FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SHA 6800 A

Product name: DUKES

Chemical active substance:

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: 11.05.2021; corr. 20.08.2021; 12.2021

Version history

When	What
09.2020	Dossier summited by Applicant
05.2021	Initial assessment by zRMS
December 2021	Final registration report after commenting period

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8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion groundwater
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
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	A

* 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 “Conclusion”

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

Table 8.1-2: Assessed (critical) uses during approval of Dithianon concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	SEU CEU	Pome fruit	F	*Venturia inaequalis, Gloeosporium spp., Nectria galligena, Venturia pirina*	High volume spraying	BBCH 10-79	12	7	-	0.525	1000-1500	21	Preventive treatment
2	SEU CEU	Wine grape	F	*Plasmopara Viticola*	High volume spraying	BBCH 10-79	8	7	-	0.560	400-1200	42	Preventive treatment. Water volume is depending on the cropping.

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

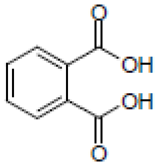
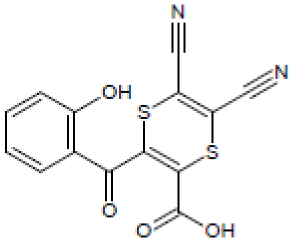
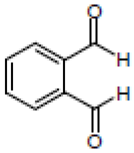
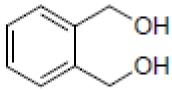
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

zRMS comments:

All comments and conclusions of the zRMS are presented in grey. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparenc

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of Dithianon potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Phthalic acid	166.14		Soil: 16 % Water: 0.00001% Sediment: 0.00001% Total system: 38.5%	PEC_{soil}: not covered by EU assessment PEC_{gw}: leaching potential to groundwater $PEC_{sw/sed}$: not covered by EU assessment
CL1017911	330.33		Soil: 0.00001% Water: 52.01% Sediment: 3.6% Total system:-	$PEC_{sw/sed}$: not covered by EU assessment
Phthalaldehyde	134.14		Soil: 0.00001% Total system: 11.2%	$PEC_{sw/sed}$: not covered by EU assessment
1,2-benzenedimethanol	138.17		Soil: 0.00001% Total system: 20.9%	$PEC_{sw/sed}$: not covered by EU assessment

zRMS comments:

Information relating to dithianon metabolites are in line with EU agreed endpoints as reported in *EFSA Scientific Report* conclusion EFSA Journal 2010;8(11):1904. *Conclusion on the pesticide peer review of dithianon* and have been considered in the exposure assessment presented in this report.

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

The rate of degradation of dithianon in soil was investigated in eight studies submitted in the original dossier, but 6 are considered valid for the normalisation. A summary of the laboratory studies are reported in the table 8.3-1.

Table 8.3-1: Summary of aerobic degradation rates for Dithianon - laboratory studies

Dithianon, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Ulm	Clay loam	6.8	20	45	14*	46.4	11.2	0.995	DFOP	y/EFSA 2010 Dithianon_Additional report_06_Vol3_B8 (January 2010)
Lufa2.3	Sandy loam	6.5	20	45	17.8*	59.1	16.2	0.985	FOMC	y/EFSA 2010 Dithianon_Additional report_06_Vol3_B8 (January 2010)
Bergen	Clay loam	7.6	20	45	8.5*	28.1	7.2	0.995	DFOP	y/EFSA 2010 Dithianon_Additional report_06_Vol3_B8 (January 2010)
Schwalbach	Silt loam	5.1	20	45	37.7**	125	33.3	0.976	SFO	y/EFSA 2010 Dithianon_Additional report_06_Vol3_B8 (January 2010)
Ulm (10°C)	-	6.8	10	45	30.8	111.4	-	-	Best-fit	y/EFSA 2010
Ulm (sterile)***	-	6.8	20	45	40.7***	1135.1***	-	-	SFO	y/EFSA 2010
Lufa2.2	Sandy loam	5.9	20	41	12.0*	39.8	11.6	0.991	DFOP	y/EFSA 2010 Dithianon_Additional report_06_Vol3_B8 (January 2010)
Bruch West	Loamy sand	7.1	20	45	2.6**	8.48	2.6	0.974	SFO	y/EFSA 2010 Dithianon_Additional report_06_Vol3_B8 (January 2010)
						Geometric mean (n=6)	**10.5**			
						pH-dependency: y/n	n			

*back-calculated from best-fit DT_{90} value: $DT_{50} = DT_{90}$ (best-fit) / 3.32
**SFO kinetic
***Sterilized soil, DT_{50} / DT_{90} not to be used for further assessment

A major metabolite in soil, Phthalic acid, was identified and the results of the aerobic degradation are summarised in the table 8.3-2.

Table 8.3-2: Summary of aerobic degradation rates for Phthalic acid - laboratory studies

Phthalic acid, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH (H_2O)**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Bruch West	Loamy Sand	8.2	20	40	0.10	0.32	-	1.696	SFO	y/Addendum to DAR – June 2014
Li10	Silty sand	7.0	20	40	0.07	0.23	-	0.8858	SFO	y/Addendum to DAR – June 2014
LUFA 5M	Loamy sand	8.0	20	40	0.26	0.86	-	3.801	SFO	y/Addendum to DAR – June 2014
Geometric mean (n=3)							0.12, **< 1**			
pH-dependency:							no			

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Dithianon degraded rapidly in anaerobic conditions forming a number of metabolites but the quantification of the individual components was not available. Although it was agreed that anaerobic conditions are unlikely to occur under the representative uses.

The summary of the anaerobic degradation rate for dithianon is reported in the table 8.3-3.

Table 8.3-3: Summary of anaerobic degradation rates for Dithianon - laboratory studies

Dithianon, Laboratory studies, anaerobic conditions										
Soil name	**Soil type**	**pH ($CaCl_2$)**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Sandy moal	5.9	20	40	5.4	59.2	-	-	-	y/EFSA 2010
-	Clay loam	6.8	20	Flooded	1.4	4.7	-	-	-	y/EFSA 2010
Geometric mean (n=2)							-			
pH-dependency: y/n							n			

8.4 Field studies (KCP 9.1.1.2)

Studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

No field study was evaluated during the EU review of Dithianon as DT_{50lab} at 20°C < 60 days and DT_{50lab} at 10°C < 90 days.

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

No field study was evaluated during the EU review of Dithianon as DT_{50lab} at 20°C < 60 days and DT_{50lab} at 10°C < 90 days.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

No field study was evaluated during the EU review of Dithianon as DT_{50lab} at 20°C < 60 days and DT_{50lab} at 10°C < 90 days.

zRMS comments:

Soil degradation data of *dithianon* and its metabolites are in line with EU agreed endpoints.

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Table 8.5-1: Summary of soil adsorption/desorption for Dithianon

Dithianon							
Soil name	**Soil type**	**OC (%)**	**pH (H_2O)**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Borstel Boden	Sandy loam	2.13	6.3	59	2750	-	y/EFSA 2010
Bruch West	Sandy loam	2.62	7.8	157	6004	-	y/EFSA 2010
LUFA 2.2	Loamy sand	2.08	6.2	85	4091	-	y/EFSA 2010
LUFA 3A	Loam	2.96	7.7	122	4122	-	y/EFSA 2010
1680	Loamy sand	0.78	6.9	9	1167	-	y/EFSA 2010
				Geomean (n=5)	**3179**	-	y/EFSA 2010
				pH-dependency y/n	n		

Table 8.5-2: Summary of soil adsorption/desorption for Phthalic acid

Phthalic acid							
Soil Name	**Soil Type**	**OC (%)**	**pH (in 0.01 M $CaCl_2$)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
LUFA 2.1	Sand	0.52	5.2	0.178	34	0.933	y/Addendum to DAR – June 2014
Li 10	Loamy sand	6.0	0.88	0.083	9	0.851	y/Addendum to DAR – June 2014
Nierswalde “Wildacker”	Silt loam	6.5	1.63	0.717	44	0.891	y/Addendum to DAR – June 2014
Grobe Erde	Loamy sand	6.8	0.92	0.027	3	0.974	y/Addendum to DAR – June 2014
Fiorentini	Silt loam	7.5	1.83	0.079	4	0.955	y/Addendum to DAR – June 2014
				Geometric mean (n=2)	**11.01**	-	n/calculated
				Arithmetic mean (n=5)	-	0.921	n/calculated
				pH-dependency y/n	n		

8.5.1 Column leaching (KCP 9.1.2.1)

Column leaching	Eluation (mm): 200 mm 0.01M $CaCl_2$ Time period (d): 2 d
	Leachate: 0.01 - 0.17% total residues/radioactivity in leachate 19.8-54.4% was dissolved CO_2 79-107% AR in top 0-6 cm of soil
Aged residues leaching	Aged for (d): 10 and 31 d Eluation (mm): 200 mm 0.01M $CaCl_2$ Time period (d): 2 d
	Analysis of soil residues post ageing (soil residues pre-leaching): 10 d - 40.1% Dithianon, many unknown metabolites each <1% AR, 22% bound residues; 30 d - 30% bound residues, not enough radioactivity in extracts to analyzed. Soil Column Segments: >75% AR remain in top 0-6 cm segments <1.3% AR remain in 6-12 cm segments <0.8% AR in remaining depths
	Leachate: < 0.9% AR

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Not required for the EU Review of Dithianon.

8.5.3 Field leaching studies (KCP 9.1.2.3)

Not required for the EU Review of Dithianon.

zRMS comments:

Soil mobility data of *dithianon* and its metabolites are in general in line with EU agreed endpoints.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Table 8.6-1: Summary of degradation in water/sediment of Dithianon

Dithianon Distribution (max. water 19.4% after 1 day/sediment 1.4% after 2 days)										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (h/d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
System R (river) – Rheinaue	8.3/7.3	Same as water	Same as water	SFO	1.4 h	4.6 h	SFO	Not detected	-	y/EFSA 2010
System H (pond) – Hellersberger Weiher	8.1/7.2	Same as water	Same as water	SFO	2.4 h	7.9 h	SFO	Not detected	-	y/EFSA 2010
Pond R – Ranschgraben	7.9/6.5	0.196	1.84	DFOS	0.22 d	0.74 d	SFO	5.07	FOMC	y/EFSA 2010
River N – Berghauser Altrhein	8.1/7.6	0.35	1.16	SFO	0.34 d	1.14 d	SFO	0.62	FOMC	y/EFSA 2010
Geometric mean (n=2-4)		0.26	1.46		0.14	0.48		1.77		n/ calculated

Table 8.6-2: Summary of degradation in water/sediment of CL1017911

CL1017911 Distribution Rapidly formed after 1 day (32-54%), rapidly degraded and nearly disappeared at 14 days										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Pond R – Ranschgraben	7.9/6.5	7.60	25.2	SFO	5.90	19.6	SFO	87.1	SFO	y/EFSA 2010
River N – Berghauser Altrhein	8.1/7.6	6.05	20.1	SFO	5.94	19.8	SFO	1.38	SFO	y/EFSA 2010
Pond R –	7.9/6.	5.92	19.7	SFO fit	-	-	-	-	-	y/EFSA

CL1017911 Distribution Rapidly formed after 1 day (32-54%), rapidly degraded and nearly disappeared at 14 days										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Ranschgraben	5			of decline from peak observed						2010
River N – Berghauser Altrhein	8.1/7.6	6.28	20.8	SFO fit of decline from peak observed	-	-	-	-	-	y/EFSA 2010
Geometric mean (n=2)		6.1	-		-	-		-		y/EFSA 2010

Table 8.6-3: Summary of observed metabolites

CL 1017911 Water/sediment system	Rapidly formed after 1 day (32-54%), rapidly degraded and nearly disappeared at 14 days	y/EFSA 2010

zRMS comments:

Information on degradation of *dithianon* and its metabolites in water/sediment systems are in line with EU agreed endpoints.

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.7.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

8.7.2 Active substance(s) and relevant metabolite(s)

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1
Crop	Pome fruits
Application rate (g as/ha)	350
Number of applications/interval	4 (7)
Crop interception (%)	60

Depth of soil layer (relevant for plateau concentration) (cm)	5 cm
Model used for calculation	HSE PECsoil calculator

Table 8.7-2: Input parameter for active substance and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
Dithianon	296.3	-	37.6 (longest first-order laboratory 7value in six aerobic soils at study conditions of 20°C and 45% MWHC)	y/EFSA 2010
Phthalic acid	166.14	16	1 at 20°C and pF2 conditions (conservative value; all lab.-study-values (n=3) are shorter than 1 day)	

Table 8.7-3: Table 8.7-4: PEC_{soil} for Dithianon on Pome fruits

PEC_{soil} (mg/kg)		Pome fruits			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.187	-	**0.622**	-
Short term	24h	0.183	0.185	0.610	0.616
	2d	0.180	0.183	0.599	0.610
	4d	0.173	0.180	0.577	0.599
Long term	7d	0.164	0.175	0.546	0.583
	14d	0.144	0.165	0.480	0.548
	21d	0.127	0.155	0.422	0.515
	28d	0.111	0.146	0.371	0.486
	50d	0.074	0.122	0.247	0.406
	100d	0.030	0.085	0.098	0.284
Plateau concentration (5 cm) after year 10		Not required	-	0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not required	-	0.621	-

PEC_{soil} of metabolites

Table 8.7-4: Table 8.7-5: PEC_{soil} for Phthalic acid on Pome fruits

PEC_{soil} (mg/kg)		Pome fruits			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.017	-	**0.017**	-
Short term	24h	0.008	0.012	0.008	0.012

	2d	0.004	0.009	0.004	0.009
	4d	0.001	0.006	0.001	0.006
Long term	7d	<0.001	0.003	<0.001	0.003
	14d	<0.001	0.002	<0.001	0.002
	21d	<0.001	0.001	<0.001	0.001
	28d	<0.001	0.001	<0.001	0.001
	50d	<0.001	<0.001	<0.001	<0.001
	100d	<0.001	<0.001	<0.001	<0.001
Plateau concentration (20 cm) after year 10		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

8.7.2.1 PEC_{soil} of ~~DITH~~ DUKES

Table 8.7-6: PEC_{soil} for DITH on Pome fruits

Active substance/ reparation	Application rate (g/ha)	Interception	PEC_{act} (mg/kg)	Tillage depth (cm)
Dithianon/~~DITH~~ DUKES	4 x 500 (7d interval)	60%	1.067	5

zRMS comments

The zRMS has been accepted the calculation of PECs values for active substance dithianon and its metabolie phtalic acid 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.

PECs = 0.622 mg/kg
Phthalic acid = 0.017 mg/kg

Formulation PECs = 1.067 mg/ha

The acceptable predicted environmental concentrations of dithianon and its metabolites in soil are appropriate to be used for the subsequent risk assessment.

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

8.8.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

8.8.2 Active substances and relevant metabolite(s) (KCP 9.2.4.1)

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1
Crop	Pome fruits (Apple)
Application rate (g as/ha)	Dithianon: 350
Number of applications/interval (d)	4 (7)
Crop interception (%)	60
Frequency of application	Annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3

Table 8.8-2: Application dates used for groundwater risk assessment

Crop	Scenario	Application dates*
Apple	Châteaudun	03/05
	Hamburg	26/05
	Jokioinen	18/05
	Kremsmünster	26/05
	Okehampton	08/05
	Piacenza	03/05
	Porto	11/05
	Sevilla	25/04
	Thiva	11/05

***First application according to AppDate v3.06 (28 June2019)**

Table 8.8-3: Input parameters related to active substance Dithianon and metabolite for PEC_{gw} calculations

Compound	Dithianon	Phthalic acid	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	296.3	166.14	y / DAR of Dithianon – Addendum of October 2010
Water solubility (mg/l):	0.3754 (@ pH 7 and 20ºC)	1000 (default)	y / DAR of Dithianon – Addendum of October 2010 and Addendum to DAR – June 2014
Saturated vapour pressure (Pa):	2.71×10^{-9} (@ 25ºC) 1.41×10^{-9} (@ 20ºC)*	0 (default)	y / DAR of Dithianon – Addendum of October 2010 and Addendum to DAR – June 2014
DT_{50} in soil (d)	33.3 d (Longest laboratory DT_{50} - normalisation to pF2, studies conducted at 20°C).	1 at 20°C and pF2 conditions (conservative value; all lab.-study-values (n=3) are shorter than 1 day)	y / DAR of Dithianon – Addendum of October 2010 and Addendum to DAR – June 2014

Compound	**Dithianon**	**Phthalic acid**	**Value in accordance with EU endpoint y/n/ Reference**
K_{foc} (mL/g) /K_{fom}	3179 / 1843.7 (geomean, n=6)	11.01 / 6.4 (geomean, n=5)	y / DAR of Dithianon – Addendum of October 2010 and Addendum to DAR – June 2014
1/n	0.9 (default)	0.9 (default)	y / DAR of Dithianon – Addendum of October 2010
Plant uptake factor	0		y / DAR of Dithianon – Addendum of October 2010 and Addendum to DAR – June 2014
Formation fraction	-	1 from parent	-

***Calculated by EVA 3 rev 2h 20/09/2017**

Table 8.8-4: PEC$_{gw}$ for Dithianon and Phthalic acid on pome fruits (apple) with FOCUS PELMO 5.5.3 and PEARL 4.4.4

Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**			
		Dithianon		**Phthalic acid**	
		PELMO	**PEARL**	**PELMO**	**PEARL**
Apple	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001

Conclusions

The PECgw values for Dithianon and its metabolite Phthalic acid were below 0.1 µg/L in all scenarios. Therefore, the use of ~~DITH~~ Dukes doesn't pose a risk for ground water and the relevance assessment of the metabolite is not necessary.

zRMS comments

The zRMS accepted the calculation of PECgw 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.

PECgw of Dithianon <0.001 µg/L

PECgw of Phtalic acid <0.001 µg/L

The 80th percentile groundwater concentrations PECgw for dithianon and its metabolites are less than trigger value 0.1 µg/L.

The use of DUKES doesn't pose a risk for ground water and the relevance assessment of the metabolite is not necessary.

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

8.9.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

8.9.2 Active substance, relevant metabolites and the formulation (KCP 9.2.5)

Table 8.9-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	~~DITH~~ DUKES
Use No.	1
Crop	Pome fruits
Application rate (kg as/ha)	Dithianon: 0.35
Number of applications/interval (d)	4 / 7
Application window (Step 1&2)	Early application: March-May Late application: June-September
Crop interception (Step 1&2)	Full canopy
Application method	Airblast
CAM (Chemical application method)	CAM 2
Soil depth (cm)	Water body: 30cm Sediment: 5cm
Models used for calculation	FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5, SWAN 5.0.0

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of Dithianon

Scenario	Application window used in modelling*	
	Apple/Almond	
	Early (BBCH 51)	Late (BBCH 61)
D3	26/05	14/06
D4	30/05	18/06
D5	03/05	18/05
R1	26/05	14/06
R2	27/05	30/06
R3	03/05	18/05
R4	25/04	14/05

***First application according to AppDate 28 June 2019**

Table 8.9-3: Input parameters related to active substance Dithianon and metabolite for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4) (if necessary)

Compound	Dithianon	CL 1017911	Phthalic acid	Phthalaldehyde	1,2-benzenedimethanol	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	296.3	330.33	166.14	134.14	138.17	y/EFSA 2010 Addendum to DAR – June 2014
Saturated vapour pressure (Pa)	2.71 x 10^{-9} (@ 25°C)	<1.0 x 10^{-16} (@ 20ºC)	Not required for step 1&2	0	Not required for step 1&2	y/EFSA 2010 Addendum to DAR – June 2014
Water solubility (mg/L)	0.3754 (@ pH 7 and 20ºC)	140000 (@ 20ºC)	1000 (default)			y/EFSA 2010 Addendum to DAR – June 2014
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}		not required for Step 1&2	4.3 x 10^{-5}	not required for Step 1&2	default
Diffusion coefficient in air (m²/d)	0.43			0.43		default
K_{foc} (mL/g)	3179 / 1843.7 (geomean, n=6)	10 (worst case)	11.01 / 6.4 (geomean, n=5)	10 (conservative estimation)	10 (conservative estimation)	y/EFSA 2010 Addendum to DAR – June 2014
Freundlich Exponent 1/n	0.9 (default)	Not required for step 1&2		0.9 (default)	Not required for step 1&2	y/EFSA 2010
Plant Uptake	0			0 (default)		y/EFSA 2010 Addendum to DAR – June 2014
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	not required for Step 1&2	0.05 (MACRO) 0.50 (PRZM)	not required for Step 1&2	default
$DT_{50,soil}$ (d)	10.5 (geometric mean value from the soil laboratory studies (N=6), corrected to 20°C and pF2)	1000 (default)	1 (conservative assumption)	1000 (default)		y/EFSA 2010 Addendum to DAR – June 2014
$DT_{50,water}$ (d)	0.505 (Geometric mean value from two water/sediment systems)	6.10	16 (derived from photolysis study)	1.4 (from photolysis study)	4.8 (from photolysis study)	y/EFSA 2010 Addendum to DAR – June 2014 Addendum_Additional

Compound	**Dithianon**	**CL 1017911**	**Phthalic acid**	**Phthalalde-hyde**	**1,2-benzenedi-methanol**	**Value in accordance to EU endpoint y/n/ Reference**
						report_06_Vol3_B8 (January 2010)
$DT_{50,sed}$ (d)	1000 (default)	6.10	1000 (default)			y/EFSA 2010 Addendum to DAR – June 2014 Addendum_Additional report_06_Vol3_B8 (January 2010)
$DT_{50,whole\ system}$ (d)	0.440 (geometric mean value from two water/sediment systems)	6.10				y/EFSA 2010 Addendum to DAR – June 2014 Addendum_Additional report_06_Vol3_B8 (January 2010)
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 1.4%	Soil: 0.00001%* Water: 52.01% Sediment: 3.6% Total system:54.45%	Soil: 16% Total system: 38.5% (from photolysis study)	Soil: 0.00001%* Total system: 11.2% (from photolysis study)	Soil: 0.00001%* Total system: 20.9% (from photolysis study)	y/EFSA 2010 Addendum to DAR – June 2014 Addendum_Additional report_06_Vol3_B8 (January 2010)
Formation fraction in soil:	-	-	-	-	-	-

***The program doesn't admit 0 as value**

$PEC_{sw/sed}$

Table 8.9-4a: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Dithianon following sin-gle/multiple applications of ~~DITH~~ DUKES to pome fruits – early application

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	56.33	Runoff/Drainage	1.66	707.97
Step 2					
Southern Europe	March-May	34.06/28.10	Spray-drift	1.66/1.94	168.09/279.70
Northern Europe				1.50/1.59	137.71/193.06

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 3					
D3	ditch	27.27/21.63	Drainage	0.911/2.069	11.99/20.64
D4	pond	1.653/1.289	Drainage	0.119/0.175	1.444/1.925
D4	stream	27.72/22.67	Drainage	0.136/0.774	2.185/8.166
D5	pond	1.654/1.288	Drainage	0.100/0.153	1.215/1.993
D5	stream	29.54/24.46	Drainage	0.132/0.733	2.104/10.32
R1	pond	1.653/1.287	Runoff	0.086/0.143	1.079/1.831
R1	stream	22.12/17.34	Runoff	0.200/0.318	3.006/4.861
R2	stream	29.63/23.24	Runoff	0.146/0.233	2.231/4.878
R3	stream	31.00/24.44	Runoff	0.366/0.622	5.656/8.817
R4	stream	22.11/17.34	Runoff	0.229/0.321	3.066/5.506

Table 8.9-5: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Dithianon following single/multiple applications of ~~DITH~~ DUKES to pome fruits– late application

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	40.62	Runoff/Drainage	1.26	707.97
Step 2					
Southern Europe	June-Sept	18.35/12.05	Spray-drift	0.96/1.05	106.62/175.61
Northern Europe				0.88/088	87.60/132.29
Step 3					
D3	ditch	12.86/8.455	Drainage	0.429/0.808	5.709/7.193
D4	pond	0.577/0.396	Drainage	0.026/0.054	0.343/0.613
D4	stream	12.89/8.528	Drainage	0.142/0.296	2.218/3.510
D5	pond	0.577/0.396	Drainage	0.035/0.060	0.432/0.670
D5	stream	13.92/9.202	Drainage	0.210/0.411	3.199/4.657
R1	pond	0.576/0.415	Runoff	0.030/0.040	0.371/0.637
R1	stream	9.879/6.522	Runoff	0.109/0.132	2.684/4.056
R2	stream	13.24/8.742	Runoff	0.060/0.121	0.972/1.503
R3	stream	13.83/9.194	Runoff	0.163/0.252	2.530/3.622
R4	stream	9.656/6.521	Runoff	0.052/0.176	0.838/2.327

FOCUS Step 4

Table 8.9-6: Global maximum PEC_{sw} values for Dithianon, following <u>single/multiple</u> applications of DITH to <u>Pome fruits– early application</u> - according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Dithianon										
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	21.43/16.56	13.16/9.647	5.920/5.196	3.009/2.401	1.151/0.802	-/-	-/-	-/-	-/-	-/-	-/-
50%		10.71/8.278	6.581/4.822	2.960/2.599	1.505/1.201	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		5.359/4.139	3.290/2.412	1.480/1.299	0.752/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		2.143/1.656	1.316/0.965	0.592/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
~~95%~~		~~1.071/0.828~~	~~0.658/-~~	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 pond	1.861/-	1.020/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50%		0.930/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
~~95%~~		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	23.81/19.16	14.62/11.16	6.580/6.014	3.345/2.779	1.279/0.928	-/-	-/-	-/-	-/-	-/-	-/-
50%		11.91/9.580	7.311/5.582	3.290/3.007	1.672/1.389	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		5.953/4.790	3.657/2.791	1.645/1.503	0.836/0.695	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		2.381/1.916	1.462/1.116	0.658/0.601	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
~~95%~~		~~1.191/0.958~~	~~0.731/-~~	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 pond	1.862/-	1.021/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

PEC$_{sw}$ (µg/L)	Scenario	STEP 4 Dithianon										
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%		0.931/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
~~95%~~		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 stream	25.38/20.67	15.59/12.04	7.013/6.448	3.565/2.998	1.363/1.001	0.686/-	-/-	-/-	-/-	-/-	-/-
50%		12.69/10.34	7.792/6.023	3.507/3.244	1.782/1.499	0.862/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		6.345/5.168	3.898/3.011	1.753/1.622	0.891/0.750	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		2.538/2.067	1.559/1.204	0.701/0.649	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
~~95%~~		~~1.269/1.034~~	~~0.779/-~~	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 pond	1.861/-	1.020/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50%		0.930/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
~~95%~~		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	19.00/14.65	11.67/8.537	5.250/4.600	2.669/2.125	1.020/0.710	-/-	-/-	-/-	-/-	-/-	-/-
50%		9.501/7.327	5.834/4.270	2.625/2.300	1.334/1.063	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		4.750/3.664	2.198/2.134	1.312/1.150	0.667/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		1.900/1.465	1.167/0.854	0.525/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
~~95%~~		~~0.950/0.733~~	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	25.46/19.64	15.63/11.44	7.034/6.165	3.576/2.849	1.367/0.951	0.688/-	-/-	-/-	-/-	-/-	-/-

PECsw (µg/L)	**Scenario**	**STEP 4 Dithianon**										
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%		12.73/9.821	7.815/5.723	3.517/3.083	1.787/1.424	0.684/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		6.364/4.190	3.909/2.861	1.758/1.541	0.894/0.712	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		2.546/1.964	1.563/1.144	0.703/0.617	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95%		1.273/0.982	0.782/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	26.63/20.66	16.36/12.03	7.630/6.483	3.741/2.996	1.430/1.000	0.720/-	-/-	-/-	-/-	-/-	-/-
50%		13.32/10.33	8.177/6.018	3.680/3.242	1.870/1.498	0.715/-	-/-	-/-	-/-	-/-	-/-	-/-
75%		6.659/5.164	4.090/3.008	1.840/1.621	0.935/0.749	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90%		2.663/2.066	1.636/1.203	0.736/0.648	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
~~95%~~		~~1.332/1.033~~	~~0.818/-~~	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	19.00/14.65	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%		9.498/7.326	5.832/4.269	2.625/2.300	1.334/1.642	-/-	-/-	-/7.326	-/4.269	-/2.300	-/1.062	-/-
75%		4.749/3.663	2.197/2.134	1.312/1.642	0.667/-	-/-	-/-	-/3.663	-/2.134	-/1.150	-/-	-/-
90%		1.900/1.642	1.167/1.642	0.556/-	-/-	-/-	-/-	-/1.465	-/0.854	-/-	-/-	-/-
~~95%~~		~~0.950/1.642~~	-/-	-/-	-/-	-/-	-/-	-/1.068	-/-	-/-	-/-	-/-

***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).**

Table 8.9-7: Global maximum PEC_{sw} values for Dithianon, following single/multiple applications of DITH to Pome fruits– late application - according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Dithianon				
Nozzle reduction	Vegetative strip (m)	None				
	No spray buffer (m)	5	10	15	20	30
None	D3 ditch	8.681/5.824	3.880/2.740	1.959/1.366	1.197/0.808	-/-
50%		4.342/2.911	1.940/1.370	0.979/0.683	-/-	-/-
75%		2.170/1.455	0.970/0.685	-/-	-/-	-/-
90%		0.868/0.582	-/-	-/-	-/-	-/-
None	D4 stream	10.06/6.742	4.497/3.174	2.270/1.583	1.388/0.936	0.690/-
50%		5.032/3.371	2.248/1.587	1.135/0.791	0.694/-	-/-
75%		2.516/1.686	1.124/0.793	-/-	-/-	-/-
90%		1.006/0.674	-/-	-/-	-/-	-/-
None	D5 stream	10.87/7.275	4.856/3.425	2.452/1.708	1.499/1.010	0.745/-
50%		5.435/3.638	2.428/1.712	1.226/0.854	0.749/-	-/-
75%		2.717/1.819	1.214/0.856	-/-	-/-	-/-
90%		1.087/0.728	-/-	-/-	-/-	-/-
None	R1 stream	7.710/5.157	3.446/2.427	1.740/1.210	1.063/-	-/-
50%		3.856/2.578	1.723/1.214	0.870/-	-/-	-/-
75%		1.928/1.289	0.861/-	-/-	-/-	-/-
90%		0.771/-	-/-	-/-	-/-	-/-
None	R2 stream	10.33/6.912	4.619/3.253	2.332/1.622	1.425/0.960	0.708/-
50%		5.169/3.456	2.309/1.627	1.166/0.811	0.712/-	-/-

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Dithianon**				
Nozzle reduction	Vegetative strip (m)	None				
	No spray buffer (m)	5	10	15	20	30
75%		2.584/1.728	1.155/0.813	-/-	-/-	-/-
90%		1.033/0.691	-/-	-/-	-/-	-/-
None	R3 stream	10.79/7.269	4.822/3.422	2.435/1.706	1.488/1.009	0.739/-
50%		5.397/3.634	2.411/1.711	1.217/0.853	0.744/-	-/-
75%		2.698/1.818	1.206/0.855	-/-	-/-	-/-
90%		1.079/0.727	-/-	-/-	-/-	-/-
None	R4 stream	7.536/5.156	3.368/2.427	1.700/1.250	1.039/-	-/-
50%		3.769/2.578	1.684/1.250	0.850/	-/-	-/-
75%		1.884/1.290	0.842/-	-/	-/-	-/-
90%		0.754/-	-/-	-/	-/-	-/-

Metabolites of Dithianon

Table 8.9-5: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for CL 1017911 following <u>single/multiple</u> applications to Pome fruits – early application as worst case

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	90.57/362.27		34.37/137.48	8.06/32.24
Step 2					
Southern Europe*	March-May	20.68/35.48		10.67/13.49	1.83/3.16
Step 3					
D3	ditch	-/6.871	Drainage	-/2.116	-/1.163
D4	pond	-/1.132	Drainage	-/0.808	-/0.358
D4	stream	-/3.368	Drainage	-/0.151	-/0.210
D5	pond	-/1.064	Drainage	-/0.804	-/0.368
D5	stream	-/3.893	Drainage	-/0.162	-/0.274
R1	pond	-/0.991	Runoff	-/0.738	-/0.326
R1	stream	-/2.393	Runoff	-/0.057	-/0.123
R2	stream	-/2.413	Runoff	-/0.032	-/0.088
R3	stream	-/4.487	Runoff	-/0.141	-/0.286
R4	stream	-/2.539	Runoff	-/0.081	-/0.125

***Worst case**

Table 8.9-9: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Phthalic acid following <u>single/multiple</u> applications to Pome fruits – early application as worst case

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	42.49/169.96		42.08/168.32	4.66/18.65
Step 2					
Southern Europe*	March-May	8.89/19.53		5.85/12.85	0.98/2.14

***Worst case**

Table 8.9-10: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Phthalaldehyde following <u>single/multiple</u> applications to Pome fruits – early application as worst case

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	7.56/30.26		7.49/29.95	0.75/3.01
Step 2					

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Southern Europe*	March-May	1.73/1.44		0.23/0.27	0.11/0.13
Step 3					
D3	ditch	0.555/0.487	Drainage	0.050/0.133	0.077/0.120
D4	pond	0.045/0.041	Drainage	0.014/0.024	0.012/0.019
D4	stream	0.162/0.247	Drainage	0.001/0.011	0.006/0.019
D5	pond	0.046/0.039	Drainage	0.014/0.019	0.012/0.020
D5	stream	0.182/0.286	Drainage	0.001/0.012	0.006/0.025
R1	pond	0.045/0.038	Runoff	0.012/0.018	0.011/0.018
R1	stream	0.193/0.173	Runoff	0.002/0.004	0.010/0.011
R2	stream	0.183/0.164	Runoff	0.001/0.002	0.007/0.007
R3	stream	0.302/0.334	Runoff	0.005/0.010	0.018/0.026
R4	stream	0.166/0.185	Runoff	0.003/0.005	0.009/0.012

***Worst case**

Table 8.9-11: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for 1,2-benzenedimethanol following single/multiple applications to Pome fruits – early application as worst case

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	14.54/58.16		14.39/57.57	1.45/5.79
Step 2					
Southern Europe	March-May	3.32/5.07		1.44/1.61	0.31/0.51

***Worst case**

8.9.2.1 $PEC_{sw/sed}$ of ~~DITH~~ DUKES

The PEC_{SW} for Dithianon was calculated using the SWASH Drift calculator v1.1. The application of DITH is 4 x 500 g/ha for Pome fruits.

Table 8.9-12: PEC_{sw} for ~~DITH~~ DUKES

Crop	Distance (m)	Drift (%)	Max PEC_{SW} (µg/L)
Apple* Early	3	20.8676	34.7793

***Worst case for Pome fruits**

The PEC_{sed} for ~~DITH~~ DUKES was calculated using the drift value from FOCUS SWASH drift calculator.

The application of ~~DITH~~ DUKES is 4 x 500 g/ha for pome fruits/almond. The resulting maximum instantaneous PEC_{sed} value is presented in the table 8.9-13.

Table 8.9-13: PEC_{sed} for DITH

Crop	Distance (m)	Drift (%)	% of Dithianon in sediment	Max PEC_{sed} (µg/kg)
Apple* Early	3	20.8676	1.4	8.989

***Worst case for Pome fruits**

zRMS comments

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 AG-ES 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.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.10-1: Dithianon Summary of atmospheric degradation and behaviour

Compound	Dithianon
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	1.01×10^{-3} mol $Einstein^{-1}$
Photochemical oxidative degradation in air	DT_{50} of < 6.3 h derived by the Atkinson model (v. 1.89). Hydroxyl-radical concentration of 1.5×10^{6} radicals/cm^3 over a 12 hour day
Volatilisation	Vapour pressure (Pa): 2.71×10^{-9} Pa at 25°C (1.41×10^{-9} Pa*) Henry's Law Constant (Pa.m3/mol): < 1.347×10^{-7} $Pa.m^3$ mol^{-1} at 20°C
Metabolites	None

***Calculated by EVA 3 rev 2h 20/09/2017**

The vapour pressure at 20 °C of the active substance Dithianon is < 10^{-5} Pa. Hence the active substance Dithianon is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Dithianon due to volatilization with subsequent deposition should not be considered.

zRMS comments

Considering the characteristics of dithianon, no environmentally relevant impact to air or risk from exposure via air can be expected following use of Dukes.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
None					

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
None					

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
None					

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
None					

Appendix 2 Detailed evaluation of the new Annex II studies

Not relevant. No new Annex II study.

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

All the input and output data of the used models are provided in K documents.