

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: 3AEY

Product name(s): Mevalone

Chemical active substances:

Eugenol 33 g/L

Geraniol 66 g/L

Thymol 66 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorization for Mevalone product)

Applicant: Eden Research plc

Submission date: 15/07/2021

Updated: 21/12/2021, 07/03/2022, 23/05/2022

MS Finalisation date: July 2022 (initial Core Assessment)

November 2022 (final Core Assessment)

Version history

When	What
July 2021	Authorization of marketing in Central Zone of the plant protection product Mevalone on grapes and pome fruits
December 2021	Update of the GAP table
March 2022	Update of the GAP table due to typographical error
May 2022	Update of surface water exposure with default values
July 2022	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency .
November 2022	Final report (Core Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow . Information no longer relevant is struck through and shaded .

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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
					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	Central Zone IE, GB, NL, BE, LU, DE, CZ, AT, SI, SK, HU, PL	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey mould (<i>Botrytis cinerea</i> BOTRCI)	Foliar. Tractor- mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 60- 89	a) 1 b) 4	7	a) 1.6 – 4.0 L/ha b) 6.4 – 16 L/ha	a) 52.8 - 132 (E) 106 - 264 (G) 106 - 264 (T) b) 211 – 528 (E) 422 – 1056 (G) 422 – 1056 (T)	400-1000	7	The product is applied so that the concentration in g a.s./hL is kept constant at 13.2 (eugenol), 26.4 (geraniol), 26.4 (thymol) g a.s / hectolitre of spray water volume. Therefore, the higher application rate is diluted in the higher water volume. Apply at 3.0 - 3.2 L/ha LWA	A
2	Central Zone IE, GB, NL, BE, LU, DE, CZ, AT, SI, SK, HU, RO, PL	Apple <i>Malus domestica</i> MABSD, pear <i>Pyrus communis</i> PYUCO, quince <i>Cydonia oblonga</i> CYDOB, crab-apple <i>Malus sylvestris</i> MABSY,	F	Post-harvest storage diseases	Foliar. Tractor- mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 75- 89	a) 1 b) 4	7	a) 2.4 – 4.0 L/ha b) 9.6 – 16 L/ha	a) 79.2- 132 (E) 158 - 264 (G) 158 - 264 (T) b) 317 – 528 (E) 634 – 1056 (G) 634 – 1056 (T)	600-1000	1	The product is applied so that the concentration in g a.s./hL is kept constant at 13.2 (eugenol), 26.4 (geraniol), 26.4 (thymol) g a.s / hectolitre of spray water volume. Therefore, the higher application rate is diluted in the higher	A

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 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			Groundwater
		loquat <i>Eryobotria japonica</i> EIOJA, medlar <i>Mespilus germanica</i> MSPGE, Nashi pear <i>Pyrus pyrifolia</i> var. <i>culita</i> PYUPC											water volume. Apply at 3.0-3.2 L/ha LWA Example or post- harvest storage diseases: <i>Phytophthora</i> spp. PHYTSP (mainly <i>P. cactorum</i> PHYTCC or <i>P. syringae</i> PHYTSY), <i>Alternaria</i> spp. ALTESP, <i>Botrytis</i> <i>cinerea</i> BOTRCI	

* 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 eugenol 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						
Zonal uses (field or outdoor uses, certain types of protected crops)																	
1	Central Zone IE, GB, NL, BE, LU, DE, CZ, AT, SI, SK, HU, PL	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey mould (<i>Botrytis cinerea</i> BOTRCI)	Foliar. Tractor- mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 60- 89	a) 1 b) 4	7	a) 1.6—4.0 L/ha b) 6.4—16 L/ha	a) 52.8—132 (E) 106—264 (G) 106—264 (T) b) 211—528 (E) 422—1056 (G) 422—1056 (T)	400-1000	7	The product is applied so that the concentration in g a.s./hL is kept constant at 13.2 (eugenol), 26.4 (geraniol), 26.4 (thymol) g a.s./ hectolitre of spray water volume. Therefore, the higher application rate is diluted in the higher water volume. Apply at 3.0 - 3.2 L/ha LWA				
2	Central Zone IE, GB, NL, BE, LU, DE, CZ, AT, SI, SK, HU, RO, PL	Apple <i>Malus domestica</i> MABSD, pear <i>Pyrus communis</i> PYUCO, quince <i>Cydonia oblonga</i> CYDOB, crab-apple <i>Malus sylvestris</i> MABSY, loquat <i>Eryobotria japonica</i> EIOJA, medlar <i>Mespilus germanica</i> MSPGE, Nashi pear <i>Pyrus pyrifolia</i> var. <i>culta</i> PYUPC	F	Post-harvest storage diseases	Foliar. Tractor- mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 75- 89	a) 1 b) 4	7	a) 2.4—4.0 L/ha b) 9.6—16 L/ha	a) 79.2—132 (E) 158—264 (G) 158—264 (T) b) 317—528 (E) 634—1056 (G) 634—1056 (T)	600-1000	1	The product is applied so that the concentration in g a.s./hL is kept constant at 13.2 (eugenol), 26.4 (geraniol), 26.4 (thymol) g a.s./ hectolitre of spray water volume. Therefore, the higher application rate is diluted in the higher water volume. Apply at 3.0-3.2 L/ha LWA Example or post-harvest storage diseases: <i>Phytophthora</i> spp. PHYTSP (mainly <i>P. cactorum</i> PHYTCC or <i>P. syringae</i> PHYTSY), <i>Alternaria</i> spp. ALTESP, <i>Botrytis cinerea</i> BOTRCI				

* 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

Table 8.1-3: Assessed (critical) uses during approval of geraniol 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						
Zonal uses (field or outdoor uses, certain types of protected crops)																	
1	Central Zone IE, GB, NL, BE, LU, DE, CZ, AT, SI, SK, HU, PL	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey-mould (<i>Botrytis cinerea</i> BOTRCI)	Foliar. Tractor- mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 60- 89	a) 1 b) 4	7	a) 1.6—4.0 L/ha b) 6.4—16 L/ha	a) 52.8—132 (E) 106—264 (G) 106—264 (T) b) 211—528 (E) 422—1056 (G) 422—1056 (T)	400-1000	7	The product is applied so that the concentration in g a.s./hL is kept constant at 13.2 (eugenol), 26.4 (geraniol), 26.4 (thymol) g a.s./ hectolitre of spray water volume. Therefore, the higher application rate is diluted in the higher water volume. Apply at 3.0 - 3.2 L/ha LWA				
2	Central Zone IE, GB, NL, BE, LU, DE, CZ, AT, SI, SK, HU, RO, PL	Apple <i>Malus domestica</i> MABSD, pear <i>Pyrus communis</i> PYUCO, quince <i>Cydonia oblonga</i> CYDOB, crab-apple <i>Malus sylvestris</i> MABSY, loquat <i>Eryobotria japonica</i> EIOJA, medlar <i>Mespilus germanica</i> MSPGE, Nashi pear <i>Pyrus pyrifolia</i> var. <i>culta</i> PYUPC	F	Post-harvest storage diseases	Foliar. Tractor- mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 75- 89	a) 1 b) 4	7	a) 2.4—4.0 L/ha b) 9.6—16 L/ha	a) 79.2—132 (E) 158—264 (G) 158—264 (T) b) 317—528 (E) 634—1056 (G) 634—1056 (T)	600-1000	1	The product is applied so that the concentration in g a.s./hL is kept constant at 13.2 (eugenol), 26.4 (geraniol), 26.4 (thymol) g a.s./ hectolitre of spray water volume. Therefore, the higher application rate is diluted in the higher water volume. Apply at 3.0-3.2 L/ha LWA Example or post-harvest storage diseases: <i>Phytophthora</i> spp. PHYTSP (mainly <i>P. cactorum</i> PHYTCC or <i>P. syringae</i> PHYTSY), <i>Alternaria</i> spp. ALTESP, <i>Botrytis cinerea</i> BOTRCI				

*— 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

Table 8.1-4: Assessed (critical) uses during approval of thymol 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			PHH (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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Central Zone IE, GB, NL, BE, LU, DE, CZ, AT, SI, SK, HU, PL	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey mould (<i>Botrytis cinerea</i> BOTRCI)	Foliar: Tractor- mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 60- 89	a) 1 b) 4	7	a) 1.6–4.0 L/ha b) 6.4–16 L/ha	a) 52.8–132 (E) 106–264 (G) 106–264 (T) b) 211–528 (E) 422–1056 (G) 422–1056 (T)	400-1000	7	The product is applied so that the concentration in g a.s./hL is kept constant at 13.2 (eugenol), 26.4 (geraniol), 26.4 (thymol) g a.s./ hectolitre of spray water volume. Therefore, the higher application rate is diluted in the higher water volume. Apply at 3.0–3.2 L/ha LWA
2	Central Zone IE, GB, NL, BE, LU, DE, CZ, AT, SI, SK, HU, RO, PL	Apple <i>Malus domestica</i> MABSD; pear <i>Pyrus communis</i> PYUCO, quince <i>Cydonia oblonga</i> CYDOB; crab-apple <i>Malus sylvestris</i> MABSY; loquat <i>Eryobotria japonica</i> EIOJA; medlar <i>Mespilus germanica</i> MSPGE; Nashi pear <i>Pyrus pyrifolia var. culta</i> PYUPC	F	Post-harvest storage diseases	Foliar: Tractor- mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 75- 89	a) 1 b) 4	7	a) 2.4–4.0 L/ha b) 9.6–16 L/ha	a) 79.2–132 (E) 158–264 (G) 158–264 (T) b) 317–528 (E) 634–1056 (G) 634–1056 (T)	600-1000	1	The product is applied so that the concentration in g a.s./hL is kept constant at 13.2 (eugenol), 26.4 (geraniol), 26.4 (thymol) g a.s./ hectolitre of spray water volume. Therefore, the higher application rate is diluted in the higher water volume. Apply at 3.0-3.2 L/ha LWA Example or post-harvest storage diseases: <i>Phytophthora</i> spp. PHYTSP (mainly <i>P. cactorum</i> PHYTCC or <i>P. syringae</i> PHYTSY); <i>Alternaria</i> spp. ALTESP, <i>Botrytis cinerea</i> BOTRCI

* 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:

GAP tables presented in Tables 8.1-2 to 8.1-4 are not EU uses evaluated in the course of the EU review of particular active compounds, but repeated Central Zone GAP. Since the Central Zone GAP is already presented in Table 8.1-1, it is not necessary to repeat this information additional 3 times. For this reason Tables 8.1-2 to 8.1-4 were struck through.

8.2 Metabolites considered in the assessment

There are no metabolites of eugenol, geraniol or thymol listed in the EFSA Conclusions for either active substance.

In the EFSA Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for thymol in light of confirmatory data (January 2017), the RMS states the following on unknown B found in one soil of the aerobic degradation study:

“The RMS notes the observation, but considers on weight of evidence that unknown B in the Ingleby soil is transient in nature and accepts the low microbial content could explain the levels seen just over 5% at days 3 and 7. However, levels at all other sampling points were below 5%. Overall, the rapid degradation of thymol and extensive incorporation into fluvic and humic acid fractions adds weight that the soil residues definition of parent only is sufficient.”

zRMS comments:

According to the EU agreed endpoints reported in EFSA Journal 2012;10(11):2914, EFSA Journal 2012;10(11):2915 and EFSA Journal 2012;10(11):2916 for eugenol, geraniol and thymol, respectively, as well as Confirmatory Data evaluated in August 2016, no metabolites at >5% AR could be found in soil for particular active compounds.

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 substances.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Eugenol

Studies on the degradation of eugenol in soil have shown that degradation is fast with DT₅₀'s <1 day and DT₉₀'s <3 days. No major degradation products were observed, and the transformation of eugenol is to carbon dioxide and bound residues.

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

Eugenol Laboratory studies, aerobic conditions										
Soil name	Soil type (UK)	pH (CaCl ₂)	t. °C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Brierlow (Jones 2015)	Clay loam	5.3	20	pF2	<1	<3	<1		NA	Y EFSA, Confirmatory data, 2016
Calke (Jones, 2015)	Loamy sand	5.1	20	pF2	0.5	1.8	0.5	7.3	SFO	
Ingleby (Jones, 2015)	Clay	4.0	20	pF2	0.6	1.9	0.6	9.4	SFO	
Empingham (Jones, 2015)	Sandy loam	7.4	20	pF2	<3	<3	<3		NA	
Geomean							1			
pH-dependency:							No			

zRMS comments:

Soil degradation data for eugenol presented in Table 8.3-1 are in line with results of the study summarised and evaluated by the RMS in Eugenol Confirmatory Data (August 2016). Information on Chi² was added by the zRMS in the table. In soil eugenol degraded very rapidly and DT₅₀ of 1 day is acceptable and can be used for exposure assessment. Methyl-eugenol was not found in any w of the samples which confirms that it is not formed in soil.

8.3.1.2 Geraniol

Studies on the degradation of geraniol in soil have shown that degradation is fast with DT₅₀'s <1 day and DT₉₀'s <2 days. No major degradation products were observed and the transformation of geraniol is to carbon dioxide and bound residues.

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

Geraniol Laboratory studies, aerobic conditions										
Soil name	Soil type (UK)	pH (CaCl ₂)	t. °C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Brierlow (Jones 2015)	Clay loam	5.3	20	pF2	0.4	1.2	0.4	na	SFO	Y EFSA, Confirmatory data, 2016
Calke (Jones, 2015)	Loamy sand	5.1	20	pF2	0.3	1.1	0.3	na	SFO	
Ingleby (Jones, 2015)	Clay	4.7	20	pF2	0.3	0.9	0.3	na	SFO	
Empingham (Jones, 2015)	Sandy loam	7.1	20	pF2	0.2	0.8	0.2	na	SFO	
Geomean							<1			
pH-dependency:							No			

zRMS comments:

Soil degradation data for geraniol presented in Table 8.3-2 are in line with results of the study summarised and evaluated by the RMS in Geraniol Confirmatory Data (August 2016). Chi² were not reported in Addendum for the Confirmatory Data.

8.3.1.3 Thymol

Studies on the degradation of thymol in soil have shown that degradation is fast with DT₅₀'s <1 day and DT₉₀'s <3 days. No major degradation products were observed and the transformation of thymol is to carbon dioxide and bound residues.

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

Thymol Laboratory studies, aerobic conditions										
Soil name	Soil type (UK)	pH (CaCl ₂)	t. °C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Brierlow (Jones 2015)	Clay loam	5.3	20	pF2	0.6	2.1	0.6	13.5	SFO	Y EFSA, Confirmatory data, 2016
Calke (Jones, 2015)	Loamy sand	5.1	20	pF2	0.3 0.6	1.1 2.1	0.3 0.6	na	SFO	
Ingleby (Jones, 2015)	Clay	4.7	20	pF2	0.8	2.6	0.8	17.7	SFO	
Empingham (Jones, 2015)	Sandy loam	7.1	20	pF2	0.2 0.6	0.8 1.8	0.2 0.6	na	SFO	
Geomean							<1			
pH-dependency:							No			

zRMS comments:

Soil degradation data for thymol presented in Table 8.3-3 are in general in line with results of the study summarised and evaluated by the RMS in Thymol Confirmatory Data (August 2016) with some corrections and additional information added introduced by the zRMS.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

No studies on anaerobic degradation have been performed. Based on the fast aerobic degradation and the application timing of Mevalone, it is unlikely that eugenol, geraniol or thymol residues would be found in anaerobic conditions.

8.4 Field studies (KCP 9.1.1.2)

Based on the laboratory DT₉₀ of < 3 days, field studies are not triggered for eugenol, geraniol, and thymol and therefore no data is submitted.

zRMS comments:

Field degradation data for eugenol, geraniol, and thymol are not required as the DT₉₀ is lower than 3 days.

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 substances.

8.5.1 Eugenol

In the EFSA Conclusion (2012) values of 10 (worst case default) were used for the modelling. A data gap was identified for a batch adsorption desorption study in four soils.

A new Annex II study has been performed on the adsorption desorption of eugenol in 5 soils which has been summarised and assessed by the RMS in the Addendum to the DAR (Addendum – Confirmatory Data, August 2016). The adsorption values ranged from 101 to 794 ml/g. The RMS did “not consider that the data provided in the study are robust enough to be used to derive the sorption endpoint for geraniol. Instead, default values will be relied upon. This approach was previously used in the 2013 Annex I evaluation.”

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

Eugenol							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Bromsgrove*	Sandy loam	1.5	4.9	2.67 1.51	178 101	0.63	Y EFSA, Confirmatory data, 2016
Evesham 3*	Clay loam	2.0	6.4	5.53 2.34	277 116	0.83	
Elmton	Sandy Clay Loam	3.9	7.2	43.1 7.18	1110 184	0.94	
Warsop*	Sand	1.1	3.9	3.95 3.49	359 317	0.73	
Calke	Sandy loam	3.5	5.2	98.9 27.8	2830 794	1.14	
Lowest of two reliable results					184	0.94	
pH-dependency					No		

* For eugenol (Jones 2015) the adsorbed quantity was between 2.1-18 % for the soils Evedham 3, Warsop and Bromsgrove, which is not sufficient for an accurate determination of sorption parameters. There are only two reliable values available (soils Calke and Elmton), hence the lower of both values are to be used (Kfoc =184, 1/n =0.94)

zRMS comments:

Soil mobility data for eugenol are not fully in line with EU agreed endpoints reported in Eugenol Confirmatory Data evaluation (August 2016). Table 8.5-1 was thus amended accordingly by the zRMS.

It has to be noted that the results of the study were considered as not fully reliable by the RMS due to instability of eugenol in test solutions and significant radioactivity no associated with eugenol visible on chromatograms for some soils. For this reason at the EU level the default Kfoc of 10 mL/g was considered relevant for exposure assessment.

8.5.2 Geraniol

In the EFSA Conclusion (2012) values of 10 (worst case default) and 70.79 ml/g (QSAR) for the adsorption of geraniol were used for the modelling. A data gap was identified for a batch adsorption desorption study in four soils.

A new Annex II study has been performed on the adsorption desorption of geraniol in 5 soils which has been summarised and assessed by the RMS in the Addendum to the DAR (Addendum – Confirmatory Data, August 2016). The adsorption values ranged from 2.0 to 2060 ml/g. The RMS did “not consider that the data provided in the study are robust enough to be used to derive the sorption endpoint for geraniol. Instead, default values will be relied upon. This approach was previously used in the 2013 Annex I evaluation.”

The RMS suggests that due to the rapid degradation of geraniol, its stability during a batch equilibrium adsorption/desorption study cannot be relied upon.

For additional information, using EPI Suite 4.1, the KOCWIN model gives K_{OC} values of 94.15 L/kg (MCI method) and 474.7 L/kg (Kow method). These values have not been used in the risk assessment but are used to argue that the K_{OC} of 10 is unrealistic, resulting in an over-conservative risk assessment.

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

Geraniol							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Bromsgrove*	Sandy loam	1.5	5.6	526 30.9	35100 2060	1.04	Y EFSA, Confirmatory data, 2016
Evesham 3*	Clay loam	4.0	7.3	25.7 1.51	643 37.8	0.79	
Elmton*	Sandy Clay Loam	4.4	7.0	1.99 0.0879	45.2 2.0	0.62	
Warsop	Sand	1.1	3.9	14.9 2.98	1350 271	0.80	
Calke*	Sandy loam	3.4	5.1	6.14 0.579	181 17.0	0.60	
Reliable value / 10					27	0.90	
pH-dependency					No		

* For geraniol (Jones 2015) the experiment on soil Bromsgrove is principally sufficient for the requirements concerning the minimum adsorbed quantity. For this soil the recovery rate was especially low and the breakdown during the experiment was practically complete. From all available values, the one taken from soil Warsop is most likely to be reliable and can be used for modelling (with a safety factor of 10) until valid sorption data are available. The following values should be used for simulations: K_{OC} = 27 (value of soil Warsop/10), 1/n = 0.9 (FOCUS default-value).

zRMS comments:

Soil mobility data for geraniol are not fully in line with EU agreed endpoints reported in Geraniol Confirmatory Data evaluation (August 2016). Table 8.5-2 was thus amended accordingly by the zRMS.

It has to be noted that the results of the study were considered as not fully reliable by the RMS due to instability of geraniol in test solutions and significant radioactivity not associated with geraniol visible on chromatograms. For this reason at the EU level the default Kfoc of 10 mL/g was considered relevant for exposure assessment.

8.5.3 Thymol

In the EFSA Conclusion (2012) values of 10 (worst case default) and 2188 mL/g (QSAR) for the adsorption of thymol were used for the modelling. A data gap was identified for a batch adsorption/desorption study in four soils.

A new Annex II study has been performed on the adsorption/desorption of thymol in 5 soils which has been summarised and assessed by the RMS in the Addendum to the DAR (Addendum – Confirmatory Data, August 2016). The adsorption values ranged from 178 to 216 mL/g. The RMS “did not consider that the data provided in the study are robust enough to be used to derive the sorption endpoint for thymol. Instead, default values will be relied upon. This approach was previously used in the 2013 Annex I evaluation.”

The RMS suggests that due to the rapid degradation of thymol, its stability during a batch equilibrium adsorption/desorption study cannot be relied upon.

For additional information, using EPI Suite 4.1, the KOCWIN model gives KOC values of 826.6 L/kg (MCI method) and 1467 L/kg (Kow method). These values have not been used in the risk assessment but are used to argue that the KOC of 10 is unrealistic, resulting in an over-conservative risk assessment.

Table 8.5-3: Summary of soil adsorption/desorption for thymol

Thymol							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Bromsgrove	Sandy loam	1.5	5.6	5.1 2.67	340 178	0.65	Y EFSA, Confirmatory data, 2016
Evesham 3	Clay loam	4.0	7.3	9.76 7.59	244 190	0.88 0.89	
Elmton	Sandy Clay Loam	4.4	7.0	16.5 8.14	375 185	0.65 0.68	
Warsop	Sand	1.1	3.9	2.46 2.38	224 216	0.82	
Calke	Sandy loam	3.4	5.1	13.2 6.15	388 181	0.74 0.78	
Geometric mean (n=5)					190	0.76	
pH-dependency					No		

zRMS comments:

Soil mobility data for thymol are not fully in line with EU agreed endpoints reported in Thymol Confirmatory Data evaluation (August 2016). Table 8.5-3 was thus amended accordingly by the zRMS.

It has to be noted that the results of the study were considered as not fully reliable by the RMS due to instability of geraniol in test solutions and significant radioactivity not associated with thymol visible on chromatograms. For this reason at the EU level the default Kfoc of 10 mL/g was considered relevant for exposure assessment.

8.5.4 Column leaching (KCP 9.1.2.1)

No data submitted.

zRMS comments:

Column leaching studies were not performed or required during the EU review.

8.5.5 Lysimeter studies (KCP 9.1.2.2)

No data submitted.

zRMS comments:

Lysimeter studies were not performed or required during the EU review.

8.5.6 Field leaching studies (KCP 9.1.2.3)

No data submitted.

zRMS comments:

Field leaching studies were not performed or required during the EU review.

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

No water/sediment studies have been submitted, however, aerobic mineralisation studies currently being performed have indicated fast degradation with a DT₅₀ of <7 days for all actives. This information will be provided once the study reports are available.

The EFSA Conclusion 2011 uses the default REACH ECHA 2010 values, based on the substances being readily biodegradable.

Table 8.6-1: DT₅₀ values for Risk Assessment

	Eugenol	Geraniol	Thymol
DT ₅₀ water	15 days	15 days	15 days
DT ₅₀ sediment	300 days	300 days	300 days

zRMS comments:

Information on degradation of eugenol, geraniol or thymol in water/sediment systems is in line with EU agreed endpoints as reported in EFSA Journals 2012;10(11): 2914 to 2916 for all substances. In absence of relevant degradation data for aquatic systems, default values were considered relevant for the exposure assessment.

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

8.7.1 Justification for new endpoints

No new endpoints used.

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

According to the EFSA Conclusion (2011) there are no metabolites for the eugenol, geraniol or thymol. The PEC_{soil} Advanced Calculator by CRD has been used to calculate the PEC_{soil} for eugenol, geraniol and thymol.

PEC_{soil} immediately after a single application was calculated using FOCUS guidance¹ using the following equation:

$$PEC_{soil}^{initial} = \frac{\text{Soil exposure}}{\text{Soil depth} \times \text{Soil density}}$$

Soil depth was 5 cm and soil bulk density was 1.5 g/m³. Soil exposure details are given in Table 8.7-1. The maximum exposure following multiple applications was calculated assuming SFO degradation during the appropriate application intervals.

The instantaneous PEC_{soil} at various time-points was calculated using the SFO degradation equation:

$$C_t = C_0 e^{-kt}$$

Where:

- C_0 = PEC_{soil} initial
- C_t = PEC_{soil} at time t
- k = $\ln 2 / DT_{50}$

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

Use No.	1	2
Crop	Grapes	Pome Fruit
Application rate (g as/ha)	0.132 kg a.s./ha eugenol 0.264 kg a.s./ha geraniol 0.264 kg a.s./ha thymol	0.132 kg a.s./ha eugenol 0.264 kg a.s./ha geraniol 0.264 kg a.s./ha thymol
Number of applications/interval	4 / 7 days	4 / 7 days
Crop interception (%)	60% (From BBCH 60)	65% (From BBCH 75)
Depth of soil layer (cm)	5	5

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

Substance	Eugenol	Geraniol	Thymol
Soil DT ₅₀ (persistence endpoint) Worst-case laboratory at 20°C	1 day (EFSA Confirmatory data 2016)	1 day (EFSA Confirmatory data 2016)	1 day (EFSA Confirmatory data 2016)

zRMS comments:

The application pattern presented in Table 8.7-1 and assumed in soil exposure assessment for eugenol, geraniol and thymol is in line with the critical Central Zone GAP and it is thus agreed. Crop interception of 60% for grapes and 65% for pome fruit is in line with FOCUS groundwater guidance (2014 and 2021).

Input parameters presented in Table 8.7-2 are in line with EU agreed parameters.

¹ FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997.

8.7.2.1 Eugenol

Table 8.7-3: PEC_{soil} for eugenol on grapes

PEC _{soil} (mg/kg)		Grapes			
		Single application		Multiple Application	
		Actual	TWA	Actual	TWA
Initial		0.070	-	0.071	-
Short term	24h	0.035	0.051	0.035	0.051
	2d	0.018	0.038	0.018	0.038
	4d	0.004	0.024	0.004	0.024
Long term	7d	0.001	0.014	0.001	0.015
	14d	<0.001	0.007	<0.001	0.007
	21d	<0.001	0.005	<0.001	0.005
	28d	<0.001	0.004	<0.001	0.004
	50d	<0.001	0.002	<0.001	0.002
	100d	<0.001	0.001	<0.001	0.001
Plateau concentration		Does not accumulate	-	Does not accumulate	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Does not accumulate	-	Does not accumulate	-

Table 8.7.2-4: PEC_{soil} values for eugenol on pome fruit

PEC _{soil} (mg/kg)		Pome Fruit			
		Single application		Multiple Application	
		Actual	TWA	Actual	TWA
Initial		0.062	-	0.062	-
Short term	24h	0.031	0.044	0.031	0.045
	2d	0.015	0.033	0.016	0.034
	4d	0.004	0.021	0.004	0.021
Long term	7d	<0.001	0.013	<0.001	0.013
	14d	<0.001	0.006	<0.001	0.006
	21d	<0.001	0.004	<0.001	0.004
	28d	<0.001	0.003	<0.001	0.003
	50d	<0.001	0.002	<0.001	0.002
	100d	<0.001	0.001	<0.001	0.001
Plateau concentration		Does not accumulate	-	Does not accumulate	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Does not accumulate	-	Does not accumulate	-

zRMS comments:

Recalculation of soil exposure for eugenol performed by the zRMS resulted with the same PEC_{SOIL} values. Soil exposure presented in Tables 8.7-3 and 8.7-4 is relevant for purposes of the risk assessment.

Due to DT₉₀ < 3 days, accumulation in soil is not expected.

8.7.2.2 Geraniol

Table 8.7.2-5: PEC_{soil} values for geraniol on grapes

PEC _{soil} (mg/kg)		Grapes			
		Single application		Multiple Application	
		Actual	TWA	Actual	TWA
Initial		0.141	-	0.142	-
Short term	24h	0.070	0.102	0.071	0.102
	2d	0.035	0.076	0.035	0.077
	4d	0.009	0.048	0.009	0.048
Long term	7d	0.001	0.029	0.001	0.029
	14d	<0.001	0.015	<0.001	0.015
	21d	<0.001	0.010	<0.001	0.010
	28d	<0.001	0.007	<0.001	0.007
	50d	<0.001	0.004	<0.001	0.004
	100d	<0.001	0.002	<0.001	0.002
Plateau concentration		Does not accumulate	-	Does not accumulate	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Does not accumulate	-	Does not accumulate	-

Table 8.7.2-6: PEC_{soil} values for geraniol on pome fruit

PEC _{soil} (mg/kg)		Pome Fruit			
		Single application		Multiple Application	
		Actual	TWA	Actual	TWA
Initial		0.123	-	0.124	-
Short term	24h	0.062	0.089	0.062	0.090
	2d	0.031	0.067	0.031	0.067
	4d	0.008	0.042	0.008	0.042
Long term	7d	0.001	0.025	0.001	0.025
	14d	<0.001	0.013	<0.001	0.013
	21d	<0.001	0.008	<0.001	0.009
	28d	<0.001	0.006	<0.001	0.006
	50d	<0.001	0.004	<0.001	0.004
	100d	<0.001	0.002	<0.001	0.002
Plateau concentration		Does not accumulate	-	Does not accumulate	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Does not accumulate	-	Does not accumulate	-

zRMS comments:

Recalculation of soil exposure for geraniol performed by the zRMS resulted with the same PEC_{SOIL} values. Soil exposure presented in Tables 8.7-5 and 8.7-6 is relevant for purposes of the risk assessment.

Due to DT₉₀ <3 days, accumulation in soil is not expected.

8.7.2.3 Thymol

Table 8.7.2-7: PEC_{soil} values for thymol on grapes

PEC _{soil} (mg/kg)		Grapes			
		Single application		Multiple Application	
		Actual	TWA	Actual	TWA
Initial		0.141	-	0.142	-
Short term	24h	0.070	0.102	0.071	0.102
	2d	0.035	0.076	0.035	0.077
	4d	0.009	0.048	0.009	0.048
Long term	7d	0.001	0.029	0.001	0.029
	14d	<0.001	0.015	<0.001	0.015
	21d	<0.001	0.010	<0.001	0.010
	28d	<0.001	0.007	<0.001	0.007
	50d	<0.001	0.004	<0.001	0.004
	100d	<0.001	0.002	<0.001	0.002
Plateau concentration		Does not accumulate	-	Does not accumulate	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Does not accumulate	-	Does not accumulate	-

Table 8.7.2-8: PEC_{soil} values for thymol on pome fruit

PEC _{soil} (mg/kg)		Pome Fruit			
		Single application		Multiple Application	
		Actual	TWA	Actual	TWA
Initial		0.123	-	0.124	-
Short term	24h	0.062	0.089	0.062	0.090
	2d	0.031	0.067	0.031	0.067
	4d	0.008	0.042	0.008	0.042
Long term	7d	0.001	0.025	0.001	0.025
	14d	<0.001	0.013	<0.001	0.013
	21d	<0.001	0.008	<0.001	0.009
	28d	<0.001	0.006	<0.001	0.006
	50d	<0.001	0.004	<0.001	0.004
	100d	<0.001	0.002	<0.001	0.002
Plateau concentration		Does not accumulate	-	Does not accumulate	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Does not accumulate	-	Does not accumulate	-

zRMS comments:

Recalculation of soil exposure for thymol performed by the zRMS resulted with the same PEC_{SOIL} values. Soil exposure presented in Tables 8.7-7 and 8.7-8 is relevant for purposes of the risk assessment.

Due to DT₉₀ <3 days, accumulation in soil is not expected.

8.7.2.4 PEC_{soil} of formulation

Please note that only the instantaneous PEC_{soil} is relevant, since the formulation will immediately separate into its components, which then degrade at different rates.

Table 8.7-9: PEC_{soil} for formulation Mevalone

Preparation	Use/Crop	Application rate (L/ha)	Product density (g/L)	Application rate (kg/ha)	Crop interception (%)	PEC _{act} (mg/kg)
Mevalone	Grapes	4	1.029 *	4.116	60	2.195
	Pome fruit	4	1.029 *	4.116	65	1.921

* Nominal density

zRMS comments:

Recalculation of soil exposure for the formulated product performed by the zRMS resulted with the same PEC_{SOIL} values. Soil exposure presented in Table 8.7-9 is relevant for purposes of the risk assessment.

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

8.8.1 Justification for new endpoints

The predicted environmental concentrations of eugenol, geraniol and thymol in groundwater have been calculated in the following report:

The adsorption values (K_{oc}) used in the modelling were provided by the Swiss MS during a previous review of the active substances eugenol, geraniol and thymol. Values were taken from the reports of Jones (2015b) as summarised in CA 7.1.3.1.1/01 (MCA S7 eugenol, geraniol and thymol).

The following information was provided by the Swiss MS:

- For eugenol (Jones 2015, Report PIF0003) the adsorbed quantity was between 2.1–18 % for the soils Evesham 3, Warsop and Bromsgrove, which is not sufficient for an accurate determination of sorption parameters. There are only two reliable values available (soils Calke and Elmton); hence the lower of both values should be used ($K_{foc} = 184$, $1/n = 0.94$)
- For geraniol (Jones 2015, Report PIF0006) the experiment on soil Bromsgrove is principally sufficient for the requirements concerning the minimum adsorbed quantity. For this soil, the recovery rate was especially low, and the breakdown during the experiment was practically complete. From all available values, the one taken from soil Warsop is most likely to be reliable and can be used for modelling (with a safety factor of 10) until valid sorption data are available. The following values should be used for simulations: $K_{foc} = 27$ (value of soil Warsop/10), $1/n = 0.9$ (FOCUS default value)
- For thymol, the geometric mean of the K_{oc} values and the arithmetic mean of the $1/n$ values from the study (Jones 2015, Report PIF0009) can be used ($K_{foc} = 190$, $1/n = 0.76$).

New OECD 106 studies are currently being performed and will be provided. New modelling will be provided with the new endpoints and this modelling is provided until the new endpoints are available.

zRMS comments:

In the course of evaluation of the confirmatory data results of studies on soil sorption of eugenol, geraniol and thymol were considered not fully reliable by the RMS and default K_{foc} of 10 mL/g due to instability of test items in test solutions and significant radioactivity not associated with particular active compounds visible on chromatograms. For this reason at the EU level the default K_{foc} of 10 mL/g was considered relevant for exposure assessment for all substances.

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

Data point:	CP 9.2.4.1
Report author	H. Walshaw
Report year	2021a
Report title	Mevalone: Predicted Environmental Concentrations of Eugenol, Geraniol, and Thymol in Groundwater Following Application to Vines and Apples, Using FOCUS-MACRO, FOCUS-PEARL and FOCUS-PELMO
Report No	21/14
Document No	Not applicable
Guidelines followed in study	FOCUS
Deviations from current test guideline	None
Previous evaluation	None
GLP/Officially recognised testing facilities	NA
Acceptability/Reliability:	Acceptable

Mevalone is a fungicide containing the active substances eugenol, geraniol, and thymol, which is used to treat vines and apples. It is a capsule suspension (CS) formulation containing 33 g/L eugenol, 66 g/L geraniol and 66 g/L thymol. Mevalone is applied as a foliar spray from BBCH 60 for vines and BBCH 75 for apples at 4 x 4L/ha, equivalent to 132 g, 264 g and 264 g a.s./ha for eugenol, geraniol and thymol respectively, with a 7 day interval.

The predicted environmental concentrations in groundwater (PEC_{gw}) of eugenol, geraniol and thymol were assessed through simulations using the environmental fate model FOCUS-MACRO (v5.5.4), FOCUS-PEARL (v4.4.4) and FOCUS-PELMO (v5.5.3) in accordance with the requirements of European Regulations (EC) No 1107/2009 and (EU) No 284/2013. This assessment was performed according to the recommendations of the FOCUS Groundwater Scenarios Workshop and EFSA. The PEC in groundwater was determined as the 80th percentile of the annual average leaching concentrations at a depth of 1m, over a 20 year period. This was compared to the EU drinking water limit of 0.1 µg/L.

The substance parameter endpoints were taken from the EU agreed endpoints from the respective EFSA Conclusions, unless stated otherwise.

All applications were made to the soil surface with crop interception accounted for manually, based on the crop type and growth stage. Crop application scenarios used in the FOCUS simulations are detailed in Tables 8.8-1 and 8.8-2.

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

Use No.	1	2
Crop Group	Vines, from BBCH 60	Apples from BBCH 75
Application rate (g as/ha)	0.132 kg a.s./ha eugenol 0.264 kg a.s./ha geraniol 0.264 kg a.s./ha thymol	0.132 kg a.s./ha eugenol 0.264 kg a.s./ha geraniol 0.264 kg a.s./ha thymol
Number of applications/interval (d)	4 / 7 days	4 / 7 days
Relative application date	AppDate program used	AppDate program used
Crop interception (%)	60	65
Frequency of application	annual	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4	

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

Crop	Scenario	Application dates (absolute)
Vines	Châteaudun	21 Jun, 28 Jun, 5 Jul, 12 Jul
	Hamburg	20 Jun, 27 Jun, 4 Jul, 11 Jul
	Jokioinen	No scenario
	Kremsmünster	20 Jun, 27 Jun, 4 Jul, 11 Jul
	Okehampton	No scenario
	Piacenza	21 Jun, 28 Jun, 5 Jul, 12 Jul
	Porto	15 Jun, 22 Jun, 29 Jun, 6 Jul
	Sevilla	21 May, 28 May, 4 Jun, 11 Jun
	Thiva	26 May, 2 Jun, 9 Jun, 16 Jun
Apples	Châteaudun	1 Jul, 8 Jul, 15 Jul, 22 Jul
	Hamburg	31 Jul, 7 Aug, 14 Aug, 21 Aug
	Jokioinen	30 Jun, 7 Jul, 14 Jul, 21 Jul
	Kremsmünster	31 Jul, 7 Aug, 14 Aug, 21 Aug
	Okehampton	8 Jul, 15 Jul, 22 Jul, 29 Jul
	Piacenza	9 Jul, 16 Jul, 23 Jul, 30 Jul
	Porto	31 Jul, 7 Aug, 14 Aug, 21 Aug
	Sevilla	4 Jul, 11 Jul, 18 Jul, 25 Jul
	Thiva	28 Jul, 4 Aug, 11 Aug, 18 Aug

zRMS comments:

The application pattern presented in Table 8.8-1 and assumed in groundwater exposure calculations is in line with the Central Zone GAP presented in Table 8.1-1. Crop interception of 60% for vines and 65% for apples is in line with FOCUS groundwater guidance (2014 and 2021).

The application windows presented in Table 8.8-2 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

8.8.2.1 Eugenol

Table 8.8-3: Input parameters related to eugenol for PEC_{gw} calculations

Input Parameter	Eugenol	Value in accordance with EU endpoint (Y/N) Reference/Justification
Molecular weight (g/mol)	164.20	Y, EFSA, LoEP, 2012
Water solubility (mg/L)	2350 1.85 (pH 7)	Y, EFSA Confirmatory Data 2016 EFSA, LoEP, 2012
Saturated vapour pressure (Pa)	2.7	Y, EFSA, LoEP, 2012
DT ₅₀ in soil (d)	1 day	Y, EFSA Confirmatory Data 2016
Transformation rate (1/d)	0.693147	= Ln(2)/DT ₅₀
K _{foc} (mL/g)/K _{fom}	10 (conservative value in the absence of reliable sorption studies) /5.8 184 (lower of 2 acceptable soils)	Y, EFSA Confirmatory Data 2016 Jones, 2016 – worst case value recommended by Swiss MS
1/n	0.9 (default value in the absence of reliable sorption studies) 0.94	Y, EFSA Confirmatory Data 2016 Jones, 2016 – worst case value recommended by Swiss MS
Plant uptake factor	0	Default

Table 8.8-4: PEC_{gw} for eugenol on vines

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		MACRO (v5.5.4)	PEARL (v4.4.4)	PELMO (v5.5.3)
Vines	Châteaudun	0.0	<0.0000005	<0.0005
	Hamburg	-	<0.0000005	<0.0005
	Kremsmünster	-	<0.0000005	<0.0005
	Piacenza	-	<0.0000005	<0.0005
	Porto	-	<0.0000005	<0.0005
	Sevilla	-	<0.0000005	<0.0005
	Thiva	-	<0.0000005	<0.0005

Table 8.8-5: PEC_{gw} for eugenol on apples

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		MACRO (v5.5.4)	PEARL (v4.4.4)	PELMO (v5.5.3)
Apples	Châteaudun	0.0	<0.0000005	<0.0005
	Hamburg	-	<0.0000005	<0.0005
	Jokioinen	-	<0.0000005	<0.0005
	Kremsmünster	-	<0.0000005	<0.0005
	Okehampton	-	<0.0000005	<0.0005
	Piacenza	-	<0.0000005	<0.0005
	Porto	-	<0.0000005	<0.0005

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		MACRO (v5.5.4)	PEARL (v4.4.4)	PELMO (v5.5.3)
	Sevilla	-	<0.0000005	<0.0005
	Thiva	-	<0.0000005	<0.0005

The predicted environmental concentrations in groundwater (PEC_{gw}) of eugenol were assessed through simulations using the environmental fate model FOCUS-MACRO (v5.5.4), FOCUS-PEARL (v4.4.4) and FOCUS-PELMO (v5.5.3).

PEC_{gw} values were below the 0.1 µg/L limit for eugenol using all models.

The risk to groundwater was determined to be acceptable for all uses of Mevalone with regard to eugenol.

zRMS comments:

Input parameters used for groundwater modelling for eugenol presented in Table 8.8-3 are in general in line with EU agreed parameters with few exceptions:

- according to the Confirmatory Data, water solubility is 2350 mg/L,
- in absence of reliable sorption studies default K_{foc} of 10 mL/g with 1/n of 0.9 was agreed by the RMS for purposes of the exposure assessment.

In simulations PUF value of 0 was assumed, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

Applicants' modelling was independently validated by the zRMS using FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 and EU agreed input data. Obtained PEC_{GW} were all <0.01 µg/L in all scenarios.

Based on results of the performed groundwater modelling, no unacceptable leaching of eugenol is expected following application of Mevalone according to the intended Central Zone use pattern.

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.8.2.2 Geraniol

Table 8.8-6: Input parameters related to eugenol for PEC_{gw} calculations

Input Parameter	Geraniol	Value in accordance with EU endpoint (Y/N) Reference/Justification
Molecular weight (g/mol)	154.25	Y, EFSA, LoEP, 2012
Water solubility (mg/L)	580 572 (pH 7)	Y, EFSA, LoEP, 2012
Saturated vapour pressure (Pa)	4.6	Y, EFSA, LoEP, 2012
DT ₅₀ in soil (d)	1	Y, EFSA Confirmatory Data 2016
Transformation rate (1/d)	0.693147	= Ln(2)/DT ₅₀
K _{foc} (mL/g)/K _{fom}	10 (conservative value in the absence of reliable sorption studies)/5.8 27 (Warsop soil/10) / 16.7	Y, EFSA Confirmatory Data 2016 N, Jones, 2016 – worst case value recommended by Swiss MS
1/n	0.9	Y, EFSA Confirmatory Data 2016 N, Jones, 2016 – worst case value recommended by Swiss MS
Plant uptake factor	0	Default

Table 8.8-7: PEC_{gw} for geraniol on vines

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		MACRO (v5.5.4)	PEARL (v4.4.4)	PELMO (v5.5.3)
Vines	Châteaudun	0.0	<0.0000005	<0.0005
	Hamburg	-	<0.0000005	<0.0005
	Kremsmünster	-	<0.0000005	<0.0005
	Piacenza	-	<0.0000005	<0.0005
	Porto	-	<0.0000005	<0.0005
	Sevilla	-	<0.0000005	<0.0005
	Thiva	-	<0.0000005	<0.0005

Table 8.8-9: PEC_{gw} for geraniol on apples

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		MACRO (v5.5.4)	PEARL (v4.4.4)	PELMO (v5.5.3)
Apples	Châteaudun	0.0	<0.0000005	<0.0005
	Hamburg	-	<0.0000005	<0.0005
	Jokioinen	-	<0.0000005	<0.0005
	Kremsmünster	-	<0.0000005	<0.0005
	Okehampton	-	<0.0000005	<0.0005
	Piacenza	-	<0.0000005	<0.0005
	Porto	-	<0.0000005	<0.0005
	Sevilla	-	<0.0000005	<0.0005
	Thiva	-	<0.0000005	<0.0005

The predicted environmental concentrations in groundwater (PEC_{gw}) of geraniol were assessed through simulations using the environmental fate model FOCUS-MACRO (v5.5.4), FOCUS-PEARL (v4.4.4) and FOCUS-PELMO (v5.5.3).

PEC_{gw} values were below the 0.1 µg/L limit for geraniol using all models.

The risk to groundwater was determined to be acceptable for all uses of Mevalone with regard to geraniol.

zRMS comments:

Input parameters used for groundwater modelling for geraniol presented in Table 8.8-6 are in general in line with EU agreed parameters with few exceptions:

- according the Confirmatory Data, water solubility is 580 mg/L,
- in absence of reliable sorption studies default K_{foc} of 10 mL/g with 1/n of 0.9 was agreed by the RMS for purposes of the exposure assessment.

In simulations PUF value of 0 was assumed, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

Applicants' modelling was independently validated by the zRMS using FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 and EU agreed input data. Obtained PEC_{GW} were all <0.01 µg/L in all scenarios.

Based on results of the performed groundwater modelling, no unacceptable leaching of geraniol is expected following application of Mevalone according to the intended Central Zone use pattern.

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.8.2.3 Thymol

Table 8.8-10: Input parameters related to thymol for PEC_{gw} calculations

Input Parameter	Thymol	Value in accordance with EU endpoint (Y/N) Reference/Justification
Molecular weight (g/mol)	150.22	Y, EFSA, LoEP, 2012
Water solubility (mg/L)	630 596	Y, EFSA, LoEP, 2012
Saturated vapour pressure (Pa)	3.4	Y, EFSA, LoEP, 2012
DT ₅₀ in soil (d)	1	Y, EFSA Confirmatory Data 2016
Transformation rate (1/d)	0.693147	= Ln(2)/DT ₅₀
K _{foc} (mL/g)/K _{fom}	10 (conservative value in the absence of reliable sorption studies)/5.8 190 (geometric mean, n=5)	Y, EFSA Confirmatory Data 2016 Jones, 2016 – worst case value recommended by Swiss MS
1/n	0.9 (default value in the absence of reliable sorption studies) 0.76 (arithmetic mean, n=5)	Y, EFSA Confirmatory Data 2016 Jones, 2016 – worst case value recommended by Swiss MS
Plant uptake factor	0	Default

Table 8.8-11: PEC_{gw} for thymol on vines

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		MACRO (v5.5.4)	PEARL (v4.4.4)	PELMO (v5.5.3)
Vines	Châteaudun	0.0	<0.0000005	<0.0005
	Hamburg	-	<0.0000005	<0.0005
	Kremsmünster	-	<0.0000005	<0.0005
	Piacenza	-	<0.0000005	<0.0005
	Porto	-	<0.0000005	<0.0005
	Sevilla	-	<0.0000005	<0.0005
	Thiva	-	<0.0000005	<0.0005

Table 8.8-12: PEC_{gw} for thymol on apples

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		MACRO (v5.5.4)	PEARL (v4.4.4)	PELMO (v5.5.3)
Apples	Châteaudun	0.0	<0.0000005	<0.0005
	Hamburg	-	<0.0000005	<0.0005
	Jokioinen	-	<0.0000005	<0.0005
	Kremsmünster	-	<0.0000005	<0.0005
	Okehampton	-	<0.0000005	<0.0005
	Piacenza	-	<0.0000005	<0.0005
	Porto	-	<0.0000005	<0.0005
	Sevilla	-	<0.0000005	<0.0005
	Thiva	-	<0.0000005	<0.0005

The predicted environmental concentrations in groundwater (PEC_{gw}) of thymol were assessed through simulations using the environmental fate model FOCUS-MACRO (v5.5.4), FOCUS-PEARL (v4.4.4) and FOCUS-PELMO (v5.5.3).

PEC_{gw} values were below the 0.1 µg/L limit for thymol using all models.

The risk to groundwater was determined to be acceptable for all uses of Mevalone with regard to thymol.

zRMS comments:

Input parameters used for groundwater modelling for thymol presented in Table 8.8-10 are in general in line with EU agreed parameters with few exceptions:

- according to the Confirmatory Data, water solubility is 630 mg/L,
- in absence of reliable sorption studies default K_{foc} of 10 mL/g with $1/n$ of 0.9 was agreed by the RMS for purposes of the exposure assessment.

In simulations PUF value of 0 was assumed, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

Applicants' modelling was independently validated by the zRMS using FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 and EU agreed input data. Obtained PEC_{GW} were all $<0.01 \mu\text{g/L}$ in all scenarios.

Based on results of the performed groundwater modelling, no unacceptable leaching of thymol is expected following application of Mevalone according to the intended Central Zone use pattern.

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

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

8.9.1 Justification for new endpoints

The default adsorption desorption value of 10 L/kg was used for eugenol, geraniol and thymol for the modelling.

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

Data point:	CP 9.2.5
Report author	H. Walshaw
Report year	2022
Report title	Mevalone: Predicted Environmental Concentrations of Eugenol, Geraniol, and Thymol in Surface Water Following Application to Vines and Apples, Using FOCUS-STEPS 1-4
Report No	22/55
Document No	Not applicable
Guidelines followed in study	FOCUS
Deviations from current test guideline	None
Previous evaluation	None
GLP/Officially recognised testing facilities	NA
Acceptability/Reliability:	Yes

Mevalone is a fungicide containing the active substances eugenol, geraniol and thymol, which is used to treat vines and apples. It is a capsule suspension (CS) formulation containing 33 g/L eugenol, 66 g/L geraniol and 66 g/L thymol. Mevalone is applied as a foliar spray from BBCH 60 for vines and BBCH 75 for apples at 4 x 4L/ha, equivalent to 132 g, 264 g and 264 g a.s./ha for eugenol, geraniol, and thymol respectively, with a 7 day interval.

The predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) of eugenol, geraniol and thymol were assessed through simulations using the environmental fate model FOCUS-STEPS 1-3 in accordance with the requirements of European Regulations (EC) No 1107/2009 and (EU) No 284/2013. The PEC was modelled using the STEPS 1-2 calculator (version 3.2), FOCUS-SWASH (version 5.3) and followed the recommendations of the FOCUS Working Group on Surface Water Scenarios (SANCO/4802/2001). Mitigation measures were modelled according to the recommendation of the FOCUS Working Group on Landscape and Mitigation Factors.

Input parameters for eugenol, geraniol and thymol were taken from the EU agreed endpoints in the EFSA conclusion.

Table 8.9-1: Input parameters related to application for PEC_{sw/sed} calculations

Plant protection product	Vines	Vines	Apples
Use No.	Vines, late application	Surrogate crop – Pome fruit with adjusted drift vlaues	Pome fruit, late application
Crop	D6, R1, R2, R3, R4	D3, D4, D5, R1, R2, R3, R4	D3, D4, D5, R1, R2, R3, R4
Application rate (kg as/ha)	AppDate from BBCH 60	AppDate from BBCH 60	AppDate from BBCH 75
Number of applications/interval (d)	Foliar spray	Foliar spray	Foliar spray
Application window	132 g a.s./ha eugenol 264 g a.s./ha geraniol 264 g a.s./ha thymol	132 g a.s./ha eugenol 264 g a.s./ha geraniol 264 g a.s./ha thymol	132 g a.s./ha eugenol 264 g a.s./ha geraniol 264 g a.s./ha thymol
Application method	4* / 7 days	4* / 7 days	4* / 7 days
CAM (Chemical application method)	2, Foliar application	2, Foliar application	2, Foliar application
Soil depth (cm)	4	4	4
Models used for calculation	FOCUS SWASH v5.1, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3		

*An additional set of STEP 3 modelling was performed using 1 application, since this can result in higher PEC values as TOXSWA uses a lower spray-drift percentage for multiple applications.

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

Crop	Scenario	Application window used in modelling	Actual dates selected by the model
BBCH 60-89 Vines	D6	2 Apr – 23 May	9 Apr, 23 Apr, 3 May, 12 May
	R1	6 Jun – 27 Jul	8 Jun, 18 Jun, 28 Jun, 10 Jul
	R2	15 Jun – 5 Aug	15 Jun, 21 Jul, 28 Jul, 4 Aug
	R3	21 Jun – 11 Aug	23 Jun, 1 Jul, 31 Jul, 7 Aug
	R4	6 Jun – 27 Jul	6 Jun, 13 Jun, 20 Jul, 27 Jul
Vines, surrogate crop Pome fruit	D3	6 Jun (157) – 27 Jul (208)	8 Jun, 18 Jun, 28 Jun, 10 Jul
	D4	21 Jun (172) – 11 Aug (223)	23 Jun, 1 Jul, 31 Jul, 7 Aug
	D5	6 Jun (157) – 27 Jul (208)	8 Jun, 18 Jun, 28 Jun, 10 Jul
BBCH 75-89 Apples	D3	31 Jul – 20 Sep	30 Jul, 18 Aug, 26 Aug, 5 Sep
	D4	3 Aug – 23 Sep	27 Aug, 9 Sep, 16 Sep, 23 Sep
	D5	3 Jul – 23 Aug	19 Jul, 4 Aug, 11 Aug, 18 Aug
	R1	31 Jul – 20 Sep	4 Aug, 20 Aug, 2 Sep, 17 Sep
	R2	15 Aug – 5 Oct	14 Sep, 21 Sep, 28 Sep, 5 Oct
	R3	4 Jul – 24 Aug	31 Jul, 7 Aug, 14 Aug, 21 Aug
	R4	4 Jul – 24 Aug	9 Jul, 17 Jul, 25 Jul, 11 Aug

The vines scenario only covers one D scenario and so a surrogate crop was chosen (pome fruits). Only D3, D4 and D5 were modelled as the R scenarios are covered with the vines crop in FOCUS.

When setting application dates for the vine D3, D4 and D5 scenarios (using the surrogate crop, pome fruit), no standard dates could be obtained from FOCUS guidance or AppDate, and the surrogate pome fruit BBCH 60 dates might not be realistic for grapevines. To ensure the timings were realistic, the dates were set to be within the range of dates for other FOCUS vines scenarios. The dates for D3 and D5 surrogates were set to match those of the vines R1 scenario, which is the closest geographically (considering the latitude in particular) and also the closest in mean annual temperature. The D4 scenario is significantly colder and further north (Skousbo, Denmark) than any of the vines scenarios, so a suitable matching scenario could not be identified. Crop flowering typically occurs later in colder climates, so the surrogate D4 dates were set to match the latest dates from the FOCUS vines scenarios. This resulted in realistic application timings, given the constraints of using a surrogate crop in locations where vines are not typically grown.

The D scenarios were initially run using Step 3 spray drift values for pome fruits (late application). The Step 2 Swashproject files were then opened in SWAN (v5.0.1) and the mass loading rates for late application vines (from the Drift Calculator in SWASH) were entered (see Table 8.9-3), along with checking the ‘add upstream catchment’ for streams. Then the deposition rates were also included (see Tables 8.9-8, 8.9-17, 8.9-26) within in the same Step 4 run to model the PEC_{sw} and PEC_{sed} for the D scenarios for vines. For these scenarios only the final (Step 4) PECs are reported as Step 3 values are not relevant.

Table 8.9-3: Mass Loadings in mg/m² for late application vines

	Ditch	Pond	Stream
4 applications			
Eugenol	0.5624	0.0658	0.4662
Geraniol	1.1249	0.1315	0.9234
Thymol	1.1249	0.1315	0.9234
1 application			
Eugenol	0.6828	0.0808	0.5667
Geraniol	1.3657	0.1616	1.1334
Thymol	1.3657	0.1616	1.1334

zRMS comments:

The application pattern assumed in surface water simulations is in line with the Central Zone GAP presented in Table 8.1-1.

The application windows presented in Table 8.9-2 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable with exception of D3 scenario where the beginning of application window should be 31st of July instead of 3rd of July.

As for the vines not all relevant scenarios are defined, the Applicant was requested by the zRMS to perform additional simulations using pome fruits as surrogate crop with drift values manually changed to these relevant for uses in vines. **The approach in setting the application windows for surrogate D scenarios was agreed by the zRMS.**

8.9.2.1 Eugenol

Table 8.9-4: Input parameters related to active substance eugenol for PEC_{sw/sed} calculations STEP 1/2 and 3

Compound	Eugenol	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	164.20	Y, EFSA, LoEP, 2012
Saturated vapour pressure (Pa) at 20°C	2.7 Pa	Y, EFSA, LoEP, 2012
Water solubility (mg/L) at 20°C	2350 1.85 (pH 7)	Y, EFSA Confirmatory Data 2016 EFSA, LoEP, 2012
Diffusion coefficient in water (m ² /d)	4.3 x 10 ⁻⁵	default
Diffusion coefficient in air (m ² /d)	0.43	default
K _{foc} (mL/g)	10 (conservative value in the absence of reliable sorption studies)	Default
Freundlich Exponent 1/n	0.9 (default value in the absence of reliable sorption studies)	Default
Plant Uptake	0	default
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	default
DT _{50,soil} (d)	1 day	Y, EFSA Confirmatory Data 2016
DT _{50,water} (d)	15 days	Y, EFSA, LoEP, 2012 (REACH)

Compound	Eugenol	Value in accordance to EU endpoint y/n/ Reference
		ECHA 2010)
DT _{50, sed} (d)	300	Y, EFSA, LoEP, 2012 (REACH ECHA 2010)
DT _{50, whole system} (d)	300	Y, EFSA, LoEP, 2012 (REACH ECHA 2010)

PEC_{sw/sed}

Table 8.9-5: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for eugenol following single/ multiple application(s) of Mevalone to vines

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	187.81	-	183.15	18.72
STEP 2					
Northern Europe	Mar-May	7.64	-	5.01	0.65
	June-Sept	7.64	-	5.01	0.65
Southern Europe	Mar-May	7.64	-	5.14	0.67
	June-Sept	7.64	-	5.07	0.66
STEP 3					
D6	ditch	2.251*	Drift	0.03462	0.1279
R1	pond	0.08063*	Drift	0.004476	0.01594
R1	stream	1.657*	Drift	0.05028	0.201
R2	stream	2.227*	Drift	0.02896	0.1652
R3	stream	2.333*	Drift	0.03245	0.1492
R4	stream	1.661*	Drift	0.01542	0.0817

*Single application gives higher PEC_{sw} than multiple application at Step 3 therefore single application values reported at Step 3.

Table 8.9-6: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for eugenol following single/ multiple application(s) of Mevalone to apples

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	201.36	-	196.21	20.05
STEP 2					
Northern Europe	Mar-May	11.67	-	7.57	0.98
	June-Sept	11.67	-	7.57	0.98
Southern Europe	Mar-May	11.67	-	7.68	1.00
	June-Sept	11.67	-	7.62	0.99
STEP 3					
D3	ditch	4.858*	Drift	0.03831	0.2988**
D4	pond	0.2173*	Drift	0.01009	0.03565
D4	stream	4.755*	Drift	0.03883	0.2508**
D5	pond	0.2174*	Drift	0.00945	0.03385
D5	stream	5.254*	Drift	0.05807	0.3167**
R1	pond	0.2172*	Drift	0.006574	0.03143**
R1	stream	3.725*	Drift	0.02867	0.2493**
R2	stream	4.993*	Drift	0.03332	0.2208**
R3	stream	5.250*	Drift	0.1834	0.8664
R4	stream	3.724*	Drift	0.1027	0.3214

*Single application gives higher PEC_{sw} than multiple application at Step 3 therefore single application values reported at Step 3.

**Single application gives higher PEC_{sed} for these scenarios

STEPS 3 and 4

Eugenol is a volatile compound and in order to account for volatilisation from the soil surface STEP 3 and 4 FOCUS modelling was performed. FOCUS STEP 3 modelling (using SWASH v5.3) does not model volatile deposition, so a STEP 4 model was required. This results in STEP 4 PEC values that are higher than those from STEP 3 and should be used as a worst-case for risk assessment.

STEP 3 modelling used foliar application as the method of application (See Table 8.9-1 for CAM/soil depth and Table 8.9-4 for input parameters). MACRO, PRZM and TOXSWA were run within SWASH to give PEC_{sw} values for drift, drainage, and runoff (Table 8.9-5 and 8.9-6). The worst-case values were for single application, and these are documented here.

EVA v3 was used to calculate the % deposition and deposition rates for eugenol from volatilisation as this version of the model calculated 24 hour deposition rates. As application is to the foliage with 60 and 65% crop interception (for vines and apples respectively), volatilisation from plants and soil have been calculated (see Tables 8.9-7 and 8.9-8). The deposition rates are not constant, however, and the deposition rates at different times (hourly) are shown in Tables 8.9-9 and 8.9-10.

Table 8.9-7: EVA 3 Deposition for eugenol vines

Distance	% volatilisation	Amount (g/ha)
3	1.859	2.440
5	1.667	2.188
10	1.270	1.667
15	0.967	1.269
20	0.737	0.967

Table 8.9-8: EVA 3 Deposition for eugenol apples

Distance	% volatilisation	Amount (g/ha)
3	1.976	2.573
5	1.772	2.308
10	1.349	1.757
15	1.028	1.339
20	0.783	1.019

Table 8.9-9: EVA 3 24 hour SRT Deposition Rates for eugenol (recommended by FOCUS-AIR) for vines

Time (h)	Distance downwind from treated crop				
	3	5	10	15	20
	Deposition rates after different times (mg/m ²)				
0-1	0.0407	0.0365	0.0278	0.0212	0.0161
1-2	0.0203	0.0182	0.0139	0.0106	0.0081
2-3	0.0203	0.0182	0.0139	0.0106	0.0081
3-4	0.0203	0.0182	0.0139	0.0106	0.0081
4-5	0.0102	0.0091	0.0069	0.0053	0.0040
5-6	0.0102	0.0091	0.0069	0.0053	0.0040
6-7	0.0102	0.0091	0.0069	0.0053	0.0040
7-8	0.0102	0.0091	0.0069	0.0053	0.0040
8-9	0.0102	0.0091	0.0069	0.0053	0.0040
9-10	0.0102	0.0091	0.0069	0.0053	0.0040
10-11	0.0102	0.0091	0.0069	0.0053	0.0040
11-12	0.0102	0.0091	0.0069	0.0053	0.0040
12-13	0.0051	0.0046	0.0035	0.0026	0.0020
13-14	0.0051	0.0046	0.0035	0.0026	0.0020
14-15	0.0051	0.0046	0.0035	0.0026	0.0020

Time (h)	Distance downwind from treated crop				
	3	5	10	15	20
15-16	0.0051	0.0046	0.0035	0.0026	0.0020
16-17	0.0051	0.0046	0.0035	0.0026	0.0020
17-18	0.0051	0.0046	0.0035	0.0026	0.0020
18-19	0.0051	0.0046	0.0035	0.0026	0.0020
19-20	0.0051	0.0046	0.0035	0.0026	0.0020
20-21	0.0051	0.0046	0.0035	0.0026	0.0020
21-22	0.0051	0.0046	0.0035	0.0026	0.0020
22-23	0.0051	0.0046	0.0035	0.0026	0.0020
23-24	0.0051	0.0046	0.0035	0.0026	0.0020

Table 8.9-10: EVA 3 24 hour SRT Deposition Rates for eugenol (recommended by FOCUS-AIR) for apples

Time (h)	Distance downwind from treated crop				
	3	5	10	15	20
	Deposition rates after different times (mg/m ²)				
0-1	0.0429	0.0385	0.0293	0.0223	0.0170
1-2	0.0214	0.0192	0.0146	0.0112	0.0085
2-3	0.0214	0.0192	0.0146	0.0112	0.0085
3-4	0.0214	0.0192	0.0146	0.0112	0.0085
4-5	0.0107	0.0096	0.0073	0.0056	0.0042
5-6	0.0107	0.0096	0.0073	0.0056	0.0042
6-7	0.0107	0.0096	0.0073	0.0056	0.0042
7-8	0.0107	0.0096	0.0073	0.0056	0.0042
8-9	0.0107	0.0096	0.0073	0.0056	0.0042
9-10	0.0107	0.0096	0.0073	0.0056	0.0042
10-11	0.0107	0.0096	0.0073	0.0056	0.0042
11-12	0.0107	0.0096	0.0073	0.0056	0.0042
12-13	0.0054	0.0048	0.0037	0.0028	0.0021
13-14	0.0054	0.0048	0.0037	0.0028	0.0021
14-15	0.0054	0.0048	0.0037	0.0028	0.0021
15-16	0.0054	0.0048	0.0037	0.0028	0.0021
16-17	0.0054	0.0048	0.0037	0.0028	0.0021
17-18	0.0054	0.0048	0.0037	0.0028	0.0021
18-19	0.0054	0.0048	0.0037	0.0028	0.0021
19-20	0.0054	0.0048	0.0037	0.0028	0.0021
20-21	0.0054	0.0048	0.0037	0.0028	0.0021
21-22	0.0054	0.0048	0.0037	0.0028	0.0021
22-23	0.0054	0.0048	0.0037	0.0028	0.0021
23-24	0.0054	0.0048	0.0037	0.0028	0.0021

At STEP 4 the results from the FOCUS STEP 3 project were run using SWAN v.5.0.1. No mitigation for runoff was included initially, the FOCUS spray drift was used, and the deposition rates from Table 8.9-9 and 8.9-10 for 3 m distance to waterbody were input into the deposition tab and TOXSWA was run again to generate PEC_{sw} values that include drainage, runoff, and deposition from volatilisation. These values are summarised in Tables 8.9-11 and 8.9-12.

Table 8.9-11: FOCUS Step 3/4 PEC_{sw} and PEC_{sed} for eugenol following single/ multiple application(s) of Mevalone to vines

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
D3	ditch	2.254	Drift	0.0486	0.1816
D4	pond	0.09251	Drift	0.01195	0.03958
D4	stream	1.82	Drift	0.03043	0.1383
D5	pond	0.09297	Drift	0.0081	0.03567
D5	stream	1.962	Drift	0.02117	0.1313
D6	ditch	2.251	Drift	0.05005	0.1941
R1	pond	0.09826	Drift	0.01163	0.03864
R1	stream	1.727	Drift	0.05776	0.2452
R2	stream	2.337	Drift	0.03129	0.2062
R3	stream	2.357	Drift	0.03412	0.1723
R4	stream	1.718	Drift	0.02034	0.1312

*Single application gives higher PEC_{sw} than multiple application at Step 3

Table 8.9-12: FOCUS Step 3/4 PEC_{sw} and PEC_{sed} for eugenol following single/ multiple application(s) of Mevalone to apples

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
D3	ditch	4.854	Drift	0.04883	0.3191**
D4	pond	0.2173	Drift	0.0188	0.06051
D4	stream	4.755	Drift	0.04864	0.2632**
D5	pond	0.2174	Drift	0.01762	0.05717
D5	stream	5.254	Drift	0.06386	0.3221**
R1	pond	0.2172	Drift	0.01225	0.05289
R1	stream	3.725	Drift	0.03419	0.2627**
R2	stream	4.993	Drift	0.04071	0.2338**
R3	stream	5.25	Drift	0.1887	0.8775
R4	stream	3.724	Drift	0.1102	0.3404

*Single application gives higher PEC_{sw} than multiple application at Step 3/4.

**Single application gives higher PEC_{sed} for these scenarios

zRMS comments:

The input parameters considered by the Applicant in surface water modelling for eugenol presented in Table 8.9-3 are in line with EU agreed endpoints with one exception:

- according to the Confirmatory Data, water solubility is 2350 mg/L.

As eugenol is a volatile compound, the deposition rates were calculated using EVA ver.3 with respective crop interception for vines and apples. The values presented by the Applicant in Tables 8.9-9 and 8.9-10 are in good agreement with values obtained by the zRMS.

Calculations performed by the Applicant at Steps 1-3 for eugenol were validated in additional modelling performed by the zRMS with the same input parameters except of water solubility (zRMS used the EU agreed value of 2350 mg/L) and application window in scenario D3 for simulations in apples (31st July to 20th September was used in line with indications of AppDate).

PEC_{sw} and PEC_{sed} calculated at Step 1-3 (with and without consideration of volatilisation) were in good agreement with values obtained by the Applicant with slightly higher PEC_{sed}. Results in tables above were, however, not corrected by the zRMS since no endpoints for sediment dwelling organisms are available in area of ecotoxicology and the risk assessment was performed only for organisms exposed via water column.

Surface water exposure presented above may be used in the aquatic risk assessment.

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.9.2.2 Geraniol

Table 8.9-13: Input parameters related to active substance geraniol for PEC_{sw/sed} calculations STEP 1/2 and 3

Compound	Geraniol	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	154.25	EFSA, LoEP, 2012
Saturated vapour pressure (Pa) at 20°C	4.6	EFSA, LoEP, 2012
Water solubility (mg/L) at 20°C	580 572 (pH 7)	EFSA, LoEP, 2012
Diffusion coefficient in water (m ² /d)	4.3 x 10 ⁻⁵	default
Diffusion coefficient in air (m ² /d)	0.43	default
K _{foc} (mL/g)	10 (conservative value in the absence of reliable sorption studies)	default
Freundlich Exponent 1/n	0.9 (default value in the absence of reliable sorption studies)	default
Plant Uptake	0	default
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	default
DT _{50,soil} (d)	1 day	EFSA Confirmatory Data 2016
DT _{50,water} (d)	15 days	EFSA, LoEP, 2012 (REACH ECHA 2010)
DT _{50,sed} (d)	300	EFSA, LoEP, 2012 (REACH ECHA 2010)
DT _{50,whole system} (d)	300	EFSA, LoEP, 2012 (REACH ECHA 2010)

PEC_{sw/sed}

Table 8.9-14: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for geraniol following single/ multiple application(s) of Mevalone to vines

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	375.63	-	366.31	37.44
STEP 2					
Northern Europe	Mar-May	15.28	-	10.02	1.30
	June-Sept	15.28	-	10.02	1.30
Southern Europe	Mar-May	15.28	-	10.28	1.35
	June-Sept	15.28	-	10.15	1.33
STEP 3					
D6	ditch	4.503*	Drift	1.197	0.8105
R1	pond	0.2113	Drift	0.1156	0.09655
R1	stream	3.314*	Drift	0.1531	0.2608**
R2	stream	4.455*	Drift	0.1193	0.2896
R3	stream	4.666*	Drift	0.1596	0.2602
R4	stream	3.323*	Drift	0.05272	0.1497**

*Single application gives higher PEC_{sw} than multiple application at Step 3 therefore single application values reported at Step 3.

**Single application gives higher PEC_{sed} for these scenarios.

Table 8.9-15: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for geraniol following single/ multiple application(s) of Mevalone to apples

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	402.72	-	392.41	40.11
STEP 2					
Northern Europe	Mar-May	23.34	-	15.13	1.96
	June-Sept	23.34	-	15.13	1.96
Southern Europe	Mar-May	23.34	-	15.36	2.00
	June-Sept	23.34	-	15.24	1.98
STEP 3					
D3	ditch	9.708*	Drift	0.9245	0.9311
D4	pond	0.5678	Drift	0.3591	0.2501
D4	stream	9.511*	Drift	0.1216	0.3479**
D5	pond	0.4751	Drift	0.2728	0.1933
D5	stream	10.51*	Drift	0.355	0.5819**
R1	pond	0.4346*	Drift	0.2151	0.1798
R1	stream	7.452*	Drift	0.09656	0.3311**
R2	stream	9.988*	Drift	0.09872	0.3035**
R3	stream	10.50*	Drift	0.8852	1.282
R4	stream	7.450*	Drift	0.3964	0.4472

*Single application gives higher PEC_{sw} than multiple application at Step 3 therefore single application values reported at Step 3.

**Single application gives higher PEC_{sed} for these scenarios.

STEPS 3 and 4

Geraniol is a volatile compound and in order to account for volatilisation from the soil surface STEP 3 and 4 FOCUS modelling was performed. FOCUS STEP 3 modelling (using SWASH v5.3) does not model volatile deposition, so a STEP 4 model was required. This results in STEP 4 PEC values that are higher than those from STEP 3 and should be used as a worst-case for risk assessment.

STEP 3 modelling used foliar application as the method of application (See Table 8.9-1 for CAM/soil depth and Table 8.9-13 for input parameters). MACRO, PRZM and TOXSWA were run within SWASH to give PEC_{sw} values for drift, drainage and runoff (Table 8.9-14 and 8.9-15). The worst-case values were for single application and these are documented here.

EVA v3 was used to calculate the % deposition and deposition rates for geraniol from volatilisation as this version of the model calculated 24 hour deposition rates. As application is to the foliage, volatilisation from soil and plants has been calculated (see Tables 8.9-16 and 8.9-17). The deposition rates are not constant, however, and the deposition rates at different times (hourly) are shown in Tables 8.9-18 and 8.9-19.

Table 8.9-16: EVA 3 Deposition for geraniol - vines

Distance	% volatilisation	Amount (g/ha)
3	1.859	4.880
5	1.667	4.377
10	1.270	3.333
15	0.967	2.539
20	0.737	1.934

Table 8.9-17: EVA 3 Deposition for geraniol - apples

Distance	% volatilisation	Amount (g/ha)
3	1.976	5.146
5	1.772	4.615
10	1.349	3.515
15	1.028	2.677
20	0.783	2.039

Table 8.9-18: EVA 3 24 hour SRT Deposition Rates for geraniol (recommended by FOCUS-AIR) vines

Time (h)	Distance downwind from treated crop				
	3	5	10	15	20
	Deposition rates after different times (mg/m ²)				
0-1	0.0813	0.0729	0.0556	0.0423	0.0322
1-2	0.0407	0.0365	0.0278	0.0212	0.0161
2-3	0.0407	0.0365	0.0278	0.0212	0.0161
3-4	0.0407	0.0365	0.0278	0.0212	0.0161
4-5	0.0203	0.0182	0.0139	0.0106	0.0081
5-6	0.0203	0.0182	0.0139	0.0106	0.0081
6-7	0.0203	0.0182	0.0139	0.0106	0.0081
7-8	0.0203	0.0182	0.0139	0.0106	0.0081
8-9	0.0203	0.0182	0.0139	0.0106	0.0081
9-10	0.0203	0.0182	0.0139	0.0106	0.0081
10-11	0.0203	0.0182	0.0139	0.0106	0.0081
11-12	0.0203	0.0182	0.0139	0.0106	0.0081
12-13	0.0102	0.0091	0.0069	0.0053	0.0040
13-14	0.0102	0.0091	0.0069	0.0053	0.0040
14-15	0.0102	0.0091	0.0069	0.0053	0.0040
15-16	0.0102	0.0091	0.0069	0.0053	0.0040
16-17	0.0102	0.0091	0.0069	0.0053	0.0040
17-18	0.0102	0.0091	0.0069	0.0053	0.0040
18-19	0.0102	0.0091	0.0069	0.0053	0.0040
19-20	0.0102	0.0091	0.0069	0.0053	0.0040
20-21	0.0102	0.0091	0.0069	0.0053	0.0040
21-22	0.0102	0.0091	0.0069	0.0053	0.0040
22-23	0.0102	0.0091	0.0069	0.0053	0.0040
23-24	0.0102	0.0091	0.0069	0.0053	0.0040

Table 8.9-19: EVA 3 24 hour SRT Deposition Rates for geraniol (recommended by FOCUS-AIR) apples

Time (h)	Distance downwind from treated crop				
	3	5	10	15	20
	Deposition rates after different times (mg/m ²)				
0-1	0.0858	0.0769	0.0586	0.0446	0.0340
1-2	0.0429	0.0385	0.0293	0.0223	0.0170
2-3	0.0429	0.0385	0.0293	0.0223	0.0170
3-4	0.0429	0.0385	0.0293	0.0223	0.0170
4-5	0.0214	0.0192	0.0146	0.0112	0.0085
5-6	0.0214	0.0192	0.0146	0.0112	0.0085
6-7	0.0214	0.0192	0.0146	0.0112	0.0085
7-8	0.0214	0.0192	0.0146	0.0112	0.0085
8-9	0.0214	0.0192	0.0146	0.0112	0.0085
9-10	0.0214	0.0192	0.0146	0.0112	0.0085
10-11	0.0214	0.0192	0.0146	0.0112	0.0085
11-12	0.0214	0.0192	0.0146	0.0112	0.0085
12-13	0.0107	0.0096	0.0073	0.0056	0.0042
13-14	0.0107	0.0096	0.0073	0.0056	0.0042
14-15	0.0107	0.0096	0.0073	0.0056	0.0042
15-16	0.0107	0.0096	0.0073	0.0056	0.0042
16-17	0.0107	0.0096	0.0073	0.0056	0.0042
17-18	0.0107	0.0096	0.0073	0.0056	0.0042
18-19	0.0107	0.0096	0.0073	0.0056	0.0042
19-20	0.0107	0.0096	0.0073	0.0056	0.0042
20-21	0.0107	0.0096	0.0073	0.0056	0.0042
21-22	0.0107	0.0096	0.0073	0.0056	0.0042
22-23	0.0107	0.0096	0.0073	0.0056	0.0042
23-24	0.0107	0.0096	0.0073	0.0056	0.0042

At STEP 4 the results from the FOCUS STEP 3 project were run using SWAN v.5.0.1. No mitigation for runoff was included initially, the FOCUS spray drift was used and the deposition rates from Tables 8.9-18 and 8.9-19 for 3 m distance to waterbody were input into the deposition tab and TOXSWA was run again to generate PEC_{sw} values that include drift, drainage, runoff, and deposition from volatilisation. These values are summarised in Tables 8.9-20 and 8.9-21.

Table 8.9-20: FOCUS Step 3/4 PEC_{sw} and PEC_{sed} for geraniol following single/ multiple application(s) of Mevalone to vines

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
D3	ditch	4.658*	Drift	0.9579	0.7277
D4	pond	0.3603*	Drift	0.3792	0.2529
D4	stream	3.897*	Drift	0.1872	0.2616
D5	pond	0.3645*	Drift	0.2558	0.1988
D5	stream	4.109*	Drift	0.1758	0.3004
D6	ditch	4.729*	Drift	1.691	1.138
R1	pond	0.4854	Drift	0.299	0.2381
R1	stream	3.703*	Drift	0.1895	0.2704
R2	stream	4.882*	Drift	0.1285	0.2982
R3	stream	4.967*	Drift	0.1881	0.3267
R4	stream	3.704*	Drift	0.07919	0.1799

*Single application gives higher PEC_{sw} than multiple application at Step 3 therefore single application values reported at Step 3.

Table 8.9-21: FOCUS Step 3/4 PEC_{sw} and PEC_{sed} for geraniol following single/ multiple application(s) of Mevalone to apples

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
D3	ditch	9.707*	Drift	1.159	1.162
D4	pond	0.9714	Drift	0.6622	0.4533
D4	stream	9.815*	Drift	0.1571	0.3700**
D5	pond	0.7855	Drift	0.5026	0.3504
D5	stream	10.54*	Drift	0.4563	0.6212**
R1	pond	0.6407	Drift	0.3964	0.3253
R1	stream	7.769*	Drift	0.1252	0.3566**
R2	stream	10.44*	Drift	0.1280	0.3238**
R3	stream	10.57*	Drift	0.9752	1.34
R4	stream	7.694*	Drift	0.3972	0.4617

*Single application gives higher PEC_{sw} than multiple application at Step 3 therefore single application values reported at Step 3.

**Single application gives higher PEC_{sed} for these scenarios.

Step 4 Mitigation for geraniol

In Swan 5.0.1, the Step 3 for geraniol was run with a 10m run-off, spray drift and deposition buffer. The deposition values from Table 8.9-19 at 10 m was included, along with the runoff values from the Landscape and Mitigation Factors in Aquatic Ecological Assessment (2007) for 10 m and 20 m.

Buffer width	10-12	18-20
Reduction in volume of runoff water (%)	60	80
Reduction in mass pesticide transported un aqueous phase (%)	60	80
Reduction in mass of eroded sediment (%)	85	95
Reduction in mass of pesticide transported in sediment phase (%)	85	95

Table 8.9-22: FOCUS Step 4 PEC_{sw} and PEC_{sed} for geraniol following single/ multiple application(s) of Mevalone to vines – 10 m runoff and spraydrift buffer

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
D6	ditch	1.488	Drift	0.5961	0.4181
R2	stream	1.468*	Drift	0.05454	0.131
R3	stream	1.575*	Drift	0.07899	0.1206

*Single application gives higher PEC_{sw} than multiple application at Step 3 therefore single application values reported at Step 3.

Table 8.9-23: FOCUS Step 4 PEC_{sw} and PEC_{sed} for geraniol following single application of Mevalone to apples – 10 m runoff and spraydrift buffer

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
D3	ditch	3.047*	Drift	0.4595	0.4764
D4	pond	0.6372	Dainflow	0.4341	0.3014
D4	stream	3.576*	Drift	0.07129	0.1403**
D5	pond	0.5153	Drainflow	0.3295	0.2329
D5	stream	3.705*	Drift	0.2013	0.2571
R1	pond	0.4203	Runoff	0.2598	0.2166
R1	stream	2.882*	Drift	0.05548	0.1366**
R2	stream	3.793*	Drift	0.05676	0.1228**
R3	stream	4.557	Runoff	0.4293	0.6045
R4	stream	2.828*	Drift	0.1903	0.2033

*Single application gives higher PEC_{sw} than multiple application at Step 3 therefore single application values reported at Step 3.

**Single application gives higher PEC_{sed} for these scenarios.

R3 still required mitigation and an 18 m-20 m runoff buffer zone.

Table 8.9-24: FOCUS Step 4 PEC_{sw} and PEC_{sed} for geraniol following single application of Mevalone to apples – 18-20 m runoff and 18 m spray drift buffer

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
R3	stream	2.363	Runoff	0.2179	0.3166

zRMS comments:

The input parameters considered by the Applicant in surface water modelling for geraniol presented in Table 8.9-13 are in line with EU agreed endpoints with one exception:

- according the Confirmatory Data, water solubility is 580 mg/L.

As geraniol is a volatile compound, the deposition rates were calculated using EVA ver.3 with respective crop interception for vines and apples. The values presented by the Applicant in Tables 8.9-18 and 8.9-19 are in good agreement with values obtained by the zRMS.

Calculations performed by the Applicant at Steps 1-4 for geraniol were validated in additional modelling performed by the zRMS with the same input parameters except of water solubility (zRMS used the EU agreed value of 580 mg/L) and application window in scenario D3 for simulations in apples (31st July to 20th September was used in line with indications of AppDate).

PEC_{sw} and PEC_{sed} calculated at Step 1-4 (with and without consideration of volatilisation) were in good agreement with values obtained by the Applicant.

Surface water exposure presented above may be used in the aquatic risk assessment.

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.9.2.3 Thymol

Table 8.9-25: Input parameters related to active substance ~~thymol~~ geraniol for PEC_{sw/sed} calculations STEP 1/2 and 3

Compound	Thymol	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	150.22	EFSA, LoEP, 2012
Saturated vapour pressure (Pa) at 20°C	3.4	EFSA, LoEP, 2012
Water solubility (mg/L) at 20°C	630 (pH 10) 596 (pH 7)	EFSA, LoEP, 2012
Diffusion coefficient in water (m ² /d)	4.3 x 10 ⁻⁵	default
Diffusion coefficient in air (m ² /d)	0.43	default
K _{foc} (mL/g)	10 (conservative value in the absence of reliable sorption studies)	default
Freundlich Exponent 1/n	0.9 (default value in the absence of reliable sorption studies)	default
Plant Uptake	0	default
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	default
DT _{50,soil} (d)	1 day	EFSA Confirmatory Data 2016
DT _{50,water} (d)	15 days	EFSA, LoEP, 2012 (REACH ECHA 2010)
DT _{50,sed} (d)	300	EFSA, LoEP, 2012 (REACH ECHA 2010)
DT _{50,whole system} (d)	300	EFSA, LoEP, 2012 (REACH ECHA 2010)

PEC_{sw/sed}

Table 8.9-26: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for thymol following single/ multiple application(s) of Mevalone to vines

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	375.63	-	366.31	37.44
STEP 2					
Northern Europe	Mar-May	15.28	-	10.02	1.30
	June-Sept	15.28	-	10.02	1.30
Southern Europe	Mar-May	15.28	-	10.28	1.35
	June-Sept	15.28	-	10.15	1.33
STEP 3					
D6	ditch	4.503*	Drift	1.475	0.9766
R1	pond	0.2364	Drift	0.1424	0.1162
R1	stream	3.314*	Drift	0.1547	0.2645**
R2	stream	4.455*	Drift	0.1224	0.2976
R3	stream	4.666*	Drift	0.1654	0.2681
R4	stream	3.323*	Drift	0.05325	0.151**

*Single application gives higher PEC_{sw} than multiple application at Step 3 therefore single application values reported at Step 3.

Table 8.9-27: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for thymol following single/ multiple application(s) of Mevalone to apples

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	402.72	-	392.41	40.11
STEP 2					
Northern Europe	Mar-May	22.34	-	15.13	1.96
	June-Sept	22.34	-	15.13	1.96
Southern Europe	Mar-May	22.34	-	15.36	2.00
	June-Sept	22.34	-	15.24	1.98
STEP 3					
D3	ditch	9.708*	Drift	1.058	1.055
D4	pond	0.6355	Drift	0.4206	0.2936
D4	stream	9.511*	Drift	0.1222	0.2858
D5	pond	0.5349	Drift	0.3271	0.2309
D5	stream	10.51*	Drift	0.3629	0.532
R1	pond	0.4346*	Drift	0.2623	0.2174
R1	stream	7.452*	Drift	0.09719	0.262
R2	stream	9.988*	Drift	0.09943	0.2444
R3	stream	10.5*	Drift	0.9175	1.327
R4	stream	7.45*	Drift	0.4056	0.4592

*Single application gives higher PEC_{sw} than multiple application at Step 3 therefore single application values reported at Step 3.

**Single application gives higher PEC_{sed} for these scenarios.

STEPS 3 and 4

Thymol is a volatile compound and in order to account for volatilisation from the soil surface STEP 3 and 4 FOCUS modelling was performed. FOCUS STEP 3 modelling (using SWASH v5.3) does not model volatile deposition, so a STEP 4 model was required. This results in STEP 4 PEC values that are higher than those from STEP 3 and should be used as a worst-case for risk assessment.

STEP 3 modelling used foliar application as the method of application (See Table 8.9-1 for CAM/soil depth and Table 8.9-24 for input parameters). MACRO, PRZM and TOXSWA were run within SWASH to give PEC_{sw} values for drift, drainage, and runoff (Table 8.9-26 and 8.9-27). The worst-case values were for single application, and these are documented here.

EVA v3 was used to calculate the % deposition and deposition rates for thymol from volatilisation as this version of the model calculated 24 hour deposition rates. As application is to the foliage, volatilisation from soil and plants has been calculated (see Tables 8.9-28 and 8.9-29). The deposition rates are not constant, however, and the deposition rates at different times (hourly) are shown in Table 8.9-30 and 8.9-31.

Table 8.9-28: EVA 3 Deposition for thymol - vines

Distance	% volatilisation	Amount (g/ha)
3	1.859	4.880
5	1.667	4.377
10	1.270	3.333
15	0.967	2.539
20	0.737	1.934

Table 8.9-29: EVA 3 Deposition for thymol - apples

Distance	% volatilisation	Amount (g/ha)
3	1.976	5.146
5	1.772	4.615
10	1.349	3.515
15	1.028	2.677
20	0.783	2.039

Table 8.9-30: EVA 3 24 hour SRT Deposition Rates for thymol (recommended by FOCUS-AIR) vines

Time (h)	Distance downwind from treated crop				
	3	5	10	15	20
	Deposition rates after different times (mg/m ²)				
0-1	0.0813	0.0729	0.0556	0.0423	0.0322
1-2	0.0407	0.0365	0.0278	0.0212	0.0161
2-3	0.0407	0.0365	0.0278	0.0212	0.0161
3-4	0.0407	0.0365	0.0278	0.0212	0.0161
4-5	0.0203	0.0182	0.0139	0.0106	0.0081
5-6	0.0203	0.0182	0.0139	0.0106	0.0081
6-7	0.0203	0.0182	0.0139	0.0106	0.0081
7-8	0.0203	0.0182	0.0139	0.0106	0.0081
8-9	0.0203	0.0182	0.0139	0.0106	0.0081
9-10	0.0203	0.0182	0.0139	0.0106	0.0081
10-11	0.0203	0.0182	0.0139	0.0106	0.0081
11-12	0.0203	0.0182	0.0139	0.0106	0.0081
12-13	0.0102	0.0091	0.0069	0.0053	0.0040
13-14	0.0102	0.0091	0.0069	0.0053	0.0040
14-15	0.0102	0.0091	0.0069	0.0053	0.0040
15-16	0.0102	0.0091	0.0069	0.0053	0.0040
16-17	0.0102	0.0091	0.0069	0.0053	0.0040
17-18	0.0102	0.0091	0.0069	0.0053	0.0040
18-19	0.0102	0.0091	0.0069	0.0053	0.0040
19-20	0.0102	0.0091	0.0069	0.0053	0.0040
20-21	0.0102	0.0091	0.0069	0.0053	0.0040
21-22	0.0102	0.0091	0.0069	0.0053	0.0040
22-23	0.0102	0.0091	0.0069	0.0053	0.0040
23-24	0.0102	0.0091	0.0069	0.0053	0.0040

Table 8.9-31: EVA 3 24 hour SRT Deposition Rates for thymol (recommended by FOCUS-AIR) apples

Time (h)	Distance downwind from treated crop				
	3	5	10	15	20
	Deposition rates after different times (mg/m ²)				
0-1	0.0858	0.0769	0.0586	0.0446	0.0340
1-2	0.0429	0.0385	0.0293	0.0223	0.0170
2-3	0.0429	0.0385	0.0293	0.0223	0.0170
3-4	0.0429	0.0385	0.0293	0.0223	0.0170
4-5	0.0214	0.0192	0.0146	0.0112	0.0085
5-6	0.0214	0.0192	0.0146	0.0112	0.0085
6-7	0.0214	0.0192	0.0146	0.0112	0.0085
7-8	0.0214	0.0192	0.0146	0.0112	0.0085
8-9	0.0214	0.0192	0.0146	0.0112	0.0085
9-10	0.0214	0.0192	0.0146	0.0112	0.0085
10-11	0.0214	0.0192	0.0146	0.0112	0.0085
11-12	0.0214	0.0192	0.0146	0.0112	0.0085
12-13	0.0107	0.0096	0.0073	0.0056	0.0042
13-14	0.0107	0.0096	0.0073	0.0056	0.0042
14-15	0.0107	0.0096	0.0073	0.0056	0.0042
15-16	0.0107	0.0096	0.0073	0.0056	0.0042
16-17	0.0107	0.0096	0.0073	0.0056	0.0042
17-18	0.0107	0.0096	0.0073	0.0056	0.0042
18-19	0.0107	0.0096	0.0073	0.0056	0.0042
19-20	0.0107	0.0096	0.0073	0.0056	0.0042
20-21	0.0107	0.0096	0.0073	0.0056	0.0042
21-22	0.0107	0.0096	0.0073	0.0056	0.0042
22-23	0.0107	0.0096	0.0073	0.0056	0.0042
23-24	0.0107	0.0096	0.0073	0.0056	0.0042

At STEP 4 the results from the FOCUS STEP 3 project were run using SWAN v.5.0.1. No mitigation for runoff was included initially, the FOCUS spray drift was used and the deposition rates from Tables 8.9-29 and 8.9-30 for 3 m distance to waterbody were input into the deposition tab and TOXSWA was run again to generate PEC_{sw} values that include drift, drainage, runoff and deposition from volatilisation. These values are summarised in Tables 8.9-32 and 8.9-33.

Table 8.9-32: FOCUS Step 4 PEC_{sw} and PEC_{sed} for thymol following single/ multiple application(s) of Mevalone to vines

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
D3	ditch	4.755	Drift	1.224	0.9186
D4	pond	0.6944	Drift	0.4933	0.3247
D4	stream	3.946	Drift	0.2164	0.3073
D5	pond	0.5412	Drift	0.3222	0.2574
D5	stream	4.172*	Drift	0.2044	0.3552
D6	ditch	4.801*	Drift	2.083	1.373
R1	pond	0.5514	Drift	0.3654	0.2872
R1	stream	3.725*	Drift	0.1916	0.273
R2	stream	4.888*	Drift	0.1318	0.3063
R3	stream	5.055*	Drift	0.1957	0.339
R4	stream	3.733*	Drift	0.08017	0.1824

*Single application gives higher PEC_{sw} than multiple application at Step 3 therefore single application values reported at Step 3.

Table 8.9-33: FOCUS Step 4 PEC_{sw} and PEC_{sed} for thymol following single/ multiple application(s) of Mevalone to apples

FOCUS STEP and Scenario	Waterbody or Season	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
D3	ditch	9.707*	Drift	1.325	1.318
D4	pond	1.106	Drift	0.7785	0.5322
D4	stream	9.852*	Drift	0.158	0.3219
D5	pond	0.9065	Drift	0.6028	0.4185
D5	stream	10.54*	Drift	0.4681	0.6142
R1	pond	0.725	Drift	0.4836	0.3935
R1	stream	7.816*	Drift	0.1261	0.2991
R2	stream	10.45*	Drift	0.1291	0.2769
R3	stream	10.57*	Drift	1.013	1.389
R4	stream	7.737*	Drift	0.4472	0.4716

*Single application gives higher PEC_{sw} than multiple application at Step 3 therefore single application values reported at Step 3.

*Single application gives higher PEC_{sed} for these scenarios.

zRMS comments:

The input parameters considered by the Applicant in surface water modelling for thymol presented in Table 8.9-25 are in line with EU agreed endpoints with one exception:

- according to the Confirmatory Data, water solubility is 630 mg/L.

As thymol is a volatile compound, the deposition rates were calculated using EVA ver.3 with respective crop interception for vines and apples. The values presented by the Applicant in Tables 8.9-30 and 8.9-31 are in good agreement with values obtained by the zRMS.

Calculations performed by the Applicant at Steps 1-3 for thymol were validated in additional modelling performed by the zRMS with the same input parameters except of water solubility (zRMS used the EU agreed value of 630 mg/L) and application window in scenario D3 for simulations in apples (31st July to 20th September was used in line with indications of AppDate).

PEC_{sw} and PEC_{sed} calculated at Step 1-3 (with and without consideration of volatilisation) were in good agreement with values obtained by the Applicant.

Surface water exposure presented above may be used in the aquatic risk assessment.

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

Conclusions

The PEC in surface water and sediment was determined for eugenol, geraniol and thymol, following application of Mevalone to vines and apples.

The PEC was modelled according to FOCUS guidelines, using the STEPS 1-2 calculator (version 3.2), and FOCUS SWASH (version 5.3).

The maximum PEC_{sw} values for eugenol, geraniol and thymol were 5.254, 10.57 and 10.57 µg/L respectively, for application of Mevalone to apples and 2.357, 4.967 and 5.055 µg/L for eugenol, geraniol and thymol respectively for application of Mevalone to vines.

A 18 m runoff and spray drift buffer was required for geraniol for apples.

8.9.2.4 PEC_{sw/sed} of Mevalone

Please note that only the instantaneous PEC_{sw} is relevant, since the formulation will immediately separate into its components, which then degrade at different rates. Only spray drift is taken into account for the formulation PEC_{sw}.

Table 8.9-34: PEC_{sw} for formulation Mevalone

Preparation	Use/Crop	Application rate (L/ha)	Product density (g/L)	Application rate (kg/ha)	Spray Drift (%)**	PEC _{act} (µg/L)
Mevalone	Grapes (late)	4	1.029*	4.116	8.02	110.034
	Pome fruit (late)	4	1.029*	4.116	15.73	215.816

* Mevalone Specification

**Applied as single application at a distance of 3 m of the surface water (Generic guidance for FOCUS surface water scenarios, version 1.4, May 2015)

zRMS comments:

Recalculation of the surface water exposure to the formulated product performed by the zRMS using Spray Drift Calculator resulted with lower PEC_{sw} values. Therefore values presented in Table 8.9-34 represent worst case and may be used in the aquatic risk assessment for the formulation.

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 eugenol

Compound	Eugenol
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air	DT ₅₀ of 1.975 hours derived by the Atkinson model (version 1.92). OH (12 h) concentration assumed = 1.5×10^6 OH radical/cm ³
Volatilisation	Vapour pressure (Pa): 2.7 Henry's Law Constant (Pa.m ³ /mol): 0.24
Metabolites	None

The vapour pressure at 20°C of the active substance eugenol is 2.7 Pa. Hence the active substance eugenol is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance eugenol due to volatilization with subsequent deposition should be considered (refer to Section 8.9).

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

Compound	Geraniol
Direct photolysis in air	Not studied - no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air	DT ₅₀ of 0.713 hours derived by the Atkinson model (version 1.92). OH (12 h) concentration assumed = 1.5×10^6 OH radical/cm ³
Volatilisation	Vapour pressure (Pa): 4.6 Henry's Law Constant (Pa.m ³ /mol): 1.22
Metabolites	None

The vapour pressure at 20°C of the active substance geraniol is 4.6 Pa. Hence the active substance geraniol is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance geraniol due to volatilization with subsequent deposition should be considered (refer to Section 8.9).

Table 8.10-3 Summary of atmospheric degradation and behaviour for thymol

Compound	Thymol
Direct photolysis in air	Not studied - no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air	DT ₅₀ of 1.197 hours derived by the Atkinson model (version 1.92). OH (12 h) concentration assumed = 1.5×10^6 OH radical/cm ³
Volatilisation	Vapour pressure (Pa): 3.4 Henry's Law Constant (Pa.m ³ /mol): 0.86
Metabolites	None

The vapour pressure at 20°C of the active substance thymol is 3.4 Pa. Hence the active substance thymol is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance thymol due to volatilization with subsequent deposition should be considered (refer to Section 8.9).

zRMS comments:

Information regarding fate and behaviour in the air presented in Tables 8.10-1 to 8.10-3 is in line with EU agreed endpoints reported in EFSA Journal 2012;10(11):2914, EFSA Journal 2012;10(11):2915 and EFSA Journal 2012;10(11):2916 for eugenol, geraniol and thymol, respectively.

Due to high vapour pressure, volatilisation from soil and plant surfaces is expected and was taken into account in the surface water exposure assessment. None of the compounds is expected to be subject of the long- and short-range transport due to rapid degradation in air (within hours after volatilisation). Therefore, unacceptable contamination of the atmosphere due to application of Mevalone is not expected.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

These data have also been submitted within the AIR dossier submitted 28th February 2021 (RMS: Spain).

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 9.2.4	H. Walshaw	2021 ^a	Mevalone: Predicted Environmental Concentrations of Eugenol, Geraniol, and Thymol in Groundwater Following Application to Vines and Apples, Using FOCUS-MACRO, FOCUS-PEARL and FOCUS-PELMO Source: Staphyt Regulatory Company Report No 21/14 GLP NA Unpublished	N	Eden Research plc
KCP 9.2.5	H. Walshaw	2022	Mevalone: Predicted Environmental Concentrations of Eugenol, Geraniol, and Thymol in Surface Water following application to vines and apples, Using FOCUS-STEPS 1-4 Source: Staphyt Regulatory Company Report No 22/55 GLP NA Unpublished	N	Eden Research plc

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
As all endpoints for eugenol, geraniol and thymol were taken from the EU review, for the list of respective studies please refer to Volume 2 of the DAR for particular active compounds.					

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
There were no data submitted by the Applicant and not relied on.					

List of data relied on and 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
There were no data relied on and not submitted by the Applicant.					

Appendix 2 Detailed evaluation of the new Annex II studies

No new Annex II studies were submitted.

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

No additional information.