L. The highest test item concentration not causing any effect on growth rate inhibition NOEC/72 h value is lower than 0.012 mg/L.

The concentration causing a 50% inhibition of yield of *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*), i.e. the E_yC_{50}/72 h value is 0.149 mg/L (95% confidence interval: 0.120 – 0.185 The E_yC_{20}/72 h value is 0.039 mg/L (95% confidence interval: 0.026 – 0.052). The E_yC_{10}/72 h value is 0.019 mg/L (95% confidence interval 0.011 – 0.029).

Statistical tests based on the yield data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure which showed significant difference between all nominal test item concentrations and the control.
The lowest test item concentration causing an effect on yield inhibition LOEC/72 h value is lower than or equal to 0.012 mg/L. The highest test item concentration not causing any effect on yield inhibition NOEC/72 h value is lower than 0.012 mg/L.

The endpoint values determined based on the nominal concentrations of dimethomorph:
The concentration causing a 50% inhibition of the average specific growth rate of *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*), i.e. the E_rC_{50}/72 h value is 0.1022 mg/L (95% confidence interval: 0.0941 – 0.1117). The E_rC_{20}/72 h value is 0.0378 mg/L (95% confidence interval: 0.0329 – 0.0424). The E_rC_{10}/72 h value is 0.0225 mg/L (95% confidence interval: 0.0184 – 0.0264).

Statistical tests based on the growth rate data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure which showed significant difference between all nominal concentrations of dimethomorph and the control. The lowest concentration of dimethomorph causing an effect on growth rate inhibition LOEC/72 h value is lower than or equal to 0.0017 mg/L. The highest concentration of dimethomorph not causing any effect on growth rate inhibition NOEC/72 h value is lower than 0.0017 mg/L.

The concentration causing a 50% inhibition of yield of *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*), i.e. the E_yC_{50}/72 h value is 0.0212 mg/L (95% confidence interval: 0.0171 –

0.0264). The E_yC_{20}/72 h value is 0.0056 mg/L (95% confidence interval: 0.0037 – 0.0075). The EyC10/72 h value is 0.0028 mg/L (95% confidence interval 0.0016 – 0.0041).

Statistical tests based on the yield data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure which showed significant difference between all nominal concentrations of dimethomorph and the control. The lowest concentration of dimethomorph causing an effect on yield inhibition LOEC/72 h value is lower than or equal to 0.0017 mg/L. The highest concentration of dimethomorph not causing any effect on yield inhibition NOEC/72 h value is lower 0.0017 mg/L.

The endpoint values determined based on the nominal concentrations of dithianon:
The concentration causing a 50% inhibition of the average specific growth rate of *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*), i.e. the ErC50/72 h value is 0.2522 mg/L (95% confidence interval: 0.2322 – 0.2757). The ErC20/72 h value is 0.0931 mg/L (95% confidence interval: 0.0810 – 0.1045). The ErC10/72 h value is 0.0553 mg/L (95% confidence interval: 0.0452 – 0.0650).

Statistical tests based on the growth rate data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure which showed significant difference between all nominal concentrations of dithianon and the control.

The lowest concentration of dithianon causing an effect on growth rate inhibition LOEC/72 h value is lower than or equal to 0.0042 mg/L. The highest concentration of dithianon not causing any effect on growth rate inhibition NOEC/72 h value is lower than 0.0042 mg/L.

The concentration causing a 50% inhibition of yield of *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*), i.e. the E_yC_{50}/72 h value is 0.0523 mg/L (95% confidence interval: 0.0421 – 0.0651). The E_yC_{20}/72 h value is 0.0137 mg/L (95% confidence interval: 0.0091 – 0.0184). The E_yC_{10}/72 h value is 0.0068 mg/L (95% confidence interval 0.0039 – 0.0100).

Statistical tests based on the yield data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure which showed significant difference between all nominal concentrations of dithianon and the control.
The lowest concentration of dithianon causing an effect on yield inhibition LOEC/72 h value is lower than or equal to 0.0042 mg/L. The highest concentration of dithianon not causing any effect on yield inhibition NOEC/72 h value is lower 0.0042 mg/L.

The endpoint values determined based on geometric means of determined concentrations of dimethomorph:
The concentration causing a 50% inhibition of the average specific growth rate of *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*), i.e. the E_rC_{50}/72 h value is 0.0869 mg/L (95% confidence interval: 0.0800 – 0.0949). The E_rC_{20}/72 h value is 0.0325 mg/L (95% confidence interval: 0.0283 – 0.0364). The E_rC_{10}/72 h value is 0.0194 mg/L (95% confidence interval: 0.0159 – 0.0228).

Statistical tests based on the growth rate data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure which showed significant difference between all geometric means of determined concentrations of dimethomorph and the control. The lowest geometric mean of determined concentration of dimethomorph causing an effect on growth rate inhibition LOEC/72 h value is lower than or equal to 0.0025 mg/L. The highest geometric mean of determined concentration of dimethomorph not causing any effect on growth rate inhibition NOEC/72 h value is lower than 0.0025 mg/L.

The concentration causing a 50% inhibition of yield of *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*), i.e. the E_yC_{50}/72 h value is 0.0166 mg/L (95% confidence interval: 0.0131 – 0.0210). The E_yC_{20}/72 h value is 0.0037 mg/L (95% confidence interval: 0.0025 – 0.0051). The E_yC_{10}/72 h value is lower than 0.0025 mg/L.

Statistical tests based on the yield data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure which showed significant difference between geometric means of determined concentrations of dimethomorph and the control. The lowest geometric mean of determined concentration of dimethomorph causing an effect on yield inhibition LOEC/72 h value is lower than or equal to 0.0025 mg/L. The highest geometric mean of determined concentration of dimethomorph not causing any effect on yield inhibition NOEC/72 h value is lower than 0.0025 mg/L.

<u>The endpoint values determined based on geometric means of determined concentrations of dithianon:</u>
The concentration causing a 50% inhibition of the average specific growth rate of *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*), i.e. the E_rC_{50}/72 h value is 0.08896 mg/L (95% confidence interval: 0.07629 – 0.10509). The E_rC_{20}/72 h value is 0.01390 mg/L (95% confidence interval: 0.01101 – 0.01694). The E_rC_{10}/72 h value is 0.00527 mg/L (95% confidence interval: 0.00377 – 0.00693).

Statistical tests based on the growth rate data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure which showed significant difference between all geometric means of determined concentrations of dithianon and the control. The lowest geometric mean of determined concentration of dithianon causing an effect on growth rate inhibition LOEC/72 h value is lower than or equal to 0.00054 mg/L.

The highest geometric mean of determined concentration of dithianon not causing any effect on growth rate inhibition NOEC/72 h value is lower than 0.00054 mg/L.

The concentration causing a 50% inhibition of yield of Raphidocelis subcapitata (formerly *Pseudokirchneriella subcapitata*), i.e. the E_yC_{50}/72 h value is 0.00651 mg/L (95% confidence interval: 0.00479 – 0.00907). The E_yC_{20}/72 h value is 0.00092 mg/L (95% confidence interval: 0.00055 – 0.00136). The E_yC_{10}/72 h value is lower than 0.00054 mg/L.

Statistical tests based on the yield data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure which showed significant difference between geometric means of determined concentrations of dithianon and the control. The lowest geometric mean of determined concentration of dithianon causing an effect on yield inhibition LOEC/72 h value is lower than or equal to 0.00054 mg/L. The highest geometric mean of determined concentration of dithianon not causing any effect on yield inhibition NOEC/72 h value is lower than 0.00054 mg/L.

Comments of zRMS:

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

- The doubling time of frond number in the control was 2.1 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 10.4).
- The average specific growth rate in the control between day 0 and day 7 was 0.334 d-1 (minimumrequirement: higher than 0.275 d-1)

Agreed endpoints:

The endpoint values based on the nominal test item concentrations [mg/l]				
	Yield inhibition based on the frond number	**Growth rate inhibition based on the frond number**	**Yield inhibition based on the dry weight**	**Growth rate inhibition based on the dry weight**

	EyC_{50}/7d/ ErC_{50}/7d	4.03 (3.54 – 4.58)	81.24 (64.83 – 104.35)	3.65 (3.23 – 4.13)	42.76 (36.06 – 51.21)
	EyC_{20}/7d/ ErC_{20}/7d	0.18 (0.14 – 0.22)	1.37 (0.98 – 1.82)	0.26 (0.20 – 0.31)	2.20 (1.67 – 2.80)
	EyC_{10}/7d/ ErC_{10}/7d	n.d.	0.16 (0.10 – 0.25)	<0.14 calc. 0.06 (0.05 – 0.08)	0.47 (0.31 – 0.66)
	LOEC/7d	≤ 0.14	0.41	≤ 0.14	0.41
	NOEC/7d	< 0.14	200.0 0.14	< 0.14	0.14
	The endpoint values based on the nominal concentrations of dimethomorph [mg/L]				
		Yield inhibition based on the frond number	**Growth rate inhibition based on the frond number**	**Yield inhibition based on the dry weight**	**Growth rate inhibition based on the dry weight**
	EyC_{50}/7d/ ErC_{50}/7d	0.5750 (0.5049 – 0.6539)	11.5843 (9.2446 – 14.8795)	0.5211 (0.4606 – 0.5889)	6.0972 (5.1423 – 7.3029)
	EyC_{20}/7d/ ErC_{20}/7d	0.0250 (0.0194 – 0.0315)	0.1948 (0.1400 – 0.2596)	0.0366 (0.0292 – 0.0449)	0.3139 (0.2382 – 0.3996)
	EyC_{10}/7d/ ErC_{10}/7d	n.d.	0.0230 (0.0137 – 0.0357)	<0.0200 calc. 0.0091 (0.0067 – 0.0120)	0.0666 (0.0446 – 0.0939)
	LOEC/7d	≤ 0.0200	0.0585	≤ 0.0200	0.0585
	NOEC/7d	< 0.0200	0.0200	< 0.0200	0.0200
	The endpoint values based on the nominal concentrations of dithianon [mg/L]				
		Yield inhibition based on the frond number	**Growth rate inhibition based on the frond number**	**Yield inhibition based on the dry weight**	**Growth rate inhibition based on the dry weight**
	EyC_{50}/7d/ ErC_{50}/7d	1.4183 (1.2454 – 1.6130)	28.5844 (22.8107 – 36.7160)	1.2855 (1.1362 – 1.4528)	15.0451 (12.6887 – 18.0205)
	EyC_{20}/7d/ ErC_{20}/7d	0.0617 (0.0479 – 0.0776)	0.4805 (0.3452 – 0.6403)	0.0902 (0.0719 – 0.1106)	0.7744 (0.5877 – 0.9859)
	EyC_{10}/7d/ ErC_{10}/7d	n.d.	0.0568 (0.0339 – 0.0879)	<0.0493 calc. 0.0225 (0.0165 – 0.0296)	0.1642 (0.1100 – 0.2316)
	LOEC/7d	≤ 0.0493	0.1440	≤ 0.0493	0.1440
	NOEC/7d	< 0.0493	0.0493	< 0.0493	0.0493

Reference: KCP 10.2.1 - 04

Report: "Dimethomorph 15% + Dithianon 35% WG: *Lemna gibba* CPCC 310, Growth inhibition test.". Tina Turek, 2019, W/85/18, Institute of Industrial Organic Chemistry Branch Pszczyna

Guideline(s): OECD Guideline No. 221 (2006)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item:

Description: Dimethomorph 15% + Dithianon 35% WG

	Batch number:	SCL- 78352
	A.i. content:	dimethomorph 14.26% (w/w); dithianon is 35.19% (w/w)
Test system:		
	Species:	*Lemna gibba*
	Strain:	CPCC 310
	Age:	-
	Source:	A standard laboratory culture at the Institute of Industrial Organic Chemistry Branch Pszczyna
	Medium:	20X AAP medium
Experimental conditions:		
	Temperature:	23.8 – 24.0ºC
	pH values:	7.46 – 8.99
	Mean light intensity:	6095 – 6147 lux, constant illumination
	Test vessels:	250 mL capacity glass beakers covered with glass petri dishes
	Initial frond number:	9
Experimental period:	7 d	

Test design: The definitive test was performed using the following test item concentrations: 300, 100, 33, 11, 3.7, 1.23, 0.41, 0.14 mg/L plus the control (with a separation factor of 3.0) in semi-static test design with daily renewals. The exposure was for 7 days.
The concentration the concentrations of dimethomorph and dithianon were determined using a validated liquid chromatographic method with DAD detection.

The number of fronds in each test vessel was counted at the start of the test, twice during exposure and at exposure termination. The dry weight of the plants was determined after exposure termination.
In fresh samples, the determined concentrations of dimethomorph were in the range of 81.1 – 115.9% of nominal concentration and the determined concentrations of dithianon were in the range of 88.5 – 115.8% of nominal concentration.
In spent samples, the determined concentrations of dimethomorph were in the range of 82.3 – 115.5% of nominal concentration and the determined concentrations of dithianon were in the range of 0.5 – 91.9% of nominal concentration. At the fifth renewal, the analysed concentration of dithianon was below LoD in the test item concentration of 0.14 mg/L. At exposure termination, the analysed concentration of dithianon was below LoD in the test item concentration of 0.14 mg/L and below LoQ in the test item concentration of 0.41 mg/L.
Therefore, the concentrations of dimethomorph were stable under test conditions between renewals and the concentrations of dithianon were not stable under test conditions between renewals.
The endpoint values were determined based on the nominal test item concentrations, the nominal concentrations of dimethomorph and dithianon, and geometric means of determined concentrations of dithianon.

Statistics: ToxRat Professional commercial software

Results: Results are summarized in the table below:

The endpoint values based on the nominal test item concentrations [mg/l]

	Yield inhibition based on the frond number	Growth rate inhibition based on the frond number	Yield inhibition based on the dry weight	Growth rate inhibition based on the dry weight
EyC_{50}/7d/ ErC_{50}/7d	4.03 (3.54 – 4.58)	81.24 (64.83 – 104.35)	3.65 (3.23 – 4.13)	42.76 (36.06 – 51.21)
EyC_{20}/7d/ ErC_{20}/7d	0.18 (0.14 – 0.22)	1.37 (0.98 – 1.82)	0.26 (0.20 – 0.31)	2.20 (1.67 – 2.80)
EyC_{10}/7d/ ErC_{10}/7d	n.d.	0.16 (0.10 – 0.25)	<0.14 calc. 0.06 (0.05 – 0.08)	0.47 (0.31 – 0.66)
LOEC/7d	≤ 0.14	0.41	≤ 0.14	0.41
NOEC/7d	< 0.14	200.0 0.14	< 0.14	0.14
The endpoint values based on the nominal concentrations of dimethomorph [mg/L]				
	Yield inhibition based on the frond number	**Growth rate inhibition based on the frond number**	**Yield inhibition based on the dry weight**	**Growth rate inhibition based on the dry weight**
EyC_{50}/7d/ ErC_{50}/7d	0.5750 (0.5049 – 0.6539)	11.5843 (9.2446 – 14.8795)	0.5211 (0.4606 – 0.5889)	6.0972 (5.1423 – 7.3029)
EyC_{20}/7d/ ErC_{20}/7d	0.0250 (0.0194 – 0.0315)	0.1948 (0.1400 – 0.2596)	0.0366 (0.0292 – 0.0449)	0.3139 (0.2382 – 0.3996)
EyC_{10}/7d/ ErC_{10}/7d	n.d.	0.0230 (0.0137 – 0.0357)	<0.0200 calc. 0.0091 (0.0067 – 0.0120)	0.0666 (0.0446 – 0.0939)
LOEC/7d	≤ 0.0200	0.0585	≤ 0.0200	0.0585
NOEC/7d	< 0.0200	0.0200	< 0.0200	0.0200
The endpoint values based on the nominal concentrations of dithianon [mg/L]				
	Yield inhibition based on the frond number	**Growth rate inhibition based on the frond number**	**Yield inhibition based on the dry weight**	**Growth rate inhibition based on the dry weight**
EyC_{50}/7d/ ErC_{50}/7d	1.4183 (1.2454 – 1.6130)	28.5844 (22.8107 – 36.7160)	1.2855 (1.1362 – 1.4528)	15.0451 (12.6887 – 18.0205)
EyC_{20}/7d/ ErC_{20}/7d	0.0617 (0.0479 – 0.0776)	0.4805 (0.3452 – 0.6403)	0.0902 (0.0719 – 0.1106)	0.7744 (0.5877 – 0.9859)
EyC_{10}/7d/ ErC_{10}/7d	n.d.	0.0568 (0.0339 – 0.0879)	<0.0493 calc. 0.0225 (0.0165 – 0.0296)	0.1642 (0.1100 – 0.2316)
LOEC/7d	≤ 0.0493	0.1440	≤ 0.0493	0.1440
NOEC/7d	< 0.0493	0.0493	< 0.0493	0.0493

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

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • The average mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%). • The 24-hour LD_{50} of the reference item (dimethoate) was 0.10 µg/bee (criterion: 0.10 - 0.35 µg a.i./bee). **Agreed endpoint:** **48h LD_{50} > 400 µg/bee**

Reference:	KCP 10.3.1.1.1
Report	"Dimethomorph 15% + Dithianon 35% WG. Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test". Natalia Lemańska, 2018, Study code B/45/17. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 213 (1998) and the EU Method C.16. (2008)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

The acute oral toxicity study of Dimethomorph 15% + Dithianon 35% WG described in this Report was conducted to determine the LD50 values for honeybees. Five doses of the test item were used.

These included: 25, 50, 100, 200 and 400 µg Dimethomorph 15% + Dithianon 35% WG/honeybee.

The range of the doses was selected on the basis of the preliminary test results. Each group of 10 bees (3 replicates containing 10 bees each) was fed with 100 µL of a 50% sucrose solution, containing the test item at the doses mentioned above, using a micropipette. During the entire experiment, the insects were caged in groups of 10.

The general condition of the test honeybees and the reliability of the tests conducted on them were controlled using the recommended reference item – dimethoate (Danadim 400 EC). After the administration, the insects were observed for mortality and other signs of toxicity. These observations were made 4 hours after the beginning of the treatment and then every 24 hours after the beginning of the treatment. The acute oral toxicity test ended after the 48-hour exposure.

Results

Table 10.3.1.1.1.1: Acute oral toxicity on honeybees (*Apis mellifera L.*)

Dose			**N° of tested bees**	**Mortality after 48 h**		**LD_{50} after 48 h**	
				Total			
Test item [µg /bee]	**Active ingredients [µg /bee]**			**[no.]**	**[%]**	**Test item [µg/bee]**	**Active ingredients [µg/bee]**
	a	**b**					
0.0 (Control)			30	0	0.0	above 400	above

25.0	3.57	8.80	30	0	0.0		(57.04_a + 140.76_b)
50.0	7.13	17.60	30	0	0.0		
100.0	14.26	35.19	30	0	10.0		
200.0	28.52	70.38	30	0	0.0		
400.0	57.04	140.76	30	5	16.7		

a: Dimethomorph
b: Dithianon

Results and conclusions

- Mortality of the bees in the control group at all time points (24 and 48 h) was 0.0%. After 24 hours of exposure to the test item at the dose of 25, 50, 100, 200 and 400 µg/bee mortality of the bees was 0.0, 0.0, 10.0, 0.0, 10.0. After 48 hours of exposure to the test item at the dose of 25, 50, 100, 200 and 400 µg/bee mortality of the bees was 0.0, 0.0, 10.0, 0.0, 16.7.
- The median lethal doses (LD50 oral) after 24 and 48 hours of exposure are above the highest used dose, i.e. 400 µg t.i./honeybee.
- No sublethal toxicity effects (behavioural abnormalities) such as excitement (uncoordinated movement, increased activity, intensive cleaning) or any signs of paralysis with respect to the test item and the control were observed over the 48 hours exposure.

Validity criteria

The following validity criteria were met during the test:

- The average mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%).
- The 24-hour LD_{50} of the reference item (dimethoate) was 0.10 µg/bee (criterion: 0.10 - 0.35 µg a.i./bee).

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • The average mortality for the total number of controls was 3.3% after 48 h (criterion: it must not exceed 10%). • The 24-hour LD_{50} of the reference item (dimethoate) was 0.25 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee). **Agreed endpoint:** **48h LD_{50} > 400 µg/bee**

Reference:	KCP 10.3.1.1.2
Report	Dimethomorph 15% + Dithianon 35% WG; Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test, Natalia Lemańska, 2018, Study code B/46/17. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	OECD Guideline No. 214 (1998) and EU Method C.17 (2008)
Deviations:	No.
GLP:	Yes
Acceptability:	Yes

Duplication (if vertebrate study) Not relevant

Materials and methods

The acute contact toxicity study of Dimethomorph 15% + Dithianon 35% WG (batch No. SCL-78352) was conducted to determine the effects on honeybees. Five doses of test item (25.0, 50.0, 100.0, 200.0 and 400.0 µg/honeybee) were selected on the basis of the preliminary tests results and a control were used.

A microapplicator was used to apply the test item. The volume was 1 µL/bee. During the experiment, the insects were caged in groups of 10.

The recommended reference item, i.e. dimethoate (Dnadim 400 EC) was used to verify the sensitivity of the honeybees and the precision of the test procedure.

After the application, the insects were observed for mortality and other signs of toxicity. These observations were made 4, 24 and 48 hours after the beginning of the treatment. The acute contact toxicity test finished after the 46 hours observation.

Results

Table 10.3.1.1.2.1: Acute contact toxicity on honeybees (*Apis mellifera* L.)

Dose			**Number of tested bees [no.]**	**Mortality after 48 h**			**LD_{50} after 48 h**	
				Total		**Corrected (Abbott)**		
Test item [µg / bee]	**Active ingredients** [µg/bee]			**[no.]**	**[%]**	**[%]**	**Test item** [µg / bee]	**Active ingredients** [µg/bee]
	a	**b**						
0.0 (control)			30	1	3.3	-	**above 400**	above ($57.04^a + 140.76^b$)
25	3.57	8.80	30	0	0.0	**-3.5**		
50	7.13	17.60	30	0	0.0	**-3.5**		
100	14.26	35.19	30	3	0.0	**-3.5**		
200	28.52	70.38	30	1	3.3	**0.0**		
400	57.04	140.76	30	3	10.0	**6.9**		

a: Dimethomorph
b: Dithianon

Findings

- Mortality of the control group after 24 and 48 hours of exposure was 3.3%
- Corrected mortality of the treated groups 25, 50.0, 100, 200 and 400 µg/honeybee after 24 hours of exposure were (-3.5), (-3.5), (-3.5), (-3.5), (-3.5) %, respectively.
- No abnormal behavioural effects were observed during the test.

Validity criteria

The following validity criteria were met during the test:

- The average mortality for the total number of controls was 3.3% after 48 h (criterion: it must not

exceed 10%).
- The 24-hour LD_{50} of the reference item (dimethoate) was 0.25 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee).

Conclusion

The median lethal doses (LD50/24 h and LD50/48 h contact) are higher than the highest dose used in the test, i.e. 400.0 µg/honeybee [> (57.04 µg dimethomorph + 140.76 µg dithianon/honeybee)].

With respect to the test results, it can be concluded that the test item, Dimethomorph 15% + Dithianon 35% WG had no adverse effect on mortality of honeybees (*Apis mellifera* L.).

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

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

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.3.2 KCP 10.3.2 Effects on arthropods other than bees

A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

No new study submitted.

A 2.3.2.2 KCP 10.3.2.2. Extended laboratory testing, aged residue studies with non-target arthropods

Comments of zRMS: The study is considered acceptable. All validity criteria were met.
- Mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%).
- Corrected mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 97.5% on day 7 of exposure (criterion: from 50 to 100%)
- The mean number of eggs per female in the control group was 4.4 (required: ≥ 4 eggs per female).
-

Agreed endpoints

Mortality and reproduction of *T. pyri* in the laboratory test

Study group [application rate]	Parameter (endpoint)				
	Mortality		Reproduction		
Test item	Total	LR_{50}	Mean number	Reproduction	ER_{50}

	[kg/ha]	[%]		of eggs/ female (Rr) [no.]	reduction Pr [%]	
	Control (0.0)	0.0	-	4.4	-	-
	Dimethomorph 15% + Dithianon 35% WG					
	0.54	1.2	n.d.	3.3+	23.4	> 8.60 [kg/ha] > (1226.4[a] + 3026.3[b]) [g/ha]
	1.08	2.5		3.2+	25.9	
	2.15	1.2		2.5+	41.8	
	4.30	1.2		2.6+	40.1	
	8.60	10.0+		2.7+	39.1	
	$NOER_{mortality}$		4.30 [kg/ha] (613.2[a]+1513.2[b]) [g/ha]	**$NOER_{reproduction}$**		< 0.54 [kg/ha] < (77.0[a] + 190.0[b]) [g/ha]
	[a]: dimethomorph [b]: dithianon n.d.: the value could not be determined due to mathematical reasons, it may be assumed that it is higher than the highest rate used in the study (> 8.60 kg of (Dimethomorph 15% + Dithianon 35% WG)/ha) +: statistically significant differences					

Reference:	KCP 10.3.2.2-01
Report	"An extended laboratory test for evaluating the effects of Dimethomorph 15% + Dithianon 35% WG on the predatory mite, *Typhlodromus pyri* (Sch.)". Natalia Lemańska, 2019, B/48/17. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and ESCORT 2 (Candolfi M.P. et al., 2001) documents as well as the guidelines developed by the Joint Initiative of IOBC, BART, EPPO (Blümel S. et al., 2000)
Deviations:	Yes. During the experiment the deviation regarding the temperature had occurred. Nevertheless, since it did not affect on morality of the control group it can be assumed that it had no adverse effect on the obtained results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

The aim of the extended laboratory test was to evaluate the effects of the test item, Dimethomorph 15% + Dithianon 35% WG on mortality and reproduction of the predatory mite, *T. pyri* (Sch.).

The mites, *T. pyri* at the protonymphal stage (24 hours old) were exposed to the test item applied to leaf discs. The mites were fed with pine pollen (*Pinus sp.*). Mortality observations were made after 7 days of the treatment. Observations of the control group reproduction and all groups treated with the test item were made after 8, 11, and 14 days of the treatment.

It was decided to use five rates of the test item in the definitive test. These were 0.54, 1.08, 2.15, 4.30 and 8.60 kg/ha. To verify the sensitivity of the mites and the precision of the test procedure, an insecticide, Bi 58 Top 400 EC (400 g dimethoate/L) was used as a reference item. The rate of the reference item was 9.0 mL/ha (3.6 g a.i./ha). The control group was treated with distilled water.

Each treatment group included 3 replicates containing 20 larvae of *T.pyri*. Mortality of *T. pyri* after 7 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment were test endpoints.

Results

Mortality and reproduction of *T. pyri* in the laboratory test

Study group [application rate]	Parameter (endpoint)				
	Mortality		Reproduction		
Test item [kg/ha]	Total [%]	LR_{50}	Mean number of eggs/ female (Rr) [no.]	Reproduction reduction Pr [%]	ER_{50}
Control (0.0)	0.0	-	4.4	-	-
Dimethomorph 15% + Dithianon 35% WG					
0.54	1.2	n.d.	3.3^{+}	23.4	> 8.60 [kg/ha] > (1226.4[a] + 3026.3[b]) [g/ha]
1.08	2.5		3.2^{+}	25.9	
2.15	1.2		2.5^{+}	41.8	
4.30	1.2		2.6^{+}	40.1	
8.60	10.0^{+}		2.7^{+}	39.1	
$NOER_{mortality}$		4.30 [kg/ha] (613.2[a]+1513.2[b]) [g/ha]	$NOER_{reproduction}$		< 0.54 [kg/ha] < (77.0[a] + 190.0[b]) [g/ha]
Reference item [mL/ha]	Bi 58 Top 400 EC				
9.0	97.5	-	-		

[a]: dimethomorph
[b]: dithianon
n.d.: the value could not be determined due to mathematical reasons, it may be assumed that it is higher than the highest rate used in the study (> 8.60 kg of (Dimethomorph 15% + Dithianon 35% WG)/ha)
[+]: statistically significant differences

Findings

- Mortality of the control group after 7 days of exposure was 0.0%. After 7 days of exposure to Dimethomorph 15% + Dithianon 35% WG at rates of 0.54, 1.08, 2.15, 4.30 and 8.60 kg/ha, the percentages of *T. pyri*, mortality were 1.2, 2.5, 1.2, 1.2 and 10.0%, respectively.
- On the basis of the obtained results the endpoints regarding mortality could not be fully determined. It can be assumed that the LR_{50} value is higher than 8.60 kg of Dimethomorph 15% + Dithianon 35% WG/ha. The $NOER_{mortality}$ value is equal to 4.3 kg of Dimethomorph 15% + Dithianon 35% WG/ha.
- On the basis of the obtained results it can be assumed that the ER_{50} value is higher than 8.60 kg/ha, whereas the $NOER_{reproduction}$ value is lower than 0.54 kg/ha.
- There were statistically significant differences in mortality between group treated with the test item at rates 8.60 kg/ha and the control group (Chi2 2x2 Table Test with Bonferroni Correction, p> 0.1).
- The mean reproduction rate (Rr) in the control group was 4.4 eggs/female. The mean Rr after 14 days of exposure to Dimethomorph 15% + Dithianon 35% WG at rates 0.54, 1.08, 2.15, 4.30 and 8.60 kg/ha were 3.3, 3.2, 2.5, 2.6 and 2.7 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by at the rates of 0.54, 1.08, 2.15, 4.30 and 8.60 kg/ha were 23.4, 25.9, 41.8, 40.1 and 39.1%, respectively. At the significance level of $\alpha \leq 0.1$, there were revealed statistically significant differences in reproduction between the group treated with the test item at all rates and the control group (Wiliams Multiple Sequential t-test Procedure, $|t|>|t^*|$).

Validity criteria

The following validity criteria were met during the study:

- Mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%).
- Corrected mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 97.5% on day 7 of exposure (criterion: from 50 to 100%)
- The mean number of eggs per female in the control group was 4.4 (required: ≥ 4 eggs per female).

Conclusion

Based on the results it can be stated that Dimethomorph 15% + Dithianon 35% WG has no significant adverse effect on mortality of *T. pyri* mites, except the rate of 8.60 kg/ha. However, all tested rates of Dimethomorph 15% + Dithianon 35% WG/ha have a significant effect on the tested organisms' reproduction.

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

- Mortality of the control group was 0.0% after 48 hours of exposure (criterion: a maximum of 10%)
- Mortality of the wasps exposed to the reference item at the rate of 5.0 mL/ha was 70.0% after 48 hours. (criterion: minimum 50%).
- All wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),
- The mean number of mummies per female in the control group was 13.5 (criterion: a minimum of 5.0 mummies/female),
- All wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).

Agreed endpoints:

Mortality and reproduction of *T. pyri* in the laboratory test

Study group [application rate]	Parameter (endpoint)						
	Mortality			Fecundity			
Test item [kg/ha]	Total [%]	LR_{50}		Mean no. of mummies/female	Fecundity reduction Pr [%]	ER_{50}	
		[kg/ha]	[kg a.i./ha]			[kg/ha]	[kg a.i./ha]
Control (0.0)	**0.0**	-		**13.5**	-	-	
Dimethomorph 15% + Dithianon 35% WP							
4.3	**0.0**	**> 17.2**	> (2.5^a+6.1^b)	**18.4**	**(-36.0.)**$^-$	**10.6 (9.4-11.9)***	1.5^a+3.7^b (1.3^a+3.6^b - 1.7^a+4.2^b)
8.6	**13.3**			**5.7**$^+$	**57.6**		
17.2	**6.7**			**5.9**$^+$	**56.2**		
$NOER_{mortality}$		**> 17.2**	> (2.5^a+6.1^b)	**$NOER_{fecundity}$**		**4.3**	> (0.6^a+1.5^b)

a: dimethomorph
b: dithianon
+: statistically significant difference
-: The negative value means that in the tested rate there was higher number of mummies than in the control group
*: ER value with 95% confidence limits

Reference:	KCP 10.3.2.2-02
Report	"An extended laboratory test for evaluating the effects of Dimethomorph 15% + Dithianon 35% WG on the parasitic wasp, *Aphidius rhopalosiphi*". Stefani-Perez (2017), B/47/17. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	The study was performed according to the ESCORT 1 and the ESCORT 2 guidance documents, the guidelines developed by the IOBC, BART, and EPPO Joint Initiative, and the Standard Operating Procedure SOP/B/28.
Deviations:	No.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

The aim of the study was to determine the effect of Dimethomorph 15% + Dithianon 35% WG on mortality and fecundity of the parasitic wasp, *Aphidius rhopalosiphi*. The endpoints of this test were mortality of the wasps after 48 hours of exposure and fecundity reduction (Pr) 12 days after the oviposition phase.

Adult female wasps were exposed to the test item applied to barley plants. Observations of settling behaviour were made during the initial 3 hours of exposure. The aims were to determine repellent effects of Dimethomorph 15% + Dithianon 35% WG and to check if the test insects had contact with barley plants sprayed with the test item. Settling behaviour of females from each replicate was observed five times. Mortality was determined 2, 24, and 48 hours after the introduction of the wasps to the test arenas.
Females which survived the 48-hour exposure to Dimethomorph 15% + Dithianon 35% WG and the ones from the control group were subjected to fecundity assessments. Fifteen female wasps from each group treated with Dimethomorph 15% + Dithianon 35% WG and the control were individually introduced into the fecundity units containing barley plants infested with the aphid, *Rhopalosiphum padi*. After the 24-hour oviposition, the wasps were removed from the test arenas. After 12 days, the number of mummies (parasitized aphids in which wasp pupae were developing) was recorded.

On the basis of the results of the preliminary test, it was decided to use three rates of the test item in the definitive test. These were 4.3, 8.6 and 17.2 kg/ha. To verify the sensitivity of the biological test system and the precision of the test procedure, Bi 58 Top 400 EC (400 g dimethoate/L), which is an insecticide, was used as a reference item. The rate of the reference item was 5.0 mL/ha (2.0 g dimethoate/ha). The control group was treated with distilled water.

Each treatment group for mortality assessment included 6 replicates containing 5 females of *Aphidius rhopalosiphi*. Each treatment group for reproduction assessment included 15 replicates containing 1 female of *Aphidius rhopalosiphi*. Wasp mortality after 48 hours of the treatment and the reduction in fecundity (Pr) after 12 days of the treatment were test endpoints.

Results

Mortality and reproduction of *T. pyri* in the laboratory test

Study group [application rate]	Parameter (endpoint)						
	Mortality			Fecundity			
Test item [kg/ha]	Total [%]	LR_{50}		Mean no. of mummies/female	Fecundity reduction Pr [%]	ER_{50}	
		[kg/ha]	[kg a.i./ha]			[kg/ha]	[kg a.i./ha]

Control (0.0)	**0.0**	-		**13.5**	-	-	
Dimethomorph 15% + Dithianon 35% WP							
4.3	**0.0**	**> 17.2**	> (2.5^a+6.1^b)	**18.4**	**(-36.0.)**$^-$	**10.6 (9.4-11.9)***	1.5^a+3.7^b (1.3^a+3.6^b -1.7^a+4.2^b)
8.6	**13.3**			**5.7**$^+$	**57.6**		
17.2	**6.7**			**5.9**$^+$	**56.2**		
$NOER_{mortality}$		**> 17.2**	> (2.5^a+6.1^b)	**$NOER_{fecundity}$**		**4.3**	> (0.6^a+1.5^b)
***Reference item* [mL/ha]**	***Bi 58 Nowy 400 EC***						
5.0	**70.0**	-	-				

a: dimethomorph
b: dithianon
+: statistically significant difference
-: The negative value means that in the tested rate there was higher number of mummies than in the control group
*: ER value with 95% confidence limits

Findings

- In the definitive test, after 48 hours of exposure, there were no dead wasps in the control group. In the groups treated with Dimethomorph 15% + Dithianon 35% WG at the rates 4.3, 8.6, and 17.2 kg/ha morality was equal to 0.0, 13.3 and 6.7%, respectively.
- On the basis of the obtained mortality results, the LR_{50} and $NOER_{mortality}$ values are higher than the maximum application rate of Dimethomorph 15% + Dithianon 35% WG, i.e. > 17.2 kg/ha.
- On the basis of the obtained results, the ER_{50} and the $NOER_{fecundity}$ were estimated. The ER_{50} value obtained on the basis of the result is equal to 10.6 kg/ha and $NOER_{fecundity}$ could value is equal to 4.3 kg/ha.
- After 7 days of exposure to Danadim 400 EC at the rate of 5.0 mL/ha, mortality of the wasps, was 70.0%. The relation between Danadim 400 EC and wasp mortality showed that the insects were sensitive to dimethoate.
- At the significance level 0.05, statistically significant differences in fecundity between the wasps exposed to the test item at rates 8.6, and 17.2 kg/ha and the control group were stated (the multiple Sequential-rejective Welsh t-test after bonferroni-Holm, p> 0.1).
- The results of Shapiro-Wilk's test ($p > 0.05$) confirmed normal data distribution in the group treated with the test item at all tested rates. Levene's test ($p < 0.05$) confirmed variances homogenity in all the study groups. At the significance level of 0.05, there were statistically significant differences in the mean percentages of wasps settled on the plants between the treated groups at all rates and the reference item in comparison to the control group (Duncan test, $p < 0.05$). On the basis of the obtained results, it can be concluded that the test item at all rates and reference item at rate of 5 mL/ha had a repellent effect on the wasps.

Validity criteria

The following validity criteria were met during the study:

- Mortality of the control group was 0.0% after 48 hours of exposure (criterion: a maximum of 10%).
- Mortality of the wasps exposed to the reference item at the rate of 5.0 mL/ha was 70.0% after 48 hours. (criterion: minimum 50%).
- All wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),
- The mean number of mummies per female in the control group was 13.5 (criterion: a minimum of 5.0 mummies/female),
- All wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).

Conclusion
Based on the test results, it can be concluded that Dimethomorph 15% + Dithianon 35% WG has no negative effects on the wasps' mortality. However, rates 8.6 and 17.2 kg of t.i/ha have an adverse impact on fecundity of *Aphidius rhopalosiphi*.

A 2.3.2.3 KCP 10.3.2.3. Semi-field studies with non-target arthropods

Not required.

A 2.3.2.4 KCP 10.3.2.4. Field studies with non-target arthropods

Not required.

A 2.3.2.5 KCP 10.3.2.5. Other routes of exposure for non-target arthropods

Not required.

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

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

- each replicate produced 120.1 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 24.2% (criterion: ≤ 30%),
- adult mortality over the initial 4 weeks of the experiment was 2.5% (criterion: ≤ 10%).

Agreed endpoints:

EC_{10}, EC_{20}, EC_{50}, LC_{50}, NOEC and LOEC values

Endpoint	Value [mg test item /kg dry weight of the artificial soil]	Value [mg NAA/kg dry weight of the artificial soil]
EC_{10}	**226.6** (150.4 – 292.4)	**32.3 + 79.7** (21.4 + 52.9 – 41.7 + 102.9)
EC_{20}	**461.1** (374.0 – 547.1)	**65.8 + 162.3** (53.3 + 131.6 – 78.0 – 192.5)
EC_{50}	**> 1000**	**> 142.6 + 351.9**
NOEC (reproduction)	**18.0**	**45.6 + 112.6**
LOEC (reproduction)	**560**	**79.9 + 197.1**
LC_{50}	**> 1000**	**> 142.6 + 351.9**
NOEC (survival)	**≥ 1000**	**≥ 142.6 + 351.9**
LOEC (survival)	**> 1000**	**> 142.6 + 351.9**

Reference:	KCP 10.4.1.1
Report	"Dimethomorph 15% + Dithianon 35% WG Earthworm Reproduction Test (*Eisenia andrei*)". Weronica Dec., 2015, G/81/18. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	OECD Guideline No. 222 (2004), Standard Operating Procedure SOP/G/36
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Dimethomorph 15% + Dithianon 35% WG; Batch Number SCL- 78352; active substance: Dimethomorph 14.26%, Dithianon 35.19% (w/w)
Test species:	*Eisenia andrei* obtained from a standard laboratory culture cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Soil Toxicology.
Soil:	5% sphagnum peat, 20% kaolin clay, 75% air-dried quartz sand
Study design:	Number of replicates: 4 replicates / concentration + 8 replicates / control Number of earthworms: 10 earthworms/replicate Test duration: 8 weeks
Application rates:	Control, 10, 18, 32, 56, 100, 180, 320, 560, and 1000 mg/kg dry weight of the artificial soil
Test conditions:	Temperature: 18.5 – 22.0℃; humidity: 18.4 – 21.8%; lighting: 16 h light : 8 h dark; light intensity: 540 – 595 lux; pH: 5.50 – 6.00
Statistical analysis:	EC_{50}, EC_{20}, EC_{10}, LC_{50} – Probit analysis using linear max. likelihood regression NOEC reproduction – Shapiro-Wilk's Test on Normal Distribution, Bartlett's test Procedure on Variance Homogeneity, Williams Multiple Sequential t-test Procedure NOEC survival – Fisher's Exact Binomial Test with Bonferroni Correction LOEC - a value suggested by the ToxRat Professional 2.10 statistical computer software
Endpoints:	LC_{50}, EC_{50}, EC_{20}, EC_{10}, NOEC, LOEC

Results and Conclusions

On the basis of the results, it was concluded that after 4 weeks, at the control group there was mortality of adult earthworm noticed and it was equal to 2.5%. At concentrations ranging from 10 to 1000 mg of the test item/kg dry weight of artificial soil, after 4 weeks of exposure to the test item, mortality of the adult earthworms was ranging from 0.0 to 5.0%.
The concentration of the test item causing 50% mortality of the adult earthworms (LC50) is higher than 1000 mg/kg dry weight of artificial soil (142.6 mg dimethomorph/kg dry weight of the artificial soil + 351.9 mg dithianon/kg dry weight of the artificial soil).

No changes in the appearance (morphology) and behavior of the earthworms were noticed.

After the application of the test item at the concentrations ranging from 10 to 560 mg/kg dry weight of artificial soil, the body weight increase was between 4.0 to 16.7%. As for the control group, it was equal to 5.0%. At the concentration equal to 1000 mg/kg dry weight of artificial soil, the body weight decrease was observed, and it was equal to 1.6%
After 8 weeks of the experiment, the obtained results led to the following conclusions:

After the application of the test item at the concentrations ranging from 10 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 76.3 – 136.8 per replicate. The mean number of juveniles in the control group was equal to 120.1 per replicate.
After 8 weeks of the experiment, it was concluded that Dimethomorph 15% + Dithianon 35% WG had statistically significant impact on reproduction of the earthworms at the concentrations: 560 and 1000 mg/kg dry weight of artificial soil.

The endpoint values showing the impact of the test item on reproduction and survival of adult earthworms are presented in the table given below.

EC_{10}, EC_{20}, EC_{50}, LC_{50}, NOEC and LOEC values

Endpoint	Value [mg test item /kg dry weight of the artificial soil]	Value [mg NAA/kg dry weight of the artificial soil]
EC_{10}	**226.6** (150.4 – 292.4)	**32.3 + 79.7** (21.4 + 52.9 – 41.7 + 102.9)
EC_{20}	**461.1** (374.0 – 547.1)	**65.8 + 162.3** (53.3 + 131.6 – 78.0 – 192.5)
EC_{50}	**> 1000**	**> 142.6 + 351.9**
NOEC (reproduction)	**18.0**	**45.6 + 112.6**
LOEC (reproduction)	**560**	**79.9 + 197.1**
LC_{50}	**> 1000**	**> 142.6 + 351.9**
NOEC (survival)	**≥ 1000**	**≥ 142.6 + 351.9**
LOEC (survival)	**> 1000**	**> 142.6 + 351.9**

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

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

A 2.4.2.1 KCP 10.4.2.1 Species level testing

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

- mean adult mortality: 7.5% (criterion: ≤ 20%),
- the mean number of juveniles per vessel at the end of the test: 726.9 (criterion: ≥ 100 juveniles at the end of the test),
- the coefficient of variation calculated for the number of juveniles: 15.8% (criterion: ≤ 30%).

Agreed endpoints:

End-point	Value [mg test item /kg dry weight of the artificial soil]	Value [mg NAA/kg dry weight of the artificial soil]
EC_{10}	**460.8** (197.7 – 597.5)	**65.7 + 162.2** (28.2 + 69.6 – 85.2 + 210.3)
EC_{20}	**621.4** (382.7 – 742.6)	**88.6 + 218.7** (54.6 + 134.7 – 105.9 + 261.3)
EC_{50}	**> 1000** (884.9 – >1000)	**> 142.6 + 351.9** (126.2 + 311.4 – 142.6 + 351.9)
NOEC	**320**	**45.6 + 112.6**
LOEC	**560**	**79.9 + 197.1**

Reference:	KCP 10.4.2.1 - 01
Report	"Dimethomorph 15% + Dithianon 35% WG: Collembolan (*Folsomia candida*) reproduction test". Weronica Dec., 2018, G/80/18. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	OECD Guideline No. 232 (2016)
Deviations:	Yes. At the end of the test the soil moisture content was determined by drying small sample of the artificial soil in 105°C instead of weighing the test vessels as it is mentioned in OECD Guideline No. 232 (2016) (chapter 3.6.6.). Physiological or pathological symptoms or distinct changes in behaviour were not described (chapter 3.6.7.).
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Dimethomorph 15% + Dithianon 35% WG; Batch Number SCL- 78352; active substance: Dimethomorph 14.26%, Dithianon 35.19% (w/w)
Test species:	*Folsomia candida* obtained from a standard laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Laboratory of Soil Toxicology. The collembolans used in the study were 9 – 12 days old.
Soil:	5% sphagnum peat, 20% kaolin clay, and 75% air-dried industrial sand
Study design:	Number of replicates: 4 replicates / concentration + 8 replicates / control Number of collembolans: 10 / replicate Test duration: 28 days
Application rates:	Control, 5.6, 10, 18, 32, 56, 100, 180, 320, 560, and 1000 mg of the test item/kg of dry weight of the artificial soil
Test conditions:	Temperature: 18.0 – 22.0℃; humidity: 12.5 – 14.0%; lighting: 16 h light : 8 h dark; light intensity: 515 – 568 lux; pH: 6.26 – 6.42
Statistical analysis:	EC_{10}, EC_{20}, and EC_{50} – a logit analysis LC_{10}, LC_{20}, and LC_{50} - a logit analysis NOEC (number of juveniles): - Shapiro-Wilk's Test on Normal Distribution, - Bartlett's Test Procedure on Variance Homogeneity, - Williams Multiple Sequential t-test Procedure, NOEC (survival): - Shapiro-Wilk's Test on Normal Distribution, - Bartlett's Test Procedure on Variance Homogeneity, - STUDENT-t test for Homogenous Variances with Bonferroni-Holm Adjustment LOEC – a value suggested by the program
Endpoints:	EC_{10}, EC_{20}, EC_{50}, NOEC, LOEC LC_{10}, LC_{20}, LC_{50}, NOEC, LOEC

Results and Conclusions

Mortality at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of the artificial soil ranged from 0.0 to 35.0%. As for the control group, it was equal to 7.5%.
The concentration of the test item causing a 50% mortality of adults within the exposure period (LC_{50}) is above 1000 mg/kg dry weight of the artificial soil (142.6 mg dimethomorph/kg dry weight of the artificial soil + 351.9 mg dithianon/kg dry weight of the artificial soil).

The endpoint values showing the impact of the test item on the survival of adult collembolans are presented in the table given below.

LC_{10}, LC_{20}, LC_{50}, NOEC and LOEC values

Endpoint	Value [mg test item /kg dry weight of the artificial soil]	Value [mg NAA/kg dry weight of the artificial soil]
LC_{10}	512.2	73.0 + 180.2
LC_{20}	> 1000	> 142.6 + 351.9
LC_{50}	> 1000	> 142.6 + 351.9
NOEC	560	79.9 + 197.1
LOEC	1000	142.6 + 351.9

After the exposure of collembolans to the test item at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 384.3 – 763.3 per replicate. As for the control group, the number of juveniles was equal to 726.9 per replicate.
The endpoint values showing the impact of the test item on reproduction of *Folsomia candida* are presented in the table given below.

EC_{10}, EC_{20}, EC_{50}, NOEC and LOEC values

Endpoint	Value [mg test item /kg dry weight of the artificial soil]	Value [mg NAA/kg dry weight of the artificial soil]
EC_{10}	**460.8** (197.7 – 597.5)	**65.7 + 162.2** (28.2 + 69.6 – 85.2 + 210.3)
EC_{20}	**621.4** (382.7 – 742.6)	**88.6 + 218.7** (54.6 + 134.7 – 105.9 + 261.3)
EC_{50}	**> 1000** (884.9 – >1000)	**> 142.6 + 351.9** (126.2 + 311.4 – 142.6 + 351.9)
NOEC	**320**	**45.6 + 112.6**
LOEC	**560**	**79.9 + 197.1**

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

A 2.5.1 KCP 10.5.1 Effects on soil nitrogen transformation

Comments of zRMS:	The study is considered acceptable. All validity criteria were met • The coefficients of variation (CV) in the control group were 7.0, 4.8, 3.3 and 5.1%, after 0, 7, 14, and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%. **Agreed endpoints**: On the basis of the results, it was concluded that Dimethomorph 15% + Dithianon 35% WG at the concentration corresponding to the PEC: 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil) and upper PEC: 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil), did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils

Reference: KCP 10.5.1

Report "Dimethomorph 15% + Dithianon 35% WG. Soil Microorganisms: Nitrogen Transformation Test" Weronika Dec, 2018, G/78/18. Institute of Industrial

	Organic Chemistry Branch Pszczyna.
Guideline(s):	OECD Guideline No. 216 (2000) / EU Method C.21.
Deviations:	Yes. The second tested concentration should be called upper PEC instead of 5 x PEC. According the Guideline, the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm for 24 hours. The modification resulted from the optimization of the nitrate extraction which showed that the extraction was more effective when the shaking rate was lower and the extraction lasted longer. The predicted environmental concentration (PEC) was calculated assuming 1 cm of the soil depth according to the German conditions for the substances with the mobility in soil KFoc > 500 mL/g. Thus, the applied soil depth is a deviation from OECD Guideline No. 216 (2000), the EU Method C.21, and SOP/G/32. These deviations did not affect the results of the study.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Test item:	
Description:	Dimethomorph 15% + Dithianon 35% WG
Production batch:	SCL- 78352
Active ingredients content:	Dimethomorph – 14.26% (w/w) Dithianon – 35.19% (w/w)
Test system:	
Species:	Microorganisms
Source:	Agricultural soil collected from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.
Experimental conditions:	
Temperature:	18 – 21°C
Humidity:	48.8% – 55% MWHC
Air changes:	-
Light and photoperiod:	Dark (24/24h)

Study design and methods

Test design and treatment:	Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500 g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. Test duration: 28 days Concentrations of the test material: ontrol, PEC: 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil), upper PEC: 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil).

Results

After 0, 7 and 28 days of incubation, There were no statistically significant differences between the control and the group treated with test item at both concentrations. i.e. PEC: 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil) and upper PEC: 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil) in nitrate concentration after 0, 7, 14 and 28 days of incubation. There were no statistically significant differences between the control and the group treated with test item at the concentration corresponding to the PEC: 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil) and upper PEC: 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil) in nitrate formation rates at time intervals: 0-7, 0-14, 0-28 days.
The percent deviation from the control calculated on the basis of the nitrate formation rate of the soil treated with the test item at the concentration corresponding to the PEC: 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil) and upper PEC: 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil) did not exceed 25% on 28 day of analysis.

Deviations from the control based on nitrogen ion formation rate for selected time intervals [%]:

Time interval [d]	**PEC** 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil)	**5 x PEC** 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil)
0 - 7	4.9	42.6
0 - 14	-47.8	16.9
0 - 28	-24.7	-18.3

"-" values of nitrate formation rate higher than the one obtained for the control group

Validity

The coefficients of variation (CV) in the control group were 7.0, 4.8, 3.3 and 5.1%, after 0, 7, 14, and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%.

Conclusion

On the basis of the results, it was concluded that Dimethomorph 15% + Dithianon 35% WG at the concentration corresponding to the PEC: 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil) and upper PEC: 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil), did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

A 2.5.2 KCP 10.5.2 Effects on soil carbon transformation

Comments of zRMS:	

Reference:	KCP 10.5.2
Report	"Dimethomorph 15% + Dithianon 35% WG. Soil Microorganisms: Carbon Transformation Test", Weronika. Dec 2018, G/79/18. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	OECD Guideline No. 217 (2000) / EU Method C.22.
Deviations:	Yes. The second tested concentration should be called upper PEC instead of 5 x PEC. The predicted environmental concentration (PEC) was calculated assuming 1 cm of the soil depth according to the German conditions for the substances with the mobility in soil KFoc > 500 mL/g. These deviations did not affect the results of the study.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Materials

Test item:

Description:	Dimethomorph 15% + Dithianon 35% WG
Production batch:	SCL- 78352
Active ingredients content:	Dimethomorph – 14.26% (w/w) Dithianon – 35.19% (w/w)

Test system:

Species:	Microorganisms
Source:	Agricultural soil taken from the area belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.

Experimental conditions:

Temperature:	18.0 – 21.0°C
Humidity:	55.0% – 57.5% of MWHC
Air changes:	-
Light and photoperiod:	Dark (24/24h)

Study design and methods

Test design and treatment: 3 portions of soil: one control group and two groups containing the test item weighing 1500 g each. Every portion was divided into three replicates weighing 500 g each. Test duration: 28 days.
Concentrations of the test material:
Control; PEC: 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil), upper PEC: 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil). The mean respiration rate in the treated soil samples was compared with that in the control, and the percent deviation of the treated from the control was calculated after 0, 7, 14, and 28 days of incubation. The Substrate-Induced Respiration (SIR) method was used to determine the intensity of soil respiration.

Statistics: In order to determine significance in the soil respiration rate of differences between the control and the treated groups, the ShapiroWilk's Test on Normal Distribution, the Levene's Test on Variance Homogeneity and Williams Multiple Sequential t-test Procedure were used.

Results The difference in the soil respiration rate between the control soil and the one treated with the test item at the concentrations corresponding to the PEC: 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil) and upper PEC: 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil) did not exceed 25% on any day of analysis.

Oxygen (O_2) consumption - deviations from the control [%]:

Day	PEC 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil)	5 x PEC 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil)
0	-0.7	-4.4
7	11.1	18.1
14	9.7	8.8
28	5.7	6.0

"-"the value of the oxygen consumption higher than the one obtained for the control group.

Conclusion

On the basis of the results, it was concluded that Dimethomorph 15% + Dithianon 35% WG at the concentrations corresponding to the PEC: 31.2 mg test item/kg dry soil (4.45 mg dimethomorph/kg dry soil + 10.98 mg dithianon/kg dry soil) and upper PEC: 104.0 mg the test item/kg dry soil (14.83 mg dimethomorph/kg dry soil + 36.60 mg dithianon/kg dry soil), did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.

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

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:

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

- - the seedling emergence in the control (validity criterion: at least 70%) was as follows:
  100% - sunflower,
  81.0% - cabbage,
  100% - pea,
  75.0% – carrot,
  80.0% – onion,
  95.0% – oats,
  - the mean survival of the emerged control seedlings was 100% for all tested species (validity criterion:
  at least 90%);
  - the control seedlings did not exhibit any visible phytotoxic effects;.
  - environmental conditions for all plants of the same species were identical.

Agreed endpoints:

ER_{10} and NOER values (as g of test item/ha)

	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
NOER	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
Shoot length (plants without roots)						
ER_{50}	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
NOER	≥ 4680	1560	≥ 4680	≥ 4680	1560	≥ 4680
Plant dry weight (plants without roots)						
ER_{50}	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
NOER	≥ 4680	≥ 4680	≥ 4680	≥ 4680	1560	≥ 4680

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

ER_{10} and NOER values (as g of dimethomorph + dithianon/ha)

	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
NOER	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
Shoot length (plants without roots)						
ER_{50}	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
NOER	≥ 667.4 + 1646.9	222.5 + 549.0	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	222.5 + 549.0	≥ 667.4 + 1646.9
Plant dry weight (plants without roots)						
ER_{50}	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
NOER	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	222.5 + 549.0	≥ 667.4 + 1646.9

Reference:	KCP 10.6.2-01
Report	"Dimethomorph 15% + Dithianon 35% WG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test". Weronika Dec., 2018, G/75/18. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	OECD Guideline No. 208 (2006)
Deviations:	Yes. According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50 μE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 50.8 – 131.8 μE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. This deviation did not affect the results of the study.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Dimethomorph 15% + Dithianon 35% WG; Batch Number SCL-78352; active substance: Dimethomorph – 14.26% (w/w), Dithianon – 35.19% (w/w)
Test species:	sunflower (*Helianthus annuus*), cabbage (*Brassica oleracea var. capitata*), pea (*Pisum sativum*), carrot (*Daucus carota*), onion (*Allium cepa*), oats (*Avena sativa*)
Soil:	Loamy sand
Study design:	number of rates: five application rates + control; number of replicates: 4 or 7 replicates/rate. The total number of plants per application rate – 20 or 21. test termination: 14 days after the emergence of 50% of the control seedlings
Application rates:	Control, 57.8, 173.3, 520, 1560, and 4680 g test item/ha (667.4 g of dimethomorph + 1646.9 g of dithianon/ha, 222.5 g of dimethomorph + 549.0 g of dithianon/ha, 74.2 g of dimethomorph + 183.0 g of dithianon/ha, 24.7 g of dimethomorph + 61.0 g of dithianon/ha, 8.2 g of dimethomorph + 20.3 g of dithianon/ha) Volume of distilled water used to prepare the highest rate: 800 L water/ha.
Test conditions:	Temperature: 22.7 – 29.3°C; humidity: 46.9 – 83.7%; lighting: 16 h light : 8 h dark; light intensity: 50.8 – 131.8 μE/m^2/s; carbon dioxide concentration: 360 – 370 ppm
Statistical analysis:	ER_{10}, ER_{25}, ER_{50} – probit analysis or Weibull analysis, NOER – Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity, Williams Multiple Sequential t-test Procedure or Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment or Fisher's Exact Binomial Test with Bonferroni Correction.
Endpoints:	ER_{10}, ER_{25}, ER_{50}, NOER

Results and Conclusions

1. The test item, i.e. Dimethomorph 15% + Dithianon 35% WG applied at rates ranging from 57.8 to 4680 g/ha had no impact on the growth and seedling emergence of sunflower, pea, carrot, and oats. The test item slightly impacted the growth of cabbage and onion.
2. Plants of all analyzed species emerged at all of analyzed concentrations. After the application of the test item at the rates ranging from 57.8 to 4680 g/ha, the emergence of all tested plants was not delayed in comparison to the control groups.

3. There was no mortality observed for all tested species.
4. On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the plant number at the end of the experiment, it was observed that the test item did not inhibit the process of growth of all tested plants.
5. On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the shoot length at the end of the experiment, it was observed that the test item slightly inhibited the process of growth of cabbage and onion.
6. On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the shoot dry weight, it was proved that the test item slightly inhibited the process of growth of onion.
7. No phytotoxic symptoms for sunflower, pea, carrot, and oats were observed after 14 days of the exposure, whereas, for cabbage and onion one phytotoxic symptom, i.e. stunted growth was observed after 14 days of the exposure.
8. The following order of the test plant sensitivity was noticed:
   onion > cabbage > sunflower, pea, carrot, oats

The ER_{50} and NOER values determined on the basis plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of test item/ha for all test species are given below.

ER_{10} and NOER values (as g of test item/ha)

	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
NOER	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
Shoot length (plants without roots)						
ER_{50}	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
NOER	≥ 4680	1560	≥ 4680	≥ 4680	1560	≥ 4680
Plant dry weight (plants without roots)						
ER_{50}	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
NOER	≥ 4680	≥ 4680	≥ 4680	≥ 4680	1560	≥ 4680

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

ER_{10} and NOER values (as g of dimethomorph + dithianon/ha)

	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
NOER	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
Shoot length (plants without roots)						
ER_{50}	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
NOER	≥ 667.4 + 1646.9	222.5 + 549.0	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	222.5 + 549.0	≥ 667.4 + 1646.9
Plant dry weight (plants without roots)						
ER_{50}	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
NOER	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	222.5 + 549.0	≥ 667.4 + 1646.9

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. The seedling emergence (validity criterion: at least 70%) was as follows: 90.5 – 95.2 – sunflower, 88.1 – 92.9 – cabbage, 90.5 – 92.9 – pea, 82.5 – 92.5 – carrot,

82.5 – 90.0 – onion,
87.5 – 95.0 – oats,
- the mean survival of the emerged control seedlings was 100% (validity criterion: at least 90%),
- the control seedlings did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

Agreed endpoints:

ER_{50} and NOER values (as g of test item/ha)

	Pea *Pisum sativum*	**Sunflower** *Helianthus annuus*	**White mustard** *Sinapis alba*	**Tomato** *Solanum lycopersicon*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
NOER	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
Shoot length (plants without roots)						
ER_{50}	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
NOER	1560	≥ 4680	≥ 4680	≥ 4680	1560	≥ 4680
Plant dry weight (plants without roots)						
ER_{50}	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
NOER	≥ 4680	≥ 4680	≥ 4680	≥ 4680	≥ 4680	≥ 4680

The ER_{50} and NOER values determined on the basis plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of dimethomorph + dithianon/ ha for all test species are given below.

ER_{50} and NOER values (as g of dimethomorph + dithianon/ha)

	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
NOER	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
Shoot length (plants without roots)						
ER_{50}	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
NOER	222.5 + 549.0	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	222.5 + 549.0	≥ 667.4 + 1646.9
Plant dry weight (plants without roots)						
ER_{50}	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
NOER	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9

Reference: KCP 10.6.2-02

Report "Dimethomorph 15% + Dithianon 35% WG. Terrestrial Plant Test: Vegetative Vigour Test". Weronika Dec., 2018, G/77/18. Institute of Industrial Organic Chemistry Branch Pszczyna.

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

Deviations: Yes. According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for

tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 52.7 – 140.1 μE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing.
Contrary to what had been planned, the study finished in October 2018, and not in November 2018.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item:	Dimethomorph 15% + Dithianon 35% WG; Batch Number SCL- 78352; active substance: Dimethomorph – 14.26% (w/w), Dithianon – 35.19% (w/w)
Test species:	sunflower (*Helianthus annuus*), cabbage (*Brassica oleracea var. capitata*), pea (*Pisum sativum*), carrot (*Daucus carota*), onion (*Allium cepa*), oats (*Avena sativa*)
Soil:	Loamy sand
Study design:	number of rates: five application rates + control; number of replicates: 4 or 7 replicates/rate. The total number of plants per application rate – 20 or 21. test termination: 21 days after the spraying.
Application rates:	Control, 57.8, 173.3, 520, 1560, and 4680 g test item/ha (667.4 g of dimethomorph + 1646.9 g of dithianon/ha, 222.5 g of dimethomorph + 549.0 g of dithianon/ha, 74.2 g of dimethomorph + 183.0 g of dithianon/ha, 24.7 g of dimethomorph + 61.0 g of dithianon/ha, 8.2 g of dimethomorph + 20.3 g of dithianon/ha) volume of distilled water used to prepare the highest rate: 500 L water/ha
Test conditions:	Temperature: 22.7 – 29.3°C; humidity: 46.9 – 83.7%; lighting: 16 hours light : 8 hours dark; light intensity: 52.7 – 141.1 μE/m^2/s; carbon dioxide concentration: 360 – 380 ppm
Statistical analysis:	ER_{10}, ER_{25}, ER_{50} – probit analyses NOER - Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure or Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment
Endpoints:	ER_{10}, ER_{25}, ER_{50}, NOER

Results and Conclusions

1. The test item, i.e. Dimethomorph 15% + Dithianon 35% WG applied at rates ranging from 57.8 to 4680 g/ha had a varied impact on vegetative vigour of the test plant species. The impact depended on the rate and species.
2. There was no mortality observed for all tested species at rates ranged from 57.8 to 4680 g/ha.
3. On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the plant number at the end of the experiment, the shoot length and shoot dry weight, it was observed that the test item caused slightly inhibition of growth of onion, carrot, and sunflower.
4. A phototoxic symptom, i.e. stunted growth was observed after 21 days of the exposure for onion, carrot, and sunflower.
   In case of cabbage, pea, and oats no phytotoxic symptoms were observed.
5. The following order of the test plant sensitivity was noticed:
   onion > carrot, sunflower > cabbage, pea, oats

The ER_{50} and NOER values determined on the basis plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of test item / ha for all test species are given below.

ER_{10} and NOER values (as g of test item/ha)

	Pea *Pisum sativum*	**Sunflower** *Helianthus annuus*	**White mustard** *Sinapis alba*	**Tomato** *Solanum lyco-persicon*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
NOER	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
Shoot length (plants without roots)						
ER_{50}	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
NOER	1560	≥ 4680	≥ 4680	≥ 4680	1560	≥ 4680
Plant dry weight (plants without roots)						
ER_{50}	> 4680	> 4680	> 4680	> 4680	> 4680	> 4680
NOER	≥ 4680	≥ 4680	≥ 4680	≥ 4680	≥ 4680	≥ 4680

The ER_{50} and NOER values determined on the basis plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of dimethomorph + dithianon/ ha for all test species are given below.

ER_{10} and NOER values (as g of dimethomorph + dithianon/ha)

	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
NOER	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
Shoot length (plants without roots)						
ER_{50}	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
NOER	222.5 + 549.0	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	222.5 + 549.0	≥ 667.4 + 1646.9
Plant dry weight (plants without roots)						
ER_{50}	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9	> 667.4 + 1646.9
NOER	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9	≥ 667.4 + 1646.9

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

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

A 2.8 KCP 10.8 Monitoring data