FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SHA 6821 A

Product name: PIORITY

Chemical active substances:

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

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: April 2019

MS Finalisation date: 02.2022; 01.2024

Version history

When	What
03.2020	Updated by Applicant
02.2022	Initial assessment by zRMS for commenting
01.2024	The final Registration Report

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8 Fate and behaviour in the environment (KCP 9)

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 transparency.

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**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CEU	**Grapevine**	F	*Plasmopara viticola*	Foliar Spray	BBCH 55-79	a) 3 b) 3	10-12	a) 1.5 b) 4.5	a) 0.225 dimethomorph + 0.525 dithianon b) 0.675 dimethomorph + 1.575 dithianon	800-1000	42		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 Dimethomorph 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: develop-mental 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	Min. interval between applications (days)	g a.s./hl	g as/ha	Water L/ha min/max		
1	N-EU & S-EU	Grapevines	F	*Plasmopara viticola*	Tractor mount-ed spray	BBCH 53-79 May – end of August	5	10	30-75	Max 300	400-1000	28	[1]
2	N-EU	Hops	F	*Pseudoperonospora humili*	Tractor mount-ed spray	BBCH 39-699 End of May – 15th of August	5	10	15-30	Max 600	2000-4000	10	[1]
3	N-EU S-EU	Potatoes	F	*Phytophthora infestans*	Tractor mount-ed spray	BBCH 11-65 June-end of august March- end of April	8 5	7	18-45	Max 180	100-400	7	Registered in co-formulation

* 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
[1] The risk assessment revealed a risk in section 5

Table 8.1-3: 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: develop-mental 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	Min. interval between applications (days)	g a.s./hl	g as/ha	Water L/ha min/max		
1	N-EU &	Pome fruit	F	*Venturia inaequalis,*	High volume	BBCH 10 –	12	7	35 – 52.5	525	1000 - 1500	21	Preventive

	S-EU			*Gloeosporium spp.Nectria galligena, Venturia pirina*	spraying	79							treatment. [1] [2] [3] [5] [6] [7]
2	N-EU & S-EU	Grape (table and wine)	F	*Plasmopara viticola*	High volume spraying	BBCH 10 – 79	8	7	47 - 140	560	400-1200	42	Preventive treatment. Water volume is depending on the cropping. [1] [2] [4] [5] [6]

* 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

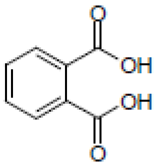
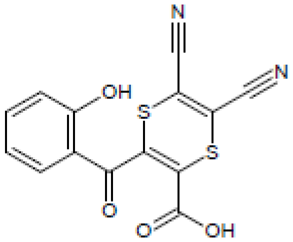
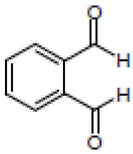
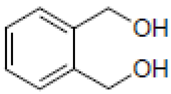
[1] The groundwater exposure assessment has not been finalised.
[2] A high long-term risk to birds has been identified.
[3] A high risk to aquatic organisms (acute for invertebrates and chronic for fish) was indicated for the majority of scenarios at FOCUS step 4.
[4] Consumer acute intake concern for table grapes (149 % of the ARfD)
[5] The consumer exposure assessment has not been finalised. In view of the uncertainties regarding the storage stability of dithianon residues in pome fruit and grape wine and the nature of the residues in processed products under standard hydrolytic conditions the potential for an exceedence of the ADI (grapes and pome fruit) and the ARfD (pome fruit) cannot be excluded.
[6] The risk to soil and aquatic organisms for phthalic acid, and risk to aquatic organisms for phthalaldehyde and 1,2-benzenedimethanol could not be finalised.
[7] The acute risk to fish for the metabolite CL 1017911 could not be finalised.

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
None.				

Table 8.2-2: Metabolites of Dithianon potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue 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)

8.3.1.1 Dimethomorph

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

Dimethomorph, Laboratory studies, aerobic conditions									
Soil type	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa***	**r²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Silty clay loam	-	22	82	96.0	319	93.8	0.991	SFO	y/ EFSA 2006 & DAR 2004
Sandy loam	-	25	75	41.3	137	45.9	0.961	SFO	
Loamy sand	-	20	33	82.1	273	55.1	0.923	SFO	
Sandy loam	-	22	75	49.8	166	41.7	0.994	SFO	
Geometric mean (n=4)						56.1			
pH-dependency:						No			

***A Q_{10} of 2.58 was used for normalization**

8.3.1.2 Dithianon and its metabolites

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

Dithianon, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**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	9.2 / 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	12.2 / 17.8*	59.1	16.2	0.985	FOMC	
Bergen	Clay loam	7.6	20	45	3.7 / 8.5*	28.1	7.2	0.995	DFOP	
Schwalbach	Silt loam	5.1	20	45	37.7**	125	33.3	0.976	SFO	
Ulm (10°C)	-	6.8	10	45	30.8	111.4	-	-	Best-fit	
Ulm (sterile)***	-	6.8	20	45	40.7***	1135.1***	-	-	SFO	

Dithianon, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Lufa2.2	Sandy loam	5.9	20	41	6.5 / 12.0*	39.8	11.6	0.991	DFOP	
Bruch West	Loamy sand	7.1	20	45	2.6**	8.48	2.6	0.974	SFO	
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

Table 8.3-3: Summary of aerobic degradation rates for Phthalic acid - laboratory studies

Phthalic acid, Laboratory studies, aerobic conditions										
Soil name	**Soil type (DIN/USDA)**	**pH (H_2O/$CaCl_2$)**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Bruch West	Loamy Sand / Sandy loam	8.2 / 7.4	20	40	0.10	0.32	-	1.696	SFO	y/Addendum to DAR – June 2014
Li10	Silty sand / Loamy sand	7.0 / 6.3	20	40	0.07	0.23	-	0.8858	SFO	
LUFA 5M	Loamy sand / Sandy loam	8.0 / 7.3	20	40	0.26	0.86	-	3.801	SFO	

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Dimethomorph

Please refer to EFSA Scientific Report (2006) 82.

Table 8.3-4: Summary of anaerobic degradation rates for Dimethomorph - laboratory studies

DT_{50lab} (anaerobic) at 25°C	chlorophenyl-label: 26.2 days (mixture of isomers, 1 soil), 28 days (E-isomer, 1 soil), 25 days (Z isomer, 1 soil).
	morpholine-label: 25.7 days (mixture of isomers, 1 soil), 27 days (E-isomer, 1 soil), 26 days (Z isomer, 1 soil).

8.3.2.2 Dithianon

Table 8.3-5: 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**
LUFA 2.2	Sandy loam	5.9	20	40	5.4	59.2	-	-	-	y/EFSA 2010 DAR october 2006
Ulm	Clayish loam	6.8	20	Flooded	1.4	4.7	-	-	-	
Geometric mean (n=2)							-			
pH-dependency: y/n							n			

8.4 Field studies (KCP 9.1.1.2)

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

8.4.1.1 Dimethomorph

Please refer to EFSA Scientific Report (2006) 82.

Table 8.4-1: Summary of aerobic degradation rates for Dimethomorph – Field studies

Dimethomorph, Field studies – Triggering endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**Kinetic parameters**	**St. (r^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Sandy loam	Schwabenheim (Germany)	7.3	20	33.8[1] 16.9[2] 48.7[3]	112.4[1] 56.1[2] 161.7[3]	-	0.951[1] 0.974[2] 0.977[3]	First order	EFSA 2006 & DAR 2004
Sandy loam	Malborn (Germany)	5.2	20	38.9[1] 16.5[2] 51.1[3]	129.3[1] 54.9[2] 196.9[3]	-	0.889[1] 0.986[2] 0.958[3]		
Clay	Leibertingen (Germany)	7.3	20	40.1[1] 31.0[2] 57.9[3]	133.3[1] 102.9[2] 192.4[3]	-	0.990[1] 0.999[2] 0.982[3]		
Sandy loam	Schwabenheim (Germany)	7.3	20	45.7	151.7	-	0.955		
Loamy sand	Krogsberg (Germany)	6.6	20	52.9[1] 38.0[2] 77.4[3]	175.7[1] 126.1[2] 257.1[3]	-	0.947[1] 0.998[2] 0.928[3]		

Dimethomorph, Field studies – Triggering endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**Kinetic parameters**	**St. (r^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Loamy sand	Staeford upon Avon (United Kingdom)	6.7	25-30	61[1] 30[2] 86[3]	203[1] 101[2] 287[3]	-	0.831[1] 0.891[2] 0.807[3]		
Loamy sand	South Merville (France)	6.5	25-30	34[1] 20[2] 42[3]	112[1] 68[2] 140[3]	-	0.995[1] 0.993[2] 0.986[3]		
Loamy sand	Utrera (Spain)	6.5	25-30	10[1] 11[2] 9[3]	33[1] 38 30[3]	-	0.98[1] 0.966[2] 0.977[3]		
Maximum (n=5)				61	203				

[1] Average value from *Z* and *E* isomers
[2] Values from E-isomer
[3]Values from Z-isomer

8.4.1.2 Dithianon

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 (EFSA, 2010).

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 Dimethomorph

No data available. Please refer to EFSA Scientific Report (2006) 82.

8.4.2.2 Dithianon

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 (EFSA, 2010).

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. Please refer to EFSA Scientific Report (2006) 82.

8.5.1 Dimethomorph

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

Dimethomorph							
Soil name	**Soil type**	**OC (%)**	**pH Water/$CaCl_2$ (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Schwabenheim	Sandy loamy silt	0.96	5.8/5.5	4.94	515	0.834	y/ EFSA 2006 & DAR 2004
Ingelheim-Moers	Sandy loam	2.26	7.5/7.4	8.51	377	0.814	
Speyer 2.1	Sand	0.7	6.0/5.8	2.72	388	0.857	
Speyer 2.3	Silty sand	0.96	5.4/4.9	3.03	316	0.872	
Lufa-Speyer 2.1	Sand	0.79	5.7	4.47	566	0.887	
Lufa-Speyer 2.2	Humus sand	2.90	6.1	11.37	402	0.921	
Lufa-Speyer 2.3	Sandy loam	0.72	5.4	2.09	290	0.814	
Garderen	Sand	0.9	5.7	4.30[1]/3.92[2]	478[1]/435[2] 456.5[3]	0.84[1]/0.92[2] 0.88[3]	
Bidinghuiden	Silty clay loam	1.8	8.2	10.3[1]/9.72[2]	574[1]/540[2] 557[3]	0.87[1]/0.87[2] 0.87[3]	
Ravenswood	Sand	3.8	5.8	21.1[1]/17.9[2]	555[1]/471[2] 513[3]	0.87[1]/0.89[2] 0.88[3]	
Princeton NJ	Sandy loam	1.4	5.7	4.84[1]/4.81[2]	346[1]/344[2] 345[3]	0.79[1]/0.85[2] 0.82[3]	
				Geomean (n=11)	419.4	-	
				Arithmetic mean (n=11)	-	0.86	
				pH-dependency	No		

[1] Values from E-isomer
[2] Values from Z-isomer
[3] Average value from *Z* and *E* isomers

8.5.2 Dithianon and its metabolites

Table 8.5-2: 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	-	
LUFA 2.2	Loamy sand	2.08	6.2	85	4091	-	

Dithianon							
Soil name	**Soil type**	**OC (%)**	**pH (H_2O)**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
LUFA 3A	Loam	2.96	7.7	122	4122	-	
1680	Loamy sand	0.78	6.9	9	1167	-	
					Geomean (n=5) 3179.5	-	
				pH-dependency y/n	n		

Table 8.5-3: 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	
Nierswalde “Wildacker”	Silt loam	6.5	1.63	0.717	44	0.891	
Grobe Erde	Loamy sand	6.8	0.92	0.027	3	0.974	
Fiorentini	Silt loam	7.5	1.83	0.079	4	0.955	
Geomean (n=5)					11	-	
Arithmetic mean (n=5)					-	0.921	
pH-dependency y/n					n		

8.5.3 Column leaching (KCP 9.1.2.1)

8.5.3.1 Dimethomorph

Please refer to EFSA Scientific Report (2006) 82.

Column leaching	4 soils (OC 0.70-2.56%, pH in $CaCl_2$ 4.9-7.7), 200 mm rainfall over 2 days < 0.67 % of applied dose (1.8 kg/ha) was detected in leachate
Aged residues leaching	Chlorophenyl-label: 3.4 % of applied dose was detected in leachate (sand soil after 60-day aging and equivalent of 20 cm rainfall. At least 7 metabolite products, each ≤ 0.5 % of applied dose.
	Morpholine-label: < 0.8 % of applied dose detected in leachate (silty clay loam after a 90-day aging and equivalent of 51 cm rainfall).

8.5.3.2 Dithianon

Please refer to EFSA Journal 2010;8(11):1904.

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 preleaching): 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 analyse 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

8.5.4 Lysimeter studies (KCP 9.1.2.2)

8.5.4.1 Dimethomorph

Not required. Please refer to EFSA Scientific Report (2006) 82.

8.5.4.2 Dithianon

Not required for the EU Review of Dithianon (EFSA, 2010).

8.5.5 Field leaching studies (KCP 9.1.2.3)

8.5.5.1 Dimethomorph

Not required. Please refer to EFSA Scientific Report (2006) 82.

8.5.5.2 Dithianon

Not required for the EU Review of Dithianon (EFSA, 2010).

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.

8.6.1 Dimethomorph

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

Dimethomorph Distribution (max. water 98 % after 0 day; max. sediment 68 % after 0 day)										
Water/sediment system	**pH**	**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**
Bickenbach	7.5	2.9	9.8		-	-	-	-	-	EFSA, 2006 DAR, 2004
Unter Widdersheim	7.3	2.1	7.0		-	-	-	-	-	
Kellmetschweiher	Water: 7.6 Sediment: 7.5	59	195	SFO, r^2 = 1.00	15	51	SFO, r^2 = 0.97	33	SFO, r^2 = 0.93	
Berghäuser Altrhein	Water: 8.51 Sediment: 7.5	16	52	SFO, r^2 = 0.99	5	16	SFO, r^2 = 0.97	7	SFO, r^2 = 0.94	
Geometric mean (n=4)		8.7	28.9		-	-		-		

8.6.2 Dithianon and its metabolites

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

Dithianon Distribution (max. water 19.4% after 1 day/ max. in 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	-	
Pond R – Ranschgraben	7.9/6.5	0.196	1.84	DFOS	0.22 d	0.74 d	SFO	5.07	FOMC	
River B – Berghauser Altrhein	8.1/7.6	0.35	1.16	SFO	0.34 d	1.14 d	SFO	0.62	FOMC	
Geometric mean (n=2-4)		0.26	1.46		0.14	0.48		1.77		n/ calculated

Table 8.6-3: 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 B – Berghauser Altrhein	8.1/7.6	6.05	20.1	SFO	5.94	19.8	SFO	1.38	SFO	y/EFSA 2010
Pond R – Ranschgraben	7.9/6.5	5.92	19.7	SFO fit of decline from peak observed	-	-	-	-	-	y/EFSA 2010
River B – 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 8.6-4: 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

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 substances and relevant metabolite(s)

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

Use No.	1
Crop	Grapevine
Application rate (g as/ha)	Dimethomorph: 225 Dithianon: 525
Number of applications/interval	3 / 10
Crop interception (%)	60 (flowering)*
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm

***Crop interception value derived from EFSA Journal 2014; 23(5): 3662**

Table 8.7-2: Input parameter for active substances and relevant metabolites for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Dimethomorph	387.9	-	93.8 (normalised worst case from laboratory studies)	y/ EFSA 2006
Dithianon	296.3	-	37.6 (longest first-order laboratory value 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)	

8.7.2.1 Dimethomorph

Table 8.7-3: PEC_{soil} for Dimethomorph on grapevine

PEC_{soil} (mg/kg)		Grapevine			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.120	-	0.335	-
Short term	24h	0.119	0.120	0.332	0.334
	2d	0.118	0.119	0.330	0.333
	4d	0.117	0.118	0.325	0.330
Long term	7d	0.114	0.117	0.318	0.326
	14d	0.108	0.114	0.302	0.318
	21d	0.103	0.111	0.287	0.310
	28d	0.098	0.108	0.272	0.303
	50d	0.083	0.100	0.231	0.280
	100d	0.057	0.085	0.160	0.237
Plateau concentration (5 cm) after year 3		-	-	0.028	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	0.363	-

8.7.2.2 Dithianon and its metabolites

Table 8.7-4: PEC_{soil} for Dithianon on grapevine

PEC_{soil} (mg/kg)		Grapevine			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.280	-	0.707	-
Short term	24h	0.275	0.277	0.694	0.700
	2d	0.270	0.275	0.681	0.694
	4d	0.260	0.270	0.656	0.681
Long term	7d	0.246	0.263	0.621	0.663
	14d	0.216	0.247	0.546	0.623
	21d	0.190	0.232	0.480	0.586
	28d	0.167	0.219	0.422	0.552
	50d	0.111	0.183	0.281	0.462
	100d	0.044	0.128	0.112	0.323
Plateau concentration (5 cm) after year x		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

PEC_{soil} of metabolite

PEC_{soil} values for the metabolite Phthalic acid were determined as if it was parent compound with an application rate corrected, taking into account the molecular weights (MW) and the maximum occurrence of the metabolite in soil as following:

Application $rate_{metabolite}$ = ($MW_{metabolite}$/ MW_{parent}) x (% maximum occurrence/100) x application $rate_{parent}$

The corresponding application rate this metabolite is summarized in the table below.

Table 8.7-5: Corrected application rate for the metabolite

Metabolite	Application rate of the parent (g/ha)	MW_{parent}	$MW_{metabolite}$	Maximum occurrence in soil (%)	Corrected application rate (g/ha)
Phthalic acid	3 x 525	296.3	166.14	16	3 x 47.10

Table 8.7-6: PEC_{soil} for Phthalic acid on grapevine

PEC_{soil} (mg/kg)		Grapevine			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.025	-	0.025	-
Short term	24h	0.013	0.018	0.013	0.018
	2d	0.006	0.014	0.006	0.014
	4d	0.002	0.008	0.002	0.009
Long term	7d	< 0.001	0.005	< 0.001	0.005
	14d	< 0.001	0.003	< 0.001	0.003
	21d	< 0.001	0.002	< 0.001	0.002
	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 (5 cm) after year x		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

8.7.2.3 PEC_{soil} of PIORITY

Table 8.7-7: PEC_{soil} for PIORITY on grapevine

Active substance / Preparation	Application rate (g/ha)	Interception (%)	Tillage depth (cm)	PEC_{act} (mg/kg)
Dimethomorph+Dithianon / PIORITY	1500 (single app.)	60	5	0.8
	4500 (multiple app.)	60	5	2.4

zRMS comments

Dithianon
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.
Agreed PECsoil:
Dithianon: PECsoil, initial = 0.707 mg/kg
Metabolite Phthalic acid: $PEC_{soil,\ initial}$ = 0.025 mg/kg.

Dimethomorph
The zRMS has been accepted the calculation of PECs values for active substance dimethomorph presented by the Applicant. The input parameters used in calculations were taken from the endpoints available in the conclusion EFSA Scientific Report (2006) 82, 1-69.
Agreed PECsoil:
Dimethomorph: PECsoil, initial = 0.335 mg/kg

The acceptable predicted environmental concentrations of dithianon and its metabolites and dimethomorph 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 substance(s) 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	Grapevine
Application rate (g as/ha)	Dimethomorph: 225 Dithianon:525
Number of applications/interval (d)	3 / 10
Relative application date	-
Crop interception (%)	60 (flowering)*
Frequency of application	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3

***Crop interception value derived from EFSA Journal 2014; 23(5): 3662**

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

Crop	Scenario	Application dates (absolute)*
Grapevine	Châteaudun	01/06
	Hamburg	08/06
	Kremsmünster	08/06
	Piacenza	01/06
	Porto	24/05
	Sevilla	09/05
	Thiva	08/05

***First application according to AppDate v3.03 (31 January 2019)**

It should be noted that as recommended in the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (FOCUS 2011), a corrected application rate is calculated taking into account the interception by the crop canopy.
Therefore, the substance is applied directly to the ground in the models, thus avoiding the internal interception routines in the models. The corrected application rates are 90 g Dimethomorph/ha and 210 g Dithianon/ha in grapevine.

8.8.2.1 Dimethomorph

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

Compound	Dimethomorph	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	387.9	EFSA 2006
Water solubility (mg/L):	47.2 (20°C) (for *E* isomer)	
Saturated vapour pressure (Pa):	1 x 10^{-6} (25°C) (for *Z* isomer) 5.2 x 10^{-7} (20°C, calculated by EVAv 3, rev 2h 20.09.2017for PELMO parameters, as worst case)	
DT_{50} in soil (d)	56.1 (geometric mean, normalisation to 10 kPa or pF2, 20 °C, Q_{10} 2.58, n =4)	
K_{foc} (mL/g)/K_{fom}	419.4 / 243.3 (geomean, n = 11)	
1/n	0.86 (Arithmetic mean, n =11)	
Plant uptake factor	0 (default)	

Table 8.8-4: PEC$_{gw}$ for Dimethomorph on grapevine (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		Dimethomorph	
		FOCUS PELMO 5.5.3	FOCUS PEARL 4.4.4
Grapevine	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

8.8.2.2 Dithianon and its metabolites

Table 8.8-5: Input parameters related to active substance Dithianon and Phthalic acid 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 / EFSA, 2010 DAR of Dithianon – Addendum of October 2010 and Addendum to DAR – June 2014
Water solubility (mg/L):	0.3754	1000 (default)	
Saturated vapour pressure (Pa):	2.2 x 10^{-13} @ 20ºC 8.9 x 10^{-13} @ 25ºC	0	
DT$_{50}$ in soil (d)	33.3 d (Longest laboratory DT50 - 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)	
K$_{foc}$ (mL/g)/K$_{fom}$	3179.5 / 1844.3 geomean (n=5)	11 / 6.4 (geomean, n=5)	
1/n	0.9 (default)	0.921	
Plant uptake factor	0		
Formation fraction	-	1 from parent	

Table 8.8-6: PEC$_{gw}$ for Dithianon on grapevine (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		Dithianon	
		FOCUS PELMO 5.5.3	FOCUS PEARL 4.4.4
Grapevine	Châteaudun	< 0.001	< 0.001

	Hamburg	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8-7: PEC$_{gw}$ for Phthalic acid on Grapevine (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		Phthalic acid	
		FOCUS PELMO 5.5.3	FOCUS PEARL 4.4.4
Grapevine	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	0.001
	Kremsmünster	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

zRMS comments

Dithianon
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.

Dimethomorph
The zRMS has been accepted the calculation of PECgw values for active substance dimethomorph presented by the Applicant. The input parameters used in calculations were taken from the endpoints available in the conclusion EFSA Scientific Report (2006) 82, 1-69.
PECgw for the active ingredient dimethomorph were predicted to be less than 0.1µg/L.

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(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

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

Plant protection product	PIORITY
Use No.	1
Crop	Grapevine
Application rate (kg as/ha)	Dimethomorph: 0.225 Dithianon: 0.525
Number of applications/interval (d)	3 / 10
Application window	March-May for steps 1/2 Full canopy
Application method	Air blast
CAM (Chemical application method)	2
Soil depth (cm)	4
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 v4.4.3

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

Crop	Scenario	Application window used in modelling*
Grapevine	**D3#**	**03/06**
	D4#	**07/06**
	D6	18/03
	R1	24/05
	R2	24/05
	R3	01/06
	R4	16/05

***First application according to AppDate v3.03 (31 January 2019)**
#Calculation done for surrogate crop - pome/stone fruits.
National scenarios relevant for Poland are D3, D4 and R1. Due to fact that drainage scenarios (D3, D4) are not available for grapevines in programs used for modelling, the surrogate crop – pome/stone fruits was proposed. Presented calculation was done for pome/stone fruits, for scenarios D3, D4 considering all input data as for pome/stone fruits.

8.9.2.1 Dimethomorph

Table 8.9-3: Input parameters related to active substance Dimethomorph for $PEC_{sw/sed}$ calculations STEP 1/2 and 3

Compound	**Dimethomorph**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	387.9	EFSA 2006
Saturated vapour pressure (Pa)	1 x 10^{-6} (25°C) (for *Z* isomer) for Step 3	
Water solubility (mg/L)	47.2 (20°C) (for *E* isomer)	
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}	Default
Diffusion coefficient in air (m²/d)	0.43	Default
K_{foc} (mL/g)	419.4 (geomean, n = 11)	EFSA 2006
Freundlich Exponent 1/n	0.86 (Arithmetic mean, n =11)	
Plant Uptake	0	
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	Default
$DT_{50,soil}$ (d)	56.1 (geometric mean, normalisation to 10 kPa or pF2, 20 °C, Q_{10} 2.58 n =4)	EFSA 2006
$DT_{50,water}$ (d)	59 (worst-case from water/sediment studies)	
$DT_{50,sed}$ (d)	1000 (default)	
$DT_{50,whole\ system}$ (d)	59 (worst-case from water/sediment studies)	
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 68	

$PEC_{sw/sed}$

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Dimethomorph following <u>single/ multiple</u> applications of PIORITY to grapevine – 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	---	54.12/162.37	-	46.10/138.30	215.39/646.16
Step 2					
Northern Europe	March-May	7.88/19.75	-	6.80/17.11	30.97/77.90
Southern Europe	March-May	11.54/29.51	-	10.17/26.08	46.32/118.81
Step 3					
D3[#]	ditch	8.264/5.895	drainage	0.693/1.164	4.837/6.032
D4[#]	pond	0.370/1.412	drainage	0.298/1.356	2.036/8.861
D4[#]	stream	8.282/5.922	drainage	0.108/0.8880	1.435/3.450

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
D6	ditch	3.837/4.069	drainage	0.375/2.182	2.391/7.682
R1	pond	0.138/0.314	runoff and erosion	0.119/0.257	0.553/1.284
R1	stream	2.826/3.567	runoff and erosion	0.090/0.181	0.950/1.851
R2	stream	3.783/3.225	runoff and erosion	0.056/0.120	0.771/1.763
R3	stream	3.977/3.404	runoff and erosion	0.184/0.224	1.782/1.705
R4	stream	2.778/3.240	runoff and erosion	0.032/0.298	0.423/2.692

*as worst case

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

Table 8.9-5 Global maximum PEC_{sw} values for Dimethomorph, following single/ multiple applications of PIORITY to surrogate crop - pome/stone fruits, late application according to the EU central zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Dimethomorph			
Nozzle reduction	Vegetative strip (m)	None			
	No spray buffer (m)	5	10	15	20
None	D3 ditch	5.576/4.038	2.492 / -	-	-
50 %		2.788/ -	-	-	-
75 %		-	-	-	-
90 %		-	-	-	-
None	D4 stream	6.463/4.668	2.888 / -	-	-
50 %		3.231/ -	-	-	-
75 %		-	-	-	-
90 %		-	-	-	-

8.9.2.2 Dithianon and its metabolites

Table 8.9-6: Input parameters related to active substance Dithianon and metabolites 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

<table>
<tr><th>Com-pound</th><th>Dithianon</th><th>CL 1017911</th><th>Phthalic acid</th><th>Phthalalde-hyde</th><th>1,2-benzenedi-methanol</th><th>Value in accordance to EU endpoint y/n/ Reference</th></tr>
<tr><td>Saturated vapour pressure (Pa)</td><td>2.71 x 10^{-9} at 25°C</td><td>not required for Step 1+2</td><td>not required for Step 1+2</td><td>0 (default)</td><td>not required for Step 1+2</td><td rowspan="2">Addendum_Additional report_06_Vol3_B8 (January 2010)</td></tr>
<tr><td>Water solubility (mg/L)</td><td>0.3754</td><td>140000</td><td colspan="3">1000 (conservative default value)</td></tr>
<tr><td>Diffusion coefficient in water (m²/d)</td><td>4.3 x 10^{-5}</td><td>not required for Step 1+2</td><td>not required for Step 1+2</td><td>4.3 x 10^{-5}</td><td>not required for Step 1+2</td><td rowspan="2">default</td></tr>
<tr><td>Diffusion coefficient in air (m²/d)</td><td>0.43</td><td>not required for Step 1+2</td><td>not required for Step 1+2</td><td>0.43</td><td>not required for Step 1+2</td></tr>
<tr><td>K_{foc} (mL/g)</td><td>3179.5 (geomean, n = 5)</td><td>10 (conservative default value)</td><td>11 (geomean, n=5)</td><td colspan="2">10 (conservative estimation)</td><td rowspan="3">y/EFSA 2010 Addendum to DAR – June 2014 Addendum_Additional report_06_Vol3_B8 (January 2010)</td></tr>
<tr><td>Freundlich Exponent 1/n</td><td>0.9 (default)</td><td>0.9 (default)</td><td>0.921</td><td colspan="2">0.9 (default)</td></tr>
<tr><td>Plant Uptake</td><td>0</td><td>not required for Step 1+2</td><td>not required for Step 1+2</td><td>0</td><td>not required for Step 1+2</td></tr>
<tr><td>Wash-Off factor from Crop (1/mm)</td><td>0.05 (MACRO) 0.50 (PRZM)</td><td>not required for Step 1+2</td><td>not required for Step 1+2</td><td>0.05 (MACRO) 0.50 (PRZM)</td><td>not required for Step 1+2</td><td>default</td></tr>
<tr><td>$DT_{50,soil}$ (d)</td><td>10.5 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =6)</td><td>1000 (default)</td><td>1 (conservative assumption since lab. DT_{50} < 1d)</td><td colspan="2">1000 (default)</td><td rowspan="4">y/EFSA 2010 Addendum to DAR – June 2014 Addendum_Additional report_06_Vol3_B8 (January 2010)</td></tr>
<tr><td>$DT_{50,water}$ (d)</td><td>0.505 (geomean value from two water/sediment systems</td><td>6.10</td><td>16 (derived from photolysis study)</td><td>1.4 (from photolysis study)</td><td>4.8 (from photolysis study)</td></tr>
<tr><td>$DT_{50,sed}$ (d)</td><td>1000 (default)</td><td>6.10</td><td colspan="3">1000 (default)</td></tr>
<tr><td>$DT_{50,whole\ system}$ (d)</td><td>0.440 (geomean value from two water/sediment systems)</td><td>6.10</td><td colspan="3">1000 (default)</td></tr>
</table>

Com-pound	Dithianon	CL 1017911	Phthalic acid	Phthalalde-hyde	1,2-benzenedi-methanol	Value in accordance to EU endpoint y/n/ Reference
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 aqueous photolysis study)	Soil: 0.00001% Total system: 11.2% (from photolysis study)	Soil: 0.00001% Total system: 20.9% (from photolysis study)	

$PEC_{sw/sed}$

Table 8.9-7: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Dithianon following single/ multiple applications of PIORITY to grapevine – 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	---	47.45/47.45	-	1.53/1.53	1060/1060
Step 2					
Northern Europe	March-May	14.05/12.20	-	0.82/0.98	103.18/156.15
Southern Europe	March-May	14.05/12.20	-	1.08/1.43	168.30/272.35
Step 3					
D3#	ditch	19.220/13.680	drainage	0.644/0.869	8.518/10.260
D4#	pond	0.860/0.626	drainage	0.039/0.057	0.511/0.738
D4#	stream	19.270/13.770	drainage	0.213/0.321	3.322/4.412
D6	ditch	**8.954/7.693**	Drift	0.357/0.702	4.580/7.733
R1	pond	0.321/0.269	Runoff and erosion	0.017/0.030	0.215/0.388
R1	stream	**6.594/5.621**	Runoff and erosion	0.075/0.129	1.149/2.171
R2	stream	**8.828/7.524**	Runoff and erosion	0.049/0.092	1.422/3.514
R3	stream	**9.280/7.942**	Runoff and erosion	0.146/0.221	2.746/3.656
R4	stream	6.483/5.634	Runoff and erosion	0.037/0.250	0.601/5.108

*as worst case
 # Calculation done for surrogate crop - pome/stone fruits, late application.

FOCUS Step 4

Table 8.9-8: Global maximum PEC_{sw} values for Dithianon, following single/ multiple applications of PIORITY to grapevine late application according to the EU central 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	5	10	15	20
None	D3 ditch#	12.970/9.3	5.794/4.	2.925/2.1	1.787/1.2	-	-	-	-
50 %		6.485/4.68	2.897/2.	1.462/1.0	0.893/0.6	-	-	-	-
75 %		3.241/2.34	1.448/1.	0.731/0.5	-	-	-	-	-
90 %		1.296/0.93	0.579/0.	-	-	-	-	-	-
None	D4 stream#	15.040/10.	6.717/5.	3.391/2.5	2.072/1.4	-	-	-	-
50 %		7.515/5.42	3.356/2.	1.695/1.2	1.03/0.73	-	-	-	-
75 %		3.756/2.71	1.678/1.	0.847/0.6	-	-	-	-	-
90 %		1.502/1.08	0.671/0.	-	-	-	-	-	-
None	D6 ditch	5.414/4.64	1.961/1.	1.065/0.8	-	-	-	-	-
50 %		2.707/2.32	0.981/0.	-	-	-	-	-	-
75 %		1.353/1.16	-	-	-	-	-	-	-
90 %		0.541/-	-	-	-	-	-	-	-
None	R1 stream	4.805/4.07	1.740/1.	0.945/0.9	-	4.805/4.0	1.740/1.4	0.945/0.78	0.610/0.50
50 %		2.402/2.04	0.870/0.	-	-	2.402/2.0	0.870/0.7	-	-
75 %		1.201/1.02	-	-	-	1.201/1.0	-	-	-
90 %		-	-	-	-	-	-	-	-
None	R2 stream	6.433/5.46	2.329/1.	1.266/1.0	-	6.433/5.4	2.329/1.9	1.266/1.05	0.817/0.67
50 %		3.216/2.73	1.165/0.	-	-	3.216/2.7	1.165/0.9	-	-
75 %		1.608/1.36	-	-	-	1.608/1.3	-	-	-
90 %		0.643/0.54	-	-	-	0.643/0.5	-	-	-
None	R3 stream	6.762/5.76	2.449/2.	1.331/1.1	0.859/-	6.762/5.7	2.449/2.0	1.331/1.11	0.859/0.71
50 %		3.380/2.88	1.224/1.	-	-	3.380/2.8	1.224/1.0	-	-
75 %		1.690/1.44	-	-	-	1.690/1.4	-	-	-
90 %		0.767/0.71	-	-	-	0.676/0.5	-	-	-
None	R4 stream	4.724/4.08	1.711/2.	0.930/2.0	-/2.097	4.724/4.0	1.711/1.4	0.930/0.78	0.600/0.50
50 %		2.362/2.09	0.855/2.	-/2.097	-	2.362/2.0	0.855/0.9	-	-
75 %		1.181/2.09	-	-	-	1.181/1.3	-	-	-
90 %		-/2.097	-	-	-	-/1.365	-	-	-

*The value used for reduction in run-off volume, run-off flux, erosion mass and erosion flux was 0.4, according to the Austrian Environmental Agency AGES.

**The value used for reduction in run-off volume and run-off flux was 0.7, and the value used for reduction in erosion mass and erosion flux was 0.9, according to the Austrian Environmental Agency AGES.

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

Table 8.9-9: FOCUS Step 1/2 PEC_{sw} and PEC_{sed} for CL 1017911 following single/ multiple applications of PIORITY to grapevine – 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	---	113.36/340.09	-	43.10/129.31	10.48/31.45
Step 2					
Northern Europe	March-May	11.81/18.05	-	4.49/6.87	1.05/1.61
Southern Europe	March-May	18.25/29.54	-	6.94/11.24	1.65/2.74

*as worst case

Table 8.9-10: FOCUS Step 1/2 PEC_{sw} and PEC_{sed} for Phthalic acid following single/ multiple applications of PIORITY to grapevine – 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	---	55.74/167.21	-	55.29/165.88	6.12/18.37
Step 2					
Northern Europe	March-May	4.89/8.67	-	3.22/5.71	0.54/0.95
Southern Europe	March-May	7.26/12.82	-	4.78/8.45	0.80/1.41

*as worst case

Table 8.9-11: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Phthalaldehyde following single/ multiple applications of PIORITY to grapevine – 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	---	9.47/28.41	-	9.39/28.17	0.95/2.84
Step 2					
Northern Europe	March-May	0.71/1.05	-	0.14/0.10	0.06/0.11
Southern Europe	March-May	1.18/2.01	-	0.12/0.20	0.12/0.20
Step 3					
D3#	ditch	0.385/0.305	drainage	0.035/0.059	0.054/0.064
D4#	pond	0.024/0.018	drainage	0.005/0.008	0.005/0.007
D4#	stream	0.200/0.148	drainage	0.003/0.004	0.012/0.011
D6	ditch	0.167/0.212	Drift	0.018/0.083	0.025/0.066
R1	pond	0.009/0.008	Runoff and erosion	0.002/0.004	0.002/0.004
R1	stream	0.057/0.048	Runoff and erosion	0.001/0.002	0.003/0.004
R2	stream	0.055/0.049	Runoff and erosion	<0.001/0.001	0.002/0.002
R3	stream	0.123/0.144	Runoff and erosion	0.003/0.005	0.008/0.011

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
R4	stream	0.043/0.060	Runoff and erosion	<0.001/0.005	0.002/0.010

*as worst case

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

Table 8.9-12: FOCUS Step 1/2 PEC_{sw} and PEC_{sed} for 1,2-benzenedimethanol following single/ multiple applications of PIORITY to grapevine – 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	---	18.20/54.60	-	18.05/54.15	1.82/5.45
Step 2					
Northern Europe	March-May	1.80/2.70	-	0.57/0.86	0.18/0.27
Southern Europe	March-May	2.83/4.54	-	0.90/1.44	0.28/0.45

*as worst case

8.9.2.3 $PEC_{sw/sed}$ of PIORITY

The PEC_{SW} for PIORITY was calculated using the following equation:

$$PEC_{SW}\,(\mu g/L) = \frac{\%\,\text{Drift}_{90th\ \%ile} \times \text{Application rate}\,(g/ha)}{\text{Water depth (cm)} \times 10}$$

The application of PIORITY is 3 x 1500 g/ha. The depth of the static water body was assumed to be 30 cm. The resulting maximum instantaneous PEC_{SW} value is presented in the table 8.9-8.

Table 8.9-13: PEC_{sw} for PIORITY following single/multiple applications to grapevines – late application*

		Nozzles reduction (%)		
Distance (m)	**PECsw (µg/L)**	**50**	**75**	**90**
3	40.100/103.500	20.050/51.750	10.025/25.875	4.010/10.350
5	18.100/46.050	9.050/23.025	4.525/11.513	1.810/4.605
10	6.150/15.300	3.075/7.650	1.538/3.825	0.615/1.530
15	3.250/8.100	1.625/4.050	0.813/2.025	0.325/0.810
20	2.100/5.100	1.050/2.550	0.525/1.275	0.210/0.510
30	1.100/2.700	0.550/1.350	0.275/0.675	-/0.270
40	0.700/1.650	0.352/0.825	0.175/0.413	-/0.165
50	0.500/1.200	0.250/0.600	-/0.300	-/0.120

***as worst case**

The PEC_{sed} for PIORITY was calculated using the following equation:

$$PEC_{sed}\ (\mu g/kg\ dw) = \frac{\%Drift\ _{90^{th}\%ile} \times \text{Application rate (g/ha)} \times \text{\% of active substance in sediment}}{1000 \times \text{Sediment density (g/cm3)} \times \text{Sediment height (cm)}}$$

The application of PIORITY is 3 x 1500 g/ha. The height of the sediment was assumed to be 5 cm and the sediment density was assumed to be 1.3 g/cm^3. The resulting maximum instantaneous PEC_{sed} value is presented in the table 8.9-9.

Table 8.9-14: PEC$_{sed}$ for PIORITY following single/multiple applications – late application*

Crop	Distance (m)	Drift (%)	% of substance active in sediment	Max PEC$_{sed}$ (µg/kg)
Grapevine	3	8.02 (single appl)	Dimethomorph: 68	125.85
			Dithianon: 1.4	2.59
		6.9 (multiple appl)	Dimethomorph: 68	324.83
			Dithianon: 1.4	6.69

*as worst case

zRMS comments

Dithianon
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).

Dimethomorph
The zRMS has been accepted the calculation of PECsw/sed values for active substance dimethomorph Presented by the Applicant. The input parameters used in calculations were taken from the endpoints available in the conclusion EFSA Scientific Report (2006) 82, 1-69. 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).

PL: National scenarios relevant for Poland are D3, D4 and R1. Due to fact that drainage scenarios (D3, D4) for grapevines in programs are not used, surrogate crop – pome/stone fruits was performed and accepted. Presented calculation was done for pome/stone fruits, for scenarios D3, D4 considering all input data as for pome/stone fruits.

The PECsw/sed values for active substances and its metabolites were used for further risk 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 Summary of atmospheric degradation and behaviour for Dimethomorph

Compound	Dimethomorph
Direct photolysis in air	Not required
Quantum yield of direct phototransformation	Not required
Photochemical oxidative degradation in air	DT50 (h): 3.6 derived by the Atkinson model OH (24h) concentration assumed = 5.10^{-5} /cm^3
Volatilisation	Not volatile, no volatilisation from soil and plant surfaces

	within 24 hours

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

Table 8.10-2 Summary of atmospheric degradation and behaviour for Dithianon

Compound	Dithianon
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	1.01 x 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 x 10^{6} radicals/cm^{3} over a 12 hour day
Volatilisation	Vapour pressure (Pa): 2.71 x 10^{-9} Pa at 25°C Henry's Law Constant (Pa.m3/mol): < 1.347 x 10^{-7} Pa.m^{3} mol^{-1} at 20°C
Metabolites	None

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.
Volatilization highly unlikely and if present in atmosphere, would rapidly degrade by reaction with hydroxyl radicals, therefore no calculation was performed.

zRMS comments

Accepted.

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

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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.