FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 6800 A

Product name(s): DUKES

Chemical active substance(s):

dithianon 700 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: September 2020

MS Finalisation date: August 2021; December 2021

Version history

When	What
August 2021	Finalisation of the assessment of ppp Dukes by zRMS.
December 2021	The updated evaluation after Commenting perid

Table of Contents

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: devel-opmental 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. num-ber a) per use b) per crop/ season	Min. inter-val 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	**Pome fruits**	F	Scab (*Venturia sp.)*	Foliar Spray	BBCH 51 – 79	a) 4 b) 4	7-12	a) 0.50 b) 2.0	a) 0.35 b) 1.4	1000-1500	21	Preventive treatment							

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

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

Explanation for column 15 – 21 "Conclusion"

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

Remarks table:

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

9.1.1 Overall conclusions

zRMS comment:

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

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 TERlt value for small insectivorous bird "tit" in pome fruits is 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 focal species, PD, PT, FIR/bw and the TER values were above the trigger showing no risk Therefore, the long-term risk to birds after the application of DUKES according to the GAP is considered acceptable.

No risk from drinking water neither due to secondary poisoning is expected.

Mammals
In the Tier I risk assessment the TERlt value for all focal species except the small herbivorous mammal "vole" and frugivorous mammal "dormouse" in pome fruits, are above the trigger of 5 for Dithianon. A further refinement of the long-term risk for these species is needed. A refinement of the risk was done by refining the focal species, PD, FIR/bw, RUD, DF, MAF and ftwa, and the TER value was above the trigger of 5 for "dormouse" ~~and focal species bank "vole".~~ In addition, a refinement of focal species based on studies from Monograph has been included by the Applicant.
For vole further refinement is needed at MSs level when lowes endpoint 25 mg a.s./kg bw ws considered in the long term risk assessment.

No risk from drinking water neither due to secondary poisoning is expected.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

Conclusions of aquatic risk assessment are presented in tables below:

Pome fruits-early application (single/multiple application)

Dithianon

Non sprayed buffer using DRN [m]					
Scenario	**None**	**50 %**	**75 %**	**90 %**	~~**95%**~~
D3/ditch	30	30	20	15	~~5~~
D4/pond	10	5	5	5	~~5~~
D4/stream	30	30	20	15	~~5~~
D5/pond	10	5	5	5	~~5~~
D5/stream	40	30	20	15	~~5~~
R1 pond	15	10	5	5	~~5~~

R1 stream	30	30	20	15	~~5~~
R2 stream	40	30	20	15	~~5~~
R3 stream	40	30	20	15	~~10~~
R4 stream	30VFS	20VFS	15VFS	10VFS	~~5VFS~~

DRN: Drift Reducing Nozzles

VFS: Vegetative filter strip

Pome fruits-late application (single/multiple application)

Dithianon

Non sprayed buffer using DRN [m]				
Scenario	**None**	**50 %**	**75 %**	**90 %**
D3/ditch	20	15	10	5
D4/stream	30	15	10	5
D5/stream	30	15	10	5
R1 stream	20	15	10	5
R2 stream	30	15	10	5
R3 stream	30	15	10	5
R4 stream	20	15	10	5

DRN: Drift Reducing Nozzles

VFS: Vegetative filter strip

Metabolites of Dithianon: for all intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

Pome fruits (early application) – Spe3: *To protect aquatic organisms respect an ~~unsprayed buffer zone of 10m with 5m of vegetative strip to surface water bodies with 95% of nozzles reduction OR~~ an unsprayed buffer zone of 15m with 10m of vegetative strip to surface water bodies with 90% of nozzles reduction OR an unsprayed buffer zone of 20m with 15m of vegetative strip to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 30m with 20m of vegetative strip to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 40m with 30m of vegetative strip to surface water bodies.*

Pome fruits (late application) – Spe3: *To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction OR an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 15 m to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 30 m to surface water bodies.*

It should be noted that final risk mitigation measures should be considered at MSs level.

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 DUKES at all proposed label rates. According to Reg.284/2009 the chronic tests to adult bees and chronic test to larvae bees should be submitted for the product Dukes.

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 DUKES accord-

ing 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)

No chronic risk for earthworms and for other soil macro- and mesofauna are expected after the application of DUKES according to the proposed GAP. The risk to soil microbial processes from the proposed uses of DUKES is considered to be acceptable when applied according to the proposed use rates.

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 DUKES 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)

9.1.2 Grouping of intended uses for risk assessment

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

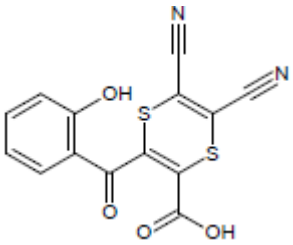
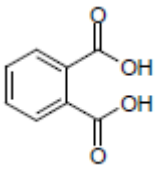
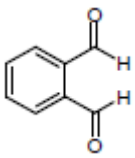
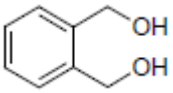
Table 9.1-2: Critical use pattern of DUKES grouped according to crop

Grouping according to crop			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
Orchards	Pome fruits	4 applications with an interval of 7-12 days, 0.50 L./ha (equivalent to 350 g a.s./ha) at BBCH 51-79	Birds and mammals Aquatic organisms Bees Non-target arthropods Soil organisms and microorganisms Non-target plants

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 DUKES is indicated in the table.

Table 9.1-3 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.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

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

Effects on birds of DUKES were not evaluated as part of the EU assessment of Dithianon.

The selection of studies and endpoints for the risk assessment is in line with from 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

Species	Substance	Exposure System	Results	Reference
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

[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/2009/1438 it is permissible to use a geometric mean 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.

Commention period remark:

In the mallard duck no mortality occurred, resulting in an LD_{50} > 2000 mg/kg b.w. However, mallards showed signs of regurgitation at the highest dose level of 2000 mg a.s./kg b.w., which does not allow this level to be considered as representing actual ingested dose. In line with EFSA/2009/1438 this dose level should be omitted and the next lower dose without signs of regurgitation should be used for setting an acute endpoint. It is proposed to use the next lower dose of 1000 mg/kg b.w. (at which no mortality and regurgitation occurred) as the LD_{50} for mallards, to calculate an overall geometric mean. From the acute studies in the quail (309) and the mallard (1000), the LD_{50} geomean = 556 mg/kg b.w.

9.2.2 Risk assessment for spray applications

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

To achieve a concise risk assessment, the risk envelope approach is applied.

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: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds due to the use of DUKES in pome fruits

Intended use	Pome fruits
Active substance/product	Dithianon
Application rate (g/ha)	4 x 350

Acute toxicity (mg/kg bw)	~~786.1~~ 556				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchard	Smal insectivourous bird for screening risk assessment	46.8	1.8	29.48	~~26.7~~ 18.86
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}**
Orchard Spring, Summer	Small insectivorous bird "tit"	18.2	2.2 × 0.53	7.43	**3.1**
Orchard BBCH ≥ 40	Small insectivorous/worm feeding species "thrush"	0.8	2.2 × 0.53	0.33	69.8
Orchard BBCH ≥ 40	Small granivorous bird "finch"	3.8	2.2 × 0.53	1.55	14.7

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

9.2.2.2 Higher-tier risk assessment

In the Tier I risk assessment the TERlt value for Small insectivorous bird "tit" in pome fruits is below the trigger of 5 for Dithianon. A further refinement of the long-term risk is needed.

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

Identification of focal bird species

The selection of focal species for the refined risk assessment is based on the results of a generic bird monitoring study conducted in pome fruit orchards of main growing regions in several European countries, covering Germany (Dietzen C. et al, 2006b), Poland and Northern Italy-Tyrol (Dietzen C. et al, 2006a) submitted in *Additional Report to the DAR-January 2010* of the active substance Dithianon.

The number of investigated pome fruit orchards was 59 (Germany), 21 (Poland), and 29 (northern Italy-Tyrol), respectively. The selected areas represented average pome fruit orchards with regard to size and structure of the surroundings. The field parts of the monitoring studies were carried out from April to June (Germany), April to June (Poland), and March to July (northern Italy-Tyrol), respectively.

To cover different crop growth stages, in each orchard surveys were conducted at three periods of crop development, covering BBCH 00 to 79 (pre-emergence to fruit development). In detail the BBCH growth stages at the individual orchard surveys have been 51 - 61, 63 - 72, 75 - 79 (Germany), 00 - 09, 10 - 19, 71 - 79 (Poland), and 00 - 69, 71 - 74, 75 - 77 (northern Italy-Tyrol), respectively. The data were collected using standard line transects comprised of 25 - 50 m bands to each side of the observer moving along a longitudinal in-crop line (field transect). By this all individuals in a 50 - 100 m wide 'in-crop transect band' were recorded.

These studies were carried out with the specific purpose of deriving generic data to conduct risk assessments for birds following SANCO/4145/2000 and EFSA recommendations. The purpose of the studies was to determine the qualitative and quantitative composition of the bird community in pome fruit orchards. As a result a list of candidate focal bird species for the use in refined risk assessments was compiled and the focal species for the use in refined risk assessments selected.).

The candidate of focal species will be selected by analyzing the qualitative and quantitative composition of the bird community for the species frequency of occurrence. These parameters were determined for both the overall study period and for each of the three seasonal periods associated to specific grapevine growth stages.

The results obtained in this study are considered representative for pome fruit orchards and almond as well, because these crop types provide comparable habitat for birds. The focal species selected for the refined risk assessment in pome fruit in central Europe are:

- Small insectivorous bird: Great tit (*Parus major*).
- Small granivorous bird "finch": Serin (*Serinus serinus*).
- Small omnivorous bird: Chaffinch (*Fringilla coelebs*)

"Great tit" and "Chaffinch" were the only one species considered in the refinement since no unacceptable risk was obtained for "finch" under Tier I and refinement was not needed.

Deposition factor (DF)
DUKES will be applied directly to crop. Since ground arthropods and seeds will be covered by the crop, an interception by the crop has to be taken into account. BBCH stages 51-79 corresponds with the flowering, early fruit development and full canopy, and according to the interception values of EFSA (2014)[1], for pome fruits at growth stage flowering, an interception factor of 60% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of **0.4** should be applied.

Great tit *(Parus major)*

PD value
According to the *Additional Report to the DAR-January 2010*:

"The diet composition of different bird species in vineyards was studied in detail by Selbach (2007). In great tits, 16 faecal and 4 stomach flushing samples were taken from individuals captured within vineyards or in surrounding habitats within 20 metres distance.
The diet of the great tit was shown to include a wide variety of insects, especially Lepidoptera larvae and spiders, but also a small amount of seeds (Selbach 2007) viii. For invertebrate remains and plant seeds, correction factors were applied to the number of items found in the diet samples in order to derive the proportion these items contribute to the dry weight actually ingested. Of the total dry weight, 95.52% were attributable to invertebrates and 4.48% to plant seeds.
The proportion of different invertebrate and plant seed taxa found in the diet of great tits is shown in tavle below.

[1] EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662

Table B.9.1/11: ***Proportion of different food items contributing to diet of great tits in vineyards based on dry weight (from Selbach 2007)***

Taxon	***Numerical proportion [%]***	***Dry weight proportion [%] PD***
Invertebrates	*92.04*	***95.52***
Lepidoptera larvae	*7.76*	*35.09*
Araneae	*8.28*	*16.51*
Diptera	*2.1*	*8.87*
Hemiptera	*67.06*	*8.17*
Coleoptera	*3.24*	*7.86*
Lepidoptera	*0.87*	*7.33*
Orthoptera	*0.36*	*6.1*
Hymenoptera larvae	*1.42*	*3.23*
Hymenoptera	*0.63*	*1.66*
Dermaptera	*0.14*	*0.53*
Gastropoda	*0.18*	*0.16*
Seeds	*7.96*	***4.48***
Other	*3.52*	*2.88*
Poaceae	*4.29*	*1.56*
Caryophyllaceae	*0.15*	*0.04*
Total	*100*	***100***

For a correct exposure calculation, the PD values of dry weight (see above) need to be converted to PD values of wet weight. The following PD (wet weight) values were obtained for the great tit in the study by Selbach (2007):

Arthropods PD (wet weight) = 0.984
Weed seeds PD (wet weight) = 0.016 PD sum = 1.0

The great tit is a typical combined stratum user feeding on the ground as well as in the foliage. A comprehensive study on the foraging behaviour of great tits was conducted by Gibb (1954) in forest environment in the UK. By means of repeated visual observations (n = 3108 for the great tit), the foraging behaviour of several tit species was evaluated. According to this study, the great tit mostly used the ground in spring whereas the canopy was preferred during summer. The proportions of ground-feeding and canopy-feeding between March to September as derived from Table 13 of (Gibb 1954) are presented in the table below.

Table B.9.1/12: ***Proportions [%] of different stratum types used (canopy, ground, other) by great tits in a forest environment in the UK (Gibb 1954)***

Month	***Canopy***				***Ground [%]***	***Other [%]***
	Leaves [%]	***Live twigs and buds [%]***	***Live branches, limbs, boles [%]***	***Dead parts [%]***		
March	*1*	*1*	*7*	*1*	*76*	***14***
April	*4*	*2*	*3*	*1*	*70*	*20*
May	*56*	*2*	*3*	*1*	*31*	*7*
June	*87*	*2*	*5*	*1*	*2*	*3*
July	*83*	*2*	*4*	*1*	*3*	*7*
August	*83*	*1*	*3*	*1*	*2*	*10*
September	*31*	*10*	*25*	*4*	*8*	*22*
Mean (March-Sep)	*49.29*	*2.86*	*7.14*	*1.43*	***27.43***	***11.86***
	60.72					

The proportion of different strata used by the great tit during the period from March to September as determined by Gibb (1954) ix is 60.72% (canopy-feeding) and 27.43% (ground-feeding). For the refined risk assessment for Dithianon in grapevine it will therefore be assumed that the arthropods taken by the great tit pertain to two groups. The first group comprises canopy-dwelling arthropods (60.72%), and the second group consists of ground-dwelling arthropods (27.43%).

The behaviour of great tits observed by Gibb (1954) indicated that animals are mostly either canopydwelling or ground-dwelling. The two values obtained in those categories add up to 0.8815 (0.6072 + 0.2743) and can be considered to represent adequately the behaviour of tits for the majority of their time. They need to be adjusted by rule of proportion from 0.8815 to 1.0 (see Table B.9.1/13). The recalculated stratum use values will then be used for attributing PD and RUD values for the refined exposure assessment.

Table B.9.1/13**: **Re-calculated stratum use for the great tit (based on Gibb 1954)

Period	***Stratum*** [1)]	***Proportional stratum use*** [1)]	***Required sum of stratum values*** [2)]	***Correction factor*** [3)]	***Recalculated stratum values*** [4)]
March to Sep.	*Canopy*	*0.6072*	*1.0*	*1.134*	***0.689***
	Ground	*0.2743*			***0.311***
---	Sum	0.8815			***1.0***

[1)] Stratum use of foraging great tits as determined by Gibb (1954).
[2)] For attributing PD and RUD values for refined exposure assessment, the values need to sum up to 1.0.
[3)] Calculated correction factor (1.0 / 0.8815 = 1.134).
[4)] Stratum use values re-calculated by multiplying with correction factor 1.134.

The resulting aligned stratum use proportions for the refined exposure assessment are as follows:

Canopy use 0.689
Ground use 0.311 sum = 1.0

The PD values for arthropods and weed seeds in the diet of great tits were determined to be 0.984 and 0.016 (wet weight) based on data from Selbach (2007). When taking into account the combined stratum use of foraging great tits, the overall arthropod proportion needs to be split into canopy-dwelling and ground-dwelling arthropods according to the stratum proportion (0.689 for canopy and 0.311 for ground) determined in the study by Gibb (1954) ix and proportionally aligned. The resulting diet proportions for the great tit using the strata canopy and ground can be calculated as follows:

*Leaf (canopy)-dwelling arthropods PD (wet weight) canopy = 0.984 * 0.689 = 0.678*
*Ground-dwelling arthropods PD (wet weight) ground = 0.984 * 0.311 = 0.306*
Weed seeds PD (wet weight) ground = 0.016
PD sum = 1.0"

In the radio-tracking study by Staab & Mossmayer (2006) in pome fruit orchards the diet composition of great tits was investigated quantitatively (as mean number of diet items) for a total of 26 samples (23 faeces and 3 stomach flushing samples). It is not directly possible to derive a PD from these data; however, the results clearly show that arthropods are the majority of the great tit's diet, while plant matter like seeds only plays a minor role. This is supported by the results obtained from the more detailed analysis of the diet composition of great tits in the radio-tracking study in grapevines (Selbach 2007).

In general, vineyards and pome fruit orchards are similar bird habitats in terms of structure, ground vegetation and surroundings, which suggests that the overall food supply for birds should be similar, resulting

in a comparable diet composition of great tits in these crops. Hence, the PD values determined for the great tit in grapevines are also considered to be suitable for the refined risk assessment for this species in pome fruit orchards. These PD values are as follows: **0.678 leaf-dwelling arthropods, 0.306 ground dwelling arthropods and 0.016 weed seeds.**

PT value

A radio tracking part of the study was conducted in Southern Germany submitted in the *Additional Report to the DAR-January 2010* of the active substance Dithianon (Staab & Moosmayer 2006). The radio tracking part of the study was conducted in Southern Germany between April and July and hence provides PT values most suitable for main growing season. The radio tracking data are based on 25 tracking sessions on 22 individuals.

Table 9.2-3: **PT values[1] determined by radio-tracking during 25 tracking sessions with 22 great tits in pome fruit orchards in Germany (Staab & Moosmayer 2006)**

Bird number / tracking session	PT value per tracking session (n = 25)
1	0.704
2	0.120
3	0.192
4	0.069
5	0.126
6	0.240
7	0.167
8	0.111
9	0.171
10	0.161
11	0.011
12/1	0.285
12/2	0.303
13	0.104
14/1	0.686
14/2	0.791
15/1	0.427
15/2	0.363
16	0.068
17	0.127
18	0.003
19	0.912
20	0.062
21	0.012
22	0.147
Mean PT	**0.254**

[1)]Note that the study by Staab & Moosmayer (2006) comprises two different approaches to calculate PT values, i.e. a multi-field approach (PT calculated based on time spent in all used pome fruit orchards plots) and a singlefield approach (PT calculated based on time spent in one predominantly used pome fruit orchards plot). The PT values listed above are for the multi-field approach, hence the worst-case values, which resemble the `home range approach used in other studies.

Based on the 25 radio-tracking sessions with 22 individuals a mean PT of 0.254 can be derived. This PT value will be used in the refined risk assessment for the great tit in pome fruit orchards.

Refinement of FIR/bw

A FIR/bw corresponding to modified diet of Great tit was calculated in accordance to the EFSA GD

Table 9.2-4: Calculation of FIR for Great tit

Species	**Body weight**	**Diet item**	**Daily energy expenditure, DEE [kJ/d]**	**Food energy, FE [kJ/d]**	**Moisture content, MC [%]**	**Assimilation efficiency, AE [%]**	**FIR**	**FIR/bw**
Small insectivorous bird Great tit	19.0*	Leaf arthropods	78.78	22.7	68.8	76	14.637	0.77
		Ground arthropods	78.78	22.7	68.8	76	14.637	0.77
		Weed seeds	78.78	21.7	9.9	80	5.037	0.27

*According to Dunning (1993)

Table 9.2-5: Higher-tier assessment of long-term risk for birds due to the use of DUKES in pome fruits– refined parameters (*) are further described and justified in the text

Intended use	**Pome fruits**
Active substance/product	Dithianon
Application rate (g/ha)	4 x 350
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}**
Great tit (*Parus major)* Spring, Summer	67.8% foliar arthropods	0.77	21.0[1] × 1	2.2 × 0.53	0.254[3]	1.136	19.4
	30.6% ground arthropods	0.77	3.5[1] × 0.4[2]	2.2 × 0.53	0.254[3]	0.034	
	1.6% weed seeds	0.27	40.2[1] × 0.4[2]	2.2 × 0.53	0.254[3]	0.007	
	Whole diet					1.178	

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]DF according to EFSA (2014).
[3]Mean PT determined for the great tit and chaffinch in pome fruit orchards (Staab and Moosmayer, 2006).

Refined reproductive risk assessment following application of Dithianon showed no unacceptable risk to small insectivorous bird: Great tit (*Parus major*).

Chaffinch (*Fringilla coelebs*)

PD value

According to the *Additional Report to the DAR-January 2010*:

"The chaffinch is an omnivorous bird species which feeds mainly on invertebrates during the breeding season and molt, and mainly on seeds after the molt until spring. In spring the chaffinch also feeds on germ buds (Glutz von Blotzheim & Bauer 1997). Newton (1967) conducted a study on the diet composition of chaffinches near Oxford/UK. The work by Newton was reviewed by CSL and then use to estimate overall diet composition for different seasons (Central Science Laboratory, Buxton et al. 1998). The result of this evaluation is shown in Table B.9.1/19.

Table B.9.1/19: ***Diet composition [% volume of gut content] of the chaffinch between May to September according to Newton (1967) and as summarized by Buxton et al. (1998)***

Months	***Diet [%]***	
	Invertebrates	***Seeds***
May – July	*81*	*19*
July-September	*15*	*85*
May-September	**48**	**52**

For the proposed use of Dithianon, the average diet composition from May to September (matching the vegetation period and the application time of Dithianon) was considered, hence for the refined risk assessment for the chaffinch in grapevine PD (weed seeds) = 0.52 and PD (arthropods) = 0.48 will be used.

The chaffinch uses different strata for foraging. The foraging behavior is described by Cramp (1998) as follows: 'Feeds most often in trees in spring and summer when taking invertebrates (especially defoliating caterpillars), and more on ground during rest of year…'. More precisely, according to Schreiber (1989) as cited in Bergmann (1993), during the breeding season 24% of feeding occurs on the ground, whereas 76% of feeding takes place above the ground (Bergmann 1993). Considering this information, for the refined risk assessment it will be assumed that the diet fractions of the chaffinch consist of 25% ground-dwelling and 75% foliage-dwelling arthropods. The resulting diet proportions for the chaffinch using the strata canopy and ground are calculated as follows:

*Leaf (canopy)-dwelling arthropods PD (volume) canopy = 0.48 * 0.75 = 0.36*
*Ground-dwelling arthropods PD (volume) ground = 0.48 * 0.25 = 0.12*
Weed seeds PD (volume) ground = 0.52
PD sum = 1.0

In general, vineyards and pome fruit orchards are similar bird habitats in terms of structure, ground vegetation and surroundings, which suggests that the overall food supply for birds should be similar, resulting in a comparable diet composition of great tits in these crops. Hence, the PD values determined for the Chaffinch in grapevines are also considered to be suitable for the refined risk assessment for this species in pome fruit orchards. These PD values are as follows: **0.52 weed seeds, 0.36 foliage-dwelling arthropods and 0.12 ground-dwelling arthropods.**

PT value

A radio tracking part of the study was conducted in Southern Germany between April and July and it was submitted in the *Additional Report to the DAR-January 2010* of the active substance Dithianon (Staab & Moosmayer 2006).

Table 9.2-6: **PT[1] values based on radio-tracking during 24 tracking sessions with 21 chaffinches in pome fruit orchards in Germany (Staab & Moosmayer 2006)**

Bird number / tracking session	PT value per tracking session (n = 24)
1	0.821
2	1.0
3	0.156
4	0.064
5	0.0
6	0.145
7	0.722
8	0.154
9	0.291
10	0.740
11	0.137
12	0.004
13	0.091
14	0.306
15/1	0.914
15/2	0.986
16	0.510
17	0.018
18/1	0.738
18/2	0.661
19/1	0.763
19/2	0.681
20	0.945
21	0.947
Mean PT	**0.49**

[1)]Note that the study by Staab & Moosmayer (2006) comprises two different approaches to calculate PT values, i.e. a multifield approach (PT calculated based on time spent in all used pome fruit orchards plots) and a single-field approach (PT calculated based on time spent in one predominantly used pome fruit orchards plot). The PT values listed above are for the multi-field approach, hence the worst-case values, which resemble the `home range approach´ used in other studies.

Based on the 24 radio-tracking sessions with 21 individuals a mean PT of 0.49 can be derived. This PT value will be used in the refined risk assessment for the chaffinch in pome fruit orchards.

The use of mean PT values for addressing the long-term risk to birds is considered to be the most adequate approach according to the use of mean values of RUD and MAF for the risk assessment in long-term.

Refinement of FIR/bw
A FIR/bw corresponding to modified diet of Chaffinch was calculated in accordance to the EFSA GD

Table 9.2-7: Calculation of FIR for Chaffinch

Species	**Body weight**	**Diet item**	**Daily energy expenditure, DEE [kJ/d]**	**Food energy, FE [kJ/d]**	**Moisture content, MC [%]**	**Assimilation efficiency, AE [%]**	**FIR**	**FIR/bw**

Small omnivorous bird Chaffinch	20.9*	Leaf arthropods	84.03	22.7	68.8	76	15.611	0.75
		Ground arthropods	84.03	22.7	68.8	76	15.611	0.75
		Weed seeds	84.03	21.7	9.9	80	5.372	0.26

*According to Dunning (1993)

Table 9.2-8: Higher-tier assessment of long-term risk for birds due to the use of DUKES in pome fruits– refined parameters (*) are further described and justified in the text

Intended use	**Pome fruits**						
Active substance/product	Dithianon						
Application rate (g/ha)	4 x 350						
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}**
Chaffinch (*Fringilla coelebs)* Spring, Summer	36% foliar arthropods	0.75	$21.0^1 \times 1$	2.6×0.53	0.49^3	1.134	14.3
	12% ground arthropods	0.75	$3.5^1 \times 0.4^2$	2.6×0.53	0.49^3	0.025	
	52% weed seeds	0.26	$40.2^1 \times 0.4^2$	2.6×0.53	0.49^3	0.435	
	Whole diet					1.594	

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]DF according to EFSA (2014).
[3]Mean PT determined for the great tit and chaffinch in pome fruit orchards (Staab and Moosmayer, 2006).

Refined reproductive risk assessment following application of Dithianon showed no unacceptable risk to small omnivorous bird: Chaffinch (*Fringilla coelebs*).

zRMS comments:

The refined long-term risk assessment to birds was revised according to the EU agreed data (RAR and respective addenda – additional report 20210) as it was reviewed and accepted in the EU review (Scenario 3 – Pome fruit (Northern Europe). The zRMS's assessment is presented in the Tables below:

Great tit (Parus major)

Refined long term risk assessment fort he great tit in pome fruit orchards

FIR/b.v.	Food type	RUD (mg a.s./kg)	PD	PT	DF	MAFxTWA	Use rate (kg a.s./ha)	DDD (mga.s./kg) bw/d
0.560 [1)]	Arthropods (foliage-dwelling)	21 [2)]	1[4)]	0.254[5)]	1.0[6)]	2.2x0.53	0.35	1.21
0.253[1)]	Arthropods	3.5[2)]	1[4)]	0.254[5)]	1.0[6)]	2.2x0.53		0.26

	(ground dwelling)							
0.013[1)]	Weed seeds)	40.2[3)]	1[4)]	0.254[5)]	0.5[6)]	2.2x0.53		0.077
Sum (mg a.s./kg b.w./d)								1.54
NOEL (mg a.s./kg b.w./d)								22.8
TER_{lt} value								14.80

1) FIR/b.w. based on values for energy content, moisure content, and assimilation efficiency from SANCO/4145/2000
2) RUD value for foliage- dweling and ground dweling arthropods in orchards/vineyards taken from the EFSA Scientific Opinion
3) RUD value for weed seeds, taken from the EFSA Scientific Opinion
4) PD values (67,8%, foliage-dwelling ard 1.6% weed seeds arthropods are integrated via the FIR/bw value
5) Mean PT determinated for great tits in pome fruit orchards
6) Highest deposition factor (worst case) applying for early application in pome fruuit orchards covering application at late grown stages. For ground dwellinf arthropods the RUD includes crop interception already Foliage dwelling arthropods remain with DF=1.0

Serin (*Serinus serinus*)

Refined long-term risk assessment for serin in pome fruit orchards

FIR/b.w.	Food type	RUD (mg a.s./kg)	PD	PT	DF	MAF_XTWA	Use rate (kg a.s./ha)	DDD (mg a.s./kg b.w./d)
0.332[1)]	Wees seeds	40.2 [2)]	1 [3)]	0.637 [4)]	0.5 [5)]	2.2x0.53	0.35	1.72
NOEL (mg a.s./kg b.w./d)								22.8
TER_{lt} value								13.25

1) FIR/b.w. based on values for energy content, moisure content, and assimilation efficiency from SANCO/4145/2000
2) RUD value for weed seeds, taken from the EFSA Scientific Opinion
3) Default PD values via the FIR/bw value
4) 90th PT determinated for great tits in pome fruit orchards
5) Highest deposition factor (worst case) applying for early application in pome fruuit orchards covering application at late grown stages.

Chaffinch (*Fringilla coelebs*)

Refined long-term risk assessment fort the chaffinch in pome fruit orchards

FIR/b.v.	Food type	RUD (mg a.s./kg)	PD	PT	DF	MAF_XTWA	Use rate (kg a.s./ha)	DDD (mg a.s./kg) bw/d
0.049 [1)]	Arthropods (ground-dwelling)	3.5 [2)]	1[4)]	0.49[5)]	1.0[6)]	2.2x0.53	0.35	0.034
0.146[1)]	Arthropods (foliage dwelling)	21[2)]	1[4)]	0.49[5)]	1.0[6)]	2.2x0.53	0.35	0.61
0.211[1)]	Weed seeds)	40.2[3)]	1[4)]	0.49[5)]	0.5[6)]	2.2x0.53	0.35	0.84
DDD sum (mg a.s./kg b.w./d)								1.48
NOEL (mg a.s./kg b.w./d)								22.8
TER_{lt} value								**15.4**

1) FIR/b.w. based on values for energy content, moisure content, and assimilation efficiency from SANCO/4145/2000
2) RUD value for foliage- dweling and ground dweling arthropods in orchards/vineyards taken from the EFSA Scientific Opinion

3) RUD value for weed seeds, taken from the EFSA Scientific Opinion
4) PD values (36%, foliage-dwelling, 12 %ground dwelling ard 52% weed seeds arthropods are integrated via the FIR/bw value
5) Mean PT determinated for great tits in pome fruit orchards
6) Highest deposition factor (worst case) applying for early application in pome fruuit orchards covering application at late grown stages. For ground dwellinf arthropods the RUD includes crop interception already.Foliage dwelling arthropods remain with DF=1.0

In the harmonisation meeting in Central Zone there majority prefers to use the 90th percentile. The 90th PT value was used by ZRMS in the refined risk assessment only in case of serin where were only 9 individuals. The number of individuals in case of great tit and chaffinch seems to be sufficient therefore, mean PT value was used in the refined risk assessment. ZRMS agrees that MS can decide at their national level which PT is the most appropriate for their specific ecological condition.

All refined TER values were higher than 5 for the proposed use.

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 DUKES is not 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)	=	770.0		
Acute toxicity (mg/kg bw)	=	786.1	quotient =	0.98
Reprod. toxicity (mg/kg bw/d)	=	22.8	quotient =	33.77

zRMS comments:

We agree that hazard quotient for Puddle scenario for ditathion is below trigger value 3000, so no specific calculations of exposure and TER are necessary.

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.

Risk assessment for earthworm-eating birds via secondary poisoning

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

To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.2-9: Assessment of the risk for earthworm-eating birds due to exposure to Dithianon via bioaccumulation in earthworms (secondary poisoning) for the intended use in pome fruits

Parameter	Dithianon	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.515	PEC_{soil} twa 21 d in pome fruits
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}	0.2738	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.141	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.148	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	22.8	EFSA Journal 2010;8(11):1904.
TER_{lt}	154.0	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 for aquatic organisms as a limit value for admissible concentrations of Dithianon in water.

To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.2-10: Assessment of the risk for fish-eating birds due to exposure to Dithianon via bioaccumulation in fish (secondary poisoning) for the intended use in pome fruits

Parameter	Dithianon	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.00194	Worst case step 2, pome fruits early multiple application for Southern Europe (please refer to section B8, table 8.9-4)
BCF_{fish}	28	EFSA Journal 2010;8(11):1904.
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)

Parameter	Dithianon	comments
PEC_{fish}	0.054	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.009	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	22.8	EFSA Journal 2010;8(11):1904.
TER_{lt}	2639.8	No risk, TERlt > 5

TER values shown in bold fall below the relevant trigger.

zRMS comments:

Based on the assessment of the risk for fish-eating birds due to exposure to Dithianon via bioaccumulation in fish (secondary poisoning) and assessment of the risk for earthworm-eating birds due to exposure to Dithianon via bioaccumulation in earthworms (secondary poisoning) for the intended use in pome fruit it can be concluded that the secondary poisoning is not expected to occur from the proposed use of Dukes.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.2.4 Overall conclusions

In the Tier I risk assessment the TERlt value for small insectivorous bird “tit” in pome fruits is 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 focal species, PD, PT, FIR/bw and the TER values were above the trigger showing no risk Therefore, the long-term risk to birds after the application of DUKES according to the GAP is considered acceptable.

No risk from drinking water neither due to secondary poisoning is expected.

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

Effects on mammals of DUKES were not evaluated as part of the EU assessment of Dithianon. New data submitted with this application are listed in Appendix 1 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}=458.9mg/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

*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 DUKES in pome fruits

Intended use	Pome fruits
Active substance/product	Dithianon
Application rate (g/ha)	4 × 350
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**
Orchards BBCH ≥ 40	Small herbivorous mammal "vole	40.9	1.8	25.77	17.8
Orchards BBCH 71-79 Currants	Frugivorous mammal "dormouse"	47.9	1.8	30.18	15.2
Orchards BBCH ≥ 40	Large herbivorous mammal “lagomorph”	10.5	1.8	6.62	69.4
Orchards BBCH ≥ 40	Small omnivorous mammal “mouse”	5.2	1.8	3.28	140.1
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}**
Orchards BBCH ≥ 40	Small herbivorous mammal "vole	21.7	2.2× 0.53	8.86	**2.8**
Orchards BBCH 71-79 Currants	Frugivorous mammal "dormouse"	22.7	2.2× 0.53	9.26	**2.7**
Orchards BBCH ≥ 40	Large herbivorous mammal “lagomorph”	4.3	2.2× 0.53	1.75	14.2
Orchards BBCH ≥ 40	Small omnivorous mammal “mouse”	2.3	2.2× 0.53	0.94	26.6

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

9.3.2.2 Higher-tier risk assessment

In the Tier I risk assessment the TERlt value for frugivorous mammal "dormouse" and small herbivorous mammal “vole” in pome fruits are below the trigger of 5 for Dithianon. A further refinement of the long-term risk is needed.

Frugivorous mammal "dormouse"

RUD
To refine risk for “Fruit stage” scenario more realistic residue values are used. As report in Dithianon DAR, residue trials were available in Southern and Northern EU region performed with 12 to 14 applications at 0.495 to 0.81 kg a.s./ha.

In the following table are summarized residue trials suitable to refine risk assessment for frugivorous organisms.

Table 9.3-3: Pome fruits: Residue trials suitable to refine mammals risk assessment

Location/Year	Commodity/ Variety	n° application	kg a.s./ha	Residue in fruit Day 0 (mg/kg)	RUD	Trial No
Germany/ NEU/ 1975	apples	14	0.630	1.0	1.59	F 75-01-06-01
Germany/ NEU/ 1975	apples	13	0.630	0.4	0.63	F 75-01-06-02

Location/Year	Commodity/ Variety	n° application	kg a.s./ha	Residue in fruit Day 0 (mg/kg)	RUD	Trial No
Germany/ NEU/ 1985	apples	13	0.600	0.85	1.42	C-85-11-06 B
Germany/ NEU/ 1985	apples	13	0.607-0.810	0.72	1.19	C-85-11-06 A
Germany/ NEU/ 1985	apples	12	0.569-0.759	1.81	3.18	C-85-11-72-01-D
Germany/ NEU/ 1995	apples	12	0.529-0.552	0.92	1.74	95-082-01
Germany/ NEU/ 1995	apples	12	0.525-0.535	1.3	2.48	95-082-02
Germany/ NEU/ 1995	apples	12	0.511-0.554	1.5	2.94	95-082-04
Germany/ NEU/ 2004	pears	12	0.525	0.85	1.62	ACK/04/04
Denmark/ NEU/ 2004	pears	12	0.525	1.74	3.31	ALB/01/04
France South/ SEU/ 2000	apples	12	0.495-0.569	0.53	1.07	00-981-641
France South/ SEU/ 2000	apples	12	0.513-0.532	0.39	0.76	00-802-01
Spain/ SEU/ 2001	apples	12	0.525	0.70	1.33	ALO/45/01
Spain/ SEU/ 2001	apples	12	0.525	1.36	2.59	ALO/46/01
Greece/ SEU/ 2001	apples	12	0.525	2.14	4.08	HEL/06/01
Italy/ SEU/ 2001	apples	12	0.525	1.89	3.60	ITA/24/01
				mean	**2.10**	
				SD	1.08	

For the refinement of long-term risk, the mean value of **2.10** was used.

zRMS comments:
The data above was evaluated by zRMS Cz for the ppp Dith , Sharda owner.
To refine risk for "Fruit stage" scenario more realistic residue values were submitted.
The result from residues studies performed in sound zone seems to be not acceptable to use for central zone assessment because of different climatic conditions (better case). The study from Denmark can be used because the results represent a worse case. Nevertheless, RUD values from SEU trials are from day 0 and therefore, such values are not influenced by different climatic conditions.
Therefore, all new data will be used in the risk assessment.
The number of new studies is not sufficient therefore, ZRMS proposes to merge the new data for dithianon in apples and pears together with the dataset for large fruits from EFSA GD (2009) (based on Baril et al. 2005) to derive a revised RUD value.
The merging of the data for dithianon in apples and pears together with the dataset for large fruits from Baril to derive a revised RUD value is provided below.

Source of the data	Measured data for dithianon in apples (see Table 9.2.3-20)	EFSA GD (2009) - based on Baril et al. (2005): Large fruits from orchards
RUD [mg/kg] corrected for use rate	1.59	14.24731183
	0.63	14.59677419
	1.42	16.33333333
	1.19	17.33333333
	3.18	20.10526316

	1.74	20.60526316
	2.48	25.02840909
	2.94	26.875
	1.62	27.69886364
	3.31	29.09090909
	1.07	0.184104176
	0.76	0.240522876
	1.33	0.24516129
	2.59	0.451540616
	4.08	0.884033613
	3.60	21.09375
	-	0.270967742
	-	0.386363636
	-	0.216487455
	-	0.46969697
	-	36.63157895
	-	37.1978022
	-	37.3125
	-	38.39673913
	-	38.5
	-	40.78313253
	-	41.13636364
	-	42.74096386
	-	43.36419753
	-	46.82795699
	-	0.440685511
	-	0.992728892
	-	1.686507937
Overall arithmetic mean of datasets merged together [mg a.s./kg fruit]	**13.79**	
Overall 90th %ile of datasets merged together [mg a.s./kg fruit]	**38.96**	

The revised RUD value **of 13.79 mg/kg (mean value) and 38.96 mg/kg (90th %ile)** based on merging of the measured data for dithianon in apples and pears together with the dataset for large fruits from orchards from EFSA GD (2009) (based on Baril et al. 2005) will be used in the risk assessment.

Table 9.3-4: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of DUKES in pome fruits– refined parameters (*) are further described and justified in the text

Intended use	Pome fruits
Active substance/product	Dithianon
Application rate (g/ha)	4 × 350
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**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Garden dormouse (*Eliomys quercinus*) BBCH 71-79 Currants	100% fruit	1.16[1]	2.10[2]× 1.0	2.2× 0.53	1.0	0.99	25.1

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] The revised RUD based on merging of the measured data for Dithianon in apples and pears together with the dataset for large fruits from orchards from EFSA GD (2009) (based on Baril et al. 2005)

Refined reproductive risk assessment following application of Dithianon showed no unacceptable risk to frugivores (*Eliomys quercinus*).

Small herbivorous mammal "vole"

PD

According to *Conclusion on the peer review of Pyrimethanil* (EFSA Scientific Report (2006) 61, 1-70), typical small herbivores like voles of the genus *Microtus* are considered not to be representative inhabitants of apple orchards. The bank vole (*Clethrionomys glareolus*) was chosen as relevant species. Based on a study on seasonal diet composition (Abt & Bock 1998: "Seasonal variations of diet composition in farmland field mice *Apodemus* spp. and bank voles *Clethrionomys glareolus*", Acta Theriologica 43: 379-389), the representative summer diet of bank voles consists of approx. 60 % grains/seeds, 20 % green plant material and 20 % invertebrates. Although one might suppose a high dependence of diet composition on the availability of food items in the habitat and many cereal grains were available at the investigated study site, the authors state that "Proportions of primary food items, i.e. seeds, tend to be similar in different food habitats". In addition, as diet composition of wood mice in orchards is not known, EFSA agreed to use the bank vole as a focal species and hence the PD of 0.2/0.6/0.2 for short grass/seeds/large insects respectively to refine the risk, since it also covers the risk to wood mouse.

Refinement of FIR/bw

A FIR/bw corresponding to modified diet of ~~Great tit~~ Bank vole was calculated in accordance to the EFSA GD

Table 9.3-5: Calculation of FIR for bank vole

Species	**Body weight**	**Diet item**	**Daily energy expenditure, DEE [kJ/d]**	**Food energy, FE [kJ/d]**	**Moisture content, MC [%]**	**Assimilation efficiency, AE [%]**	**FIR**	**FIR/bw**
Small herbivorous mammal bank vole	25	Short grass	65.09	17.6	76.4	47	33.343	1.33
		Cereal seeds	65.09	18.4	14.7	84	4.937	0.20
		Large insects	65.09	22.7	68.8	87	10.564	0.42

Deposition factor (DF)

DUKES will be applied directly to crop. Since grass and seeds will be covered by the crop, an interception by the crop has to be taken into account. BBCH stages 51-79 corresponds with the flowering, early fruit development and full canopy, and according to the interception values of EFSA (2014)[2], for pome fruits at growth stage flowering, an interception factor of 60% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of **0.4** should be applied.

DT_{50}

In the Tier I assessment, the default foliar DT_{50} is 10 days. However, the foliar DT_{50} was 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 with 6-9 days of interval were applied for these studies. The information used for the determination of the DT_{50} is showed in the table below.

Report/Trial/ country/year	Crop	Appl. rate (g a.s./ha)	BBCH	Analyzed	Residue Dithianon (mg/kg)	Time (days)	DT_{50}
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	~~5.46~~ 6.65
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	~~5.36~~ 5.0
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	~~6.69~~ 5.92
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	~~7.52~~ 8.35
						Mean DT_{50}	~~6.26,~~ **6.48**
						90^{th} percentile	~~7.27,~~ **8.35**

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

[2] EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662

below than the default value of 10 days, with a mean DT_{50} of 6.26 days and 90th percentile of 7.27 d. The mean values of 6.26 was used for long-term refinement of vole.

zRMS comment:
Commenting Process:
After evaluation of the Report of Kinetic degradation of residue decline in wheat ((Izquierdo J.J., 2021) by e-fate expert it can be concluded that the refined DT_{50} is 8.35 d (90 th percentile) and 6.48 d (mean value).
These values were considered not sufficiently relible by some ecotox expert during commenting period for the use risk assessment.
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.
Furthermore, possibility of extrapolation to non grass plants should be considered by the applicant.
Therfore, these values can be use in the WoE approch only as supportative information.
The defult value of 10 d was used in the risk assessment.

MAF and TWA
In the Tier I, the default twa value used is 0.53. However, since the DT_{50} is lower than 10 days, the 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.

The standard MAF_m value from EFSA Journal 2009; 7(12): 1438 was used in the Tier I. However, according to refined DT_{50} value obtained, a MAF_m of **1.7** is obtained and used in the vole refinement.

Table 9.3-6: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of DUKES in pome fruits– refined parameters (*) are further described and justified in the text

Intended use	Pome fruits
Active substance/product	Dithianon
Application rate (g/ha)	4 × 350
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**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Bank vole (*Clethrionomys glareolus*) BBCH ≥ 40	Short grass, 20%	1.33	54.2[1]× 0.4[2]	1.7[3] × 0.39[3]	1.0	1.34	13.5
	Seeds, 60%	0.20	40.2[1]× 0.4[2]	1.7[3] × 0.39[3]	1.0	0.45	
	Large insects, 20%	0.42	3.5[1]× 1.0	1.7[3] × 0.39[3]	1.0	0.07	
	Whole diet					1.85	

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]DF according to EFSA (2014).
[3]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).

After the refinement, no unacceptable long-term risk is expected for bank vole. Nevertheless, a weight of evidence approach based on Monograph of Dithianon is proposed below:

Identification of focal mammal species

According to the *Additional Report to the DAR-January 2010*:

The vole has been identified by SANCO/4145/2000 as the small herbivorous indicator species feeding in different grass-like crop types, because of its strong preference for grassland habitats. Typical central European orchards have ground vegetation cover between the tree rows. Hence, typical central European orchards can also be interpreted somehow as grassland habitats.

In Central Europe the most frequent vole species in agricultural land, particularly in grassland habitats, is the common vole (Microtus arvalis; Niethammer & Krapp 1982[3]). The population densities vary seasonally as well as annually. The common vole is well known to show characteristic population cycles with years of mass occurrences (gradation), in which densities may reach up to more than 3000 individuals per hectare (e.g. Truszkowski 1982[4]). In Central Europe mass occurrences of common voles take place every 2-4 years and are generally followed by a population break-down, the so-called latency phase (e.g. Heise & Stubbe 1987[5], Niethamer & Krapp 1982[3]).

For the common vole primary habitats are open, dry, grassy and largely undisturbed areas such as permanent grassland or set-aside (Niethammer & Krapp 1982[3], Lauenstein 1979[6]; Dieterlen 2005[7]). These primary habitats are permanent habitation and retreat for common voles even in latency phase. However, the species also occurs in secondary habitats (sub-optimal habitats) like intensively managed agricultural landscape (including orchards), areas with high groundwater or occasional flooding and hedgerows (Niethammer & Krapp 1982[3], Lauenstein 1979[6]; Dieterlen 2005[7]). If the conditions are favorable, secondary habitats are colonized with increasing population density especially in mass occurrence (gradation) years. While regular extinction occurs in secondary habitats, prime habitats harbour permanent vole populations and hence are essential strongholds (source habitats) for the survival of common vole populations.

Orchards are intensively managed crops, in particular during the reproduction season of voles in spring and summer. Besides the use of pesticides particularly mechanical husbandry activities such as mowing, mulching and pruning take place. Despite the fact that common voles are capable of enormous population increases and thus are able to rapidly colonize new habitats, populations of this species are more sensitive to disturbances (Adamczewska-Andrzejewska 1981[8]) compared to other small mammal species, not least due to their small home ranges (Jacob & Hempel 2003[9]) and ultradian rhythm with short-term polyphasic activity patterns (i.e. diurnal and nocturnal activity; Halle 2000[10]).

---

[3] Niethammer, J. & F. Krapp (1982). Microtus arvalis (Pallas, 1779) – Feldmaus; pp 285-318 in J. Niethammer & F. Krapp (eds) Handbuch der Säugetiere Europas. Aula-Verlag, Wiesbaden

[4] Truszkowski, J. (1982). The impact of common vole on the vegetation of agroecosystems. Acta Theriologica 27(23): 105-106

[5] Heise, S. & Stubbe, M. (1987). Populationsoekologische Untersuchungen zum Massenwechsel der Feldmaus Microtus arvalis (Pallas, 1778). Saeugetierkundliche Informationen 11(2): 403-414

[6] Lauenstein, G. (1979). Zur Problematik der Bekämpfung von Feldmäusen (Microtus arvalis (Pall.)) auf Grünland. Zeitschrift für angewandte Zoologie 66: 35-59

[7] Dieterlen, F. (2005). Feldmaus Microtus arvalis (Pallas, 1778) pp 297-311 in M. Braun & F. Dieterlen (eds) Die Säugetiere Baden-Württembergs. Ulmer, Stuttgart

[8] Adamczewska-Andrzejewska, K. A. (1981). Population structure of Microtus arvalis (Pall.) against the background of a community of rodents in crop fields. Polish Ecological Studies 7(2): 193-211

[9] Jacob, J. & Hempel, N. (2003). Effects of farming practices on spatial behaviour of common voles. Journal of Ethology 21: 45-50

[10] Halle, S. (2000). Voles – small graminivores with polyphasic patterns. In: Activity patterns in small mammals. An ecological approach. (Ed.: Halle, S. & Stenseth, N.C.). Pp. 191-215. Springer-Verlag, Berlin, Heidelberg, New York.

Mowing as typical cultural practice in commercial orchards is known to reduce the attractiveness of orchard habitats for voles substantially (Jaworska 1996[11], Sulivan & Hogue 1987[12]). Regular disturbances and lower/lack of vegetation cover (also by herbicidal weeding) lead to vole population decline predominantly through increased exposure to predation through both diurnal and nocturnal predators. In conventional silage grassland, frequent mowing was even followed by 'crashes' in common vole numbers (Jacob & Halle 2001[13]) which was largely due to an increased predation risk through birds of prey, owls and mammalian predators. Likewise, Edge et al. (1995)[14] found populations of grey-tailed voles (Microtus canicaudus) reduced by 50 % after mowing. Hence, the ground vegetation height seems to be a central point for spatial common vole population dynamics and is considered to be a main factor determining the habitat quality. Therefore, intensively managed orchards by mowing, mulching and herbicidal weeding pose adverse habitat conditions for the common vole and are therefore considered only as secondary habitats for this species (Lauenstein 1979xl, Dieterlen 2005[7]).

Besides the colonization behavior of primary and secondary habitat of common voles, hints for a possible source - sink model (Pulliam 1988[15], Dias 1996[16], Tattersall et al. 2004[17]) were found in a study co ducted on voles in old field and orchards habitats in Canada. According to this model animals from "source" populations, which produce surplus individuals (birth rates are higher than mortality rates), migrate to "sink" populations, which can not sustain themselves alone (birth rate are lower than mortality rates). On the long term "sink" populations can not survive without the regularly introduction of animals from "source" populations. In the study of Sullivan et al. (2003)[18], orchard populations might represent "sink" populations, which are supplied by animals from primary habitats. A four year study on the montane vole (Microtus montanus) was conducted in two orchard habitats and 'old fields'. The orchards were mowed 5-6 times in each summer. The 'old field' habitats were abandoned (_ 25 years) hay fields. The study showed that population dynamics in orchards followed the population dynamic of voles in 'old fields', but at a significant lower level. Mean body mass of voles was consistently higher in old field than orchard sites. The mean survival of voles tended to decline through time in orchard sites. Therefore, the orchards seemed to be linked to source area dynamics of populations in old fields 10.

Orchards are mulched regularly during the vegetation season in contrast to primary vole habitats like setasides. Regular mulching reduces the vegetation height which increases the predation risk. Therefore orchards are secondary habitats which will be colonized only in high density years. Primary habitats instead are permanently inhabited by common voles even in low density years. There are also hints that orchards are not able to carry stable vole populations which implies that vole populations would vanish when not supplied by immigrants from primary habitats.

Therefore, the exposure of common voles to plant protection products within orchards is not ecologically relevant for the persistence of the populations. Instead primary habitats are responsible for the common vole persistence in the agricultural landscape.

---

[11] Jaworska, K. (1996). The cover of herbaceous plants in an IPM apple orchard and its influence on the occurrence of rodents. Acta Horticulturae 422: 431-432

[12] Sulivan, T. P. & Hogue, E. J. (1987). Influence of orchard floor management on vole and pocket gopher populations and damage in apple orchards. J. Am. Soc. Hort. Sci. 112: 972-977

[13] Jacob, J., & S. Halle (2001). The importance of land management for population parameters and spatial behaviour in common voles (Microtus arvalis); pp 319-330 in H.-J. Pelz & C.J. Feare (eds) Advances in Vertebrate Pest Management. Filander-Verlag, Fürth

[14] Edge, W. D., Wolff, G. O. & Carey, R. L. (1995). Density-dependent responses of grey-tailed voles to mowing. Journal of Wildlife Management 59: 245-251

[15] Pulliam H.R. (1988). Sources, sinks, and population regulation. Am. Nat. 132: 652-661.

[16] Dias, P.C. (1996). Sources and sinks in population biology. Trends Ecol. Evol. 11: 326-330

[17] Tattersall F.H., Macdonald D.W., Hart B.J., and Manley W. (2004). Balanced dispersal or source-sink - do both models describe wood mice in farmed landscapes? Oikos 106: 536-550

[18] Sullivan, T.P., Sullivan, D.S. & E.J. Hogue (2003). Demography of montane voles in old field and orchard habitats in Southern British Columbia. Northwest Science 77: 228-236

*Since the exposure of common voles to plant protection products in orchards is not ecologically relevant for the survival and reproduction of the populations, the refined risk assessment will be carried for two representative species of herbivorous (**European hare, Lepus europaeus**) and omnivorous (**wood mouse, Apodemus sylvaticus**) mammals.*

The Applicant wishes to note that no unacceptable risk was obtained for **wood mouse (***Apodemus sylvaticus*) in tier I (please, refer to the risk assessment performed in Table 9.3-2).

Regarding the European hare (*Lepus europaeus*), the following risk assessment is proposed below:

Table 9.3-7: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of DUKES in pome fruits– refined parameters (*) are further described and justified in the text

Intended use	Pome fruits
Active substance/product	Dithianon
Application rate (g/ha)	4 × 350
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**	**DDD_m** **(mg/kg bw/d)**	**TER_{lt}**
Brown Hare (*Lepus europaeus*)	Grass+cereals	0.32[1]	54.2[1]× 0.4[2]	1.7[3] × 0.39[3]	1.0	1.61	15.5

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]DF according to EFSA (2014).
[3]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).
According to results above, no unacceptable risk is expected for focal species.

zRMS comments:

The refined risk assessment was verified by zRMS and provided in theTables below.

Refined reproductive risk assessment for mammals following application of dithianon to pome fruits

Focal species	**FIR/bw**	**Rate, kg as/ha**	**RUD unit**	**RUD_m**	**PD**	**PT**	**TWA**	**MAF_m**	**AV**	**DF**	**DDD**	**NOEL**	**TER**
Garden dormouse (*Eliomys quercinus*)	1.16[1]	0.35	Apples	13.79[2]	1	1	0.53	2.2 1.7	1	1	6.52* 5.04**	25	**3.83** **4.96** [A]
Common vole (*Microtus arvalis*)	1.33		Grass+cereals	54.2[3]	1	1	0.53	2.2 1.7	1	0.4	11.76* 9.09**		**2.12** **2.75**

[1]FIR/bw from EFSA/2009/1438.
[2] The revised RUD based on merging of the measured data for dithianon in apples and pears together with the dataset for large fruits from orchards from EFSA GD (2009) (based on Baril et al. 2005)
[3] RUD value without interception could be used because deposition factor is already applied.
*7 days
** 12 days

A) the acceptable risk (the value closed to trigger of 5)

Even with application restrictions acceptable long-term risk for Garden dormouse (*Eliomys quercinus*) for interval 7 day between application and for Common vole (*Microtus arvalis*) cannot be concluded.
Further refinement is required for vole and for garden Garden dormouse (*Eliomys quercinus*) only for interval 7 day between application. For application with 12 days the trigger valu is slight below 5.
Therefore, the ecological relevant NOAEL of 34.9 mg/kg b.w./day for the long-term risk assessment (please see DAR, Table B.9.3/1, p. 590) based on body weight and food consumption data of the gestation period as body weight effects correlated with lower food consumption was most prominent in this period was proposed. This endpoint is employed in the long-term risk assessment for wild mammals.
For details on the calculation of the daily dose please refer to the toxicological section of the DAR of Dithianon (see DAR, Vol. 3, Annex B 6, B 6.6.1.1, p. 153 ff).

Refined reproductive risk assessment for mammals following application of dithianon to pome fruits.

Focal species	FIR/bw	Rate, kg as/ha	RUD unit	RUD_m	PD	PT	TWA	MAF_m	AV	DF	DDD	NOEL	TER
Garden dormouse (*Eliomys quercinus*)	1.16[1]	0.35	Apples	13.79[2]	1	1	0.53	2.2 1.7	1	1	6.52* 5.04**	34.9	5.35 6.92

[1] FIR/bw from EFSA/2009/1438.

[2] The revised RUD based on merging of the measured data for dithianon in apples and pears together with the dataset for large fruits from orchards from EFSA GD (2009) (based on Baril et al. 2005)

*7 days
** 12 days
The risk is considered acceptable for frugivorouse mammals as the trigger value of >5 is achived.
In addition, for vole the refinement of PD value is further considered.
In the study by Rinke (1991) “Percentage of volume versus number of species: Availability and intake of grasses and forbs in microtus arvalis. Folia zoologica 40 (2): 143-151” were investigates vole feeding preferences (mono versus dicot) via stomach content analysis. No exact percentages of each per animal were determined, instead, animals were categorized into 5 potential categories of dicot consumption (20% intervals). Overall, despite the fact that more monocots were available in the surrounding areas (70%), voles showed a preference for dicots, with the majority of voles (all seasons, sexes, ages) showing >80% dicot material in stomach contents. For the chronic risk assessment, in spring and summer, the diet can be set on 25% monocots and 75% dicots.

Refinement of the long-term risk for vole.

Indicator/generic focal species	Typ of food	FIR/bw	RUD_{mean}	DF*	PD	SV_m
Small herbivorous mammal "vole”	Monocotyledons	1.33	54.2	0.35	0.25	6.31
	Dicotyledonos	1.46	28.7	0.35	0.75	11.0
				SUM	1.0	17.31

Reprod. toxicity (mg/kg bw/d)	34.9
TER criterion	5

Crop scenario Growth stage	Indicator/generic focal species	SV_{mean}	MAF	f_{TWA}	DDD_m (mg/kg bw/d)	TER_{LT}
Orchard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole”	17.31	2.2	0.53	7.06	**4.94**

4 x 0.35 kg a.s./ha						

*according to EFSA $_{GW}$ GD, 2014 the deposition facto is 0.4 however for application is made and interception factor will increse.

Based on the result the long – term risk assessment the risk for vole is acceptable as TER_{LT} is imperceptibly below trigger value of 5.

The refinement of the long-term risk assessment for Brown Hare.

Intended use	Pome fruits
Active substance/product	Dithianon
Application rate (g/ha)	4 × 350
Reprod. toxicity (mg/kg bw/d)	34.9
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}**
Brown Hare (*Lepus europaeus*)	Grass+cereals	0.32[1]	54.2[1]× 0.4[2]	2.2 1.7	1.0	5.34* 4.13**	6.53 8.45

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]DF according to EFSA (2014).
*7 days
** 12 days

According to results above, no unacceptable risk is expected for focal species - Brown hare as the TER_{LT} value is above the trigger of 5.

December, 2021 updated risk assessment with refined DT_{50} value:

After Commenting period the risk assessment was updated based on refined MAF and twa values and lowest endpoint NOEL=25 mg a.s./kg bw.
The risk is considered acceptable for frugivorouse mammals as the trigger value of >5 is achived.

Refined reproductive risk assessment for mammals following application of dithianon to pome fruits.

Focal species	**FIR/bw**	**Rate, kg as/ha**	**RUD unit**	**RUD_m**	**PD**	**PT**	**TWA**	**MAF_m**	**AV**	**DF**	**DDD**	**NOEL**	**TER**
Garden dormouse (*Eliomys quercinus*)	1.16[1]	0.35	Apples	13.79[2]	1	1	0.53	2.2 1.7	1	1	6.52* 5.04**	25	**4.67*** **4.96****

[1] FIR/bw from EFSA/2009/1438.
[2] The revised RUD based on merging of the measured data for dithianon in apples and pears together with the dataset for large fruits from orchards from EFSA GD (2009) (based on Baril et al. 2005)
*7 days
** 12 days

Based on the refined MAF and ftwa parameters and the lowest toxicity endpoint of 25 mg a.s./kg bw, the assessment is considered as acceptable for garden dormouse when 7 and 12 days interval will be applied.

The TER_{LT} is closed to trigger of 5.

The refinement of the long-term risk assessment for Brown Hare.

Intended use	Pome fruits
Active substance/product	Dithianon
Application rate (g/ha)	4 × 350
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**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Brown Hare (*Lepus europaeus*)	Grass+cereals	0.39[1]	54.2[1]× 0.4[2]	1.16	1.0	3.46*	7.22*

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]DF according to EFSA (2014).
*7 days

Based on the refined MAF and ftwa parameters and the lowest toxicity endpoint of 25 mg a.s./kg bw the assessment is considered as acceptable for brown hare.

Refinement of the long-term risk for vole.

Indicator/generic focal species	**Typ of food**	**FIR/bw**	**RUD_{mean}**	**DF***	**PD**	**SV_m**
Small herbivorous mammal "vole"	Monocotyledons	1.33	54.2	0.4	0.25	2.52
	Dicotyledonos	1.46	28.7	0.4	0.75	4.4
				SUM	1.0	6.52

Reprod. toxicity (mg/kg bw/d)	25
TER criterion	5

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{mean}**	**MAF**	**f_{TWA}**	**DDD_m (mg/kg bw/d)**	**TER_{LT}**
Orchard Application crop directed BBCH ≥ 40 4 x 0.35 kg a.s./ha	Small herbivorous mammal "vole"	6.52	2.2* 1.7**	0.53	7.6 5.87	**3.28*** **4.25****

*7 days
** 12 days

The risk for vole needs further consideration at MSs level.

9.3.2.3 Drinking water exposure

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

Puddle scenario

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

With a K(f)oc of 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)	=	1365		
Acute toxicity (mg/kg bw)	=	458.9	quotient =	1.68
Reprod. toxicity (mg/kg bw/d)	=	25	quotient =	30.80

zRMS comments:

We agree that hazard quotient for Puddle scenario for ditathion below trigger value 3000, so no specific calculations of exposure and TER are necessary.

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.

Risk assessment for earthworm-eating mammals via secondary poisoning

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

To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.3-8: Assessment of the risk for earthworm-eating mammals due to exposure to Dithianon via bioaccumulation in earthworms (secondary poisoning) for the intended use in pome fruits

Parameter	Dithianon	Comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.515	PEC_{soil} twa 21 d in pome fruits
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}	0.2738	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.141	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.180	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	25	EFSA Journal 2010;8(11):1904.
TER_{lt}	138.5	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 as a limit value for admissible concentrations of Dithianon in water.

To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.3-9: Assessment of the risk for fish-eating mammals due to exposure to Dithianon via bioaccumulation in fish (secondary poisoning) for the intended use in pome fruits

Parameter	Dithianon	Comments
PEC_{sw} (twa = 21 d) (mg/L)	0.00194	Worst case step 2, pome fruits early multiple application for Southern Europe (please refer to section B8, table 8.9-4)
BCF_{fish}	28	EFSA Journal 2010;8(11):1904.
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.054	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.008	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	25	EFSA Journal 2010;8(11):1904.
TER_{lt}	3241.1	No risk, TERlt > 5

TER values shown in bold fall below the relevant trigger.

zRMS comments:

Based on the assessment of the risk for fish-eating mammals due to exposure to Dithianon via bioaccumulation in fish (secondary poisoning) and assessment of the risk for earthworm-eating mammals due to exposure to Dithianon via bioaccumulation in earthworms (secondary poisoning) for the intended use in pome frui it can be concluded that the secondary poisoning is not expected to occur from the proposed use of Dukes.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.3.4 Overall conclusions

In the Tier I risk assessment the TERlt value for all focal species except the small herbivorous mammal “vole” and frugivorous mammal "dormouse" in pome fruits, are above the trigger of 5 for Dithianon. A further refinement of the long-term risk for these species is needed. A refinement of the risk was done by

refining the focal species, PD, FIR/bw, RUD, DF, MAF and ftwa, and the TER value was above the trigger of 5 for "dormouse" and focal species bank "vole". In addition, a refinement of focal species based on studies from Monograph has been included by the Applicant.

No risk from drinking water neither due to secondary poisoning is expected.

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

Not relevant.

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

Effects on aquatic organisms of DUKES were not evaluated as part of the EU assessment of Dithianon. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
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
Fish – Species Sensivity Distribution (SSD)	Dithianon	SSD	HC5=19.4 µg a.s./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)	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)	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)	28 d, f	NOEC < 0.43 µg a.s./L	EFSA Journal 2010;8(11):1904
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

Species	Substance	Exposure System	Results	Reference
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)	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
Sed. dwell. Insects				
Chironomus riparius	Dithianon	28 d, s	**NOEC = 125 µg a.s./L nom**	EFSA Journal 2010;8(11):1904
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)	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)	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
Higher-tier studies (micro- or mesocosms studies)*				
O. mykiss *Zooplankton*	Delan 70 WG (BAS 216 03 F)		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

* The mesocosm study has several limitations and therefore cannot be used in the risk assessment. However, it confirms the higher sensitivities of fish (EFSA Journal 2010;8(11):1904)

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

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	Dithianon 70% WG	96 h, ss	LC_{50} = 0.0135 mg/L $_{nom}$	…
Daphnia magna	Dithianon 70% WG	48 h, ss	EC_{50} = 0~~.1656 mg/L $_{nom}$~~ 0.1165 mg/L nom	KCP 10.2.1-02 Konfederak, E., 2016 W/83/16
Pseudokirchneriella subcapitata	Dithianon 70% WG	72 h	E_rC_{50} = 0.304 mg/L $_{nom}$ E_yC_{50} = 0.080 mg/L $_{nom}$	KCP 10.2.1-03 Konfederak, E., 2016 W/82/16
Lemna gibba	Dithianon 70% WG	7 d, ss	E_rC_{50} = 15.43 mg/L $_{nom}$ E_yC_{50} = 0.67 mg/L $_{nom}$	KCP 10.2.1-04 Konfederak, E., 2016 W/84/16

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.

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, 3 and 4 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC and RAC ratios comparisons presented in the table below.

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

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC < RAC) for Dithianon for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of DUKES in pome fruits-early application (single / multiple applications)

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							
	56.33	**393.916**	**1224.565**	**21.665**	**9.467**	**6.259**	**4.506**
Step 2							
N-Europe	34.06/28.10	**238.182/196.503**	**740.435/610.870**	**13.100/10.808**	**5.724/4.723**	**3.784/3.122**	**2.725/2.248**
S-Europe							
Step 3							
D3/ditch	27.27/21.63	**190.699/151.259**	**592.826/470.217**	**10.488/8.319**	**4.583/3.635**	**3.030/2.403**	**2.182/1.730**
D4/pond	1.653/1.289	**11.559/9.014**	**35.935/28.022**	0.636/0.496	0.278/0.217	0.184/0.143	0.132/0.103
D4/stream	27.72/22.67	**193.846/158.531**	**602.609/492.826**	**10.662/8.719**	**4.659/3.810**	**3.080/2.519**	**2.218/1.814**
D5/pond	1.654/1.288	**11.566/9.007**	**35.957/28.000**	0.636/0.495	0.278/0.216	0.184/0.143	0.132/0.103
D5/stream	29.54/24.46	**206.573/171.049**	**642.174/531.739**	**11.362/9.408**	**4.965/4.111**	**3.282/2.718**	**2.363/1.957**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
R1/pond	1.653/1.287	**11.559/9.000**	**35.935/27.978**	0.636/0.495	0.278/0.216	0.184/0.143	0.132/0.103
R1/stream	22.12/17.34	**154.685/121.259**	**480.870/376.957**	**8.508/6.669**	**3.718/2.914**	**2.458/1.927**	**1.770/1.387**
R2/stream	29.63/23.24	**207.203/162.517**	**644.130/505.217**	**11.396/8.938**	**4.980/3.906**	**3.292/2.582**	**2.370/1.859**
R3/stream	31.00/24.44	**216.783/170.909**	**673.913/531.304**	**11.923/9.400**	**5.210/4.108**	**3.444/2.716**	**2.480/1.955**
R4/stream	22.11/17.34	**154.615/121.259**	**480.652/376.957**	**8.504/6.669**	**3.716/2.914**	**2.457/1.927**	**1.769/1.387**

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

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 $_{gl\text{-}max}$ (µg/L)**						
Step 1							
	40.62	**284.056**	**883.043**	**15.623**	**6.827**	**4.513**	**3.250**
Step 2							
N-Europe	18.35/12.05	**128.322/84.266**	**398.913/261.957**	**7.058/4.635**	**3.084/2.025**	**2.039/1.339**	**1.468**/0.964
S-Europe							
Step 3							

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**
D3/ditch	12.86/8.455	**89.930/59.126**	**279.565/183.804**	**4.946/3.252**	**2.161/1.421**	**1.429**/0.939	**1.029**/0.676
D4/pond	0.577/0.396	**4.035/2.769**	**12.543/8.609**	0.222/0.152	0.097/0.067	0.064/0.044	0.046/0.032
D4/stream	12.89/8.528	**90.140/59.636**	**280.217/185.391**	**4.958/3.280**	**2.166/1.433**	**1.432**/0.948	**1.031**/0.682
D5/pond	0.577/0.396	**4.035/2.769**	**12.543/8.609**	0.222/0.152	0.097/0.067	0.064/0.044	0.046/0.032
D5/stream	13.92/9.202	**97.343/64.350**	**302.609/200.043**	**5.354/3.539**	**2.339/1.547**	**1.547/1.022**	**1.114**/0.736
R1/pond	0.576/0.415	**4.028/2.902**	**12.522/9.022**	0.222/0.160	0.097/0.070	0.064/0.046	0.046/0.033
R1/stream	9.879/6.522	**69.084/45.608**	**214.761/141.783**	**3.800/2.508**	**1.660/1.096**	**1.098**/0.725	0.790/0.522
R2/stream	13.24/8.742	**92.587/61.133**	**287.826/190.043**	**5.092/3.362**	**2.225/1.469**	**1.471/0.971**	**1.059**/0.699
R3/stream	13.83/9.194	**96.713/64.294**	**300.652/199.870**	**5.319/3.536**	**2.324/1.545**	**1.537/1.022**	**1.106**/0.736
R4/stream	9.656/6.521	**67.524/45.601**	**209.913/141.761**	**3.714/2.508**	**1.623/1.096**	**1.073/0.725**	0.772/0.522

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

For the intended uses pome fruits and almond, calculated PEC/RAC ratios did not indicate an acceptable risk for all aquatic organisms in several FOCUS Steps 1-3 scenarios. The most sensitive group is fish (acute risk for *Ictalurus punctatus* as characterised by an LC_{50} of 14.3 µg/L in connection with an assessment factor of 100 and chronic risk for *Oncorhynchus mykiss* as characterised by an NOEC of 0.46 µg/L in connection with an assessment factor of 10). Therefore, further refinement is required.

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.

The worse case RAC value of 1.30 µg/L was used in the risk assessment at Step 4 considering reduced exposure of surface water bodies.

Table 9.5-5: Aquatic organisms: PEC calculation and acceptability of risk (PEC < RAC) for Dithianon based on FOCUS Step 4 calculations and toxicity data for group with mitigation of spray drift and run-off for the use of DUKES in pome fruits -early application (single/multiple application)

Intended use		Pome fruits (early application)										
Active substance		Dithianon										
Application rate (g/ha)		4 x 350										
Nozzle reduction	Vegetative strip (m)	None						5*	10	15**	20	
	No spray buffer (m)	5	10	15	20	30	40	5	10	15	20	30
None	D3 ditch	21.43/16.5	13.16/9.647	5.920/5.196	3.009/2.401	1.151/0.802	-/-	-/-	-/-	-/-	-/-	-/-
50%		10.71/8.27	6.581/4.822	2.960/2.599	1.505/1.201	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		5.359/4.13	3.290/2.412	1.480/1.299	0.752/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		2.143/1.65	1.316/0.965	0.592/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		1.071/0.82	0.658/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 pond	1.861/-	1.020/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50%		0.930/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	23.81/19.1	14.62/11.16	6.580/6.014	3.345/2.779	1.279/0.928	-/-	-/-	-/-	-/-	-/-	-/-
50%		11.91/9.58	7.311/5.582	3.290/3.007	1.672/1.389	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		5.953/4.79	3.657/2.791	1.645/1.503	0.836/0.695	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		2.381/1.91	1.462/1.116	0.658/0.601	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		1.191/0.95	0.731/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Pome fruits (early application)										
Active substance		Dithianon										
Application rate (g/ha)		4 x 350										
Nozzle reduction	Vegetative strip (m)	None						5*	10	15**	20	
	No spray buffer (m)	5	10	15	20	30	40	5	10	15	20	30
None	D5 pond	1.862/-	1.021/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50%		0.931/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 stream	25.38/20.6	15.59/12.04	7.013/6.448	3.565/2.998	1.363/1.001	0.686/-	-/-	-/-	-/-	-/-	-/-
50%		12.69/10.3	7.792/6.023	3.507/3.244	1.782/1.499	0.862/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		6.345/5.16	3.898/3.011	1.753/1.622	0.891/0.750	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		2.538/2.06	1.559/1.204	0.701/0.649	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		1.269/1.03	0.779/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 pond	1.861/-	1.020/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50%		0.930/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	19.00/14.6	11.67/8.537	5.250/4.600	2.669/2.125	1.020/0.710	-/-	-/-	-/-	-/-	-/-	-/-
50%		9.501/7.32	5.834/4.270	2.625/2.300	1.334/1.063	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		4.750/3.66	2.198/2.134	1.312/1.150	0.667/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		1.900/1.46	1.167/0.854	0.525/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Pome fruits (early application)										
Active substance		Dithianon										
Application rate (g/ha)		4 x 350										
Nozzle reduction	Vegetative strip (m)	None						5*	10	15**	20	
	No spray buffer (m)	5	10	15	20	30	40	5	10	15	20	30
95%		0.950/0.73	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	25.46/19.6	15.63/11.44	7.034/6.165	3.576/2.849	1.367/0.951	0.688/-	-/-	-/-	-/-	-/-	-/-
50%		12.73/9.82	7.815/5.723	3.517/3.083	1.787/1.424	0.684/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		6.364/4.19	3.909/2.861	1.758/1.541	0.894/0.712	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		2.546/1.96	1.563/1.144	0.703/0.617	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		1.273/0.98	0.782/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	26.63/20.6	16.36/12.03	7.630/6.483	3.741/2.996	1.430/1.000	0.720/-	-/-	-/-	-/-	-/-	-/-
50%		13.32/10.3	8.177/6.018	3.680/3.242	1.870/1.498	0.715/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		6.659/5.16	4.090/3.008	1.840/1.621	0.935/0.749	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		2.663/2.06	1.636/1.203	0.736/0.648	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		1.332/1.03	0.818/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	19.00/14.6	11.67/8.535	5.249/4.599	2.668/2.125	1.020/1.642	-/-	-/14.65	-/8.535	-/4.599	-/2.125	-/0.710
50%		9.498/7.32	5.832/4.269	2.625/2.300	1.334/1.642	-/-	-/-	-/7.326	-/4.269	-/2.300	-/1.062	-/-
75%		4.749/3.66	2.197/2.134	1.312/1.642	0.667/1.642	-/-	-/-	-/3.663	-/2.134	-/1.150	-/-	-/-
90%		1.900/1.64	1.167/1.642	0.556/1.642	-/-	-/-	-/-	-/1.465	-/0.854	-/-	-/-	-/-
95%		0.950/1.64	-/-	-/-	-/-	-/-	-/-	-/1.068	-/-	-/-	-/-	-/-
RAC (µg/L)												
1.3		**PEC/RAC ratio**										
None	D3 ditch	**16.485/12.**	**10.123/7.42**	**4.554/3.997**	**2.315/1.847**	0.885/0.617	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Pome fruits (early application)										
Active substance		Dithianon										
Application rate (g/ha)		4 x 350										
Nozzle reduction	Vegetative strip (m)	None						5*	10	15**	20	
	No spray buffer (m)	5	10	15	20	30	40	5	10	15	20	30
50%		**8.238/6.36**	**5.062/3.709**	**2.277/1.999**	**1.158**/0.924	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		**4.122/3.18**	**2.531/1.855**	**1.138**/0.999	0.578/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		**1.648/1.27**	**1.012**/0.742	0.455/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		0.824/0.63	0.506/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 pond	**1.432**/-	0.785/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50%		0.715/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	**18.315/14.**	**11.246/8.58**	**5.062/4.626**	**2.573/2.138**	0.984/0.714	-/-	-/-	-/-	-/-	-/-	-/-
50%		**9.162/7.36**	**5.624/4.294**	**2.531/2.313**	**1.286/1.068**	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		**4.579/3.68**	**2.813/2.147**	**1.265/1.156**	0.643/0.535	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		**1.832/1.47**	**1.125**/0.858	0.506/0.462	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		0.916/0.73	0.562/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 pond	**1.432**/-	0.785/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50%		0.716/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use	Pome fruits (early application)										
Active substance	Dithianon										
Application rate (g/ha)	4 x 350										
Nozzle reduction	Vegetative strip (m)	None						5*	10	15**	20	
	No spray buffer (m)	5	10	15	20	30	40	5	10	15	20	30
None	D5 stream	**19.523/15.**	**11.992/9.26**	**5.395/4.960**	**2.742/2.306**	**1.048**/0.770	0.528/-	-/-	-/-	-/-	-/-	-/-
50%		**9.762/7.95**	**5.994/4.633**	**2.698/2.495**	**1.371/1.153**	0.663/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		**4.881/3.97**	**2.998/2.316**	**1.348/1.248**	0.685/0.577	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		**1.952/1.59**	**1.199**/0.926	0.539/0.499	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		0.976/0.79	0.599/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 pond	**1.432**/-	0.785/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50%		0.715/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	**14.615/11.**	**8.977/6.567**	**4.038/3.538**	**2.053**/1.635	0.785/0.546	-/-	-/-	-/-	-/-	-/-	-/-
50%		**7.308/5.63**	**4.488/3.285**	**2.019/1.769**	**1.026**/0.818	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		**3.654/2.81**	**1.691/1.642**	**1.009**/0.885	0.513/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		**1.462/1.12**	0.898/0.657	0.404/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		0.731/0.56	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	**19.585/15.**	**12.023/8.80**	**5.411/4.742**	**2.751/2.192**	**1.052**/0.732	0.529/-	-/-	-/-	-/-	-/-	-/-
50%		**9.792/7.55**	**6.012/4.402**	**2.705/2.372**	**1.375/1.095**	0.526/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		**4.895/3.22**	**3.007/2.201**	**1.352/1.185**	0.688/0.548	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		**1.958/1.51**	**1.202**/0.880	0.541/0.475	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Pome fruits (early application)										
Active substance		Dithianon										
Application rate (g/ha)		4 x 350										
Nozzle reduction	Vegetative strip (m)	None						5*	10	15**	20	
	No spray buffer (m)	5	10	15	20	30	40	5	10	15	20	30
95%		0.979/0.75	0.602/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	**20.485/15.**	**12.585/9.25**	**5.869/4.987**	**2.878/2.305**	**1.100**/0.769	0.554/-	-/-	-/-	-/-	-/-	-/-
50%		**10.246/7.9**	**6.290/4.629**	**2.831/2.494**	**1.438/1.152**	0.550/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		**5.122/3.97**	**3.146/2.314**	**1.415/1.247**	0.719/0.576	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		**2.048/1.58**	**1.258**/0.925	0.566/0.498	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		**1.025**/0.79	0.629/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	**14.615/11.**	**8.977/6.565**	**4.038/3.538**	**2.052/1.635**	0.785/**1.263**	-/-	**-/11.269**	**-/6.565**	**-/3.538**	-/**1.635**	-/0.546
50%		**7.306/5.63**	**4.486/3.284**	**2.019/1.769**	**1.026/1.263**	-/-	-/-	**-/5.635**	**-/3.284**	**-/1.769**	-/0.817	-/-
75%		**3.653/2.81**	**1.690/1.642**	**1.009/1.263**	0.513/**1.263**	-/-	-/-	**-/2.818**	**-/1.642**	-/0.885	-/-	-/-
90%		**1.462/1.26**	0.898/**1.263**	0.428/**1.263**	-/-	-/-	-/-	**-/1.127**	-/0.657	-/-	-/-	-/-
95%		0.731/**1.26**	-/-	-/-	-/-	-/-	-/-	-/0.822	-/-	-/-	-/-	-/-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*The values used for reduction in run off volume and flux and erosion mass and flux were 0.4 and 0.4 respectively for 5 meters of vegetative buffer strip according to the Austrian Environmental Agency (AGES).
**The values used for reduction in run off volume and flux and erosion mass and flux were 0.7 and 0.9respectively for 15 meters of vegetative buffer strip according to the Austrian Environmental Agency (AGES).

After step 4 calculations, PEC/RAC ratio values are below the trigger of 1 considering the following risk mitigation measures for each scenario:

- D3/ditch, D4/stream and R1/stream: no-spray buffer zone of 5 m + 95% of nozzles reduction or no-spray buffer zone of 15 m + 90% of nozzles reduction or no-spray buffer zone of 20 m + 75% of nozzles reduction or no-spray buffer zone of 30 m.
- D4/pond and D5/pond: no-spray buffer zone of 5 m + 50% of nozzles reduction or no-spray buffer zone of 10 m.
- D5/stream and R2/stream: no-spray buffer zone of 5 m + 95% of nozzles reduction or no-spray buffer zone of 15 m + 90% of nozzles reduction or no-

spray buffer zone of 20 m + 75% of nozzles reduction or no-spray buffer zone of 30 m + 50% of nozzles reduction or no-spray buffer zone of 40 m.

- R3/stream: no-spray buffer zone of 10 m + 95% of nozzles reduction or no-spray buffer zone of 15 m + 90% of nozzles reduction or no-spray buffer zone of 20 m + 75% of nozzles reduction or no-spray buffer zone of 30 m + 50% of nozzles reduction or no-spray buffer zone of 40 m.
- R4/stream: no-spray buffer zone of 5 m + vegetative strip of 5 m + 95% of nozzles reduction or no-spray buffer zone of 10 m + vegetative strip of 10 m + 90% of nozzles reduction or no-spray buffer zone of 15 m + vegetative strip of 15 m + 75% of nozzles reduction or no-spray buffer zone of 20 m + vegetative strip of 20 m + 50% of nozzles reduction or no-spray buffer zone of 30 m + vegetative strip of 30 m.

Table 9.5-6: Aquatic organisms: PEC calculation and acceptability of risk (PEC < RAC) for Dithianon based on FOCUS Step 4 calculations and toxicity data for group with mitigation of spray drift and run-off for the use of DUKES in pome fruits -late application (single/multiple application)

Intended use		Pome fruits (late application)				
Active substance		Dithianon				
Application rate (g/ha)		4 x 350				
Nozzle reduction	Vegetative strip (m)	None				
	No spray buffer (m)	5	10	15	20	30
None	D3 ditch	8.681/5.	3.880/2.740	1.959/1.366	1.197/0.808	-/-
50%		4.342/2.	1.940/1.370	0.979/0.683	-/-	-/-
75%		2.170/1.	0.970/0.685	-/-	-/-	-/-
90%		0.868/0.	-/-	-/-	-/-	-/-
None	D4 stream	10.06/6.	4.497/3.174	2.270/1.583	1.388/0.936	0.690/-
50%		5.032/3.	2.248/1.587	1.135/0.791	0.694/-	-/-
75%		2.516/1.	1.124/0.793	-/-	-/-	-/-
90%		1.006/0.	-/-	-/-	-/-	-/-
None	D5 stream	10.87/7.	4.856/3.425	2.452/1.708	1.499/1.010	0.745/-
50%		5.435/3.	2.428/1.712	1.226/0.854	0.749/-	-/-
75%		2.717/1.	1.214/0.856	-/-	-/-	-/-

Intended use		Pome fruits (late application)				
Active substance		Dithianon				
Application rate (g/ha)		4 x 350				
Nozzle reduction	Vegetative strip (m)	None				
	No spray buffer (m)	5	10	15	20	30
90%		1.087/0.	-/-	-/-	-/-	-/-
None	R1 stream	7.710/5.	3.446/2.427	1.740/1.210	1.063/-	-/-
50%		3.856/2.	1.723/1.214	0.870/-	-/-	-/-
75%		1.928/1.	0.861/-	-/-	-/-	-/-
90%		0.771/-	-/-	-/-	-/-	-/-
None	R2 stream	10.33/6.	4.619/3.253	2.332/1.622	1.425/0.960	0.708/-
50%		5.169/3.	2.309/1.627	1.166/0.811	0.712/-	-/-
75%		2.584/1.	1.155/0.813	-/-	-/-	-/-
90%		1.033/0.	-/-	-/-	-/-	-/-
None	R3 stream	10.79/7.	4.822/3.422	2.435/1.706	1.488/1.009	0.739/-
50%		5.397/3.	2.411/1.711	1.217/0.853	0.744/-	-/-
75%		2.698/1.	1.206/0.855	-/-	-/-	-/-
90%		1.079/0.	-/-	-/-	-/-	-/-
None	R4 stream	7.536/5.	3.368/2.427	1.700/1.250	1.039/-	-/-
50%		3.769/2.	1.684/1.250	0.850/	-/-	-/-
75%		1.884/1.	0.842/-	-/	-/-	-/-
90%		0.754/-	-/-	-/	-/-	-/-
RAC (µg/L) 1.3		**PEC/RAC ratio**				

Intended use		Pome fruits (late application)				
Active substance		Dithianon				
Application rate (g/ha)		4 x 350				
Nozzle reduction	Vegetative strip (m)	None				
	No spray buffer (m)	5	10	15	20	30
None	D3 ditch	**6.678/4.**	**2.985/2.108**	**1.507/1.051**	0.921/0.622	-/-
50%		**3.340/2.**	**1.492/1.054**	0.753/0.525	-/-	-/-
75%		**1.669/1.**	0.746/0.527	-/-	-/-	-/-
90%		0.668/0.	-/-	-/-	-/-	-/-
None	D4 stream	**7.738/5.**	**3.459/2.442**	**1.746/1.218**	**1.068**/0.720	0.531/-
50%		**3.871/2.**	**1.729/1.221**	0.873/0.608	0.534/-	-/-
75%		**1.935/1.**	0.865/0.610	-/-	-/-	-/-
90%		0.774/0.	-/-	-/-	-/-	-/-
None	D5 stream	**8.362/5.**	**3.735/2.635**	**1.886/1.314**	**1.153**/0.777	0.573/-
50%		**4.181/2.**	**1.868/1.317**	0.943/0.657	0.576/-	-/-
75%		**2.090/1.**	0.934/0.658	-/-	-/-	-/-
90%		0.836/0.	-/-	-/-	-/-	-/-
None	R1 stream	**5.931/3.**	**2.651/1.867**	**1.338**/0.931	0.818/-	-/-
50%		**2.966/1.**	**1.325**/0.934	0.669/-	-/-	-/-
75%		**1.483**/0.	0.662/-	-/-	-/-	-/-
90%		0.593/-	-/-	-/-	-/-	-/-
None	R2 stream	**7.946/5.**	**3.553/2.502**	**1.794/1.248**	**1.096**/0.738	0.545/-
50%		**3.976/2.**	**1.776/1.252**	0.897/0.624	0.548/-	-/-
75%		**1.988/1.**	0.888/0.625	-/-	-/-	-/-

Intended use		Pome fruits (late application)				
Active substance		Dithianon				
Application rate (g/ha)		4 x 350				
Nozzle reduction	Vegetative strip (m)	None				
	No spray buffer (m)	5	10	15	20	30
90%		0.795/0.	-/-	-/-	-/-	-/-
None	R3 stream	**8.300/5.**	**3.709/2.632**	**1.873/1.312**	**1.145**/0.776	0.568/-
50%		**4.152/2.**	**1.855/1.316**	0.936/0.656	0.572/-	-/-
75%		**2.075/1.**	0.928/0.658	-/-	-/-	-/-
90%		0.830/0.	-/-	-/-	-/-	-/-
None	R4 stream	**5.797/3.**	**2.591/1.867**	**1.308**/0.962	0.799/-	-/-
50%		**2.899/1.**	**1.295**/0.962	0.654/-	-/-	-/-
75%		**1.449**/0.	0.648/-	-/-	-/-	-/-
90%		0.580/-	-/-	-/-	-/-	-/-

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

After step 4 calculations, PEC/RAC ratio values are below the trigger of 1 considering the following risk mitigation measures for each scenario:

- D3/ditch, R1/stream and R4/stream: no-spray buffer zone of 5 m + 90% of nozzles reduction or no-spray buffer zone of 10 m + 75% of nozzles reduction or no-spray buffer zone of 15 m + 50% of nozzles reduction or no-spray buffer zone of 20 m.
- D4/stream, D5/stream, R2/stream and R3/stream: no-spray buffer zone of 5 m + 90% of nozzles reduction or no-spray buffer zone of 10 m + 75% of nozzles reduction or no-spray buffer zone of 15 m + 50% of nozzles reduction or no-spray buffer zone of 30 m.

Metabolites of Dithianon

CL 1017911

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC< RAC) for CL 1017911 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of DUKES in pome fruits – early application (single / multiple applications) as worst case

Group		**Fish acute**	**Inverteb. Acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint		LC_{50}	EC_{50}	E_rC_{50}
(µg/L)		3260	45600	4340
AF		100	100	10
RAC (µg/L)		32.6	456	434
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	90.57/362.27	**2.778/11.113**	0.199/0.794	0.209/0.835
Step 2				
N-Europe	20.68/35.48	0.634/**1.088**	0.045/0.078	0.048/0.082
S-Europe				
Step 3				
D3/ditch	-/6.871	-/0.211	-/0.015	-/0.016
D4/pond	-/1.132	-/0.035	-/0.002	-/0.003
D4/stream	-/3.368	-/0.103	-/0.007	-/0.008
D5/pond	-/1.064	-/0.033	-/0.002	-/0.002
D5/stream	-/3.893	-/0.119	-/0.009	-/0.009
R1/pond	-/0.991	-/0.030	-/0.002	-/0.002
R1/stream	-/2.393	-/0.073	-/0.005	-/0.006
R2/stream	-/2.413	-/0.074	-/0.005	-/0.006
R3/stream	-/4.487	-/0.138	-/0.010	-/0.010
R4/stream	-/2.539	-/0.078	-/0.006	-/0.006

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

Phthalic acid

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC< RAC) for Phthalic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of DUKES in pome fruits– early application (single / multiple applications) as 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				
	42.49/169.96	0.042/0.170	0.042/0.170	0.004/0.017
Step 2				
N-Europe	8.89/19.53	0.009/0.020	0.009/0.020	0.001/0.002
S-Europe				

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

Phthalaldehyde

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC< RAC) for Phthalaldehyde for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of DUKES in pome fruits– early application (single / multiple applications) as worst case

Group		**Fish acute**	**Inverteb. acute**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***
Endpoint (µg/L)		LC_{50} 83	EC_{50} 136
AF		100	100
RAC (µg/L)		0.83	1.36
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**		
Step 1			
	7.56/30.26	**9.108/36.458**	**5.559/22.250**
Step 2			
N-Europe	1.73/1.44	**2.084/1.735**	**1.272/1.059**
S-Europe			

Group		Fish acute	Inverteb. acute
Step 3			
D3/ditch	0.555/0.487	0.669/0.587	0.408/0.358
D4/pond	0.045/0.041	0.054/0.049	0.033/0.030
D4/stream	0.162/0.247	0.195/0.298	0.119/0.182
D5/pond	0.046/0.039	0.055/0.047	0.034/0.029
D5/stream	0.182/0.286	0.219/0.345	0.134/0.210
R1/pond	0.045/0.038	0.054/0.046	0.033/0.028
R1/stream	0.193/0.173	0.233/0.208	0.142/0.127
R2/stream	0.183/0.164	0.220/0.198	0.135/0.121
R3/stream	0.302/0.334	0.364/0.402	0.222/0.246
R4/stream	0.166/0.185	0.200/0.223	0.122/0.136

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

1,2-benzenedimethanol

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC< RAC) for 1,2-benzenedimethanol for each organism group based on FOCUS Steps 1 and 2 calculations for the use of DUKES in pome fruits– early application (single / multiple applications)

Group		Fish acute	Inverteb. acute
Test species		***Oncorhynchus mykiss***	***Daphnia magna***
Endpoint (µg/L)		LC_{50} >100000	EC_{50} >100000
AF		100	100
RAC (µg/L)		>1000	>1000
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**		
Step 1			
	14.54/58.16	<0.015/<0.058	<0.015/<0.058
Step 2			
N-Europe	3.32/5.07	<0.003/<0.005	<0.003/<0.005

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

9.5.3 Overall conclusions

Conclusions of aquatic risk assessment are presented in tables below:

Table 9.5-11: Pome fruits-early application (single/multiple application)

Dithianon

Non sprayed buffer using DRN [m]					
Scenario	**None**	**50 %**	**75 %**	**90 %**	**95%**
D3/ditch	30	30	20	15	5
D4/pond	10	5	5	5	5
D4/stream	30	30	20	15	5
D5/pond	10	5	5	5	5
D5/stream	40	30	20	15	5
R1 pond	15	10	5	5	5
R1 stream	30	30	20	15	5
R2 stream	40	30	20	15	5
R3 stream	40	30	20	15	10
R4 stream	30VFS	20VFS	15VFS	10VFS	5VFS

DRN: Drift Reducing Nozzles

VFS: Vegetative filter strip

Table 9.5-12: Pome fruits-late application (single/multiple application)

Dithianon

Non sprayed buffer using DRN [m]				
Scenario	**None**	**50 %**	**75 %**	**90 %**
D3/ditch	20	15	10	5
D4/stream	30	15	10	5
D5/stream	30	15	10	5
R1 stream	20	15	10	5
R2 stream	30	15	10	5
R3 stream	30	15	10	5
R4 stream	20	15	10	5

DRN: Drift Reducing Nozzles

VFS: Vegetative filter strip

Metabolites of Dithianon: for all intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

Pome fruits (early application) – Spe3: *To protect aquatic organisms respect an unsprayed buffer zone of 10m with 5m of vegetative strip to surface water bodies with 95% of nozzles reduction OR an unsprayed buffer zone of 15m with 10m of vegetative strip to surface water bodies with 90% of nozzles reduction OR an unsprayed buffer zone of 20m with 15m of vegetative strip to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 30m with 20m of vegetative strip to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 40m with 30m of vegetative strip to surface water bodies.*

Pome fruits (late application) – Spe3: *To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction OR an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 15 m to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 30 m to surface water bodies.*

zRMS comment:

zRMS verfided the risk assessment for aquatic organism and mitigation measures provided by the applicant.
Based on the results mitigation measures are as follows:

Pome fruits (early application)*– Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 15m with 10m of vegetative strip to surface water bodies with 90% of nozzles reduction OR an unsprayed buffer zone of 20m with 15m of vegetative strip to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 30m with 20m of vegetative strip to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 40m with 30m of vegetative strip to surface water bodies.

Pome fruits (late application)* – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction OR an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 15 m to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 30 m to surface water bodies.
***Remarks from e-fate expert (Section B8):**

The zRMS has been accepted the calculations of PECsw/sed values for active substance dithianon presented by the Applicant.

The input parameters used in calculations were taken from the endpoints available in the conclusion EFSA Journal 2010;8(11):1904 and Addendum of October 2010 and Addendum to DAR – June 2014.
The geometric mean of the DT_{50} and Koc were considered in the assessment in accordance with the latest EFSA guideline (EFSA 2014). The crop interception were set in accordance to the actual guideline (EFSA Journal 2014;12(5):3662).

In opinion of zRMS, the Step 4 PECsw/sed calculations are not accepted for calculations performed according AGES approach and calculations with 95% drift reduction.
According to Working Document of the Central Zone in the Authorisation of Plant Protection Products (2018), simulating in Step 4 are recommended according guidance SANCO/10422/2005, version 2.0, September 2007. Other approaches for simulating run-off mitigation reductions (e.g. VSFMod) are not recommended for the Core Assessment.

Other approaches should only be presented in *National Assessment Report*. Therefore mitigation measures should be decided on national level.

Therefore, the final risk mitigation measures for aquatic organism should be considered at MSs level.

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

Effects on bees of DUKES were not evaluated as part of the EU assessment of Dithianon. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Table 9.6-1: 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
Apis mellifera	Delan 70 WG (BAS 216 03 F)[1]	Oral	LD_{50} > 91.77[1] µg a.s./bee	EFSA Journal 2010;8(11):1904
Apis mellifera	Delan 70 WG (BAS 216 03 F)[1]	Contact	LD_{50} > 100[1] µg a.s./bee	EFSA Journal 2010;8(11):1904
Apis mellifera	Dithianon 70% WG	Oral	LD_{50} >200 µg/bee (> 140.0 µg a.s/bee)	KCP 10.3.1.1.1 Czarnecka, M., 2016 B/164/15
Apis mellifera	Dithianon 70% WG	Contact	LD_{50} >200 µg/bee (> 140.0 µg a.s/bee)	KCP 10.3.1.1.2 Czarnecka, M., 2016 B/165/15
Higher-tier studies (tunnel test, field studies)				

1) = 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 DUKES 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).

To achieve a concise risk assessment, the risk envelope approach is applied.

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 DUKES in pome fruits

Intended use	Pome fruits
Active substance	Dithianon
Application rate (g/ha)	4 × 350 g a.s./ha

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	350	<13.8
Contact toxicity	> 100		<3.5
Product	DUKES		
Application rate (g/ha)	4 × 500 g f.p./ha		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>200	~~750~~ 500	<2.5
Contact toxicity	>200		<2.5

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

zRMS comments:
The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).
zRMS agrees basically with assessment above however, according to the Commission Regulation (EU) No 283, 284/2013 chronic toxicity to bees and effects on honeybee development and other honeybee life stages tests were required .
These tests were not submitted by applicant therefore, the influence of missing studies on registration process should be considered at national levels.

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

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

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

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	Delan 70 WG	Laboratory test glass plates (2D)	LR_{50} > 0.96 kg/ha	EFSA Journal 2010;8(11):1904
Typhlodromus pyri (protonymphs)	Delan 70 WG	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	Laboratory test glass plates (2D)	LR_{50} > 6 kg/ha (> 4.2 kg a.s./ha)	EFSA Journal 2010;8(11):1904
Aphidius rhopalosiphi (adults)	Delan 70 WG	Extended laboratory test barley plants (3D)	LR_{50} > 3.02 kg Delan 70 WG/ha ER_{50} > 2.076 kgDelan 70 WG/ha	EFSA Journal 2010;8(11):1904
Aphidius rhopalosiphi (adults)	Delan 70 WG	Aged-residue test Natural substrate barley plants (3D)	Mortality at 4 kg/ha: 47 % at 0 DAT 0 % at 7 DAT Mortality at 6 kg/ha: 80 % at 0 DAT 0 % at 7 DAT Effects sublethal at 4 kg/ha: 50 % at 0 DAT -47 % at 7 DAT Effects sublethal at 6 kg/ha: - % at 0 DAT -41 % at 7 DAT	EFSA Journal 2010;8(11):1904

Species	Substance	Exposure System	Results	Reference
Chrysoperla Carnea	Delan 70 WG	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 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	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
Typhlodromus pyri (protonymphs)	Dithianon 70% WG	Laboratory test, glass plate (2D)	LR_{50} > 4.05 kg f.p./ha (equivalent to >2839.05 g a.s./ha) ER_{50} > 4.0500 kg f.p./ha (equivalent to >2839.05 g a.s./ha)	KCP 10.3.2.1-01 Luna, F. 2017 TRC17-139BA
Aphidius rhopalosiphi	Dithianon 70% WG	Laboratory test, glass plate (2D)	LR_{50} > 4.05 kg f.p./ha (equivalent to >2839.05 g a.s./ha) ER_{50} > 4.0500 kg f.p./ha (equivalent to >2839.05 g a.s./ha)	KCP 10.3.2.1-02 Varela Cervero, S. 2017 TRC17-100BA
Field or semi-field tests				

Negative values indicate an increase compared to the control

9.7.1.1 Justification for new endpoints

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

9.7.2 Risk assessment

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

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied.

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

Intended use	Pome fruits		
Active substance/product	Dithianon/ DUKES		
Application rate (g/ha)	4 × 500 g f.p./ha		
MAF	2.7 (foliar)		
Test species Tier I	**LR_{50} (lab.) (g f.p./ha)**	**$PER_{in\text{-}field}$ (g f.p./ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	> 4050	1350	<0.33
Aphidius rhopalosiphi	> 4050		<0.33
~~**Intended use**~~	~~Pome fruits~~		
~~**Active substance/product**~~	~~Dithianon/ DUKES~~		
~~**Application rate (g/ha)**~~	~~4 × 500 g f.p./ha (4 × 200** g f.p./ha)~~		
~~**MAF**~~	~~3.4 (soil)~~		
~~**Test species Tier I**~~	~~**LR_{50} (lab.) (g f.p./ha)**~~	~~**$PER_{in\text{-}field}$ (g f.p./ha)**~~	~~**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**~~
~~*Typhlodromus pyri*~~	~~> 4050~~	~~680~~	~~<0.17~~
~~*Aphidius rhopalosiphi*~~	~~> 4050~~		~~<0.17~~

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 60% of interception.at BBCH 51-79. According to the interception values of EFSA (2014).

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of DUKES in pome fruits (early application)

Intended use	Pome fruits
Active substance/product	Dithianon/ DUKES
Application rate (g/ha)	4 × 500 g f.p./ha
MAF	2.7
Vdf	10 (2D)/ 1(3D)

Test species Tier I	**LR_{50} (lab.) (g f.p./ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	> 4050	23.61	31.87	10	<0.08
Aphidius rhopalosiphi	> 4050				<0.08

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.

ZRMS comments:

The calculations of the risk assessment for in – field and off-field for Dukes for two indicator species were accepted by zRMS-PL. $HQ_{in\text{-}field}$ and $HQ_{off\ field}$ are below 2 based on laboratory studies (Tier1). Therefore, this assessment indicates that Dukes poses low risk to in-field and off-field to non-target arthropods following application according to the proposed use patterns.

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 DUKES 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. 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 DUKES were not evaluated as part of the EU assessment of Dithianon. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	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
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)	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)	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)	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

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Dithianon 70% WG	Chronic Mixed into substrate 56 d, chronic 5 % peat content (atificial soil)	NOEC = 56 mg/kg dw (34.9 mg a.s./kg dw)* **$NOEC_{corr}$ = 28 mg f.p./kg d.w.soil (17.45 mg a.s/~~ha~~ dws***	KCP 10.4.1.1 Weronika, D. 2017 G/278/15
Folsomia candida	Dithianon 70% WG	Mixed into substrate 28 d, chronic 5 % peat content	NOEC = 18 mg/kg dw (12.7 mg a.s./kg dw) **$NOEC_{corr}$ = 9 mg f.p./kg d.w.soil (6.35 mg a.s/~~ha~~)*** **EC_{10}=15.4** mg/kg dw EC_{10}corr=7.7 mg /kg dws (5.4 mg a.s./kg dws)	KCP 10.4.2-01 Weronika, D. 2016 G/279/15
Hypoaspis aculeifer	Dithianon 70% WG	Mixed into substrate 14 d, chronic 5 % peat content	NOEC = 1000 mg f.p./kg dw (701 mg a.s./kg dw) **$NOEC_{corr}$ = 500 mg f.p./kg d.w.soil (350.5 mg a.s/~~ha~~ dws)***	KCP 10.4.2-02 Lozano, J. 2017 TRC17-127BA
Field studies				
Litter bag test				

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

9.8.1.1 Justification for new endpoints

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

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 is not considered for Dithianon.

To achieve a concise risk assessment, the risk envelope approach is applied.

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 DUKES in pome fruits

Intended use	Pome fruits		
Chronic effects on earthworms			
Product/active substance	**NOEC/EC10 (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Dithianon	24	0.622	38.6
DUKES	28	1.067	26.2
DUKES	17.45	0.622	28.1
Chronic effects on other soil macro- and mesofauna-*Folsomia candidia*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
DUKES	9	1.067	8.4
DUKES*	~~6.35~~ 5.4	0.622	~~10.2~~ 8.7
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
DUKES	~~1000~~ 500	1.067	~~937.2~~ 468.60
DUKES*	500	0.622	803.9

TER values shown in bold fall below the relevant trigger.
* Risk assessment based on a NOECexpressed as mg as/kg dw from DUKES study.

zRMS comments:

The acute and long-term risks of soil macro-organisms were assessed from toxicity exposure ratios between toxicity endpoints and maximum PEC_{soil}.
Safe use of Dukes in orchards were confirmed based on TER_A and TER_{LT} calculations for active substance, its metabolites and for formulation.
No chronic risk for earthworms and chronic risk for are expected after the application of Dukes according to the proposed GAP.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

No chronic risk for earthworms and for other soil macro- and mesofauna are expected after the application of DUKES according to the proposed GAP.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

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

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

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	DELAN 70 WG (BAS 216 03 F)	28 d, aerobic soil type	+5.4 % effect at day 28 at **26.71 mg a.s./kg d.w.soil** (eq. 14 kg a.s/ha)[1]	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 a.s/ha)[1]	EFSA Journal 2010;8(11):1904
N-mineralisation	Dithianon 70% WG	28 d, aerobic soil type	At 6.3 of the test item/kg of soil (4.4 mg a.s./kg of soil) and 5 x PEC: **31.5 mg of the test item/kg of soil (22.1 mg a.s./kg of soil)** < 25%	KCP 10.5-01 Weronika, D., 2016 G/277/15
C-mineralisation	Dithianon 70% WG	28 d, aerobic soil type	At 6.3 of the test item/kg of soil (4.4 mg a.s./kg of soil) and 5 x PEC: **31.5 mg of the test item/kg of soil (22.1 mg a.s./kg of soil)** < 25%	KCP 10.5-02 Weronika, D., 2016 G/276/15

[1] - = inhibition; + = stimulation

9.9.1.1 Justification for new endpoints

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

To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of DUKES in pome fruits

Intended use	Pome fruits		
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)	0.622	yes
DUKES	31.5 (at 28 d)	1.067	yes
DUKES*	22.1 (at 28 d)	0.622	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)	0.622	yes
DUKES	31.5 (at 28 d)	1.067	yes
DUKES*	22.1 (at 28 d)	0.622	yes

TER values shown in bold fall below the relevant trigger.
* Risk assessment based on an endpoint expressed as mg as/kg dw from DUKES study.

zRMS comments:

The risk assessment for soil micro-organism after exposure of Dukes was accepted by the zRMS. The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher (4.4-31.4 mg product/kg dws) than the maximum relevant PECsoil for the maximum application.

9.9.3 Overall conclusions

The risk to soil microbial processes from the proposed uses of DUKES is considered to be acceptable when applied according to the proposed use rates.

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

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

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

Table 9.10-1: 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)	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)	21 d Post-emergence application	ER_{50}> 6 kg f.p./ha (>4.2 kg a.s./ha)	EFSA Journal 2010;8(11):1904
Pisum sativum[d] *Helianthus annuus*[d] *Sinapis alba*[d] *Solanum lycopersicon*[d] *Allium cepa*[m] *Avena sativa*[m]	Dithianon 70% WG	21 d Seedling emergence	ER_{50} > 9 kg f.p./ha (equivalent to > 6.3 kg a.s./ha)	KCP 10.6.2-01 Weronika, D. 2017 G/281/15
Pisum sativum[d] *Helianthus annuus*[d] *Sinapis alba*[d] *Solanum lycopersicon*[d] *Allium cepa*[m] *Avena sativa*[m]	Dithianon 70% WG	21 d Vegetative vigour	ER_{50} > 9 kg f.p./ha (equivalent to > 6.3 kg a.s./ha)	KCP 10.6.2-02 Weronika, D. 2017 G/282/15

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

The EU agreed endpoints for Dithianon are used for the assessments, except for formulation, corresponding to data proper to DUKES 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.

To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of DUKES in pome fruits (early application)

Intended use	Pome fruits (early application)			
Product	DUKES			
Application rate (g/ha)	4 × 500 g f.p./ha			
MAF	~~2.7~~ 1			
Test species	**ER_{50} (g/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Pisum sativum *Helianthus annuus* *Sinapis alba* *Solanu lycopersicon* *Allium cepa* *Avena sativa*	> 9000 g f.p./ha	~~23.61~~ 29.20*	~~318.74 g f.p./ha~~ 146	~~>28.2~~ 61.65

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

Table 9.10-3: Assessment of the risk for non-target plants due to the use of DUKES in pome fruits (late application)

Intended use	Pome fruits (late application)			
Product	DUKES			
Application rate (g/ha)	4 × 500 g f.p./ha			
MAF	~~2.7~~			
Test species	**ER_{50} (g/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Pisum sativum *Helianthus annuus* *Sinapis alba* *Solanu lycopersicon* *Allium cepa* *Avena sativa*	> 9000 g f.p./ha	~~10.12~~ 15.73	~~136.62 g f.p./ha~~ 78.65	~~>65.9~~ 114.43

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 DUKES in pome fruits (early application)

Intended use	Pome fruits (application)
Product	DUKES
Application rate (g/ha)	4 × 500 g f.p./ha
MAF	~~2.7~~ 1

Test species	**ER_{50} (g/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Pisum sativum *Helianthus annuus* *Sinapis alba* *Solanu lycopersicon* *Allium cepa* *Avena sativa*	> 9000 g f.p./ha	29.2	146	6.16

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

zRMS comment:

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived from the spray-drift predictions of Ganzelmeier & Rautmann (2000).
Only a single application was considered as factors such as plant growth will reduce residues per unit area between multiple applications.
For a single application to fruit crops, 29.2% and 15.73 % of the application rate was assumed to reach areas at 3m from the edge of the crop for early and late application.
The highest single application rate of Dukesis 500 g a.s./ha, giving a maximum off-field predicted environmental rate ($PER_{off\text{-}field}$) of 146 g product/ha and 78.65 g product/ha.
Based on the calculation provided in the Table above the risk assessment for non-target plants is considered as an acceptable as the TER_{LT} value was above the trigger of 5.

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 DUKES 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.

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

	Dithianon 70% WG	
Common Name	DUKES	
Classification and proposed labelling		
With regard to ecotoxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories:	Aquatic Acute 1 H400, Aquatic Chronic 1 H410
	Code(s) for hazard pictogram(s):	GHS09
	Signal word:	Warning
	Hazard statement(s):	H410: Very toxic to aquatic life with long lasting effects
	Precautionary statement:	~~P273~~, P391, P501

1.Based on experimental data with the formulation, DUKES is estimated to be very toxic to aquatic life, therefore Dithianon is classified as Aquatic Acute Category 1. Hazard statement H400 is proposed with pictogram GHS09 and signal word “Warning”. (Please refer to study reports in Section B9 for details).

2. classification derived by calculation
Dithianon is classified as Aquatic Chronic Category 1.
DUKES contains 1 × 71.79 ≥ 25% [M × Chronic 1 ≥ 25%] of this active substance, therefore hazard statement H410, with pictogram GHS09 and signal word “Warning” is proposed.

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	…	2016	Dithianon 70% WG Rainbow trout Acute toxicity test … … 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	Konfederak, E.	2016	Dithianon 70% WG *Daphnia magna*, Acute Immobilization Test W/83/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-03	Konfederak, E.	2016	Dithianon 70% WG *Pseudokirchneriella subcapitata* SAG 61.81 Growth inhibition test W/82/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-04	Konfederak, E.	2016	Dithianon 70% WG *Lemna gibba* CPCC 310, Growth inhibition test W/84/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.1.1	Małgorzata, C.	2016	Dithianon 70% WG Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test B/164/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.1.2	Małgorzata, C.	2016	Dithianon 70% WG Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test B/165/15 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 10.3.2.1-01	Luna, F.	2017	DITHIANON 70% WDG: Toxicity to the Predatory Mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) under Laboratory Conditions TRC17-139BA Trialcamp S.L.U. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.1-02	Varela Cervero, S.	2017	Dithianon 70%, WDG: Toxicity to the Aphid Parasitoid *Aphidius rhopalosiphi* De Stefani Perez (Hymenoptera, Braconidae) under Laboratory Conditions TRC17-100BA Trialcamp S.L.U. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.1.1	Weronika, D.	2017	Dithianon 70% WG Earthworm Reproduction Test (*Eisenia fetida*) G/278/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-01	Weronika, D.	2016	Dithianon 70% WG Collembolan (*Folsomia candida*) Reproduction Test G/279/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-02	Lozano Garcia, J.	2017	Dithianon 70% WDG: Effects on the Reproductive Output of the Predatory Soil Mite *Hypoaspis (Geolaelaps) aculeifer Canestrini* (Acari: Laelapidae) in Artificial Soil TRC17-127BA Trialcamp S.L.U. 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 10.5-01	Weronika, D.	2016	Dithianon 70% WG Soil Microorganisms: Nitrogen Transformation Test G/277/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.5-02	Weronika, D.	2016	Dithianon 70% WG Soil Microorganisms: Carbon Transformation Test G/276/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-01	Weronika, D.	2017	Dithianon 70% WG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test G/281/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-02	Weronika, D.	2017	Dithianon 70% WG Terrestrial Plant Test: Vegetative Vigour Test G/282/15 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

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

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

Comments of zRMS:

The DT_{50} is not considered in the risk assessment. ~~Kinetic degradation analysis should be provided by the applicant.~~

December, 2021

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 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: 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 sys-

tem. 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	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Dithianon		
	(a)	(b)				(c)				(d)	(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

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	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)
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

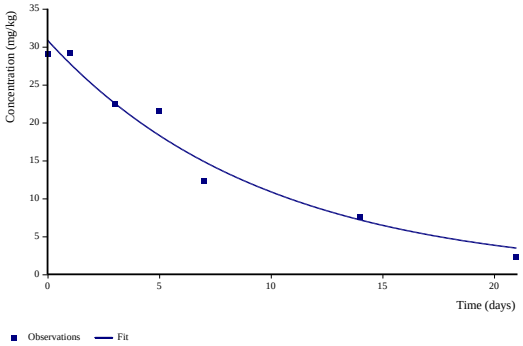
Parameter	Error %	Degrees of Freedom
All data	8.16	5
Parent	8.16	5

Decay Times:

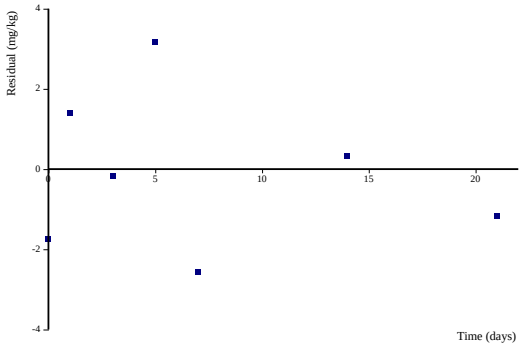
Compartment	DT50 (hours)	DT90 (hours)
Parent	6.65	22.1

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

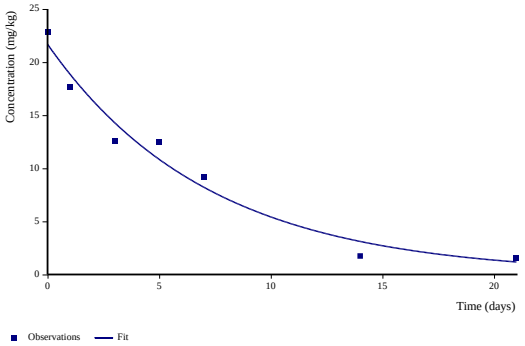
Parameter	Error %	Degrees of Freedom
All data	9.05	5
Parent	9.05	5

Decay Times:

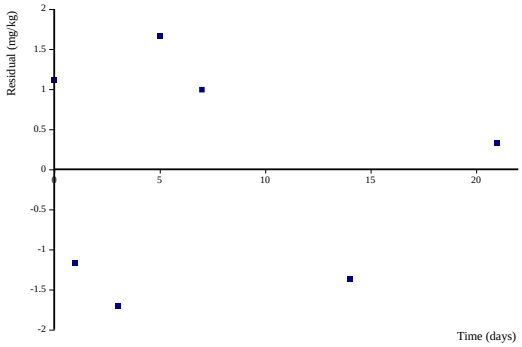
Compartment	DT50 (hours)	DT90 (hours)
Parent	5	16.6

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 (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 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	103 2.5 102 3.8 102 3.8 105 8.7	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	108 4.7 108 0.5 103 2.2 104 1.3	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

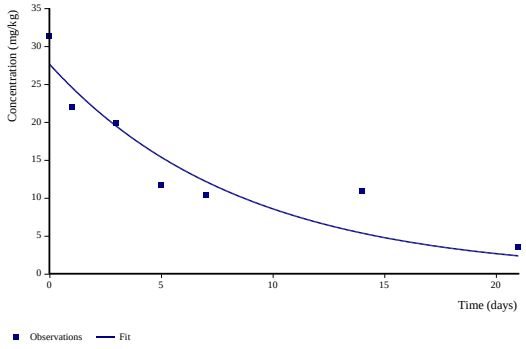
Parameter	Error %	Degrees of Freedom
All data	15.9	5
Parent	15.9	5

Decay Times:

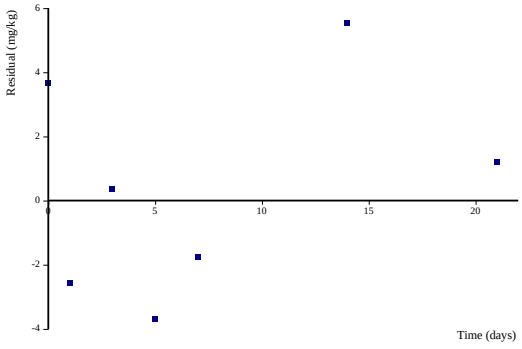
Compartment	DT50 (hours)	DT90 (hours)
Parent	5.92	19.7

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

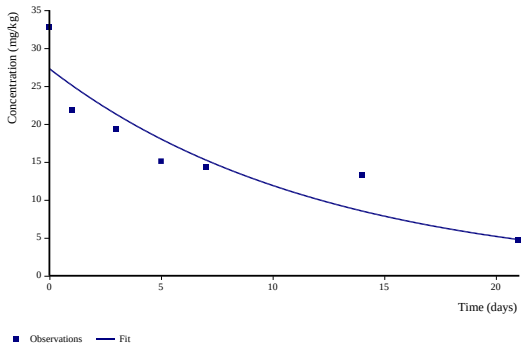
Parameter	Error %	Degrees of Freedom
All data	15.2	5
Parent	15.2	5

Decay Times:

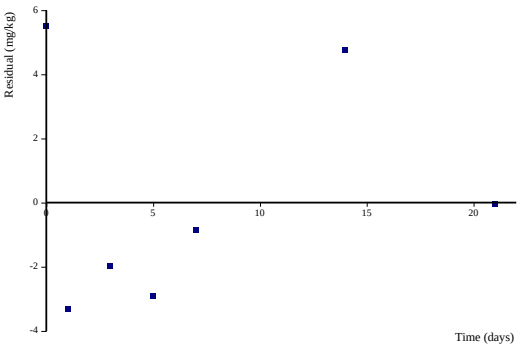
Compartment	DT50 (hours)	DT90 (hours)
Parent	8.35	27.8

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 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

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

A 2.2 KCP 10.2 Effects on aquatic organisms

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

Comments of zRMS:	The study is considered valid. All validity criteria were met. - In the control, the mortality of fish should not exceed 10 per cent (or one fish if less than ten fish are used). The mortality of fish in the control was 0%. - The dissolved oxygen concentration should be higher than 60 per cent of air saturation value throughout exposure. The dissolved oxygen concentration was in the range of 88 – 100% of air saturation value. **Agreed endpoints:** The 96h LC_{50} value: 0.0135 mg/L (nominal test item concentrations). The 96h LC_{50} value: 0.0095 mg/L (nominal concentration of Dithianon in the test item). The 96h LC_{50} value: 0.0032 mg/L (geometric mean of determined concentration of Dithianon).

Reference: KCP 10.2.1 – 01

Report "Dithianon 70% WG Rainbow trout Acute toxicity test".
…

Guideline(s): Yes (OECD 203)

Deviations: Yes. During the study one deviation from the study plan occurred. The study plan stated the deadline for final report was October, 2016. However, due to obligation acquire sponsor's acceptance of the report, the deadline was post-poned. The deviation did not have any impact on the study results.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Yes

Materials and methods

Materials

Test item:

Description: Dithianon 70% WG

Production batch: SWEPL-48752
A.i. content: Dithianon 70.3% (w/w)

Test system:

Species: Rainbow trout (*Oncorhynchus mykiss*)
Strain: -
Age: Approximately 4 months, average body length: 4.8 cm ± 0.38 cm
Source: The culture of the salmonidae fish in Zawoja, Poland (Hodowla Ryb Łososiowatych w Zawoi, Polska).
Acclimation period: 7 days
Diet: the fish were not fed during the test

Experimental conditions:

Temperature: 14.5– 15.7°C
Dissolved O_2: 92 – 100 %
Hardness : 63.6 mg/L $CaCO_3$.
pH: 7.16-7.43
Light and photoperiod: 16h light and 8h dark.
Loading : 0.88 g fish/L test solution. Each aquarium comprised 7 fish and 10L test solution.
Test procedure: -

Experimental period: 96h

Test design and treatment:

Semi-static system (96 hours) with daily renewals, one replicate of seven fish for each test item concentration and the control.
The following nominal test item concentrations were used: 0.05, 0.025, 0.0125, 0.0063, 0.0031, 0.0016 mg/L plus the control.
Geometric mean of determined concentrations of Dithianon: 0.0124, 0.0058, 0.0029, 0.0014, 0.0010, 0.0005 mg/L plus the control; nominal concentration of Dithianon: 0.0352, 0.0176, 0.0088, 0.0044, 0.0022, 0.0011 plus the control.
Fish were observed for survival and changes in behavior, respiration and pigmentation after 3, 6, 24, 48, 72 and 96 h of exposure.
The concentrations of Dithianon were chemically determined with a validated liquid chromatographic method with DAD detection. At exposure initiation in the range of the test item concentrations from 0.05 to 0.0031 mg/L the concentrations of Dithianon in fresh samples were in the range of 84.7 – 96.7% of the nominal concentration. In the test item concentration 0.0016 mg/L the concentration of Dithianon was below LoQ value (LoQ=0.001 mg/L).
Probit method calculations and analysis by STUDENT-t test for Homogeneous Variances with Bonferroni-Holm Adjustment were used.

Results:

In the definitive test no mortality of fish and no symptoms of intoxication were observed in the control and in the test item concentrations of 0.0016, 0.0031, 0.0063 mg/L. However, in higher test item concentrations used for exposure the symptoms of intoxication were observed: loss of equilibrium, unbalanced swimming behaviour and respiratory problems. At exposure termination in test item concentrations of 0.0125, 0.025 and 0.05 mg/L the fish mortality was 28.6, 100, 100%, respectively.

- The endpoint values based on the mortality of rainbow trout after 96 hours of exposure <u>to the nominal test item concentrations</u>:
  The LC50/96 h is 0.0135 mg/L.
  The LOEC/96 h is 0.0125 mg/L.

The NOEC/96 h is 0.0063 mg/L.

- The endpoint values based on the mortality of rainbow trout after 96 hours of exposure to the nominal concentration of Dithianon in the test item:
  The LC50/96 h is 0.0095 mg/L.
  The LOEC/96 h is 0.0088 mg/L.
  The NOEC/96 h is 0.0044 mg/L.
- The endpoint values based on the mortality of rainbow trout after 96 hours of exposure to the geometric mean of determined concentration of Dithianon.
  The LC50/96 h is 0.0032 mg/L.
  The LOEC/96 h is 0.0029 mg/L.
  The NOEC/96 h is 0.0014 mg/L.

Conclusion

The 96h LC_{50} value: 0.0135 mg/L (nominal test item concentrations).
The 96h LC_{50} value: 0.0095 mg/L (nominal concentration of Dithianon in the test item).
The 96h LC_{50} value: 0.0032 mg/L (geometric mean of determined concentration of Dithianon).

The 96h No-Observed Effect Concentration (NOEC): 0.0063 mg/L (nominal test item concentrations); 0.0044 mg/L (nominal concentration of Dithianon in the test item); 0.0014 mg/L (geometric mean of determined concentration of Dithianon).

Comments of zRMS:	The study is considered valid. 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 8.0 – 8.9 mg/L (criterion: not less than 3 mg/L). **Agreed endpoints:** **48 h EC_{50} =0.1165 mg/L (95% confidence limits: 0.0952 – 0.1422)** **LOEC= 0.0879 mg/L** **NOEC = 0.0439 mg/L**

Reference:	KCP 10.2.1 - 02
Report	Dithianon 70% WG. *Daphnia magna*, Acute Immobilization Test Konfederak E., 2016, W/83/16.
Guideline(s):	Yes (OECD 202)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Materials

Test item:

Description:	Dithianon 70% WG
Production batch:	SWEPL-48752
A.i. content:	Dithianon 70.3% (w/w)

Test system:

Species:	*Daphnia magna Straus*

Strain: -
Age: neonatal daphnids (less than 24h old)
Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Aquatic Toxicology.
Acclimation period: -
Diet: -

Experimental conditions:

.. Temperature: 20.1 – 20.8 °C
Dissolved O2: 8.0 – 8.9 mg/L
pH: pH 7.16 – 7.25
Light and photoperiod: 16h light and 8h dark.
Fluorescent light source; no feeding; no aeration.

Experimental period: 48h

Test design and treatment:

Semi-static test (48 hours); 4 replicates per each test item concentration and the control; 5 daphnids in each replicate. The daphnids were exposed in glass beakers of 150 mL capacity, containing 100 mL of a given test item concentration or the control. A preliminary range finding study was conducted using four test item concentrations: 10, 1.0, 0.1, 0.01 mg/L plus the control.

The definitive test was performed using the following test item concentrations: 2.0, 1.0, 0.5, 0.25, 0.125, 0.0625 mg/L plus the control were used. The daphnids were observed for immobilization after 24 and 48 hours of exposure. A test with reference material, potassium dichromate was performed.
The concentrations of Dithianon were determined with a validated liquid chromatographic method with DAD detection.

Results:

During exposure, in the control and in test item concentration of 0.0625 mg/L no immobilization of daphnids was observed. In the test item concentration of 2.0, 1.0, 0.5, 0.25, 0.125 mg/L the immobilization of Daphnia magna was 100, 100, 100, 75, 35%, respectively.

Conclusion

<u>The endpoint values determined on the basis of the nominal test item concentrations are given below.</u>
After 48 h the EC_{50} is 0.1656 mg/L (95% confidence limits: 0.1355 – 0.2023). After 48 h the LOEC value is 0.1250 mg/L and the NOEC value is 0.0625 mg/L.

<u>The endpoint values determined on the basis of the geometric mean of determined Dithianon concentrations are given below.</u>
After 48 h the EC_{50} is 0.0278 mg/L (95% confidence limits: 0.0217 – 0.0358). After 48 h the LOEC value is 0.0190 mg/L and the NOEC value is 0.0090 mg/L.

<u>The endpoint values based on the nominal concentrations of Dithianon in the test item concentrations are given below:</u>
After 48 h the EC_{50} is 0.1165 mg/L (95% confidence limits: 0.0952 – 0.1422). After 48 h the LOEC value is 0.0879 mg/L and the NOEC value is 0.0439 mg/L.

Comments of zRMS:	The study is considered valid. All validity criteria were met. - the biomass in the control increased by a factor of 144.0 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 1.2% (criterion: it must not exceed 7%). - the mean coefficient of variation for the section-by-section growth rate in the control culture was 16.1% (criterion: it must not exceed 35%). **Agreed endpoints:** **The ErC_{50}/72 h value = 0.304 mg/L (0.249 – 0.376).** **The LOEC/72 h value for growth rate = 0.063 mg/L.** **The NOEC/72 h value for growth rate =0.031 mg/L.** **The EyC_{50}/72 h value = 0.080 mg/L (0.073 – 0.087).** **The LOEC/72 h value for yield is lower than or equal to 0.016 mg/L.** **The NOEC/72 h value for yield is lower than 0.016 mg/L.**

Reference:	KCP 10.2.1 – 03
Report	"Dithianon 70% WG. *Pseudokirchneriella subcapitata* SAG 61.81 Growth inhibition test" Konfederak, E., 2016, W/82/16
Guideline(s):	Yes (OECD 201)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Materials

Test item:

Description:	Dithianon 70% WG
Production batch:	SWEPL-48752
A.i. content:	Dithianon 70.3% (w/w)

Test system:

Species:	*Pseudokirchneriella subcapitata (Reinsch) Korshikov* (formerly known as *Selenastrum capricornutum*)
Strain:	61.81 SAG cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Aquatic Toxicology. The algae were obtained from the Culture Collection of Algae at Göttingen University, Germany.
Age:	The pre-culture whose density was 1 x 10^4 cells/mL was renewed three days before the definitive test initiation.
Source:	SAG: Collection of Algal Cultures, Inst. Plant Physiology, University of Göttingen, Germany.
Acclimation period:	-
Diet:	-

Experimental conditions:

Temperature:	21.9 – 22.4 °C
pH values:	7.36-7.94
Humidity:	-
Air changes:	-

Light and photoperiod: 6550-6675 lux;
Constant illumination and shaking; the AAP medium.

Experimental period: 72h

Test design and treatment:

72 hours of exposure; three replicates of each test item concentration and six replicates of the control; a background for the control and each test item concentration; initial algal cell density: 1 x 10^4 cells/mL.
The preliminary test was conducted with the test item concentrations: 10, 1.0, 0.1 0.01, 0.001mg/L plus control.
Based on the results of the range study, the following test item concentrations were used: 1.0, 0.5, 0.25, 0.125, 0.063, 0.031, 0.016 mg/L plus the control. Geometric mean concentration of determined concentrations of Dithianon: 0.555, 0.217, 0.057, 0.007, 0.005, 0.003, 0.002 mg/L plus the control.
Nominal concentration of Dithianon: 0.7030, 0.3515, 0.1758, 0.0879, 0.0443, 0.0218, 0.0112 mg/L plus the control.

Density of algae cells was determined in each replicate after 24, 48 and 72 h of exposure. The concentrations of the Dithianon were determined with a validated liquid chromatographic method with DAD detection. The determined concentration of Dithianon in samples collected at exposure initiation was in the range of 100.3 – 108.6% of the nominal concentration.

Statistics: Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment.

Results:
The endpoint values determined on the basis of the nominal test item concentrations are given below.
The concentration causing a **50% inhibition of the growth** rate of Pseudokirchneriella subcapitata, i.e. the ErC_{50}/72 h value is 0.304 mg/L (95% confidence interval: 0.249 – 0.376).
The LOEC/72 h value for growth rate is 0.063 mg/L.
The NOEC/72 h value for growth rate is 0.031 mg/L.
The concentration causing a **50% inhibition of yield** of Pseudokirchneriella subcapitata,
i.e. the EyC50/72 h value is 0.080 mg/L (95% confidence interval: 0.073 – 0.087).
The LOEC/72 h value for yield is lower than or equal to 0.016 mg/L.
The NOEC/72 h value for yield is lower than 0.016 mg/L.

The endpoint values determined on the basis of the geometric mean of determined Dithianon concentrations are given below.
The concentration causing a **50% inhibition of the growth** rate of Pseudokirchneriella subcapitata, i.e. the ErC_{50}/72 h value is 0.076 mg/L (95% confidence interval: 0.053 – 0.114).
The LOEC/72 h value for growth rate is 0.005 mg/L.
The NOEC/72 h value for growth rate is 0.003 mg/L.

The concentration causing a **50% inhibition of yield** of Pseudokirchneriella subcapitata, i.e. the EyC50/72 h value is 0.006 mg/L (95% confidence interval: 0.005 – 0.006).
The LOEC/72 h value for yield is lower than or equal 0.002 mg/L.
The NOEC/72 h value for yield is lower than 0.002 mg/L.

The endpoint values based on the nominal concentration of Dithianon in the test item concentrations are
given below:
The concentration causing a **50% inhibition of the growth** rate of Pseudokirchneriella subcapitata,
i.e. the ErC_{50}/72 h value is 0.2135 mg/L (95% confidence interval: 0.1752 – 0.2640).
The LOEC/72 h value for growth rate is 0.0443 mg/L.
The NOEC/72 h value for growth rate is 0.0218 mg/L.
The concentration causing a **50% inhibition of yield** of Pseudokirchneriella subcapitata,
i.e. the EyC_{50}/72 h value is 0.0559 mg/L (95% confidence interval: 0.0514 – 0.0609).
The LOEC/72 h value for yield is lower than or equal 0.0112 mg/L.
The NOEC/72 h value for yield is lower than 0.0112 mg/L.

Conclusion

The ErC_{50}/72 h value is 0.304 mg/L (0.249 – 0.376).
The LOEC/72 h value for growth rate is 0.063 mg/L.
The NOEC/72 h value for growth rate is 0.031 mg/L.
The EyC_{50}/72 h value is 0.080 mg/L (0.073 – 0.087).
The LOEC/72 h value for yield is lower than or equal to 0.016 mg/L.
The NOEC/72 h value for yield is lower than 0.016 mg/L.

Comments of zRMS:	The study is considered valid. All validity criteria were met. **Agreed endpoints:** • The endpoint values determined on the basis of the nominal test item concentrations are given below: • **Endpoint values calculated on the basis of the frond number:** The ErC50/7 d value is 17.91 mg/L (95% confidence limit: 16.43 – 19.58), The EyC50/7 d value is 0.67 mg/L (95% confidence limit: 0.64 – 0.71), The NOEC/7 d value for growth rate and yield is 0.09 mg/L and the LOEC/7 d value for growth rate and yield is 0.3 mg/L. **Endpoint values calculated on the basis of the dry weight**: The ErC50/7 d value is 15.43 mg/L (95% confidence limit: 13.63 – 17.57), The EyC507 d value is 0.71 mg/L (95% confidence limit: 0.65 – 0.78), The NOEC/7 d value for growth rate is 0.09 mg/L and the LOEC/7 d value for growth rate is 0.3 mg/L. The NOEC/7 d value for yield lower than 0.09 mg/L and the LOEC/7 d value for yield is lower than or equal to 0.09 mg/L. • The endpoint values determined on the basis of the nominal concentrations of Dithianon in the test item are given below: **Endpoint values calculated on the basis of the frond number:** The ErC50/7 d value is 12.59 mg/L (95% confidence limit: 11.55 – 13.77), The EyC50/7 d value is 0.47 mg/L (95% confidence limit: 0.45 – 0.50),

	The NOEC/7 d value for growth rate and yield is 0.06 mg/L and the LOEC/7 d value for growth rate and yield is 0.21 mg/L. **Endpoint values calculated on the basis of the dry weight:** The ErC50/7 d value is 10.85 mg/L (95% confidence limit: 9.58 – 12.35), The EyC507 d value is 0.50 mg/L (95% confidence limit: 0.45 – 0.55), The NOEC/7 d value for growth rate is 0.06 mg/L and the LOEC/7 d value for growth rate is 0.21 mg/L. The NOEC/7 d value for yield lower than 0.06 mg/L and the LOEC/7 d value for yield is lower than or equal to 0.06 mg/L. • <u>The endpoint values determined on the basis of the geometric mean of determined concentrations of Dithianon are given below:</u> **Endpoint values calculated on the basis of the frond number:** The ErC50/7 d value is 9.34 mg/L (95% confidence limit: 8.46 – 10.35), The EyC50/7 d value is 0.22 mg/L (95% confidence limit: 0.20 – 0.23), The NOEC/7 d value for growth rate and yield is 0.02 mg/L and the LOEC/7 d value for growth rate and yield is 0.08 mg/L. **Endpoint values calculated on the basis of the dry weight:** The ErC50/7 d value is 7.87 mg/L (95% confidence limit: 6.82 – 9.14), The EyC507 d value is 0.23 mg/L (95% confidence limit: 0.20 – 0.25), The NOEC/7 d value for growth rate is 0.02 mg/L and the LOEC/7 d value for growth rate is 0.08 mg/L. The NOEC/7 d value for yield lower than 0.02 mg/L and the LOEC/7 d value for yield is lower than or equal to 0.02 mg/L.

Reference:	KCP 10.2.1 - 04
Report	"Dithianon 70% WG. *Lemna gibba* CPCC 310, Growth inhibition test". Konfederak E., 2016, W/84/16
Guideline(s):	Yes (OECD 221)
Deviations:	Yes. During the study one deviation from the study plan occurred. The study plan stated the deadline for final report was October, 2016. However, due to obligation acquire sponsor's acceptance of the report, the deadline was postponed. The deviation did not have any impact on the study results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods
Materials

Test item:

Description:	Dithianon 70% WG
Batch number:	SWEPL- 48752
A.i. content:	Dithianon 70.3% (w/w)

Test system:

Species:	*Lemna gibba* CPCC 310 cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Depart-

ment of Ecotoxicology, Laboratory of Aquatic Toxicology.

Strain: -
Age: -
Source: The plants were obtained from the Canadian Phycological Culture Centre, Department of Biology, University of Waterloo, Ontario, Canada.
Medium: 20X APP

Experimental conditions:

Temperature: 24.1 – 24.6 °C
pH values: 7.32 – 7.73. Control 7.84 – 9.05.
Mean light intensity: 7845-8183 lux, illumination constant
Test vessels: glass crystallizer containing 150 mL of each treatment, medium: 20X AAP
Initial frond number: 9 (i.e. 3 plants consisting of 3 fronds each)

Experimental period: 7 d

Test design:

Semi-static (7 days with daily renewals); three replicates of each test item concentration; six replicates of the control.

The test item concentrations in definitive test were: 100, 31.3, 9.77, 3.05, 0.95, 0.3, 0.09 mg/L plus the control. Nominal concentration of Dithianon in the test item: 70.30, 22.00, 6.87, 2.14, 0.67, 0.21, 0.06 mg/L plus the control. Geometric mean of determined concentrations of Dithianon: 69.65, 16.87, 4.84, 1.19, 0.34, 0.08, 0.02 mg/L plus the control).

The concentrations of the Dithianon were determined with a validated liquid chromatographic method with DAD detection.

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

Results:

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

Endpoint values calculated on the basis of the frond number:
The ErC50/7 d value is 17.91 mg/L (95% confidence limit: 16.43 – 19.58),
The EyC50/7 d value is 0.67 mg/L (95% confidence limit: 0.64 – 0.71),
The NOEC/7 d value for growth rate and yield is 0.09 mg/L and the LOEC/7 d value for growth rate and yield is 0.3 mg/L.
Endpoint values calculated on the basis of the dry weight:
The ErC50/7 d value is 15.43 mg/L (95% confidence limit: 13.63 – 17.57),
The EyC507 d value is 0.71 mg/L (95% confidence limit: 0.65 – 0.78),
The NOEC/7 d value for growth rate is 0.09 mg/L and the LOEC/7 d value for growth rate is 0.3 mg/L.
The NOEC/7 d value for yield lower than 0.09 mg/L and the LOEC/7 d value for yield is lower than or equal to 0.09 mg/L.

- The endpoint values determined on the basis of the nominal concentrations of Dithianon in the test
  item are given below:

Endpoint values calculated on the basis of the frond number:
The ErC50/7 d value is 12.59 mg/L (95% confidence limit: 11.55 – 13.77),
The EyC50/7 d value is 0.47 mg/L (95% confidence limit: 0.45 – 0.50),

The NOEC/7 d value for growth rate and yield is 0.06 mg/L and the LOEC/7 d value for growth rate and yield is 0.21 mg/L.

Endpoint values calculated on the basis of the dry weight:

The ErC50/7 d value is 10.85 mg/L (95% confidence limit: 9.58 – 12.35),
The EyC507 d value is 0.50 mg/L (95% confidence limit: 0.45 – 0.55),
The NOEC/7 d value for growth rate is 0.06 mg/L and the LOEC/7 d value for growth rate is 0.21 mg/L.
The NOEC/7 d value for yield lower than 0.06 mg/L and the LOEC/7 d value for yield is lower than or equal to 0.06 mg/L.

- The endpoint values determined on the basis of the geometric mean of determined concentrations of Dithianon are given below:

Endpoint values calculated on the basis of the frond number:

The ErC50/7 d value is 9.34 mg/L (95% confidence limit: 8.46 – 10.35),
The EyC50/7 d value is 0.22 mg/L (95% confidence limit: 0.20 – 0.23),
The NOEC/7 d value for growth rate and yield is 0.02 mg/L and the LOEC/7 d value for growth rate and yield is 0.08 mg/L.

Endpoint values calculated on the basis of the dry weight:

The ErC50/7 d value is 7.87 mg/L (95% confidence limit: 6.82 – 9.14),
The EyC507 d value is 0.23 mg/L (95% confidence limit: 0.20 – 0.25),
The NOEC/7 d value for growth rate is 0.02 mg/L and the LOEC/7 d value for growth rate is 0.08 mg/L.
The NOEC/7 d value for yield lower than 0.02 mg/L and the LOEC/7 d value for yield is lower than or equal to 0.02 mg/L.

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 valid. All validity criteria were met. - the average mortality for the total number of controls was 0.0% at the end of the experiment (criterion: it must not exceed 10%), - the LD_{50}/24h of the reference item (dimethoate) was 0.11 µg/bee (criterion: 0.10-0.35 µg a.i./bee). **Agreed endpoints:** **LD_{50}/48 h >200 mg test item/honeybee (140.0 mg a.i./honeybee).**

Reference KCP 10.3.1.1.1
Report Dithianon 70% WG Honeybees (*Apis mellifera* L.), Acute Oral Toxicity

Test. Czarnecka M., 2016, B/164/15

Guideline(s): Yes (OECD 213)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Materials

Test item:

Description: Dithianon 70% WG
Production batch: SWEPL-48752
A.i. content: Dithianon 70.3% (w/w)

Test system:

Species: *Apis mellifera L.;* strain: *carnica.*
Age: Approximately 3 weeks
Source: Institute of Industrial Organic Chemistry, Branch Pszczyna
Acclimation period: -
Diet: 50% sucrose solution containing the test item using a micropipette.

Experimental conditions:

Temperature: 25 - 26 °C
Humidity: 58 –63%
Air changes: -
Light and photoperiod: dark

Experimental period: 48h

Test design and treatment:

Exposure duration: 48 hours; number of doses: 5 doses
and a control; number of replicates: 3; number of bees: 10 bees/replicate.
A preliminary range finding study was conducted with doses of 8.0, 40.0, and 200.0 mg test item/bee (5.6, 28.0, and 140.0 mg a.i./bee) and a control were used. There was one replicate of each dose (10 bees/replicate).
Based on the results of the range study in the definitive test, five doses of 12.5, 25.0, 50.0, 100.0, and 200.0 mg test item/bee (8.75, 17.5, 35.0, 70.0, and 140.0 mg a.i./bee) were used.

Each group of bees (3 replicates/group; 10 bees/replicate) was fed with 100 mL of a 50% sucrose solution containing the test item using a micropipette. During the entire experiment, the insects were caged in groups of 10 under controlled conditions of the temperature and the humidity.
The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the bees and the precision of the test procedure.
After the administration, 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 oral toxicity test ended after the 48-hour exposure.

Statistics: Probit analysis using linear max. likelihood regression.

Results:

Honeybee mortality and the LD50 after 48 hours of exposure- definitive test:

Dose		Number of tested bees [no.]	Mortality					LD_{50}	
			Number of dead bees [no.] replicates			Total			
[µg test item/bee]	[µg a.i./bee]		I	II	III	[no.]	[%]	[µg test item/bee]	[µg a.i./bee]
0.0 (Control)		30	0	0	0	0	0.0	above 200.0	above 140.0
12.5	8.75	30	0	0	0	0	0.0		
25.0	17.5	30	0	0	0	0	0.0		
50.0	35.0	30	0	0	1	1	3.3		
100.0	70.0	30	0	0	0	0	0.0		
200.0	140.0	30	0	0	1	1	3.3		

Conclusion …..…….. The median lethal doses (LD_{50}/24 h and LD_{50}/48 h) are above the maxi-mum used dose, i.e. 200 mg test item/honeybee (140.0 mg a.i./honeybee).

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study is considered valid.All validity criteria were met. - the average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%), - the LD_{50}/24 h of the reference item (dimethoate) was 0.23 µg/bee (criterion: 0.10 - 0.30 µg a.i./bee). **Agreed endpoints:** **LD_{50}/48 h >200 mg test item/honeybee (140.0 mg a.i./honeybee).**

Reference Report KCP 10.3.1.1.2
Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test. Czarnecka M., 2016, B/165/15

Guideline(s): Yes (OECD 214)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Materials

Test item:

Description: Dithianon 70% WG;

Production batch: SWEPL-48752
A.i. content: Dithianon 70.3% (w/w)

Test system:

Species: *Apis mellifera L.;* strain: *carnica,*
Age: approximately 3 weeks
Source: Institute of Industrial Organic Chemistry, Branch Pszczyna
Acclimation period: -
Diet: 50% sucrose solution alone, from a 5-mL syringe
Experimental conditions:

Temperature: 24-25.5°C
Humidity: 59 – 67 %
Air changes: -
Light and photoperiod: dark

Experimental period: 48h

Test design and treatment: exposure duration: 48 hours; number of doses: 4 doses and a control; number of replicates: 3; number of bees: 10 bees/replicate. In order to select the range of doses to be used in the definitive test, the non-GLP preliminary test was conducted with the doses of 8.0, 40.0, and 200.0 mg test item/bee (5.6, 28.0, and 140.0 mg a.i./bee) and a control were used. In the definitive test the doses were 25.0, 50.0, 100.0, and 200.0 mg test item/bee (17.5, 35.0, 70.0, and 140.0 mg a.i./bee). There was one replicate of each dose (10 bees/replicate). 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 48 hours.

Statistics: Probit analysis using linear max. likelihood regression.

Results: Honeybee mortality and the LD_{50} after 48 hours of exposure:

Table 5. Honeybee mortality and the LD_{50} after 48 hours of exposure – definitive test.

Dose		Number of tested bees [no.]	Mortality					LD_{50}	
			Number of dead bees [no.] replicates			Total			
[µg test item/bee]	[µg a.i./bee][a]		I	II	III	[no.]	[%]	[µg test item/bee]	[µg a.i./bee]
0.0 (Control)		30	0	0	0	0	0.0	above 200.0	above 140.0
25.0	17.5	30	0	0	0	0	0.0		
50.0	35.0	30	0	0	0	0	0.0		
100.0	70.0	30	0	0	0	0	0.0		
200.0	140.0	30	0	0	0	0	0.0		

[a] :[µg active ingredient/bee]

Conclusion …..……..… The median lethal doses (LD_{50}/24h and LD_{50}/48h) are above the maximum used dose, i.e. 200 mg test item/honeybee (140.0 mg a.i./honeybee).

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

A 2.3.1.3 KCP 10.3.1.3 Effects on 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 2.4 KCP 10.3.2 Effects on non-target arthropods other than bees

A 2.4.1.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

Comments of zRMS:

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

- The mean mortality (dead and escaped individuals) in the control should be ≤ 20 % on day 7 of exposure (actual: 5.0 % mortality).
- The corrected cumulative mean mortality in the reference item group should range between 50 % and 100 % on day 7 after application (actual: 72.6 % corrected mortality).
- The cumulative mean number of eggs per female in the control (from day 7 to day 14) should be ≥ 4.0 eggs/female (actual: 10.5 eggs/female).

Agreed endpoints:

Treatment group [application rate]	Parameter (endpoint)					
	Mortality after 7 days of exposure (%)			Reproduction from day 7 to day 14 (n° of eggs / female)		
[g a.i./ha][a]	Mean[b]	Corrected	LR_{50} [g a.i./ha]	Mean	Reduction [%]	ER_{50} [g a.i./ha]
Control (0.0)	5.0	-		10.5	-	
177.44	10.0	5.3	> 2839.05	9.2	12.0	> 2839.05
354.88	17.0 *	12.6		7. 9 **	24.7	
709.76	14.0	9.5		8.2 **	22.3	
1419.53	11.3	6.6		7.4 **	29.1	
2839.05	13.0	8.4		8.4 **	20.0	
Reference item						
L product/ha						
0.009	74.0	72.6	-	-	-	

a: [g active ingredient of the test item/ha]
b: Based on the sum of dead and escaped mites
*: Statistically significantly increased compared to control (Chi²-2 x 2 Test with Bonferroni Correction, one-sided greater, p≤0.05). [Significance is considered to be due to biological variability and not dose related].
**: Statistically significantly decreased compared to control (Williams Test, one-sided smaller, p≤0.05)

Reference: KCP 10.3.2.1-01

Report	"Dithianon 70% WDG - Toxicity to the Predatory Mite, Typhlodromus pyri Scheuten (Acari, Phytoseiidae) under Laboratory Conditions". Francisco Luna (2017), TRC17-139BA
Guideline(s):	IOBC (BLÜMEL et al., 2000)
Deviations:	None
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

The toxicity of the test item Dithianon 70% WDG (batch no. FRE-001302) to the predatory mite species *Typhlodromus pyri* Scheuten was determined under worst-case laboratory conditions according to the IOBC guideline. Protonymphs (≤ 24 hours old) of *T. pyri* were exposed to dried spray residues of Dithianon 70% WDG on glass plates. A control and a reference item treatment were included in the test. The total test duration was 14 days. Mortality and any change in behavior with respect to the control were assessed after 1, 3 and 7 days. Reproduction was assessed from day 7 to day 14 of exposure with a maximum interval of 3 days.

The study was conducted as a rate-response test with seven treatment groups including the test item at five application rates (177.44, 354.88, 709.76, 1419.53 and 2839.05 g a.i./ha, equivalent to 0.253125, 0.50625, 1.0125, 2.025 and 4.05 kg product/ha respectively), the reference item at a single application rate (Dimethoate 40% EC, 9.0 mL of formulated product/ha) and the control (applied with deionised water). The test organisms were provided with pollen of apple (70%) and walnut (30%) as a food source. Each treatment group included 5 replicates containing 20 impartially selected protonymphs. The following endpoints were determined and subjected to statistical analysis: LR50 (median lethal rate) and ER50 (median effect rate), where possible.

Results

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

Treatment group [application rate]	Parameter (endpoint)					
	Mortality after 7 days of exposure (%)			Reproduction from day 7 to day 14 (nº of eggs / female)		
[g a.i./ha][a]	Mean[b]	Corrected	LR_{50} [g a.i./ha]	Mean	Reduction [%]	ER_{50} [g a.i./ha]
Control (0.0)	5.0	-		10.5	-	
177.44	10.0	5.3	> 2839.05	9.2	12.0	> 2839.05
354.88	17.0 *	12.6		7. 9 **	24.7	
709.76	14.0	9.5		8.2 **	22.3	
1419.53	11.3	6.6		7.4 **	29.1	
2839.05	13.0	8.4		8.4 **	20.0	
Reference item						
L product/ha						
0.009	74.0	72.6	-	-	-	

a: [g active ingredient of the test item/ha]
b: Based on the sum of dead and escaped mites
*: Statistically significantly increased compared to control (Chi²-2 x 2 Test with Bonferroni Correction, one-sided greater, p≤0.05). [Significance is considered to be due to biological variability and not dose related].

**: Statistically significantly decreased compared to control (Williams Test, one-sided smaller, p≤0.05)

Findings

- Dithianon 70% WDG caused a statistically significant increase in the mortality of *T. pyri* only at the rate tested of 0.50625 kg FP/ha (Chi²-2 x 2 Test with Bonferroni Correction, one-sided greater, p≤0.05). But the effects on mortality were all below the trigger value of 50 %. No significant differences were observed with rates above that and therefore, the significance with the rate of treatment "T2" is considered to be due to biological variability and not dose related. Therefore, the NOER for lethal effects was determined to be equal or greater than 4.05 kg FP/ha (equivalent to 2839.05 g a.i./ha based on the analysed content of active ingredient).

  The maximum rate of escaping in the test item groups was 11.6 % compared to the control in the treatment T2 (rate of 0.50625 kg FP/ha) and the rate of escaping with the maximum tested rate of 4.05 kg FP/ha was equal to the control group; 5 %.

  The mortality in the reference item was 74.0 % (72.6 % corrected to control). The mites in the test item groups showed no abnormal behaviour compared to the control group.
- The test item significantly decreased the reproduction of *T. pyri* at the tested rates from 0.50625 to 4.05 kg FP/ha (Williams Test, one-sided smaller, p≤0.05). But the reduction of reproduction in these groups was all below the trigger value of 50 %; maximum reduction was 29.1 % with the rate of 2.025 kg FP/ha, treatment "T4". Reduction relative to control at the maximum tested rate, 4.05 kg FP/ha, was 20.0 %.

  Therefore, the NOER for sub-lethal effects (cumulative offspring/female) was determined in 0.253125 kg FP/ha, equivalent to 177.44 g a.i./ha based on the analysed content of active ingredient.

Validity criteria

The test was considered valid because the following criteria were satisfied:

- The mean mortality (dead and escaped individuals) in the control should be ≤ 20 % on day 7 of exposure (actual: 5.0 % mortality).
- The corrected cumulative mean mortality in the reference item group should range between 50 % and 100 % on day 7 after application (actual: 72.6 % corrected mortality).
- The cumulative mean number of eggs per female in the control (from day 7 to day 14) should be ≥ 4.0 eggs/female (actual: 10.5 eggs/female).

Conclusion

Mortality below 20% (5.0%) was achieved 7 days after the application, and an acceptable reproductive capacity (10.5 eggs /female) was assessed over a further 7 days in the control group, meeting the validity criteria. The toxic reference product caused 72.6% mortality (corrected relative to control) and confirmed the sensitivity of the test species and the test conditions.

Under these standard laboratory test conditions, LR_{50} and ER_{50} were estimated to be greater than the maximum tested rate of 4.05 kg/ha of product, equivalent to 2839.05 g a.i./ha.

The NOER for lethal effects was determined to be equal or greater than 4.05 kg product/ha (equivalent to 2839.05 g a.i./ha) and the NOER for sub-lethal effects (cumulative offspring/female) was determined in 0.253125 kg product/ha, equivalent to 177.44 g a.i./ha.

Com-ments of zRMS:

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

Control mortality:	The mean mortality in control should be ≤ 13 % after 48 hours of exposure (actual: 2.50 %).
Reference item mortality:	The reference item should cause cumulative 48 hour corrected mortality ≥ 50 % (actual: 100.00 %).
Control reproduction:	The mean number of mummies per female in the control should be ≥ 5.0 mummies/female (actual: 15.13) No more than 2 females should fail to produce mummies (actual: 0 females).

Agreed endpoints:

Treatment [application rate]		Parameter (endpoint)					
		Mortality after 48 h of the exposure			% Settling not on glass (3 h)	Fecundity(3)	
[g a.i.(1)/ha]	Rate in kg FP(2)/ha	Total [%]	Corrected Mortality [%]	LR_{50} kg FP/ha		[Mummies/female]	Reduction [%]
Control (0.0)		2.50	-	> 4.0500	30.00	15.13	
177.44	**0.2531**	2.50	0.00		32.5	11.00	27.31
354.88	**0.5063**	12.50	10.26		27.5	9.29	38.64
709.76	**1.0125**	15.00 SD	12.82		50.0	12.13	19.82
1419.53	**2.0250**	27.50 SD	25.64		40.0	10.21	32.50
2839.05	**4.0500**	37.50 SD	35.90		45.0	10.23	32.40
Reference item							
[g a.i./ha]	**mL/ha**						
0.122	**0.3**	100	100.0	-	45.0	not assessed	

(1): a.i.= active ingredient
(2): FP = Formulated product.
(3): Fecundity expressed as mummies per female.
SD = Significantly different to the control (Jonckheere-Terpstra test, exact sig-. 1-tailed

Reference: KCP 10.3.2.1-02

Report: "Dithianon 70% WDG - Toxicity to the Aphid Parasitoid *Aphidius rhopalosiphi* De Stefani Perez (Hymenoptera, Braconidae) under Laboratory Conditions". Sara Varela Cervero, 2016, TRC17-100BA.

Guideline(s): IOBC (MEAD-BRIGGS et al., 2000).

Deviations: None

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Materials and methods
Materials

Test item:

Description:	Dithianon 70% WDG
Batch number:	SCL-75423
A.i. content:	701 g/kg

Test system:

Species:	*Aphidius rhopalosiphi* (De Stefani-Perez).
Strain:	Hymenoptera: Braconidae, Aphiidinae.
Age:	Males and females adult wasps (less than 48 hours old).
Source:	*A. rhopalosiphi* mummies were obtained from a commercial supplier (Katz Biotech AG).

Plant material:

Species:	*Hordeum vulgare*
Nº of plants/height:	10-40 seedlings per reproduction unit.
Source:	In-house culture at the test facility
Rearing:	>100 *Rhopalosiphum padi* L. per reproduction unit.

Experimental conditions:

Temperature:	19.9 – 21.0° C
Relative air humidity:	79.9 – 88.3 %
Mean light intensity:	602 – 674 lux during mortality. 2163 – 2940 lux during parasitisation, 7094 – 11628 lux during development of mummies. 16 hour photoperiod.
Test units:	Exposure units: glass plates (10x10 cm) assembled with a metal frame (length: 10 cm, height: 2 cm, thickness: 0.3 cm). Reproduction units: Plexiglas tube (diameter: ~8-11 cm; length: ~20 cm) upon a pot containing aphid invested barley seedlings, the soil was covered with sand and the top of the tube was covered with gauze.
Initial animals:	Each treatment group included 4 replicates, containing 10 adult wasps (3 males and 7 females for the exposure phase) each. For the reproduction test 15 (at T1-T4) and 14 (T5) individually confined female survivors (alive or affected) were taken from each treatment group without bias.

Experimental period:

The exposure phase lasted 48 hours. Parasitization lasted from 48 to 72 hours after introduction of the wasps in the exposure test units, followed by additional 10 days of developing the wasp pupal stage within the parasitized aphids (= mummies).

Test design:

The respective amounts of test and reference item were diluted in deionised water and applied with a laboratory track sprayer to glass plates in a spray volume of 200 L/ha. A control group was applied with deionised water. After assembling of test units 10 adult wasps were introduced per replicate unit (4 replicates per treatment group). Direct treatment effects (mortality) and any change in behaviour with respect to the control were assessed 2, 24 and 48 hours after start of exposure. Reproduction (aphid mummies/female) was assessed 10 days following a 24 h-parasitisation period. Reproduction was assessed for the control group and each test item group, where the corrected mortality was ≤ 50 %.The preliminary test (non-GLP) was performed to determine the final number and the range of application rates to be used in the definitive test.

The definitive test was performed with the following five application rates of the test item: 0.2531, 0.5063, 1.0125, 2.0250, 4.0500 kg product/ha. The reference item treatment was applied at a rate of 0.3 mL Dimethoate 40% w/v EC /ha.

The exposure phase was conducted on glass plates with dried residues shortly after application. 10 wasps per replicate were transferred into the test cages (start of test). Introduction of the wasps was completed approximately 1 hour after the application of the corresponding treatment group. During the mortality period the wasps were fed with a water saturated cotton pads and a honey water solution (1:3 v/v, honey: deionized water) (*ad libitum*).

After approximately 2, 24 and 48 hours of exposure, the condition of the wasps in the treated test units were assessed and classified as live, affected, moribund and dead.

To determine repellent effect, an assessment of the position of the individual insects was carried out during the first 3 h after their release. For each replicate group of wasps a record was made of whether they were settled on the glass plates or in untreated walls of the frame.

The reproduction phase was carried out with the control and all test item treatments, when at least 15 females survived the mortality test period. 14 females were recovered, instead of the minimum 15 females for fecundity at the rate of 4.0500 kg FP/ha. Surviving females were removed from the exposure units and transferred individually to the reproduction units. The number of parasitised aphids was counted in each replicate 10 days after the end of the parasitisation period (13 days after start of exposure). The test item cause a repellent effect on *Aphidius rhopalosiphi* during the initial 3 hours of exposure at the rate of 4.0500 kg FP/ha when compared with the control treatment (Jonckheere-Terpstra test, exact sig-. 1-tailed). However, no significant differences were found in the mean of wasps located not on the glass with lower rates of the test item treatment groups when compared to the control group (Jonckheere-Terpstra test, exact sig-. 1-tailed).

The temperature and the relative air humidity during the experimental phase were recorded throughout the trial at regular intervals (1 hour). The light intensity was measured once per phase with a luxmeter.

Statistics:

For mortality, Shapiro-Wilk's test for normality of data distribution and Levene's test for homoscedasticity were used. For NOER, the statistic Jonckheere-Terpstra test, exact sig-. 1-tailed was used. The percentage of in-

dividuals placed not on the glass just after the exposure were analysed with the Shapiro-Wilk's test for normality of data distribution and with the Levene's test for homoscedasticity. The statistic Jonckheere-Terpstra test, exact sig-. 1-tailed was used. The number of mummies per female was also analysed with the Shapiro-Wilk's test for normality of data distribution and with the Levene's test for homoscedasticity. The statistic parametric Dunnett's t-Test, one-sided smaller, $p \leq 0.05$ was used.

Results: The effects of the test item, Dithianon 70%, WDG on mortality and fecundity of *A. rhopalosiphi* under laboratory conditions are summarized below:

Treatment [application rate]		**Parameter (endpoint)**						
		Mortality after 48 h of the exposure			**% Settling not on glass (3 h)**	**Fecundity(3)**		
[g a.i.(1)/ha]	**Rate in kg FP(2)/ha**	**Total [%]**	**Corrected Mortality [%]**	**LR_{50} kg FP/ha**		**[Mummies/female]**	**Reduction [%]**	**ER_{50} kg FP/ha**
Control (0.0)		2.50	-	> 4.0500	30.00	15.13		> 4.0500
177.44	**0.2531**	2.50	0.00		32.5	11.00	27.31	
354.88	**0.5063**	12.50	10.26		27.5	9.29	38.64	
709.76	**1.0125**	15.00 SD	12.82		50.0	12.13	19.82	
1419.53	**2.0250**	27.50 SD	25.64		40.0	10.21	32.50	
2839.05	**4.0500**	37.50 SD	35.90		45.0	10.23	32.40	
Reference item								
[g a.i./ha]	**mL/ha**							
0.122	**0.3**	100	100.0	-	45.0	not assessed		

(1): a.i.= active ingredient
(2): FP = Formulated product.
(3): Fecundity expressed as mummies per female.
SD = Significantly different to the control (Jonckheere-Terpstra test, exact sig-. 1-tailed)

The 48-hour LR50 of Dithianon 70%, WDG, under laboratory test conditions, was determined to be higher than 4.0500 kg formulated product (FP)/ha (equivalent to 2839.05 g Dithianon/ha). The NOER (no observed-lethal effect rate) was determined to be 0.5063 kg formulated product (FP)/ha (equivalent to 354.88 g Dithianon/ha). The ER50 was estimated to be higher than higher than 4.0500 kg formulated product (FP)/ha (equivalent to 2839.05 g Dithianon/ha). The NOER for sublethal effects was determined to be equal than 2.0250 kg formulated product (FP)/ha (equivalent to 1419.53 g Dithianon/ha).

A 2.4.1.2 KCP 10.3.2.2 Extended laboratory testing, aged residue with non-target arthropods

A 2.5 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.5.1 KCP 10.4.1 Earthworms

A 2.5.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

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

- each replicate produced 123.4 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 16% (criterion: ≤ 30%),
- adult mortality over the initial 4 weeks of the experiment was 2.5% (criterion: ≤ 10%).

Agreed endpoints:

Parameter	Value [mg/kg dry weight of artificial soil]	Value [mg a.s./kg dry weight of artificial soil]
EC_{10}	103.3 (41.0 – 152.0)	72.6 (28.8 – 106.9)
EC_{20}	154.7 (83.0 – 206.9)	108.8 (58.3 – 145.5)
EC_{50}	334.4 (260.8 – 456.9)	235.1 (183.3 – 321.3)
NOEC	56	39.4
LOEC	100	70.3
LC_{50} (mortality)	> 560	> 393.7

Reference: KCP 10.4.1.1

Report "Dithianon 70% WG. Earthworm Reproduction Test (*Eisenia fetida*)". Weronika Dec, 2017, G/278/15.

Guideline(s): Yes OECD Guideline 222

Deviations: Yes. One deviations from the Study Plan was occurred. The study was finished in January 2017 and not in August 2016. However, it did not affect the results.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Materials

Test item:

Description:	Dithianon 70% WG
Production batch:	SWEPL-48752
Active ingredients content:	Dithianon - 70.3% w/w
Artificial soil:	5% peat, 20% clay, and 75% sand

Test system:

Species:	The earthworm, *Eisenia fetida*, obtained from a standard laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Laboratory of Soil Toxicology

Experimental conditions:

Temperature:	18.0-22.0°C
soil moisture content:	beginning: 20.0 – 20.30% (54.04 – 54.85% of the maximum water holding capacity); end: 18.50 – 19.60% (49.99 – 52.96% of the maximum water holding capacity);
pH:	5.90-6.40 (beginning); 5.90-6.38(end)
Air changes:	-
Light and photoperiod:	16 h light and 8 h dark; light intensity: 490 – 580 lux

Study design and methods

Experimental period:	18/05/16 - 13/07/2016

Test design and treatment:	Test duration: 56 days. The test item in the form of a aqueous suspension was mixed with the artificial soil. During the experiment, the earthworms were fed on air-dried finely ground cow manure. At the beginning of the experiment, it was mixed with the soil substrate (3 g food/ 500 g dry soil). The food prepared in this way was provided once a week during the four-week period (3 -5 g food/container).After 4 weeks (when the adult earthworms were removed from the soil), the juvenile worms were fed only once (5 g food/container). The concentrations of the test item were 10, 18, 32, 56, 100, 180, 320, and 560 mg/kg dry weight of artificial soil. Each of them was divided into four replicates. There was also an untreated control group divided into eight replicates. In order to determine the sensitivity of the test organisms to chemical substances and to verify that the response of the test organisms would not change over time, a test of a reference substance, i.e. carbendazima was conducted. The exposure period lasted 8 weeks. After 4 weeks of exposure, all adult worms were removed from the test containers and observed. All changes in their behavior and morphology were recorded. The number of earthworms and their body weights were also determined. The impact of the test item on reproduction was evaluated after an additional 4-week period on the basis of the number of juveniles hatched from cocoons during the experiment.
Statistics:	EC10, EC20, EC50 – the probit method NOEC (reproduction) – the Shapiro-Wilk's Test on Normal Distribution, the Levene's Test Procedure on Variance Homogeneity, the Williams Multiple Sequential t-test Procedure NOEC (survival) - Fisher's Exact Binomial Test with Bonferroni Correction LOEC : a value suggested by ToxRat Professional 2.10.

Results and conclusions

After 4 weeks of the exposure, mortality of the of the earthworms exposed to the test item at the concentrations ranging from 10 to 560 mg/kg dry weight of artificial soil was between 0.0 – 2.5%. Mortality of the control group was 2.5%
No changes in the appearance (morphology) and behaviour of the earthworms were noticed.
After the application of the test item at the concentrations ranging from 10 to 560 mg/kg dry artificial soil, the body weight increase was between 31.2 – 50.8%. As for the control group, it was equal to 37.2%.
After 8 weeks of the exposure, it was concluded that Dithianon 70% WG had a significant effects on reproduction of the earthworms at the concentrations ranging from 100 to 560 mg/kg dry weight of artificial soil.

The endpoint values determined during the earthworm reproduction test (*Eisenia fetida*) are presented in the table given below.

Parameter	Value [mg/kg dry weight of artificial soil]	Value [mg a.s./kg dry weight of artificial soil]
EC_{10}	103.3 (41.0 – 152.0)	72.6 (28.8 – 106.9)
EC_{20}	154.7 (83.0 – 206.9)	108.8 (58.3 – 145.5)
EC_{50}	334.4 (260.8 – 456.9)	235.1 (183.3 – 321.3)
NOEC	56	39.4
LOEC	100	70.3
LC_{50} (mortality)	> 560	> 393.7

The table below shows the number of juveniles hatched from the cocoons during the reference test, the NOEC, and the LOEC.

According to the OECD Guideline No. 222, the LOEC should be between 1 – 5 mg/kg dry weight of soil; hence, it may be concluded that the sensitivity of the test organisms was proper.

Concentration [mg/kg dry soil]	Replicate	Number of juveniles [no.]	Mean ±SD	Comparison to the control [%]	CV [%]
0.0 (control + aceton)	1	84	105.0 ± 16.5	100.0	15.7
	2	131			
	3	97			
	4	108			
	5	95			
	6	121			
	7	115			
	8	89			
0.0 (control)	1	139	108.8 ± 17.0	103.6	15.7
	2	125			
	3	98			
	4	98			
	5	112			
	6	115			
	7	91			
	8	98			
1.0	1	105	100.5 ± 8.7	95.7	8.7
	2	109			
	3	89			
	4	99			
1.5	1	134	99.5 ± 23.5	94.8	23.6
	2	81			
	3	91			
	4	92			
2.25	1	67	71.0* ± 9.8	67.6	13.5
	2	60			
	3	82			
	4	75			
3.37	1	68	61.8* ± 6.3	58.8	10.3
	2	53			
	3	62			
	4	64			
5.0	1	5	2.0* ± 2.4	1.9	122.5
	2	0			
	3	0			
	4	3			
NOEC	mg/kg dry weight of artificial soil	1.5			
LOEC		2.25			

*- statistically significant differences (significance was Alpha = 0.05, one-sided smaller)

In order to determine significance of differences between the control and the treated groups, the Shapiro-Wilk's Test on Normal Distribution, Levene's Test Procedure on Variance Homogeneity, and Williams Multiple Sequential t-test Procedure were used.

A 2.5.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.5.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.5.2.1 KCP 10.4.2.1 Species level testing

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

- mean adult mortality was 8.8% (criterion: ≤ 20%),
- the mean number of juveniles per vessel was 301.4 at the end of the test (criterion: ≥ 100 juveniles at the end of the test),
- the coefficient of variation calculated for the number of juveniles was 5.2% (criterion: ≤ 30%),

Agreed endpoints:

Endpoint	Value [mg/kg of dry soil]	Value [mg a.s./kg of dry soil]
EC_{10}	15.4 (6.0 – 26.6)	10.8 (4.2 – 18.7)
EC_{20}	33.3 (17.3 – 50.0)	23.4 (12.2 – 35.2)
EC_{50}	145.4 (106.1 – 207.8)	102.2 (74.6 – 146.1)
NOEC	18	12.7
LOEC	32	22.5

Reference: KCP 10.4.2.1-01

Report "Dithianon 70% WG Collembolan (*Folsomia candida*) Reproduction Test. Dec W., 2016, G/279/15.

Guideline(s): Yes OECD Guideline 232

Deviations: Yes. One deviation from the Study Plan occurred. The study was finished in September 2016 and not in July 2016. However, it did not affect the results.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Materials

Test item:

Description: Dithianon 70% WG

Production batch: SWEPL-48752

Active ingredients content: Dithianon - 70.3% w/w

Vehicle and control: Artificial soil, 5% peat, 20% clay, and 75% sand

Test system:

Species: *collembolans, Folsomia candida*, obtained from a standard laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Laboratory of Soil Toxicology

Experimental conditions:

Temperature:	18-21°C
soil moisture content:	beginning: 11.3 – 12.5% (46.4 – 51.3% of the maximum water holding capacity); end: 11.0 – 12.1% (45.2 – 49.7% of the maximum water holding capacity);
pH:	6.23-6.38 (beginning); 6.14-6.25(end)
Air changes:	-
Light and photoperiod:	12 h light and 12 h dark; light intensity: 490 – 580 lux

Study design and methods

Experimental period:	13/05/16 - 13/06/2016
Test design and treatment:	Test duration: 28 days. The test item in the form of a water solution was mixed with the artificial soil. During the experiment, the collembolans were fed with granulated dried baker's yeast. The amount of food was 2 mg/container. The collembolans were fed at the beginning of the experiment and after 2 weeks of incubation. The concentrations of the test item were 15.6, 10, 18, 32, 56, 100, 180, 320, and 560 mg/kg dry soil. In order to determine the sensitivity of the test organisms to chemical substances and to verify that the response of the test organisms would not change over time, a test of a reference substance, i.e. boric acid was conducted. Each of them was divided into four replicates. There was also an untreated control group divided into eight replicates. There were 30 g (i.e. 28.9 g dry soil) in each replicate.
Statistics:	NOEC: Offspring number: Shapiro-Wilk's Test on Normal Distribution, Barlett's Test Procedure on Variance Homogeneity, and Williams Multiple Sequential t-test Procedure (significance of differences). Survival: Fisher`s Exact Binomial Test with Bonferroni Correction EC_{50}, EC_{20}, EC_{10}: probit method.

Results and conclusions

On the basis of the obtained results, it was concluded that Dithianon 70% WG caused mortality of adult collembolans after 28 days of the experiment. Mortality (at the concentrations ranging from 5.6 to 560

mg/kg dry soil) ranged from 7.5 to 42.5%. As for the control group, it was 8.8%.

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

Endpoint	Value [mg/kg of dry soil]	Value [mg a.s./kg of dry soil]
LC_{10}	**12.6** (< 5.6 – 24.9)	**8.9** (< 3.9 – 17.5)
LC_{20}	**57.7** (30.5 – 97.6)	**> 40.6** (21.4 – 68.6)
LC_{50}	**> 560**	**> 393.7**
NOEC	**18**	**12.7**
LOEC	**32**	**22.5**

After the exposure of the adult collembolans to the test item at the concentrations ranging from 5.6 to 560 mg/kg dry soil, the mean number of juveniles was between 312.0 – 77.5. As for the control group, it was 301.4.
The endpoint values showing the impact of the test item on reproduction of *Folsomia candida* are presented in the table given below.

Endpoint	Value [mg/kg of dry soil]	Value [mg a.s./kg of dry soil]
EC_{10}	**15.4** (6.0 – 26.6)	**10.8** (4.2 – 18.7)
EC_{20}	**33.3** (17.3 – 50.0)	**23.4** (12.2 – 35.2)
EC_{50}	**145.4** (106.1 – 207.8)	**102.2** (74.6 – 146.1)
NOEC	**18**	**12.7**
LOEC	**32**	**22.5**

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

Parameter	Required	Observed
Mean mortality of adult females	≤ 20 %	7.50 %
Mean number of juveniles per replicate	≥ 50	120.88
Coefficient of variation of reproductive output	≤ 30 %	21.18 %

Agreed endpoints:

Endpoint	Value [mg t.s./kg sdw]	Value [mg a.i./kg sdw]
NOECmortality	1000.00	701.00
LOECmortality	> 1000.00	> 701.00
NOECreproduction	1000.00	701.00
LOECreproduction	> 1000.00	> 701.00
EC_{50}	> 1000.00	> 701.00

Reference:	KCP 10.4.2.1-02
Report	"Dithianon 70% WDG: Effects on the Reproductive Output of the Predatory Soil Mite *Hypoaspis* (*Geolaelaps*) *aculeifer* Canestrini (Acari: Laelapidae) in Artificial Soil". Josep Lozano Garcia. 2017. Study code: TRC17-127BA. Trialcamp S.L.U.
Guideline(s):	OECD 226 (2016): OECD Guidelines for the testing of chemicals, No. 226; Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil.
Deviations:	None.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Dithianon 70% WDG batch no.: SCL-75423 active substance: Dithianon – 70.1 % (w/w)
Artificial soil	5% sphagnum peat; 20% kaolin clay; 74.94% industrial sand; 0.06 % calcium carbonate
Biological test system :	*Hypoaspis aculeifer* Canestrini (Acari, Laelapidae), from in-house culture, adult mites (33 days after starting of the egg-laying for synchronisation).
Test design:	Adult females were exposed to the test substance in artificial soil. After 14 days, the surviving individuals were extracted from the test units. The number of juveniles per test unit and additionally the number of surviving adult females were determined. The reproductive output and the mortality in each test item group were compared to that of the control group. A Dose-response test with 8 different test substance concentrations and 4 replicates each as well as a water control (without test substance) with eight replicates; 10 adult females were exposed per replicate.
Test doses:	0 (control), 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000.00 mg test substance/kg soil dry weight. Equivalent to: 11.45, 20.61, 37.10, 66.78, 120.20, 216.36, 389.44 and 701.00 mg Dithianon/kg soil dry weight.
Test conditions:	Temperature during exposure: 20.05° C to 20.81°C pH at the beginning of the test: 5.95 to 6.23 pH at the end of the test: 6.26 to 6.36 Soil moisture content at the beginning of the test: 20.21 % to 21.37 % (corresponding to 46.48 – 49.15 % of the WHC_{max}) Soil moisture content at the end of the test: 18.99 % to 19.99 % (corresponding to 43.67 – 45.97 % of the WHC_{max}) Lighting: 16 h light and 8 h dark (long day conditions); light intensity: 438 lux to551 lux
Endpoints:	LOEC, NOEC for mortality and reproductive output; EC_{10}, EC_{20}, EC_{50} for reproductive output, where possible.

Results and discussions

No statistically significant increase in mortality of *Hypoaspis aculeifer* was detected at any of the test substance concentrations as compared to the control group after 14 days of exposure. Mean mortality of adult females in control group was ≤ 20 % (7.50 %).

No behavioural abnormalities or any pathological symptoms of the test organisms could be observed in

the control group and in any of the test substance groups.

No statistically significant reduction in the number of juveniles was detected at any of the test substance concentrations as compared to the control group after 14 days of exposure. Mean number of juveniles per replicate in control group was ≥ 50 (120.88).

The endpoint values showing the impact of the test item on reproduction of *Hypoaspis aculeifer* are presented in the table given below:

Endpoint	**Value [mg t.s./kg sdw]**	**Value [mg a.i./kg sdw]**
NOECmortality	1000.00	701.00
LOECmortality	> 1000.00	> 701.00
NOECreproduction	1000.00	701.00
LOECreproduction	> 1000.00	> 701.00
EC_{50}	> 1000.00	> 701.00

Conclusion

All validity criteria were met and the sensitivity of the test organisms was confirmed. Accordingly, the study was deemed valid.
The LOEC for mortality could not be determined. The NOEC for mortality was determined as 1000.00 mg test substance/kg soil dry weight.
The LOEC for reproductive output could not be determined. The NOEC for reproductive output was determined as 1000.00 mg test substance/kg soil dry weight.
Since there was no dose-response relationship the EC_{10}, EC_{20} and EC_{50} for reproductive output could not be calculated. The EC_{50} for reproductive output is assumed as > 1000.00 mg test substance/kg soil dry weight.

A 2.5.2.2 KCP 10.4.2.2 Higher tier testing

A 2.6 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study is considered valid. All validity criteria were met. On the basis of the obtained results, it was stated that the validity criterion was met. The coefficients of variation (CV) in the control group were 12.7, 4.5, 2.5 and 1.6%, after 0, 7, 14, and 28 days of incubation (validity criterion: the variation between replicate control samples should be less than ± 15%). **Agreed endpoints:** **On the basis of the results, it was concluded that Dithianon 70% WG at the concentrations corresponding to the PEC: 6.3 of the test item/kg of soil (4.4 mg a.s./kg of soil) and 5 x PEC: 31.5 mg of the test item/kg of soil (22.1 mg a.s./kg of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils**

Reference:	KCP 10.5-01
Report	"Dithianon 70% WG Soil Microorganisms: Nitrogen Transformation Test" Dec W., 2016, G/277/15
Guideline(s):	Yes, OECD Guideline 216
Deviations:	Yes. Two deviations from the Study Plan occurred: 1. The temperature in the test room was between 19 – 22.5°C. According to the Study Plan, it should have ranged from 18 to 22°C. It was a short-term deviation (approximately 12 hours) which did not affect the result of the experiment; 2. The study was not finished in June 2016.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Materials

Test item:	
Description:	Dithianon 70% WG
Production batch:	SWEPL - 48752
Active ingredients content:	Dithianon - 70.3% w/w
Vehicle and control:	Distilled water
Test system:	
Species:	Microorganisms
Source:	Agricultural soil taken from the area belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.
Experimental conditions:	
Temperature:	19 –22.5 °C
Humidity:	46.2– 22.5% MWHC
Air changes:	-
Light and photoperiod:	Dark (24/24h)

Study design and methods

Experimental period:	07/04/2016 – 06/05/2016
Test design and treatment:	3 portions of soil weighing 1500 g each: one control group and two groups containing the test item. Every portion was divided into three replicates weighing 500 g each. Test duration: 28 days. Concentrations of the test material: Control; PEC: 6.3 mg of the test item/kg of soil (4.4 mg a.s./kg of soil) and 5 x PEC: 31.5 mg of the test item/kg of soil (22.1 mg a.s./kg of soil). The nitrate formation rate in each treated group was compared with that in the control, and the percent deviation of the treated from the control was calculated on days 0, 7, 14, and 28 of incubation.

Statistics: In order to determine significance of differences between the control and the treated groups, the Shapiro-Wilk's Test on Normal Distribution, the Levene's Test on Variance Homogeneity, and the William's Multiple Sequential t-test were used.

Results The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentrations corresponding to the PEC did not exceed 25% on any day of the analysis.

Mean nitrate ion concentration-deviations from the control [%]:

Day of incubation	PEC 6.3 mg of the test item/kg of soil (4.4 mg a.s./kg of soil)	5 x PEC 31.5 mg of the test item/kg of soil (22.1 mg a.s./kg of soil)
0	20.0*	-7.8
7	14.3*	-2.9
14	0.8	-9.8*
28	-12.5	-7.9

" – " higher concentration of nitrate as compared to the control
* Significant difference to control (p<=0.05)

Conclusion

On the basis of the results, it was concluded that Dithianon 70% WG at the concentrations corresponding to the PEC: 6.3 of the test item/kg of soil (4.4 mg a.s./kg of soil) and 5 x PEC: 31.5 mg of the test item/kg of soil (22.1 mg a.s./kg of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils

Comments of zRMS:	The study is considered valid. All validity criteria were met. On the basis of the obtained results, it may be stated that the validity criterion was met. The coefficient of variation in the control group was as follows: 0.9, 2.5, 2.4 and 2.3% on 0, the 7th, 14th and 28th day of soil incubation, respectively. The criterion of validity: the variation between replicate samples in the control should be less than ± 15%. **Agreed endpoints:** **On the basis of the results, it was concluded that Dithianon 70% WG at the concentrations corresponding to the PEC: 6.3 of the test item/kg of soil (4.4 mg a.s./kg of soil) and 5 x PEC: 31.5 mg of the test item/kg of soil (22.1 mg a.s./kg of soil), did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.**

Reference:	KCP 10.5-02
Report	"Dithianon 70% WG Soil Microorganisms: Carbon Transformation Test" Dec W., 2016, G/276/15
Guideline(s):	Yes, OECD Guideline 217
Deviations:	Yes. Two deviations from the Study Plan occurred: 1. The temperature in the test room was between 19 – 22.5°C. According to the Study Plan, it should have ranged from 18 to 22°C. It was a short-term deviation (approximately 12 hours) which did not affect the result of the experiment; 2. The study was not finished in June 2016.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Materials

Test item:	
Description:	Dithianon 70% WG
Production batch:	SWEPL - 48752
Active ingredients content:	Dithianon - 70.3% w/w
Vehicle and control:	Distilled water
Test system:	
Species:	Microorganisms
Source:	Agricultural soil taken from the area belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.
Experimental conditions:	
Temperature:	19 –22.5 °C
Humidity:	45.6– 56.7% MWHC
Air changes:	-
Light and photoperiod:	Dark (24/24h)

Study design and methods

Experimental period:	07/04/2016 – 06/05/2016
Test design and treatment:	3 portions of soil weighing 1500 g each: one control group and two groups containing the test item. Every portion was divided into three replicates weighing 500 g each. Test duration: 28 days. Concentrations of the test material: Control; PEC: 6.3 mg of the test item/kg of soil (4.4 mg a.s./kg of soil) and 5 x PEC: 31.5 mg of the test item/kg of soil (22.1 mg a.s./kg of 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.

Statistics: In order to determine significance of differences between the control and the treated groups, the Shapiro-Wilk's Test on Normal Distribution, the Levene's Test on Variance Homogeneity, and the William's Multiple Sequential t-test 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 and 5 x PEC did not exceed 25% on any day of analysis.

Oxygen (O2) consumption-deviations from the control [%] is shown below:

Day	PEC 6.3 mg of the test item/kg of soil (4.4 mg a.s./kg of soil)	5 x PEC 31.5 mg of the test item/kg of soil (22.1 mg a.s./kg of soil)
0	15.4	14.1
7	9.6	9.5
14	6.7	5.4
28	2.5	7.7

Conclusion

On the basis of the results, it was concluded that **Dithianon 70% WG** at the concentrations corresponding to the PEC: 6.3 of the test item/kg of soil (4.4 mg a.s./kg of soil) and 5 x PEC: 31.5 mg of the test item/kg of soil (22.1 mg a.s./kg of soil), did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.

A 2.7 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.7.1 KCP 10.6.1 Summary of screening data

A 2.7.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	The study is considered valid. All validity criteria were met.
	- the seedling emergence in the control (validity criterion: at least 70%) was as follows: 90% – pea, 90% – sunflower.

	100% – white mustard, 90% – tomato, 80% – onion, 85% – 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 effects;. - environmental conditions for all plants of the same species were identical.
	Agreed endpoints: The ER_{50} values determined on the basis of the plant number, the plant shoot length and plant shoot weight at the end of the experiment were > 9.0 kg/ha (> 6.33 kg a.s./ha) for all of the tested species. The following order of the test plant sensitivity was noticed: oats > pea, sunflower, white mustard, tomato, and onion.

Reference:	KCP 10.6.2-01
Report	"Dithianon 70% WG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test". Weronika Dec. 2017. Study code: G/281/15. 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 ± 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 4800 – 5130 lux. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Dithianon 70% WG; Batch Number SWEPL - 48752; active substance: Dithianon - 70.3% w/w.
Test species:	pea (*Pisum sativum*), sunflower (*Helianthus annuus*), white mustard (*Sinapis alba*), tomato (Solanum lycopersicon), onion (Allium cepa), and oats (*Avena sativa*)
Soil:	Sandy loam
Study design:	number of concentrations: 5 application rates + a control number of replicates: 4 replicates of each application rate and the control number of seeds: 5 seeds/replicate test termination: 14 days after the emergence of 50% of the control seedlings
Application rates:	a control, 0.23; 0.58; 1.45; 3.6 and 9.0 kg/ha; 1300 L water/ha
Test conditions:	temperature: 22. – 29.0°C; humidity: 48 – 75%; lighting: 16 hours light : 8 hours dark; light intensity: 4500 – 5720 lux; carbon dioxide concentration: 335 – 360 ppm

Statistical analysis: ER_{10}, ER_{25}, ER_{50} – probit analyses
NOER (emergence) - Chi¸ 2x2 Table Test with Bonferroni Correction or Fisher`s Exact Binomial Test with Bonferroni Correction.
NOER (shoot length and plant weight) – 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

Table 36. ER_{10}. ER_{25}. ER_{50} and NOER values (kg/ha).

	Pea	Sunflower	White mustard	Tomato	Onion	Oats
	Pisum sativum	*Helianthus annuus*	*Sinapis alba*	*Solanum lycopersicon*	*Allium cepa*	*Avena sativa*
Emergence						
ER_{10}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
ER_{25}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
ER_{50}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
NOER	≥ 9.0	≥ 9.0	> 9.0	≥ 9.0	≥ 9.0	≥ 9.0
Plant number at the end of the experiment						
ER_{10}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
ER_{25}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
ER_{50}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
NOER	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
Shoot length (plants without roots)						
ER_{10}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	3.87 (1.59 – 6.49)
ER_{25}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
ER_{50}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
NOER	≥ 9.0	≥ 9.0	≥ 9.0	≥ 9.0	≥ 9.0	3.6

Table 36. - cont. ER_{10}. ER_{25}. ER_{50} and NOER values (kg/ha).

	Pea	Sunflower	White mustard	Tomato	Onion	Oats
	Pisum sativum	*Helianthus annuus*	*Sinapis alba*	*Solanum lycopersicon*	*Allium cepa*	*Avena sativa*
Plant dry weight (plants without roots)						
ER_{10}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	3.05 (0.01 – > 9.0)
ER_{25}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
ER_{50}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
NOER	≥ 9.0	≥ 9.0	≥ 9.0	≥ 9.0	≥ 9.0	≥ 9.0

The ER_{10}. ER_{25}. ER_{50}. and NOER values were calculated using the ToxRat Professional 2.10 computer software

Table 37. ER_{10}. ER_{25}. ER_{50} and NOER values (kg a.s./ha).

	Pea	Sunflower	White mustard	Tomato	Onion	Oats
	Pisum sativum	*Helianthus annuus*	*Sinapis alba*	*Solanum lycopersicon*	*Allium cepa*	*Avena sativa*
Emergence						
ER_{10}	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33
ER_{25}	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33
ER_{50}	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33
NOER	≥ 6.33	≥ 6.33	> 6.33	≥ 6.33	≥ 6.33	≥ 6.33
Plant number at the end of the experiment						
ER_{10}	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33
ER_{25}	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33
ER_{50}	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33
NOER	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33
Shoot length (plants without roots)						
ER_{10}	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	2.72 (1.12 – 4.56)
ER_{25}	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33
ER_{50}	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33
NOER	≥ 6.33	≥ 6.33	≥ 6.33	≥ 6.33	≥ 6.33	2.53

Table 37. - cont. ER_{10}. ER_{25}. ER_{50} and NOER values (kg a.s./ha).

	Pea	Sunflower	White mustard	Tomato	Onion	Oats
	Pisum sativum	*Helianthus annuus*	*Sinapis alba*	*Solanum lycopersicon*	*Allium cepa*	*Avena sativa*
Plant dry weight (plants without roots)						
ER_{10}	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	2.14 (0.007 – > 6.33)
ER_{25}	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33
ER_{50}	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33	> 6.33
NOER	≥ 6.33	≥ 6.33	≥ 6.33	≥ 6.33	≥ 6.33	≥ 6.33

The ER_{10}. ER_{25}. ER_{50}. and NOER values were calculated using the ToxRat Professional 2.10 computer software

The test item i.e. Dithianon 70% WG had a varied impact on the growth and seedling emergence of the test plant species. The impact depended on the concentration and species.

After the application of the test item at the rates ranging from 0.23 to 9.0 kg/ha (from 0.16 to 6.33 kg a.s/ha) all test plant species: pea (Pisum sativum), sunflower (Helianthus annuus), white mustard (Sinapis alba), tomato (Solanum lycopersicon), onion (Allium cepa), and oats (Avena sativa) emerged.

Shoot length measurements proved that the test item slightly inhibited the process of growth of oats. The growth inhibition of pea, sunflower, white mustard, tomato and onion was not observed.

Shoot weight measurements proved that the test item slightly inhibited the process of growth of oats. The growth inhibition of pea, sunflower, white mustard, tomato and onion was not observed.

One phytotoxic symptom was observed. It was stunted growth for oats.

The ER_{50} values determined on the basis of the plant number, the plant shoot length and plant shoot weight at the end of the experiment were > 9.0 kg/ha (> 6.33 kg a.s./ha) for all of the tested species.

The following order of the test plant sensitivity was noticed:

oats > pea, sunflower, white mustard, tomato, and onion.

Comments of zRMS:	The study is considered valid. All validity criteria were met. - the seedling emergence (validity criterion: at least 70%) was as follows: 92.5 – 97.5% – pea, 85.0 – 95.0% – sunflower, 92.5 – 100.0% – white mustard, 85.0 – 95.0% – tomato, 77.5 – 92.5% – onion, 80.0 – 95.0% – oats, - the mean survival of the emerged control seedlings was 100% in case of all species (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:** **The ER_{50} values determined on the basis of the plant shoot length and plant shoot weight at the end of the experiment were > 9.0 kg/ha (> 6.3 kg of a.s./ha) for all of the tested species.** **The following order of the test plant sensitivity was noticed:** **white mustard > onion > oats > sunflower > pea, tomato**.

Reference:	KCP 10.6.2-02
Report	"Dithianon 70% WG Terrestrial Plant Test: Vegetative Vigour Test". Weronika Dec. 2017. Study code: G/282/15. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD Guideline No. 227 (2006)
Deviations:	According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50µE/m2/s. The number of seeds per pot is a deviation from the OECD Guideline No. 227.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Dithianon 70% WG; Batch Number SWEPL - 48752; active substance: Dithianon - 70.3% w/w.
Test species:	pea (*Pisum sativum*), sunflower (*Helianthus annuus*), white mustard (*Sinapis alba*), tomato (*Solanum lycopersicon*), onion (*Allium cepa*), and oats (*Avena sativa*)
Soil:	loam
Study design:	number of rates: 5 application rates + control; number of replicates: 4 replicates/rate and 4 replicates/control; number of seeds: 5 seeds/replicate; test termination: 21 days after the spraying
Application rates:	a control, 0.23; 0.58; 1.45; 3.6 and 9,0 kg/ha. 1300 L water/ha
Test conditions:	temperature: 22. – 29.0°C; humidity: 48 – 75%; lighting: 16 hours light : 8 hours dark; light intensity: 4090 – 6200 lux; carbon dioxide concentration: 335 – 360

	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
Endpoints:	ER_{10}, ER_{25}, ER_{50}, NOER

Results and Conclusions

Table 30. ER_{10}, ER_{25}, ER_{50} and NOER values (kg/ha).

	Pea	Sunflower	White mustard	Tomato	Onion	Oats
	Pisum sativum	*Helianthus annuus*	*Sinapis alba*	*Solanum lycopersicon*	*Allium cepa*	*Avena sativa*
Plant number at the end of the experiment						
ER_{10}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
ER_{25}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
ER_{50}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
NOER	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
Shoot length (plants without roots)						
ER_{10}	> 9.0	> 9.0	0.64	> 9.0	3.97 (< 0.23 – 6.11)	> 9.0
ER_{25}	> 9.0	> 9.0	4.98	> 9.0	> 9.0 (6.51 – > 9.0)	> 9.0
ER_{50}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
NOER	≥ 9.0	≥ 9.0	0.58	≥ 9.0	≥ 9.0	≥ 9.0
Plant dry weight (plants without roots)						
ER_{10}	> 9.0	1.25	0.3	> 9.0	2.19 (0.34 – 3.77)	2.05 (< 0.23 – 3.76)
ER_{25}	> 9.0	> 9.0	2.18	> 9.0	8.79 (5.35 - > 9.0)	5.65 (2.38 - > 9.0)
ER_{50}	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0	> 9.0
NOER	≥ 9.0	≥ 9.0	0.58	≥ 9.0	1.45	0.58

The ER_{10}, ER_{25}, ER_{50} and NOER values were calculated using the ToxRat Professional 2.10 computer software

Table 31. ER_{10}, ER_{25}, ER_{50} and NOER values (kg of a.s./ha).

	Pea	Sunflower	White mustard	Tomato	Onion	Oats
	Pisum sativum	*Helianthus annuus*	*Sinapis alba*	*Solanum lycopersicon*	*Allium cepa*	*Avena sativa*
Plant number at the end of the experiment						
ER_{10}	> 6.3	> 6.3	> 6.3	> 6.3	> 6.3	> 6.3
ER_{25}	> 6.3	> 6.3	> 6.3	> 6.3	> 6.3	> 6.3
ER_{50}	> 6.3	> 6.3	> 6.3	> 6.3	> 6.3	> 6.3
NOER	> 6.3	> 6.3	> 6.3	> 6.3	> 6.3	> 6.3
Shoot length (plants without roots)						
ER_{10}	> 6.3	> 6.3	0.4	> 6.3	2.8 (< 0.2 – 4.3)	> 6.3
ER_{25}	> 6.3	> 6.3	3.5	> 6.3	> 6.3 (4.6 – > 6.3)	> 6.3
ER_{50}	> 6.3	> 6.3	> 6.3	> 6.3	> 6.3	> 6.3
NOER	≥ 6.3	≥ 6.3	0.4	≥ 6.3	≥ 6.3	≥ 6.3
Plant dry weight (plants without roots)						
ER_{10}	> 6.3	0.9	0.2	> 6.3	1.5 (0.2 – 2.7)	1.4 (< 0.2 – 2.6)
ER_{25}	> 6.3	> 6.3	1.5	> 6.3	6.2 (3.8 - > 6.3)	4.0 (1.7 - > 6.3)
ER_{50}	> 6.3	> 6.3	> 6.3	> 6.3	> 6.3	> 6.3
NOER	≥ 6.3	≥ 6.3	0.4	≥ 6.3	1.0	0.4

The ER_{10}, ER_{25}, ER_{50}, and NOER values were calculated using the ToxRat Professional 2.10 computer software

The test item, i.e. Dithianon 70% WG had a varied impact on vegetative vigour of the test plant species. The impact depended on the rate and species.

After the application of the test item at rates ranging from 0.23 to 9.0 kg/ha (from 0.2 to 6.3 kg of a.s./ha), the mortality of tested species, i.e. pea (*Pisum sativum*), sunflower (*Helianthus annuus*), white mustard (*Sinapis alba*), tomato (*Solanum lycopersicon*), onion (*Allium cepa*), and oats (*Avena sativa*) was not observed.

Shoot length measurements proved that the test item slightly inhibited the process of growth of white mustard and onion. The process of growth inhibition of pea, sunflower, tomato and oats was not observed.

Shoot weight measurements proved that the test item slightly inhibited the process of growth of sunflower, white mustard, onion and oats. The process of growth inhibition of pea and tomato was not observed.

One phytotoxic symptom was observed. It was stunted growth for white mustard and onion.

The ER_{50} values determined on the basis of the plant shoot length and plant shoot weight at the end of the experiment were > 9.0 kg/ha (> 6.3 kg of a.s./ha) for all of the tested species.

The following order of the test plant sensitivity was noticed:

white mustard > onion > oats > sunflower > pea, tomato.

A 2.7.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.8 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.9 KCP 10.8 Monitoring data