

REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: Mevalone

Product name(s): Mevalone

Chemical active substance(s):

Thymol, 66 g/L

Geraniol, 66 g/L

Eugenol, 33 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorization for Mevalone product)

Applicant: Eden Research plc

Submission date: 15/07/2021

MS Finalisation date: April 2022 (initial Core Assessment)

December 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.
April 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 .
December 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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Reviewer comments:

This part of dossier summarizes data related to the toxicological assessment and exposure data for the plant protection product Mevalone (product code 3AEY) as CS (Capsule Suspension) and has been submitted to support registration according art. 33 of 1107/2009 in Poland.

Product contain eugenol, geraniol and thymol which were approved as active substances in accordance with Regulation (EC) No 1107/2009 by Commission Implementing Regulation (EU) No 546/2013 of 14 June 2013, No 570/2013 of 17 June 2013 and No 568/2013 of 18 June 2013, respectively.

Product was a representative formulation reviewed during the Annex I inclusion of active substance(s). (please refer DAR's listed below):

Geraniol - Volume 3, Annex B.6 : Toxicology and Metabolism, May 2011; pp.92-99

Thymol - Volume 3, Annex B.6 : Toxicology and Metabolism, May 2011; pp. 120-125

Eugenol - Volume 3, Annex B.6 : Toxicology and Metabolism, May 2011; pp.122-127

Mevalone has already been authorized on grapes and other various crops in several Southern Europe countries. Application on pome fruits has also been authorized in France. Currently dossier is for application in the Central Zone for first approval, with Poland as zRMS.

The present application is for professional use of the plant protection product Mevalone/3AEY against fungal diseases in grapes and pome fruits (apple, pear, quince, crab-apple, loquat, medlar, nashi pear).

For the current registration of the product (Mevalone/3AEY), applicant provided the same data set of *in vivo* toxicity studies which were performed for Annex I inclusion of active substance(s) and accepted by the experts during Pesticides Peer Review Meeting PPR 90 (16 – 20 April 2012).

Due to this zRMS accepted already existing *in vivo* studies and do not request for the new one. Existing animal studies has been accepted in 2011. They are allow to identify of effects following a single exposure to the plant protection product. The data is sufficient to indicate the time course and characteristics of the effect with full details of behavioural changes and possible gross pathological findings at post-mortem. These studies are still valid for hazard classification and toxicological risk assessment.

NDE assessment and combined exposure calculations provided for operator, workers and B&R resulting from use of Mevalone (product code 3AEY) (*Mevalone (product code 3AEY) is CS (Capsule Suspension) product, containing three active substances, eugenol, geraniol and thymol at 33 g/L, 66 g/L and 66 g/L respectively, and acting as a fungicide; refer dRR part B0*) considering critical use(s), identify safe applications of the product.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on Mevalone*

Product name and code	Mevalone (3AEY)
Formulation type	Capsule Suspension (CS)
Active substance(s) (incl. content)	Eugenol 33 g/L, geraniol 66 g/L, thymol 66 g/L
Function	Fungicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	Yes (see dRR part B0 for details)
Product previously evaluated in another MS according to Uniform Principles	Yes (see dRR part B0 for details)

* Information on the detailed composition of Mevalone can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for Mevalone according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Serious eye damage/eye irritation, Category 2 Skin sensitisation, Category 1
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07
Signal word	Warning
Hazard statement(s)	H317, H319
Precautionary statement(s)	P264 Wash ... thoroughly after handling P280 Wear protective gloves/eye protection/face protection. P302 + P352 IF ON SKIN, Wash with plenty of water/... P305 + P351 + P338 IF IN EYES, Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P333 + P313 If skin irritation or rash occurs: Get medical advice/attention. P337 + P313 If eye irritation persists: Get medical advice/attention. P362 + P364 Take off contaminated clothing and wash it before reuse.
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. To avoid risks to human health and the environment, comply with the instructions for use [EUH401] Contains (eugenol, geraniol). May produce an allergic reaction [EUH208].

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for Mevalone

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear, protective gloves and eye protection worn when mix/loading*. Work wear (only) when applying the diluted product
Workers	Acceptable	Gloves and work wear are to be worn during crop re-entry activities
Residents	Acceptable	None
Bystanders	Acceptable	None

***Reviewer comment:** considering NDE assessment, for safe use of the product one need to use work wear but not protective. Additional measures like protective gloves and eye protection result from toxicity potential (hazard assessment).
Mevalone is classified as a skin sensitizer according to CLP (H317: May cause an allergic skin reaction) and as an eye irritant (H319 Causes serious eye irritation) therefore eye protection and protective gloves are required when handling the concentrated product.

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10				
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, resident or bystander exposure based on [Exposure model]	Acceptability of exposure assessment				
			Method / Kind (incl. application technique ***	Max. number (min. interval between applications) a) per use b) per crop/season	Max. application rate kg as/ha a) Eugenol b) Geraniol c) Thymol	Water L/ha			Operator	Worker	Residents	Bystander	
1	Grape (BBCH 60-89)	F	Spraying, HCTM HCHH	a) 1 b) 4 (7 days)	a) 0.132 b) 0.264 c) 0.264	1000	7		#				

1	2	3	4	5	6	7	8	9	10
2	Pome Fruit (BBCH 75-87)	F	Spraying, HCTM HCHH	a) 1 b) 4 (7 days)	a) 0.132 b) 0.264 c) 0.264	1000	1	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	

* 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

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Reviewer comment: Regarding Vineyard use predicted levels of exposure for workers are all within the AOEL values of eugenol, geraniol and thymol where work wear (long sleeved) and gloves PPE are worn during crop re-entry activities.

Reviewer comment: Regarding operator exposure to the active substances during application of the product Mevalone, according to the critical use(s) is presented in part B0, considering this information it must be noted that 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.

#Reviewer comment: considering NDE assessment, for safe use of the product one need to use work wear but not protective. Additional measures like protective gloves and eye protection result from toxicity potential (hazard assessment).

Mevalone is classified as a skin sensitiser according to CLP (H317: May cause an allergic skin reaction) and as an eye irritant (H319 Causes serious eye irritation) therefore eye protection and protective gloves are required when handling the concentrated product.

Explanation for column 10 "Acceptability of exposure assessment"

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

Data gaps

No data gaps noted.

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

	Eugenol	Geraniol	Thymol
Common Name	Eugenol	Geraniol	Thymol
CAS-No.	97-53-0	106-24-1	89-83-8
Classification and proposed labelling *			
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Acute-Oral-Cat 4 Skin Irritation-Cat 2 Eye Irritation-Cat 2 Skin Sensitisation-Cat 1 Code(s) for hazard pictogram(s): GSH07 Signal word: Warning Hazard statement(s): H302 Harmful if swallowed H315 Causes skin irritation H319 Causes serious eye irritation H317 May cause an allergic skin reaction	Skin Irritation-Cat 2 Eye Irritation-Cat 2 Skin Sensitisation Cat 1 (Annex VI of CLP) Code(s) for hazard pictogram(s): GHS07 Signal word: Warning Hazard statement(s): H315 Causes skin irritation H317 May cause allergic skin reaction H319 Causes serious eye irritation EChA Harmonised classification CLP ATP 15: H317 May cause allergic skin reaction	Acute Oral Cat 4 (Annex VI of CLP) Skin Corrosion Cat 1B (Annex VI of CLP) Code(s) for hazard pictogram(s): GHS05, GHS07 Signal word: Danger Hazard statement(s): H302 Harmful if swallowed H314 Causes severe skin burns and eye damage
Additional C&L proposal	None According MSDS eugenol hazard identification is as follows: Eye Irritation Cat 2 Skin Sensitisation Cat 1 Code(s) for hazard pictogram(s): GSH07 Hazard statement(s): H319 Causes serious eye irritation H317 May cause an allergic skin reaction	None	None
Agreed EU endpoints			
AOEL systemic	1.0 mg/kg bw/d (no correction for oral absorption)	0.5 mg/kg bw/d (no correction for oral absorption)	0.4 mg/kg bw/d (no correction for oral absorption)
Reference	SANCO/10577/2013 EFSA Conclusion 2012 (EFSA Journal 2012;10(11):2914)	SANCO/10579/2013 EFSA Conclusion 2012 (EFSA Journal 2012;10(11):2915)	SANCO/10581/2013 EFSA Conclusion 2012 (EFSA Journal 2012;10(11):2916)
Conditions to take into account/critical areas of concern with regard to toxicology			
According to EFSA Conclusion for active substance	Protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate		

* The classification of active substances eugenol, geraniol and thymol will be reviewed during Renewal and a CLH report has been submitted within the AIR dossier submitted 28th February 2021 (RMS: Spain)

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for Mevalone is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Mevalone

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (OECD 423)	> 2000 mg/kg bw	Yes*	None	XXXXXX, 2007a
LD ₅₀ dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes*	None	XXXXXX, 2007b
LC ₅₀ inhalation, rat (OECD 403)	LC ₅₀ > 2.28 mg/L air (maximum achievable)	Yes*	None	XXXXXX, 2007
Skin irritation, rabbit (OECD 404)	Mild Irritant	Yes*	None	XXXXXX, 2007c
Eye irritation, rabbit (OECD 405)	Irritant	Yes*	H319 Eye Irrit. 2, H319	XXXXXX, 2007d
Skin sensitisation, mouse (OECD 429, LLNA)	Sensitising	Yes*	H317 Skin Sens. 1, H317	XXXXXX, 2007
Supplementary studies for combinations of plant protection products	No data – not required	--		

*zRMS note: Product was a representative formulation reviewed during the Annex I inclusion of active substance(s). All acute toxicity studies has been evaluated and accepted in the DAR's (Eugenol, Thymol, Geraniol Volume 3CP B6, 2011). For detailed information regarding current zonal registration and product per review refer Appendix 2.

Table 6.3-2: Additional toxicological information relevant for classification/labelling of Mevalone

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Eugenol (3.21% (w/w))	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317	Reg. 1272/2008	H317, H319 Eye Irrit. 2, H319 Skin Sens. 1, H317
	Geraniol (6.41% (w/w))	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317	Reg. 1272/2008	
	Thymol (6.41% (w/w))	Acute Tox. 4, H302 Skin Corr. 1B, H314	Reg. 1272/2008	
Toxicological properties of non-active substance(s) (relevant for classification of product)	None			
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

There are no metabolites of eugenol, geraniol or thymol listed in the EFSA Conclusions for the active substances. – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in Mevalone are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in Mevalone

	Eugenol		Geraniol		Thymol	
	Value	Reference	Value	Reference	Value	Reference
Concentrate	70%	EFSA Guidance 2017, 4873 default value for dilution as <5% w/w in concentrate	25%	EFSA Guidance 2017, 4873 default value for concentrate	25%	EFSA Guidance 2017, 4873 default value for concentrate
Dilution (1 : 250)	70%	EFSA Guidance 2017, 4873 default value for dilution	70%	EFSA Guidance 2017, 4873 default value for dilution	70%	EFSA Guidance 2017, 4873 default value for dilution

6.5.1 Justification for proposed values - Eugenol

No data on dermal absorption for eugenol in Mevalone is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for eugenol

	Value	Justification for value	Acceptability of justification
Concentrate	70%	Dermal absorption of Mevalone was initially evaluated as part of the EU review of eugenol, geraniol and thymol and the default dermal absorption value of 100% was assumed for both the concentrate and spray dilution. Since then the new EFSA guidance on dermal absorption has been published which indicates default values of 25% and 70% for concentrate and diluted product respectively for “other” type formulations. Supplementary guidance clarified the definition of a concentrate as “when the active substance is present in the plant protection product at a concentration higher than or equal to 50 g/L (or 50 g/kg or 5%).” As eugenol is present at less than 5% w/w this is treated as a “dilution”.	Justification accepted. Endpoint can be used for current product
Dilution	70%	The new EFSA guidance on dermal absorption has been published which indicates default values of 25% and 70% for concentrate and diluted product respectively for other type formulations.	Justification accepted. Endpoint can be used for current product

6.5.2 Justification for proposed values – Geraniol

No data on dermal absorption for geraniol in Mevalone is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) are presented in the following table.

Table 6.5-3: Default dermal absorption rates for geraniol

	Value	Justification for value	Acceptability of justification
Concentrate	25%	Dermal absorption of Mevalone was initially evaluated as part of the EU review of	Justification accepted. Endpoint can be used for current product

	Value	Justification for value	Acceptability of justification
		eugenol, geraniol and thymol and the default dermal absorption value of 100% was assumed for both the concentrate and spray dilution. Since then the new EFSA guidance on dermal absorption has been published which indicates default values of 25% and 70% for concentrate and diluted product respectively for “other” type formulations.	
Dilution	70%	The new EFSA guidance on dermal absorption has been published which indicates default values of 25% and 70% for concentrate and diluted product respectively for “other” type formulations.	Justification accepted. Endpoint can be used for current product

6.5.3 Justification for proposed values - Thymol

No data on dermal absorption for thymol in Mevalone is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) are presented in the following table.

Table 6.5-4: Default dermal absorption rates for thymol

	Value	Justification for value	Acceptability of justification
Concentrate	25%	Dermal absorption of Mevalone was initially evaluated as part of the EU review of eugenol, geraniol and thymol and the default dermal absorption value of 100% was assumed for both the concentrate and spray dilution. Since then the new EFSA guidance on dermal absorption has been published which indicates default values of 25% and 70% for concentrate and diluted product respectively for “other” type formulations.	Justification accepted. Endpoint can be used for current product
Dilution	70%	The new EFSA guidance on dermal absorption has been published which indicates default values of 25% and 70% for concentrate and diluted product respectively for “other type” formulations.	Justification accepted. Endpoint can be used for current product

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

The product Mevalone is a capsule suspension (CS) formulation containing 33 g/L eugenol, 66 g/L geraniol and 66 g/L thymol which is applied to grape and pome fruit as a fungicide.

Table 6.6-01: Product information and toxicological reference values used for exposure assessment

Product name and code	Mevalone		
Formulation type	CS		
Category	Fungicide		
Active substance(s) (incl. content)	Eugenol 33 g/L	Geraniol 66 g/L	Thymol 66 g/L

AOEL systemic	1 mg/kg bw/d ¹	0.5 mg/kg bw/d ²	0.4 mg/kg bw/d ³
AAOEL systemic	Not set (substance is not acutely toxic)	Not set (substance is not acutely toxic)	Not set (substance is not acutely toxic)
Inhalation absorption	100%	100%	100%
Oral absorption	100%	100%	100%
Dermal absorption	Concentrated: 70% Diluted: 70%	Concentrated: 25% Diluted: 70%	Concentrated: 25% Diluted: 70%

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product are shown in Table 6.1-4. A list of all intended uses within the zone is given in Part B, Section 0.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of the product Mevalone according to the critical use(s) is presented in Table 6.6.2-01.

Table 6.6.2-01: Exposure models for intended uses

Critical uses	Grape / Pome fruit Application rate: 4 L of product/ha (equivalent to 0.132 kg eugenol/ha, 0.264 kg geraniol/ha and 0.264 kg thymol/ha) Water volume: 1000 L/ha Grape BBCH 60-89 Pome fruit BBCH 75-87
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874
Grape Pome Fruit	Application equipment: Vehicle-mounted and Manual-knapsack sprayer Application method: Upward spraying (5 m buffer)

Operator exposure was assessed using EFSA guidance⁴. Exposure calculations are performed assuming that no personal protective equipment (PPE) is worn and also where PPE is used. The resulting exposure estimates for eugenol, geraniol and thymol are summarised below in Tables 6.6.2-02, 6.6.2-03 and 6.6.2-04. EFSA calculations detailing all considered input parameters are presented in Appendix 3.

Table 6.6.2-02: Estimated operator exposure to eugenol

Model Data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Vehicle mounted (upward spraying) application to grape or pome fruit Application rate: 0.132 kg a.s./ha			
Spray application (EFSA Calc; 75 th percentile)	None Potential exposure	0.3141	31.41

¹ EFSA Journal 2012;10(11):2914 – Conclusion on the peer review of the pesticide risk assessment of the active substance eugenol.

² Final Review report for the active substance geraniol finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 17 May 2013 in view of the approval of geraniol in accordance with Regulation (EC) No 1107/2009 (SANCO/10579/2013 rev 3).

³ Final Review report for the active substance thymol finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 17 May 2013 in view of the approval of thymol in accordance with Regulation (EC) No 1107/2009 (SANCO/10579/2013 rev 3).

⁴ EFSA (European Food Safety Authority) Guidance, 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp.

Model Data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and application.	0.1299	12.99
Hand-held knapsack (upward spraying) application to grape or pome fruit Application rate: 0.132 kg a.s./ha			
Spray application (EFSA Calc; 75 th percentile) Body weight: 60 kg	None Potential exposure	0.6499	64.99
	Work wear (arms, body and legs covered) M/L and application.	0.1306	13.06

Estimated exposure to eugenol for operators applying Mevalone to pome fruit or grape using vehicle mounted (upward) sprayers or a knapsack sprayer is within the AOEL when adequate work clothing is worn.

Table 6.6.2-03: Estimated operator exposure to geraniol

Model Data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Vehicle mounted (upward spraying) application to grape or pome fruit Application rate: 0.264 kg a.s./ha			
Spray application (EFSA Calc; 75 th percentile) Body weight: 60 kg	None Potential exposure	0.4513	90.27
	Work wear (arms, body and legs covered) M/L and application.	0.1543	30.86
Hand-held knapsack (upward spraying) application to grape or pome fruit (season not relevant) Application rate: 0.264 kg a.s./ha			
Spray application (EFSA Calc; 75 th percentile) Body weight: 60 kg	None Potential exposure	0.6375	127.50
	Work wear (arms, body and legs covered) M/L and application.	0.0642	12.84

Estimated exposure to geraniol for operators applying Mevalone to pome fruit or grape using vehicle mounted (upward) sprayers or a knapsack sprayer is within the AOEL when adequate work clothing is worn.

Table 6.6.2-04: Estimated operator exposure to thymol

Model Data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Vehicle mounted (upward spraying) application to grape or pome fruit Application rate: 0.264 kg a.s./ha			
Spray application (EFSA Calc; 75 th percentile) Body weight: 60 kg	None Potential exposure	0.4513	112.83
	Work wear (arms, body and legs covered) M/L and application.	0.1543	38.57
Hand-held knapsack (upward spraying) application to grape or pome fruit (season not relevant) Application rate: 0.264 kg a.s./ha			
Spray application (EFSA Calc; 75 th percentile) Body weight: 60 kg	None Potential exposure	0.6375	159.38
	Work wear (arms, body and legs covered) M/L and application.	0.0642	16.05

Estimated exposure to thymol for operators applying Mevalone to pome fruit or grape using vehicle mounted (upward) sprayers or a knapsack sprayer is within the AOEL when adequate work clothing is worn.

Conclusion

Predicted levels of exposure to eugenol, geraniol and thymol are within the respective AOEL values for operators applying Mevalone to pome fruit or grape using vehicle mounted sprayers when typical work clothing is worn. The estimated levels of exposure are also within acceptable limits when applying Mevalone to grape or pome fruit using a knapsack sprayer whilst wearing adequate work wear.

Mevalone is classified as a skin sensitiser according to CLP (H317: May cause an allergic skin reaction) and as an eye irritant (H319 Causes serious eye irritation) therefore eye protection and protective gloves are required when handling the concentrated product.

6.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the AOEL will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6.3.1-01 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Mevalone according to the critical uses. EFSA calculations detailing all considered input parameters are presented in Appendix 3.

Table 6.6.3.1-01: Exposure models for intended uses

Critical uses	Grape 1 x 4 L of product/ha (equivalent to 0.132 kg eugenol/ha, 0.264 kg geraniol/ha and 0.264 kg thymol/ha) Pome fruit 1 x 4 L of product/ha (equivalent to 0.132 kg eugenol/ha, 0.264 kg geraniol/ha and 0.264 kg thymol/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 Calculator version: 30/03/2015

In considering the volatility of the active substances eugenol, geraniol and thymol (2.7 Pa, 4.6 Pa and 3.4 Pa at 20°C respectively), the accumulation of surface residues between applications is not envisaged. The substances would rapidly dissipate during the 7-day interval between each of the 4 proposed applications. The rapid decline of eugenol, geraniol and thymol on leaf surfaces post application is supported by the results of a terpene release study (Kant, A, 2008, Report N°. RFM039) as detailed in the EU review report (DAR May 2011).

In the Kant (2008) study, terpene release under different environmental conditions was simulated in the laboratory using the diluted product Mevalone. A continuous wet system (an aqueous suspension representing formulation overspray onto the surface of a body of water), continuously dry conditions (an aqueous suspension applied to a piece of filter paper, suspended inside a sampling vessel and allowed to dry) and dry-wet-dry cycling (dried filter paper was re-wetted and dried several times to mimic wetting and drying cycles in the natural environment) were simulated. Terpene concentrations (eugenol, geraniol, and thymol) were measured in the headspace above the source at pre-determined time points under a constant flow of

air. The treated filter paper samples were also analysed by GC-MS to determine the terpenes mass remaining on the treated media.

At 72 hours (post treatment), the amount of eugenol, geraniol and thymol remaining on the (continuously) dry filter paper represented 40%, 19% and 21% of the initially applied material. The wet-dry-wet cycled paper was found to contain 19% of the originally applied eugenol whilst levels of geraniol and thymol were below the LOD. The findings of the Kant (2008) study support the position that there will be no accumulation of residues between each of the 4 proposed applications.

The following worker exposure assessments consider exposure to surface residues following a single application of the product Mevalone. The accumulation of residues following multiple (4) applications is not foreseen.

zRMS additional information reflecting cMS: it is demonstrated in dRR Part B Section 7 that there are no residues (below the LOQ or LOD) in grapes or pome fruit following application of Mevalone.

To assess worker re-entry activities in vineyards EFSA guidance provides two preliminary transfer coefficient (TC) values: 30,000 cm²/h for total potential exposure and 10,100 cm²/h for actual dermal exposure assuming that the arms, body and legs are covered by long sleeved work wear. Both of the EFSA values are based on unpublished US Agricultural Re-entry Task Force data, and do not allow for the assessment of protective gloves worn by re-entry workers.

Refined re-entry assessments have also been conducted using TC data generated by the ECPA Bystander, Resident, Orchard (BROV) re-entry project. The BROV project⁵ (comprising of the HSE, BVL, TNO, JKI, ECPA and EFSA) derived TC values reflecting European working practices in vines using concurrent re-entry worker exposure studies and DFR studies performed in the Czech Republic, Germany, France and Italy between 2004 and 2017. The BROV re-entry database includes five matched pairs of worker re-entry exposure and DFR studies presented in a total of eight study reports. In two of these studies (study pairs 2 & 3 and 4 & 5), field plots of DFR sampling were separate and in vicinity of the locations where worker exposure monitoring was performed but belonged to the same set-up of study. Worker activities in the vineyards comprised hand harvesting, pruning, training and shoot lifting. At each of the 16 field sites 4 to 6 experienced workers were monitored for a full working day (a total of 73 workers involved).

The BROV project derived a 75th percentile TC value of 660 cm²/hr for a worker wearing full length clothing and work gloves. The work gloves used in the study represent those typically used in the field (protective nitrile coating on palms of hands and fingers, with uncoated fabric on the back of gloves to allow breathability).

The results of the exposure assessments considering worker re-entry to orchards are contained in Tables 6.6.3.1-02, 6.6.3.1-03 and 6.6.3.1-04. The estimations of worker exposure to eugenol, geraniol and thymol when re-entering treated vineyards are summarised below in Tables 6.6.3.1-05, 6.6.3.1-06 and 6.6.3.1-07.

Table 6.6.3.1-02: Estimated worker exposure to eugenol when re-entering treated pome fruit crops

Model Data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Application to pome fruit Activity - Search/reach/pick Application rate: 1 x 0.264 0.132 kg a.s./ha			
Body weight: 60 kg Work rate: 8 hrs/day	None (Potential) TC: 22500 cm ² /person/h	0.8316	83.16
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.1663	16.63

⁵ <https://www.ecpa.eu/media/news/bystander-resident-orchard-vineyard-brov-re-entry-project-report>

	Work wear (arms, body and legs covered) and gloves (PPE) TC: 2250 cm ² /person/h	0.0832	8.32
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Table 6.6.3.1-03: Estimated worker exposure to geraniol when re-entering treated pome fruit crops

Model Data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Application to pome fruit Activity - Search/reach/pick Application rate: 1 x 0.264 kg a.s./ha			
Body weight: 60 kg Work rate: 8 hrs/day	None (Potential) TC: 22500 cm ² /person/h	1.6632	332.64
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.3326	66.53
	Work wear (arms, body and legs covered) and gloves (PPE) TC: 2250 cm ² /person/h	0.1663	33.26

Table 6.6.3.1-04: Estimated worker exposure to thymol when re-entering treated pome fruit crops

Model Data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Application to pome fruit Activity - Search/reach/pick Application rate: 1 x 0.264 kg a.s./ha			
Body weight: 60 kg Work rate: 8 hrs/day	None (Potential) TC: 22500 cm ² /person/h	1.6632	415.80
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.3326	83.16
	Work wear (arms, body and legs covered) and gloves (PPE) TC: 2250 cm ² /person/h	0.1663	41.58

Pome fruit use overall conclusion

Predicted levels of exposure for workers are all within the AOEL values of eugenol, geraniol and thymol where work wear (long sleeved) and gloves PPE are worn during crop re-entry activities.

Table 6.6.3.1-05: Estimated worker exposure to eugenol when re-entering treated vineyards

Model Data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Application to grape Activity - Hand harvesting/leaf pulling/tying Application rate: 1 x 0.132 kg a.s./ha			
Body weight: 60 kg Work rate: 8 hrs/day	None (Potential) TC: 30000 cm ² /person/h	1.1088	110.88
	Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h	0.3733	37.33
	Work wear (arms, body and legs covered) and gloves (PPE) TC: 660 cm ² /person/h	0.0244	2.44

Table 6.6.3.1-06: Estimated worker exposure to geraniol when re-entering treated vineyards

Model Data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Application to grape Activity - Hand harvesting/leaf pulling/tying Application rate: 1 x 0.264 kg a.s./ha			
Body weight: 60 kg Work rate: 8 hrs/day	None (Potential) TC: 30000 cm ² /person/h	2.2176	443.52
	Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h	0.7466	149.32
	Work wear (arms, body and legs covered) and gloves (PPE) TC: 660 cm ² /person/h	0.0488	9.76

Table 6.6.3.1-07: Estimated worker exposure to thymol when re-entering treated vineyards

Model Data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Application to grape Activity - Hand harvesting/leaf pulling/tying Application rate: 1 x 0.264 kg a.s./ha			
Body weight: 60 kg Work rate: 8 hrs/day	None (Potential) TC: 30000 cm ² /person/h	2.2176	554.40
	Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h	0.7466	186.65
	Work wear (arms, body and legs covered) and gloves (PPE) TC: 660 cm ² /person/h	0.0488	12.20

Vineyard use overall conclusion

Predicted levels of exposure for workers are all within the AOEL values of eugenol, geraniol and thymol where work wear (long sleeved) and gloves PPE are worn during crop re-entry activities.

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Refinement of the generic DFR value is not required and has not been undertaken.

6.6.3.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the AOEL will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

Resident exposure to eugenol, geraniol and thymol was assessed using the EFSA Calculator. The Calculator estimates exposure for four exposure pathways; drift, vapour, deposits and re-entry (75th percentile). The sum (mean) of all pathways is also calculated.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure. There is no evidence that the active substances in Mevalone could cause significant toxicity following a single exposure; estimations of bystander exposure are therefore not required.

As stated in Section 6.6.3.1, the accumulation of surface residues between applications is not envisaged. The active substances eugenol, geraniol and thymol would dissipate during the 7-day interval between each of the 4 proposed applications. The following resident exposure estimates consider exposure to foliar residues following a single application of the product Mevalone.

The estimations of resident exposure to eugenol, geraniol and thymol are summarised below in Tables 6.6.4.1-01, 6.6.4.1-02 and 6.6.4.1-03. Hereafter are presented only outcomes for Pome fruit since this use represents a worst-case exposure in comparison to the Grapes one. EFSA calculations for both Pome fruit and Grapes detailing all considered input parameters are presented in Appendix 3.

Table 6.6.4.1-01: Exposure models for intended uses

Critical use	Pome fruit and grapes 1 x 4 L of product/ha (equivalent to 0.132 kg eugenol/ha, 0.264 kg geraniol/ha and 0.264 kg thymol/ha) Water volume: 1000 L/ha BBCH 75-89
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 Calculator version: 30/03/2015 Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032 Calculator version: v 0.3.22

Table 6.6.4.1-02: Estimated resident exposure to eugenol

Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
EFSA 2014 Vehicle mounted (upward spraying) application to pome fruit 1 x 0.132 kg a.s./ha			
Resident child Body weight: 10 kg	Spray drift (75 th percentile)	0.0128	Resident child Body weight: 10 kg
	Vapour (75 th percentile)	0.0161	1.61
	Surface deposits (75 th percentile)	0.0041	0.41
	Re-entry (75 th percentile)	0.0156	1.56
	Sum (mean)	0.0379	3.99
Resident adult Body weight: 60 kg	Spray drift (75 th percentile)	0.0071	Resident adult Body weight: 60 kg
	Vapour (75 th percentile)	0.0035	0.35
	Surface deposits (75 th percentile)	0.0018	0.18
	Re-entry (75 th percentile)	0.0087	0.87
	Sum (mean)	0.0154	1.63
EFSA 2022 (SVC approach) Vehicle mounted (upward spraying) application to pome fruit 1 x 0.132 kg a.s./ha			
Resident child Body weight: 10 kg	Spray drift (75 th percentile)	0.01	Resident child Body weight: 10 kg
	Vapour (75 th percentile)	0.01	1.61
	Surface deposits (75 th percentile)	0.004	0.08
	Re-entry (75 th percentile)	0.02	1.56
	Sum (mean)	0.04	3.75
Resident adult Body weight: 60 kg	Spray drift (75 th percentile)	0.007	Resident adult Body weight: 60 kg
	Vapour (75 th percentile)	0.004	0.35

	Surface deposits (75 th percentile)	0.002	0.03
	Re-entry (75 th percentile)	0.009	0.87
	Sum (mean)	0.01	1.53

Table 6.6.4.1-03: Estimated resident exposure to geraniol

Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
EFSA 2014			
Vehicle mounted (upward spraying) application to pome fruit 1 x 0.264 kg a.s./ha			
Resident child Body weight: 10kg	Spray drift (75 th percentile)	0.0256	Resident child Body weight: 10kg
	Vapour (75 th percentile)	0.0161	3.21
	Surface deposits (75 th percentile)	0.0082	1.64
	Re-entry (75 th percentile)	0.0312	6.24
	Sum (mean)	0.0597	12.77
Resident adult Body weight: 60 kg	Spray drift (75 th percentile)	0.0142	Resident adult Body weight: 60 kg
	Vapour (75 th percentile)	0.0035	0.69
	Surface deposits (75 th percentile)	0.0036	0.71
	Re-entry (75 th percentile)	0.0173	3.47
	Sum (mean)	0.0274	5.84
EFSA 2022 (SVC approach)			
Vehicle mounted (upward spraying) application to pome fruit 1 x 0.264 kg a.s./ha			
Resident child Body weight: 10kg	Spray drift (75 th percentile)	0.03	Resident child Body weight: 10kg
	Vapour (75 th percentile)	0.01	3.21
	Surface deposits (75 th percentile)	0.008	0.32
	Re-entry (75 th percentile)	0.03	6.24
	Sum (mean)	0.06	11.79
Resident adult Body weight: 60 kg	Spray drift (75 th percentile)	0.01	Resident adult Body weight: 60 kg
	Vapour (75 th percentile)	0.004	0.69
	Surface deposits (75 th percentile)	0.004	0.14
	Re-entry (75 th percentile)	0.02	3.47
	Sum (mean)	0.03	5.42

Table 6.6.4.1-04: Estimated resident exposure to thymol

Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
EFSA 2014			
Vehicle mounted (upward spraying) application to pome fruit 1 x 0.264 kg a.s./ha			
Resident child Body weight: 10kg	Spray drift (75 th percentile)	0.0256	Resident child Body weight: 10kg
	Vapour (75 th percentile)	0.0161	4.01
	Surface deposits (75 th percentile)	0.0082	2.05
	Re-entry (75 th percentile)	0.0312	7.80
	Sum (mean)	0.0597	15.96
Resident adult Body weight: 60 kg	Spray drift (75 th percentile)	0.0142	Resident adult Body weight: 60 kg
	Vapour (75 th percentile)	0.0035	0.86
	Surface deposits (75 th percentile)	0.0036	0.89
	Re-entry (75 th percentile)	0.0173	4.33
	Sum (mean)	0.0274	7.30
EFSA 2022 (SVC approach)			
Vehicle mounted (upward spraying) application to pome fruit 1 x 0.264 kg a.s./ha			
Resident child Body weight: 10kg	Spray drift (75 th percentile)	0.03	Resident child Body weight: 10kg
	Vapour (75 th percentile)	0.01	4.01
	Surface deposits (75 th percentile)	0.008	0.40
	Re-entry (75 th percentile)	0.03	7.80
	Sum (mean)	0.06	14.74

Resident adult Body weight: 60 kg	Spray drift (75 th percentile)	0.01	Resident adult Body weight: 60 kg
	Vapour (75 th percentile)	0.004	0.86
	Surface deposits (75 th percentile)	0.004	0.17
	Re-entry (75 th percentile)	0.02	4.33
	Sum (mean)	0.03	6.77

Model Data	Level of PPE	Eugenol exposure as % of AOEL	Geraniol exposure as % of AOEL	Thymol exposure as % of AOEL	Cumulative exposure
Vehicle mounted (upward spraying) application to grape or pome fruit Application rate: 0.264 kg a.s./ha					
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and application.	12.99	30.86	38.57	82.42
Hand-held knapsack (upward spraying) application to grape or pome fruit (season not relevant) Application rate: 0.264 kg a.s./ha					
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and application.	13.06	12.84	16.05	41.95

Conclusion

Predicted levels of exposure for residents are all less than the AOEL values for eugenol, geraniol and thymol. It is concluded that there is no undue risk to any bystander or resident during and/or following the local application of Mevalone

6.6.4.2 Measurement of resident and/or bystander exposure

Since the resident and/or bystander exposure estimations carried out indicated that the AOEL for eugenol, geraniol and/or thymol will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

6.6.5 Combined exposure

6.6.5.1 Exposure assessment of eugenol, geraniol and thymol in the product Mevalone

Table 6.6.5.1-01: Combined operator exposure to eugenol, geraniol and thymol

Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

Conclusion

The predicted combined exposure (to eugenol, geraniol and thymol) for operators applying Mevalone to pome fruit or grape using vehicle mounted sprayers is below 100 and therefore within acceptable limits when typical work clothing is worn. The combined exposure is also within acceptable limits when applying Mevalone to grape or pome fruit using a knapsack sprayer whilst wearing adequate work wear.

Table 6.6.5.1-02: Combined worker exposure to eugenol, geraniol and thymol when re-entering treated vineyards

Model Data	Level of PPE	Eugenol exposure as % of AOEL	Geraniol exposure as % of AOEL	Thymol exposure as % of AOEL	Cumulative exposure
Application to grape Activity - Hand harvesting/leaf pulling/tying Application rate: 1 x 4 L product/ha					
Body weight: 60 kg Work rate: 8 hrs/day	None (Potential) TC: 30000 cm ² /person/h	110.88	443.52	554.40	1108.80
	Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h	37.33	149.32	186.65	373.30
	Work wear (arms, body and legs covered) and gloves (PPE) TC: 660 cm ² /person/h	2.44	9.76 0	12.2	24.40

Table 6.6.5.1-03: Combined worker exposure to eugenol, geraniol and thymol when re-entering treated pome fruit crops

Model Data	Level of PPE	Eugenol exposure as % of AOEL	Geraniol exposure as % of AOEL	Thymol exposure as % of AOEL	Cumulative exposure
Application to pome fruit Activity - Search/reach/pick Application rate: 1 x 4 L product/ha					
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	16.63	66.53	83.16	166.32
	Work wear (arms, body and legs covered) and gloves (PPE) TC: 2250 cm ² /person/h	8.32	33.26	41.58	83.16

Conclusion

The predicted combined exposure (to eugenol, geraniol and thymol) is below 100 and therefore within acceptable limits, where work wear (long sleeved) and gloves PPE are worn during crop re-entry activities (for either vineyard or pome fruit uses).

Table 6.6.5.1-04: Combined resident exposure to eugenol, geraniol and thymol

Model data		Eugenol exposure as % of AOEL	Geraniol exposure as % of AOEL	Thymol exposure as % of AOEL	Cumulative exposure
EFSA 2014 Vehicle mounted (upward spraying) application to pome fruit 1 x 4 L product/ha					
Resident child Body weight: 10kg	Spray drift (75 th percentile)	1.28	5.13	6.41	12.82
	Vapour (75 th percentile)	1.61	3.21	4.01	8.83
	Surface deposits (75 th percentile)	0.41	1.64	2.05	4.1
	Re-entry (75 th percentile)	1.56	6.24	7.80	15.6
	Sum (mean)	3.99	12.77	15.96	32.72
Resident adult Body weight: 60 kg	Spray drift (75 th percentile)	0.71	2.85	3.56	7.12
	Vapour (75 th percentile)	0.35	0.69	0.86	1.9
	Surface deposits (75 th percentile)	0.18	0.71	0.89	1.78
	Re-entry (75 th percentile)	0.87	3.47	4.33	8.67
	Sum (mean)	1.63	5.84	7.30	14.77
EFSA 2022 (SVC approach) Vehicle mounted (upward spraying) application to pome fruit 1 x 4 L product/ha					

Resident child Body weight: 10kg	Spray drift (75 th percentile)	1.3	5.1	6.4	12.8
	Vapour (75 th percentile)	1.2	2.4	3	6.6
	Surface deposits (75 th percentile)	0.4	1.6	2	4.0
	Re-entry (75 th percentile)	1.6	6.2	7.8	15.6
	Sum (mean)	3.6	12	14.9	30.5
Resident adult Body weight: 60 kg	Spray drift (75 th percentile)	0.7	2.8	3.6	7.1
	Vapour (75 th percentile)	0.4	0.8	1	2.2
	Surface deposits (75 th percentile)	0.2	0.7	0.9	1.8
	Re-entry (75 th percentile)	0.9	3.5	4.3	8.7
	Sum (mean)	1.7	6	7.4	15.1

Conclusion

The predicted combined exposure (to eugenol, geraniol and thymol) for residents is below 100 and therefore within acceptable limits.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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

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

These studies have been submitted within the first approval dossier of active substances (RMS: UK) and/or for registration of product in SEU (see part B0 for Regulatory history of active substances and product).

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 7.1.1/01	XXXXXX	2007a	Acute oral toxicity study of product 3AEY in rats Jai Research Foundation Eden Research plc Report No.: 6733 GLP, Unpublished	Y	Eden Research plc
KCP 7.1.2/01	XXXXXX	2007b	Acute dermal toxicity study of product 3AEY in rats Jai Research Foundation Eden Research plc Report No.: 6734 GLP, Unpublished	Y	Eden Research plc
KCP 7.1.3/01	XXXXXX	2007	Acute inhalation toxicity study of product 3AEY in rats Jai Research Foundation Eden Research plc Report No.: 6735 GLP, Unpublished	Y	Eden Research plc

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 7.1.4/01	XXXXXX	2007c	Acute dermal irritation study of product 3AEY in rats Jai Research Foundation Eden Research plc Report No.: 6736 GLP, Unpublished	Y	Eden Research plc
KCP 7.1.5/01	XXXXXX	2007d	Acute eye irritation study of product 3AEY in rats Jai Research Foundation Eden Research plc Report No.: 6737 GLP, Unpublished	Y	Eden Research plc
KCP 7.1.6/01	XXXXXX	2007	3AEY: Local lymph node assay in the mouse Safepharm Laboratories Limited Eden Research plc Report No.: 2408/0001 GLP, Unpublished	Y	Eden Research plc

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

The studies described were conducted on 3AEY, which is an alternative name for Mevalone, therefore no bridging statement is necessary.

Comments of zRMS:	Statement is acceptable.
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These studies have been submitted within the first approval dossier of active substances (RMS: UK) and/or for registration of product in SEU (see part B0 for Regulatory history of active substances and product).

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	<p>Study (XXXX 2007a) has been reviewed and accepted during first approval of active substances (Pesticides Peer Review Meeting PPR 90 (16 – 20 April 2012). Now study has been checked only for compliance with the current guidelines, resulting from scientific progress. Study TG implements 3R rules minimizing the number of animals required to estimate the acute oral toxicity of a chemical. Method uses pre-defined doses and the results allow a substance to be ranked and classified according to the CLP for the classification of chemicals which cause acute toxicity</p> <p>Study outcome and conclusions are still valid and adequate for risk assessment and classification purpose.</p> <p>Note: Study details (see below) marked in grey was not highlighted by the zRMS. This is due to the auto-complete template used by the applicant.</p>
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Reference	KCP 7.1.1/01
Report	Acute oral toxicity study of product 3AEY in rats, XXXXX, 2007a, report No 6733
Guideline(s)	OECD 423
Deviations	No
GLP	Yes
Acceptability	Yes, evaluated and accepted in the DAR (Eugenol, Volume 3, Annex B6, 2013); B.6.11.1 (IIIA 7.1.1)
Duplication (if vertebrate study)	No

Executive summary

Mevalone (3AEY) was administered orally via gavage at a dose of 300 mg/kg bw and 2000 mg/kg bw to fasted Wistar rats. Two groups of 3 female rats were treated in a stepwise manner at each dose level. Animals were observed at frequent intervals from 30 minutes up six hours after dosing on Day 1 and subsequently twice daily for the remainder of the 14-day observation period.

No mortality was observed at either dose level. Rats treated at both levels showed lethargy in the hours after dosing with abdominal breathing also observed in the 2000 mg/kg bw dose group from 1 hour post dosing. No signs were observed from 24 hours onwards at either dose level.

The acute oral LD₅₀ was > 2000 mg/kg bw (females). Classification according to Regulation (EC) No 1272/2008 is not required.

Materials and methods

Test material

Name:	Product 3AEY
Description:	Light brown opaque liquid
Lot/batch no.:	YPOA3Y424-1.1 (1206)
Purity:	Eugenol (3.23%), Geraniol (6.56%), Thymol (6.47%)
Stability of test compound:	Assumed stable for duration of study
Vehicle:	Distilled water

Test animals

Species/strain:	Rat (<i>Rattus norvegicus</i>), Wistar
Source:	Rajbiotech (India) Pvt. Ltd - Pune
Age at dosing:	9 - 11 weeks
Weight:	158 - 184 g females
Acclimation period:	At least 5 days
Diet:	Nutrilab Rodent Feed, Tetragon Chemic Pvt. Ltd. Bangalore <i>ad libitum</i>
Water:	Filtered tap water <i>ad libitum</i>
Housing:	3 rats in polypropylene cages with stainless steel grid top and clean rice husk bedding

Environmental conditions

Temperature:	20 - 23 °C
Humidity:	65 - 67%
Air changes:	15/hour
Photoperiod:	12 hours light/dark

Study design and methods

In-life dates:	09 July – 09 Aug 2007
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Animal assignment and treatment

Groups of 3 female Wistar rats received single doses of 3AEY in a stepwise manner. 3AEY was administered at doses of 300 and 2000 mg/kg bw as a solution in distilled water. The doses were administered orally via gavage at a dose volume of 10 mL/kg. Rats were fasted overnight prior to dosing (food was returned approximately three hours after dosing). Two groups of 3 female rats were treated at each dose level. Animals were observed at frequent intervals from 30 minutes up six hours after dosing on Day 1 and subsequently twice daily for the remainder of the 14 day observation period. Animals were weighed on Days 0, 7 and 14 after dosing. At Day 14 animals were all subject to gross necropsy.

Results and discussions

Mortality

No mortality was observed at either dose level (Table 7.1.1-01).

Table 7.1.1-01 Mortality in the rat

Dose level (mg/kg bw)	Mortality / animals treated
300 Group I	0/3
300 Group II	0/3
2000 Group III	0/3
2000 Group IV	0/3

Clinical observations

Rats treated at 300 mg/kg bw showed lethargy from 30 minutes to 2 hours after dosing.

Rats treated at 2000 mg/kg bw showed lethargy in the hours after dosing and abdominal breathing from 1 hour post dosing. Neither of these signs were observed from 24 hours and onwards at either dose level.

Body weight

All rats dosed at 300 mg/kg bw showed normal body weight gain but there was a slight reduction in body weight gain at the 2000 mg/kg bw treatment level.

Necropsy findings

Terminal necropsy revealed no treatment-related changes. Distended uterus was observed in two rats. These lesions were mild and are physiological/cyclic in nature so were considered as spontaneous findings and not considered to be treatment related.

Conclusion

The acute oral LD₅₀ was > 2000 mg/kg bw (females).

Classification of 3AEY is not required according to CLP Regulation (EC) No 1272/2008.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	<p>Study (XXXXX 2007b) has been reviewed and accepted during first approval of active substances (Pesticides Peer Review Meeting PPR 90 (16 – 20 April 2012). Now study has been checked only for compliance with the current guide-lines, resulting from scientific progress. In the study tested material has not been administered at doses which cause pain and distress due to potential corrosive or severely irritant actions.</p> <p>Study outcome and conclusions are still valid and adequate for risk assessment also for classification purpose.</p> <p>Note: Study details (see below) marked in grey was not highlighted by the zRMS. This is due to the auto-complete template used by the applicant.</p>
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Reference	KCP 7.1.2/01
Report	Acute dermal toxicity study of product 3AEY in rats, XXXXX, 2007b, report No 6734
Guideline(s)	OECD 402
Deviations	No. OECD 402 was updated in 2017 to include a stepwise approach and improvements to animal welfare, however the basic principles of the limit test remain the same and there are no major deviations in this respect
GLP	Yes
Acceptability	Yes. Evaluated and accepted in the DAR (Eugenol, Volume 3, Annex B6, 2013); B.6.11.2 (IIIA 7.1.2)
Duplication (if vertebrate study)	No

Executive summary

Groups of 5 Wistar rats for each sex were treated with a single dermal dose of 2000 mg/kg bw of Mevalone (3AEY). 3AEY was applied undiluted to clipped skin under a gauze dressing and tape for 24 hours. Clinical observations and dermal reactions were recorded for 14 days after dosing and body weights were recorded on Days 0, 7 and 14. A gross pathological examination was performed on Day 14.

No mortalities and no clinical signs of reaction were observed during the study in either the control or at the 2000 mg/kg bw treatment level. There were no indications of any adverse irritant effects. There were no effects on body weight gain. The acute dermal LD₅₀ for males and female rats was > 2000 mg/kg bw. Classification of 3AEY is not required according to CLP Regulation (EC) No 1272/2008.

Materials and methods

Test material

Name:	Product 3AEY
Description:	Light brown opaque liquid
Lot/batch no.:	YPOA3Y424-1.1 (1206)
Purity:	Eugenol (3.23%), Geraniol (6.56%), Thymol (6.47%)
Stability of test compound:	Assumed stable for duration of study.
Vehicle:	None

Test animals

Species/strain:	Rat (<i>Rattus norvegicus</i>), Wistar
Source:	Rajbiotech (India) Pvt. Ltd - Pune
Age at dosing:	10 - 11 weeks
Weight:	277 - 299 g males, 207 - 228 g females
Acclimation period:	6 days
Diet:	Nutrilab Rodent Feed, Tetragon Chemic Pvt. Ltd. Bangalore <i>ad libitum</i>
Water:	Filtered tap water <i>ad libitum</i>
Housing:	Individually in polypropylene cages with stainless steel grid top and clean rice husk bedding

Environmental conditions

Temperature:	20 - 23 °C
Humidity:	64 - 66%
Air changes:	15/hour
Photoperiod:	12 hours light/dark

Study design and methods

In-life dates:	19 July – 08 August 2007
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Animal assignment and treatment

Groups of 5 Wistar rats for each sex were treated with a single dermal dose of 2000 mg/kg bw of undiluted 3AEY. 3AEY was applied undiluted to clipped skin under a gauze dressing and tape for 24 hours. Following the treatment period residual test material was removed using cotton soaked in distilled water. A similar group of 5 rats per sex were treated with distilled water to act as a control group. Animals were observed at frequent intervals from 1 hour up to six hours after dosing on Day 1 and subsequently twice daily for the remainder of the 14-day observation period. Animals were weighed on Days 0, 7 and 14 after dosing. At Day 14, animals were all subject to gross necropsy.

Results and discussion

Mortality and clinical observations

No mortalities and no clinical signs of reaction were observed during the study in either the control or at the 2000 mg/kg bw treatment level (Table 7.1.2-01). There were no indications of any adverse irritant effects.

Table 7.1.2-01 Mortality in the rat

Dose level (mg/kg bw)	Mortality/Animals treated		
	Males	Females	Combined
0	0/5	0/5	0/10
2000	0/5	0/5	0/10

Body weight

All rats showed normal body weight gains.

Necropsy findings

No treatment related macroscopic abnormalities were detected at necropsy.

Conclusion

The acute dermal LD₅₀ for males and female rats was > 2000 mg/kg bw.

Classification of 3AEY is not required according to CLP Regulation (EC) No 1272/2008.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	Study (XXXXX 2007) has been reviewed and accepted during first approval of active substances (Pesticides Peer Review Meeting PPR 90 (16 – 20 April 2012). Currently study has been checked only for compliance with the current guide-lines, resulting from scientific progress. In the following study animals are exposed to one limit concentration for a predetermined duration (4 hours) and obtain sufficient information on the acute toxicity of test article to enable its classification and to provide lethality data (LC ₅₀) for both sexes as needed for quantitative risk assessments. Study outcome and conclusions are still valid and adequate for risk assessment also for classification purpose. Note: Study details (see below) marked in grey was not highlighted by the zRMS. This is due to the auto-complete template used by the applicant.
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Reference	KCP 7.1.3/01
Report	Acute inhalation toxicity study of product 3AEY in rats, XXXXX, 2007, report No 6735
Guideline(s)	OECD 403
Deviations	No
GLP	Yes
Acceptability	Yes. Evaluated and accepted in the DAR (Eugenol, Volume 3, Annex B6, 2013); B.6.11.3 (IIIA 7.1.3)
Duplication (if vertebrate study)	No

Executive summary

Groups of 5 male and 5 female Wistar rats were exposed, head/nose only, for four hours to Mevalone (3AEY) mixed with water. The control group received water only. The maximum achievable breathing zone concentration was 2.280 mg/L. Animals were observed for 14 days after exposure.

There were no mortalities. Animals treated with the test substance showed signs of nasal irritation and discharge at the end of the exposure period, but these had disappeared by the following day. Under the conditions of the study, the 4-hour acute inhalation LC₅₀ is > 2.280 mg/L in rats. This represents the maximum practical concentration that could be attained, and therefore classification according to Regulation (EC) No 1272/2008 is not required.

Materials and methods

Test material

Name:	Product 3AEY
Description:	Light brown opaque liquid
Lot/batch no.:	YPOA3Y424-1.1 (1206)
Purity:	Eugenol (3.23%), Geraniol (6.56%), Thymol (6.47%)

Stability of test compound: Assumed stable for duration of study.
Vehicle: Distilled water

Test animals

Species/strain: Rat (*Rattus norvegicus*), Wistar
Source: Animal Breeding Facility, Jai Research Foundation, India
Age at dosing: 9 - 10 weeks
Weight: 233 - 251 g males, 176 - 190 g females
Acclimation period: 6 or 7 days
Diet: Nutrilab Rodent Feed, Tetragon Chemic Pvt. Ltd. Bangalore *ad libitum*, except during the exposure period
Water: Filtered tap water *ad libitum*, except during the exposure period
Housing: 5 rats in polypropylene cages with stainless steel grid top and clean rice husk bedding

Environmental conditions

Temperature: 19 - 23 °C
Humidity: 64 - 66%
Air changes: 15/hour
Photoperiod: 12 hours light/dark

Study design and methods

In-life dates: 17 August – 07 September 2007

Animal assignment and treatment

Groups of 5 male and 5 female Wistar rats were exposed, head/nose only, for four hours to the test material. The product was a viscous liquid so was mixed with distilled water in order to form an aerosol when infused into a spray atomiser. The study consisted of a test group exposed to an aerosol of the test substance and a group exposed to an aerosol of distilled water. The exposure period was 4 hours, following a 30 minute equilibration period.

Animals were observed at hourly intervals during the exposure period, after exposure, and twice daily for the following 14 days for mortality and clinical signs of toxicity. Body weights were recorded on Day 0, 7 and 14. After 14 days, the animals were sacrificed and subject to a gross pathological examination.

Generation of the test atmosphere

Inhalation chambers consisted of inlet, exposure and outlet chambers, with an overall capacity of 63.5 litres. The inlet unit was a glass cylinder with a connection for a spray atomiser. The exposure chamber was constructed in stainless steel with port holes to allow connection of individual perspex rat exposure tubes. The outlet chamber was connected to a suction pump. The test solution was drawn into an infusion syringe and loaded into an infusion syringe pump which fed into a spray atomiser to generate the required test atmosphere. The test atmosphere was measured by gravimetric analysis each hour. Samples were also taken to determine particle size distribution using a seven stage cascade impactor. Atmosphere concentrations and particle size were measured on four occasions throughout the 4 hour exposure period. The environmental conditions in the chamber were monitored during each exposure.

Results and discussions

Chamber conditions

The mean concentration of product 3AEY was 2.280 mg/L (std dev \pm 0.085), with a mass median aerodynamic diameter (MMAD) of 2.94 μ m with a geometric standard deviation of 2.77. Over the four analyses (one per hour of exposure) the concentration remained very stable (range 2.169 – 2.362 mg/L). The test atmosphere was considered to be the maximum achievable breathing zone concentration (the proportion of respirable aerosols is acceptable).

Mortality and clinical observations

No mortalities were observed during the study in either the control or following treatment with the test substance (Table 7.1.3-01). Animals treated with the test substance showed signs of nasal irritation and discharge at the end of the exposure period, but these had disappeared by the following day.

Table 7.1.3-01 Mortality in the rat

Nominal Concentration of product (mg/L)	Mean measured Concentration in the inhalation chamber (mg/L)	Mortality/Animals treated		
		Males	Females	Combined
0	0	0/5	0/5	0/10
22.222	2.280	0/5	0/5	0/10

Body weight

All rats showed normal body weight gains.

Necropsy findings

No treatment related macroscopic abnormalities were detected at necropsy. Distended uterus was observed in two rats however, since this was found in both control and exposed rats it was not considered to be treatment related.

Conclusion

Under the conditions of the study, the 4-hour acute inhalation LC₅₀ is > 2.280 mg/L in rats. This represents the maximum achievable breathable concentration that could be attained.

Classification of 3AEY is not required according to CLP Regulation (EC) No 1272/2008.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	<p>Study (XXXXXX 2007c) has been reviewed and accepted during first approval of active substances (Pesticides Peer Review Meeting PPR 90 (16 – 20 April 2012). Now study has been checked only for compliance with the current guide-lines, resulting from scientific progress.</p> <p>Test product was applied in a single dose to the skin of an experimental animal; untreated skin areas of the test animal serve as the control. The degree of irritation/corrosion was read and scored at specified intervals in order to provide a complete evaluation of the effects. The duration of the study was sufficient to evaluate the reversibility or irreversibility of the effects observed.</p> <p>Study outcome and conclusions are still valid and adequate for risk assessment also for classification purpose.</p> <p>Note: Study details (see below) marked in grey was not highlighted by the zRMS. This is due to the auto-complete template used by the applicant.</p>
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Reference	KCP 7.1.4/01
Report	Acute dermal irritation study of product 3AEY in rabbits, XXXXXX, 2007c, report No 6736
Guideline(s)	OECD 404
Deviations	No
GLP	Yes
Acceptability	Yes. Evaluated and accepted in the DAR (Eugenol, Volume 3, Annex B6, 2013); B.6.11.4 (IIIA 7.1.4)
Duplication (if vertebrate study)	No

Executive summary

The skin irritation potential of Mevalone (3AEY) was evaluated in 3 male New Zealand White rabbits. One rabbit was initially treated and based on observations up to 24 hours two further rabbits were subsequently treated. A single dose of test material (0.5 mL) was applied to clipped skin for 4 hours and then removed using cotton soaked in distilled water. Skin reactions were observed at 1, 24, 48, 72 hours and 7 days after patch removal (Draize scale). No toxic signs other than dermal irritation were observed in any rabbit throughout the experimental period. Mean scores for erythema (24 – 72 hours) were 1.33 and 0 for oedema for each animal. Under the conditions of the study, 3AEY is not irritating to skin and classification according to Regulation (EC) No 1272/2008 is not required.

Materials and methods

Test material

Name:	Product 3AEY
Description:	Light brown opaque liquid
Lot/batch no.:	YPOA3Y424-1.1 (1206)
Purity:	Eugenol (3.23%), Geraniol (6.56%), Thymol (6.47%)
Stability of test compound:	Assumed stable for duration of study.
Vehicle:	None

Test animals

Species/strain:	Rabbit (<i>Oryctolagus cuniculus</i>), New Zealand White
Source:	Animal Breeding Facility, Jai Research Foundation, India
Age at dosing:	17 - 18 weeks
Weight:	2.208 - 2.610 kg males
Acclimation period:	6 or 8 days
Diet:	Rabbit pellet feed (Amrut brand) <i>ad libitum</i>
Water:	Filtered and UV sterilised tap water <i>ad libitum</i>
Housing:	Individually in stainless steel wire meshed rabbit cages

Environmental conditions

Temperature:	20 - 23 °C
Humidity:	65 - 66%
Air changes:	15/hour
Photoperiod:	12 hours light/dark

Study design and methods

In-life dates:	31 July –15 August 2007
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Animal assignment and treatment

Three male New Zealand White rabbits were treated with a single dose of 0.5 mL of undiluted 3AEY. One rabbit was initially treated and based on the observations at 24 hours two further rabbits were subsequently treated. The test material (0.5 mL) was applied to clipped skin for 4 hours under a gauze patch secured with non-irritating tape. Following the treatment period residual test material was removed using cotton soaked in distilled water. Distilled water was applied to a contralateral control site. Skin reactions were observed at 1, 24, 48, 72 hours and 7 days after patch removal (Draize scale).

Results and discussions

No toxic signs other than dermal irritation were observed in any rabbit throughout the experimental period. Skin irritation scores are shown in Table 7.1.4-01.

Table 7.1.4-01 Skin irritation scores

Rabbit No	Erythema / Oedema *, time after patch removal				
	1 hour	24 hours	48 hours	72 hours	7 days
1	1 / 0	2 / 0	1 / 0	1 / 0	0 / 0
2	1 / 0	2 / 0	1 / 0	1 / 0	0 / 0
3	1 / 0	2 / 0	1 / 0	1 / 0	0 / 0
Average	1 / 0	2 / 0	1 / 0	1 / 0	0 / 0

* scores in the range of 0 to 4

Very slight erythema (grade 1) was recorded in all animals after 1 hour, increasing to grade 2 at 24 hours but then decreasing to grade 1 at 48 and 72 hours. All erythema had resolved by Day 7 and no oedema was observed at any time.

Mean scores for erythema (24 – 72 hours) were 1.33 and 0 for oedema for each animal.

The control skin sites of all the rabbits appeared normal throughout the experiment.

Conclusion

Under the conditions of the study, there were no dermal reactions to treatment.

Classification of 3AEY is not required according to CLP Regulation (EC) No 1272/2008.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	<p>Study (XXXXX 2007d) has been reviewed and accepted during first approval of active substances (Pesticides Peer Review Meeting PPR 90 (16 – 20 April 2012). Now study has been checked only for compliance with the current guide-lines, resulting from scientific progress. In the following study degree of eye irritation/serious eye damage were evaluated by scoring lesions of conjunctiva, cornea, and iris, at specific intervals. Duration of the study was sufficient to evaluate the reversibility or irreversibility of the effects.</p> <p>Study outcome and conclusions are still valid and adequate for risk assessment also for classification purpose.</p> <p>Note: Study details (see below) marked in grey was not highlighted by the zRMS. This is due to the auto-complete template used by the applicant.</p>
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Reference	KCP 7.1.5/01
Report	Acute eye irritation study of product 3AEY in rabbits, XXXXX, 2007d, report No 6737
Guideline(s)	OECD 405
Deviations	No
GLP	Yes
Acceptability	Yes. Evaluated and accepted in the DAR (Eugenol, Volume 3, Annex B6, 2013); B.6.11.5 (IIIA 7.1.5)
Duplication (if vertebrate study)	No

Executive summary

The eye irritation potential of Mevalone (3AEY) was evaluated in 3 male New Zealand White rabbits. One rabbit was initially treated and based on observations up to 24 hours two further rabbits were subsequently treated. A single dose of test material (0.1 mL) was instilled in one eye for 24 hours and then removed using

saline. The contralateral eye remained untreated. The eyes of all the rabbits were observed for signs of ocular irritation (Draize scale) at 1, 24, 48 and 72 hours and 7, 14 and 21 days after treatment.

The iris of the treated eyes appeared normal throughout the experiment and there were no treatment related clinical signs other than eye irritation. Conjunctival effects (redness and chemosis) were recorded for up to 7 days and corneal opacity persisted for up to 14 days but was resolved by Day 21. Mean scores (24 – 72 hours) were 1.00 - 1.33 for corneal opacity, 0.00 for iritis and 2.00 for conjunctival redness and chemosis in each animal. No abnormalities were detected in control eyes throughout the experiment. Based on the results at 24 – 72 hours, 3AEY should be classified as H319: Causes serious eye irritation according to Regulation (EC) No 1272/2008.

Materials and methods

Test material

Name:	Product 3AEY
Description:	Light brown opaque liquid
Lot/batch no.:	YPOA3Y424-1.1 (1206)
Purity:	Eugenol (3.23%), Geraniol (6.56%), Thymol (6.47%)
Stability of test compound:	Assumed stable for duration of study.
Vehicle:	None

Test animals

Species/strain:	Rabbit (<i>Oryctolagus cuniculus</i>), New Zealand White
Source:	Animal Breeding Facility, Jai Research Foundation, India
Age at dosing:	15 - 18 weeks
Weight:	2.238 - 2.412 kg males
Acclimation period:	6 or 8 days
Diet:	Rabbit pellet feed (Amrut brand) <i>ad libitum</i>
Water:	Filtered tap water <i>ad libitum</i>
Housing:	Individually in stainless steel wire meshed rabbit cages

Environmental conditions

Temperature:	20 - 23 °C
Humidity:	65 - 67%
Air changes:	15/hour
Photoperiod:	12 hours light/dark

Study design and methods

In-life dates:	04 August – 02 September 2007
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Animal assignment and treatment

Undiluted 3AEY (0.1 mL) was instilled in one eye of three male New Zealand White rabbits. Eyelids were gently held together for 1 second after instillation. The untreated eye served as a control for each animal and received an instillation of saline (0.1 mL). One rabbit was initially treated and based on the observations at 24 hours, two further rabbits were subsequently treated. At 24 hours after instillation, the eyes were gently washed with saline. The eyes of all the rabbits were observed for signs of ocular irritation (Draize scale) at 1, 24, 48 and 72 hours and 7, 14 and 21 days after treatment. Fluorescein staining was used to assist corneal observations at 24 hours.

Results and discussions

Eye irritation scores are shown in Table 7.1.5-01.

Table 7.1.5-01 Eye irritation scores

	Irritation score, time after instillation							Mean irritation score (24 – 72 hr)
	1 hr	24 hr	48 hr	72 hr	7 day	14 day	21 day	
Rabbit 1 M (Right eye)								

Corneal opacity ^a		0	1	1	2	1	1	0	1.33
Iris ^b		0	0	0	0	0	0	0	0
Conjunctiva	Redness ^c	2	2	2	2	2	0	0	2
	Chemosis ^c	1	2	2	2	2	0	0	2
Rabbit 2 M (Left eye)									
Corneal opacity ^a		0	1	1	1	2	1	0	1
Iris ^b		0	0	0	0	0	0	0	0
Conjunctiva	Redness ^c	2	2	2	2	2	0	0	2
	Chemosis ^c	2	2	2	2	2	0	0	2
Rabbit 3 M (Right eye)									
Corneal opacity ^a		0	1	1	2	2	1	0	1.33
Iris ^b		0	0	0	0	0	0	0	0
Conjunctiva	Redness ^c	2	2	2	2	2	0	0	2
	Chemosis ^c	2	2	2	2	2	0	0	2

^a: scores in the range of 0 to 4, ^b: scores in the range 0 to 2, ^c: scores in the range 0 to 3

The iris of the treated eyes appeared normal throughout the experiment and there was no treatment related clinical signs other than eye irritation. Conjunctival effects (redness and chemosis) were recorded for up to 7 days and corneal opacity persisted for up to 14 days but was resolved by Day 21.

Mean scores (24 – 72 hours) were 1.00 - 1.33 for corneal opacity, 0.00 for iritis and 2.00 for conjunctival redness and chemosis in each animal.

No abnormalities were detected in the control eyes throughout the experiment.

Conclusion

Instillation of 3AEY into rabbit eyes resulted in conjunctival redness and chemosis until day 7 and corneal opacity which persisted until day 14. Based on the results at 24 - 72 hours, 3AEY should be classified as H319: Causes serious eye irritation according to Regulation (EC) No 1272/2008.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	<p>Study (XXXXXX 2007d) has been reviewed and accepted during first approval of active substances (Pesticides Peer Review Meeting PPR 90 (16 – 20 April 2012). Now study has been checked only for compliance with the current guide-lines, resulting from scientific progress.</p> <p>In the following study ratio of the primary proliferation of lymphocytes in the lymph node draining the site of chemical application in treated groups to that in vehicular controls has been sufficiently measured.</p> <p>Study outcome and conclusions are still valid and adequate for risk assessment also for classification purpose.</p> <p>Note: Study details (see below) marked in grey was not highlighted by the zRMS. This is due to the auto-complete template used by the applicant.</p>
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Reference	KCP 7.1.6/01
Report	Local lymph node assay in the mouse, XXXXX, 2007, report No 2408/0001
Guideline(s)	OECD 429, EEC B42
Deviations	No
GLP	Yes. Evaluated and accepted in the DAR (Eugenol, Volume 3, Annex B6, 2013); B.6.11.6 (IIIA 7.1.6).
Acceptability	Yes
Duplication (if vertebrate study)	No

Executive summary

A mouse local lymph node assay (LLNA) was performed with Mevalone (3AEY) in groups of 4 female CBA/Ca mice. A preliminary test was conducted to determine concentrations for the main test. Based on the results, concentrations of 25% and 50% w/v in DMF along with undiluted product, were selected. The negative control group received vehicle only, and a concurrent positive control group received α -Hexylcinnamaldehyde. The test substance (25 μ L) was applied to the dorsal skin of each ear of the animals once daily for 3 consecutive days. Five days after the first application, 20 μ Ci [methyl- 3 H] thymidine (3 H-TdR) was administered intravenously to each mouse *via* the tail vein (250 μ L of 80 μ Ci/mL). Approximately 5 hours after injection all mice were sacrificed and the ear draining lymph nodes removed. Incorporation of 3 H-TdR was determined by liquid scintillation counting.

The only clinical signs were fur loss around the base of the ears and neck from Day 3 onwards in the undiluted material group. There were no effects on body weight. The Stimulation Index value for undiluted material was below the threshold (≥ 3), whereas higher values were obtained for the 25% and 50% dilutions in dimethylformamide showing an inverse dose response.

It was proposed that the inverse dose response was likely to be due to interaction between the dimethylformamide (vehicle) and the formulated product (3AEY). In the presence of the dimethyl formamide the active ingredients may be extracted from the microencapsulated formulation by this solvent and thereby becoming more bioavailable. The inverse dose response is explained by the increased level of solvent in the higher dilutions.

In this study, values of SI > 3 were obtained for the 25% and 50% dilutions. In the DAR it was concluded that no classification is required since an inverse dose response occurred due to interaction between the product and the vehicle used in the study, which caused the active substances to be extracted from the microencapsulated formulation, causing the sensitisation response. However, as these results are not conclusive and considering the classification of eugenol and geraniol as skin sensitisers, it seems appropriate to classify the product as a skin sensitiser.

Therefore, 3AEY should be classified as H317: May cause an allergic skin reaction according to Regulation (EC) 1272/2008.

Materials and methods

Test material

Name:	Product 3AEY
Description:	Opaque beige coloured liquid
Lot/batch no.:	YPOA3Y424-1.1 (Dec 2008)
Purity:	Eugenol (3.25%), Geraniol (6.55%), Thymol (6.64%)
Stability of test compound:	Assumed stable for duration of study.
Vehicle:	None or dimethylformamide

Test animals

Species/strain:	Mouse (<i>Mus musculus</i>), Main test: CBA/Ca (CBA/CaBkl) or Preliminary test: CBA/Ca (CBA/Ca CruBR)
Source:	B & K Universal Ltd, Hull, UK for CBA/CaBkl and Charles River UK Ltd., Kent, UK for CBA/Ca CruBR
Age at dosing:	Not recorded
Weight:	15 - 23 g females
Acclimation period:	At least 5 days
Diet:	Certified Rat and Mouse Diet <i>ad libitum</i>
Water:	Tap water <i>ad libitum</i>
Housing:	Individually in suspended solid-floor polypropylene cages with softwood wood flakes

Environmental conditions

Temperature:	19 - 25 °C
Humidity:	30 - 70%
Air changes:	15/hour
Photoperiod:	12 hours light/dark

Study design and methods

Study dates:	21 May – 17 July 2007
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Animal assignment and treatment

In formulation tests the first choice vehicle acetone/olive oil (4:1) produced an emulsion which was not suitable for dosing. Dimethyl formamide produced a solution suitable for dosing and was chosen for the study. Undiluted test substance was also used.

A preliminary screening test with the undiluted test material and the test material at a concentration of 50% v/v in dimethyl formamide was conducted. Treatments were applied (25 µL) to the dorsal skin surface of both auricles of each animal (1 mouse/group), once a day for 3 consecutive days. The application sites were assessed twice daily on Days 1, 2 and 3 and once daily on Days 4, 5 and 6 following the application.

The preliminary test indicated there would be no systemic toxicity or excessive local irritation so groups of 4 mice were treated with the undiluted 3AEY product, plus dilutions of 25% and 50% in dimethyl formamide. The control group was treated with dimethyl formamide alone. Each treatment was 25 µL per ear for 3 consecutive days. The animals were observed twice daily on Days 1, 2 and 3 and once daily on Days 4, 5 and 6 following the application. The body weight of each mouse was recorded on Day 1 and Day 6 (termination).

Five days after the first topical application, all mice were injected with 20 µCi of ³H-methyl thymidine (³H-TdR, 250 µL) via the tail vein and were sacrificed 5 hours later by carbon dioxide asphyxiation. The draining auricular lymph nodes were excised and pooled for each experimental group. Single cell suspensions

were prepared and the amount of radioactivity incorporated was determined. Liquid scintillation fluid was added and after approximately 20 minutes ^3H -TdR incorporation was measured and the stimulation index (SI, ratio of ^3H -TdR incorporation into the lymph node cells of test nodes compared to that recorded for the control nodes) was calculated. The results of a positive control assay with α -hexylcinnamaldehyde in dimethyl formamide were reported.

Results and discussions

In the preliminary test, the mouse treated with undiluted material showed fur loss around the base of the ears and neck and a 2 g body weight loss. A slight weight loss (up to 1.6 g) was noted in the animal treated with material at 50% v/v in dimethyl formamide. Based on this information, the dose levels selected for the main test were 100%, then 25% and 50% v/v in dimethyl formamide.

In the main study, there were no deaths and no signs of systemic toxicity. The only clinical signs were fur loss around the base of the ears and neck from Day 3 onwards in the undiluted material group.

There were no effects on body weight.

The radioactivity incorporated per lymph node for each group and the Stimulation Index for each treated group compared to the controls are shown in Table 7.1.6-01.

Table 7.1.6-01 Stimulation index

Treatment	Number of mice	DPM/node	Stimulation index	Result
Negative control (DMF)	4	1043.51	-	-
25% in DMF	4	5638.21	5.40	Positive
50% in DMF	4	3214.67	3.08	Positive
100%	4	2001.94	1.92	Negative

The threshold for a positive response in OECD 429 (2002) is a SI value of ≥ 3 . The SI value for undiluted material was below this threshold, whereas higher values were obtained for the 25% and 50% dilutions in dimethyl formamide showing an inverse dose response.

It was proposed that the inverse dose response was likely to be due to interaction between the dimethyl formamide (vehicle) and the formulated product (3AEY). The product is an aqueous suspension of micro-encapsulated active ingredient. In the undiluted material, the encapsulated active ingredients may not be able to reach and activate the cellular targets in the skin due to the epidermal barrier. In the presence of the dimethyl formamide, the active ingredients may be extracted from the microencapsulated formulation by this solvent and thereby becoming more bioavailable. The inverse dose response is explained by the increased level of solvent in the higher dilutions.

Conclusion

The study concluded that the result with undiluted test material is the most relevant for classification for human risk assessment. The Study Director suggested that the presence of dimethyl formamide resulted in false positive findings (as an artefact of the test system) and produced results which are not relevant to the risk assessment. Further they concluded that “Under the conditions of the test, the undiluted test material was considered not to be a sensitiser. The 25 and 50% dilutions in dimethyl formamide gave a positive result but this was probably due to extraction of the active substances from the microencapsulated formulation”.

In this study, values of $\text{SI} > 3$ were obtained for the 25% and 50% dilutions. In the DAR it is concluded that no classification is required since an inverse dose response occurred due to interaction between the product and the vehicle used in the study, which caused the active substances to be extracted from the microencapsulated formulation, causing the sensitization response. However, as these results are not conclusive and considering the classification of eugenol (3.24% in the product) and geraniol (6.54% in the product) as skin sensitisers, it seems appropriate to classify the product as a skin sensitiser.

Therefore, according to Regulation (EC) 1272/2008, the product should be classified as a skin sensitiser, *that is*, H317: May cause an allergic skin reaction.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies are required and none are provided.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

No studies are available. The default dermal absorption values according to Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) were used for the risk assessments.

A 2.11 Other/Special Studies

None required.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for eugenol

Operator exposure to eugenol: Input parameters for vehicle mounted (upward spray) application to grape and pome fruit

Substance name	Eugenol
Product name	Mevalone (3AEY) - Eugenol
Reference value non acutely toxic active substance (RVNAS)	1 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Pome fruit
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.132 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	70.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Operator exposure to eugenol: Vehicle mounted application: Potential exposure

Operator exposure for Mevalone (3AEY) - Eugenol outdoor spray applications

Operator exposure for mixtures (PNEC) - Emission Outdoor spray applications					
Application rate of active substance		0.132 kg a.s./ha		i_AppRate	
Assumed area treated		10 ha/day		d_AreaTreated	
Amount of active substance applied		1.32 kg a.s./day		i_AmountAS	
Dermal absorption of the product		70.00%		i_AbsorpProduct	
Dermal absorption of in-use dilution		70.00%		i_AbsorInuse	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Upward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
Outdoor soluble concentrate, emulsifiable concentrate, etc. Upward spray, vehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	6014	22091	AOEM	
	Body	4336	78074	AOEM	
	Head	68	376	AOEM	
	Protected hands (gloves)	41	261	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	30	193	AOEM	
	Protected head (hood and face shield)	1	21	AOEM	
	Inhalation	4	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	3228	8233	AOEM	No data available for a drift reduction scenario
	Body	11631	67869	AOEM	
	Head	1529	9382	AOEM	
	Protected hands (gloves)	46	1214	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	152	297	AOEM	
	Inhalation	75	109	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	18.8431956	18.8431956	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.3140533	0.3140533	
% of RVNAS	31.41%	31.41%	

Operator exposure to eugenol: Vehicle mounted application: Work wear (only)

Operator exposure for Mevalone (3AEY) - Eugenol outdoor spray applications

Application rate of active substance	0.132	kg a.s./ha	<i>i_AppRate</i>		
Assumed area treated	10	ha/day	<i>d_AreaTreated</i>		
Amount of active substance applied	1.32	kg a.s./day	<i>i_AmountAS</i>		
Dermal absorption of the product	70.00%		<i>i_AbsorpProduct</i>		
Dermal absorption of in-use dilution	70.00%		<i>i_AbsorInuse</i>		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Upward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	6014	22091	AOEM	
	Body	4336	78074	AOEM	
	Head	68	376	AOEM	
	Protected hands (gloves)	41	261	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	30	193	AOEM	
	Protected head (hood and face shield)	1	21	AOEM	
	Inhalation	4	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	3228	8233	AOEM	No data available for a drift reduction scenario
	Body	11631	67869	AOEM	
	Head	1529	9382	AOEM	
	Protected hands (gloves)	46	1214	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	152	297	AOEM	
	Inhalation	75	109	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	18.8431956	7.7935171	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.3140533	0.1298920	
% of RVNAS	31.41%	12.99%	

Operator exposure to eugenol: Input parameters for knapsack (upward spray) application to grape or pome fruit

Substance name	Eugenol
Product name	Mevalone (3AEY) - Eugenol
Reference value non acutely toxic active substance (RVNAS)	1 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Grapes
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.132 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	70.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Manual-Knapsack
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Operator exposure to eugenol: Knapsack application: Potential exposure

Operator exposure for Mevalone (3AEY) - Eugenol outdoor spray applications

Application rate of active substance	0.132 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	1 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0.132 kg a.s./day	<i>i_AmoutAS</i>
Dermal absorption of the product	70.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Season	not relevant	
	OutdoorSoluble concentrates, emulsifiable concentrate, etc Upward sprayingManual-Knapsack	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	500	1869	AOEM	No data available for a drift reduction scenario
	Body	44767	175392	AOEM	
	Head	79	424	AOEM	
	Protected hands (gloves)	3	16	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	15	55	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	38.9951636	38.9951636
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.6499194	0.6499194
% of RVNAS	64.99%	64.99%

Operator exposure to eugenol: Knapsack application: Work wear (only)

Operator exposure for Mevalone (3AEY) - Eugenol outdoor spray applications

Application rate of active substance	0.132 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	1 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0.132 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	70.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	500	1869	AOEM	No data available for a drift reduction scenario
	Body	44767	175392	AOEM	
	Head	79	424	AOEM	
	Protected hands (gloves)	3	16	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	15	55	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	38.9951636	7.8365071
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.6499194	0.1306085
% of RVNAS	64.99%	13.06%

A 3.1.2 Calculations for geraniol

Operator exposure to geraniol: Input parameters for vehicle mounted (upward spray) application to grape and pome fruit

Substance name	Geraniol
Product name	Mevalone (3AEY) - Geraniol
Reference value non acutely toxic active substance (RVNAS)	0.5 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Pome fruit
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Operator exposure to geraniol: Vehicle mounted application: Potential exposure

Operator exposure for Mevalone (3AEY) - Geraniol outdoor spray applications

Application rate of active substance		0.264 kg a.s./ha	<i>l_AppRate</i>		
Assumed area treated		10 ha/day	<i>d_AreaTreated</i>		
Amount of active substance applied		2.64 kg a.s./day	<i>i_AmountAS</i>		
Dermal absorption of the product		25.00%	<i>i_AbsorpProduct</i>		
Dermal absorption of in-use dilution		70.00%	<i>i_AbsorInuse</i>		
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Upward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Upward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	10255	37898	AOEM	
	Body	7058	95492	AOEM	
	Head	137	751	AOEM	
	Protected hands (gloves)	65	523	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	56	386	AOEM	
	Protected head (hood and face shield)	2	43	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	5968	16465	AOEM	No data available for a drift reduction scenario
	Body	23263	135739	AOEM	
	Head	3057	18763	AOEM	
	Protected hands (gloves)	93	2427	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	304	593	AOEM	
	Inhalation	110	218	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	27.0796153	27.0796153	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.4513269	0.4513269	
% of RVNAS	90.27%	90.27%	

Operator exposure to geraniol: Vehicle mounted application: Work wear (only)

Operator exposure for Mevalone (3AEY) - Geraniol outdoor spray applications

Operator exposure for mixtures (ENV)		Soluble concentrates, emulsifiable concentrates, etc.		Upward spraying applications	
Application rate of active substance		0.264 kg a.s./ha		i_AppRate	
Assumed area treated		10 ha/day		d_AreaTreated	
Amount of active substance applied		2.64 kg a.s./day		i_AmountAS	
Dermal absorption of the product		25.00%		i_AbsorpProduct	
Dermal absorption of in-use dilution		70.00%		i_AbsorInuse	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Upward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
Outdoor soluble concentrates, emulsifiable concentrates, etc. Upward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	10255	37898	AOEM	
	Body	7058	95492	AOEM	
	Head	137	751	AOEM	
	Protected hands (gloves)	65	523	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	56	386	AOEM	
	Protected head (hood and face shield)	2	43	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	5968	16465	AOEM	No data available for a drift reduction scenario
	Body	23263	135739	AOEM	
	Head	3057	18763	AOEM	
	Protected hands (gloves)	93	2427	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	304	593	AOEM	
	Inhalation	110	218	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	27.0796153	9.2575624	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.4513269	0.1542927	
% of RVNAS	90.27%	30.86%	

Operator exposure to geraniol – Input parameters for knapsack (upward spray) application to grape or pome fruit

Substance name	Geraniol
Product name	Mevalone (3AEY) - Geraniol
Reference value non acutely toxic active substance (RVNAS)	0.5 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Grapes
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Manual-Knapsack
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Operator exposure to geraniol: Knapsack application: Potential exposure

Operator exposure for Mevalone (3AEY) - Geraniol outdoor spray applications

Product exposure for: Insecticide (active), Soluble concentrates, spray applications					
Application rate of active substance		0.264 kg a.s./ha		i_AppRate	
Assumed area treated		1 ha/day		d_AreaTreated	
Amount of active substance applied		0.264 kg a.s./day		i_AmountAS	
Dermal absorption of the product		25.00%		i_AbsorpProduct	
Dermal absorption of in-use dilution		70.00%		i_AbsorInuse	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Upward spraying			
Application equipment		Manual-Knapsack			
Season		not relevant			
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Upward sprayingManual-Knapsack					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	893	3177	AOEM	No data available for a drift reduction scenario
	Body	49898	176533	AOEM	
	Head	99	532	AOEM	
	Protected hands (gloves)	6	33	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	27	82	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	38.2505503	38.2505503
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.6375092	0.6375092
% of RVNAS	127.50%	127.50%

Operator exposure to geraniol: Knapsack application: Work wear (only)

Operator exposure for Mevalone (3AEY) - Geraniol outdoor spray applications

Application rate of active substance	0.264 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	1 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0.264 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	25.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	893	3177	AOEM	No data available for a drift reduction scenario
	Body	49898	176533	AOEM	
	Head	99	532	AOEM	
	Protected hands (gloves)	6	33	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	27	82	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	38.2505503	3.8508966
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.6375092	0.0641816
% of RVNAS	127.50%	12.84%

A 3.1.3 Calculations for thymol

Operator exposure to thymol: Input parameters for vehicle mounted (upward spray) application to grape and pome fruit

Substance name	Thymol
Product name	Mevalone (3AEY) -Thymol
Reference value non acutely toxic active substance (RVNAS)	0.4 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Pome fruit
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	late (dense foliage)

Operator exposure to thymol: Vehicle mounted application: Potential exposure

Operator exposure for Mevalone (3AEY) -Thymol outdoor spray applications

Application rate of active substance		0.264 kg a.s./ha	<i>i_AppRate</i>		
Assumed area treated		10 ha/day	<i>d_AreaTreated</i>		
Amount of active substance applied		2.64 kg a.s./day	<i>i_AmountAS</i>		
Dermal absorption of the product		25.00%	<i>i_AbsorpProduct</i>		
Dermal absorption of in-use dilution		70.00%	<i>i_AbsorInuse</i>		
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Upward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Upward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	10255	37898	AOEM	
	Body	7058	95492	AOEM	
	Head	137	751	AOEM	
	Protected hands (gloves)	65	523	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	56	386	AOEM	
	Protected head (hood and face shield)	2	43	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	5968	16465	AOEM	No data available for a drift reduction scenario
	Body	23263	135739	AOEM	
	Head	3057	18763	AOEM	
	Protected hands (gloves)	93	2427	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	304	593	AOEM	
	Inhalation	110	218	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	27.0796153	27.0796153	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.4513269	0.4513269	
% of RVNAS	112.83%	112.83%	

Operator exposure to thymol: Vehicle mounted application: Work wear (only)

Operator exposure for Mevalone (3AEY) -Thymol outdoor spray applications

Application rate of active substance		0.264 kg a.s./ha	<i>l_AppRate</i>		
Assumed area treated		10 ha/day	<i>d_AreaTreated</i>		
Amount of active substance applied		2.64 kg a.s./day	<i>i_AmountAS</i>		
Dermal absorption of the product		25.00%	<i>i_AbsorpProduct</i>		
Dermal absorption of in-use dilution		70.00%	<i>i_AbsorInuse</i>		
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Upward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Upward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	10255	37898	AOEM	
	Body	7058	95492	AOEM	
	Head	137	751	AOEM	
	Protected hands (gloves)	65	523	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	56	386	AOEM	
	Protected head (hood and face shield)	2	43	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	5968	16465	AOEM	No data available for a drift reduction scenario
	Body	23263	135739	AOEM	
	Head	3057	18763	AOEM	
	Protected hands (gloves)	93	2427	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	304	593	AOEM	
	Inhalation	110	218	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	27.0796153	9.2575624	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.4513269	0.1542927	
% of RVNAS	112.83%	38.57%	

Operator exposure to thymol – Input parameters for knapsack (upward spray) application to grape or pome fruit

Substance name	Thymol
Product name	Mevalone (3AEY) -Thymol
Reference value non acutely toxic active substance (RVNAS)	0.4 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Grapes
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Manual-Knapsack
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Operator exposure to thymol: Knapsack application: Potential exposure

Operator exposure for Mevalone (3AEY) -Thymol outdoor spray applications

Application rate of active substance	0.264 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	1 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0.264 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	25.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Season	not relevant	
	OutdoorSoluble concentrates, emulsifiable concentrate, etc Upward sprayingManual-Knapsack	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	893	3177	AOEM	No data available for a drift reduction scenario
	Body	49898	176533	AOEM	
	Head	99	532	AOEM	
	Protected hands (gloves)	6	33	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	27	82	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	38.2505503	38.2505503
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.6375092	0.6375092
% of RVNAS	159.38%	159.38%

Operator exposure to thymol: Knapsack application: Work wear (only)

Operator exposure for Mevalone (3AEY) -Thymol outdoor spray applications

Application rate of active substance	0.264 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	1 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0.264 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	25.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	893	3177	AOEM	No data available for a drift reduction scenario
	Body	49898	176533	AOEM	
	Head	99	532	AOEM	
	Protected hands (gloves)	6	33	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	27	82	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	38.2505503	3.8508966
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.6375092	0.0641816
% of RVNAS	159.38%	16.05%

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for eugenol

Worker re-entry exposure to eugenol – Application to pome fruit

Substance name	Eugenol
Product name	Mevalone (3AEY) - Eugenol
Reference value non acutely toxic active substance (RVNAS)	1 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Pome fruit
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.132 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	70.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Worker exposure from residues on foliage for Mevalone (3AEY) - Eugenol

Crop type	Pome fruit
Indoor or outdoor	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Worker's task	Searching, reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0.132 kg a.s./ha
Number of applications	1
Interval between multiple applications	365 days
Half-life of active substance	30 days
Multiple application factor	1.0
Dermal absorption of the product	70.00%
Dermal absorption of the in-use dilution	70.00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.396 µg a.s./cm ²
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	22500 cm ² /hr
Dermal transfer coefficient - arms, body and legs covered	4500 cm ² /hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250 cm ² /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^(-3)}
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^(-3)}
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^(-3)}

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	49.8960000	9.9792000	4.9896000
Total systemic exposure per kg body weight (mg/kg bw/day)	0.8316000	0.1663200	0.0831600
% of RVNAS	83.16%	16.63%	8.32%

Worker re-entry exposure to eugenol – Application to grape

Substance name	Eugenol
Product name	Mevalone (3AEY) - Eugenol
Reference value non acutely toxic active substance (RVNAS)	1 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Grapes
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.132 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	70.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Worker exposure from residues on foliage for Mevalone (3AEY) - Eugenol			
Crop type	Grapes		
Indoor or outdoor	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Hand harvesting		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0.132	kg a.s./ha	
Number of applications	1		
Interval between multiple applications	365	days	
Half-life of active substance	30	days	
Multiple application factor	1.0		
Dermal absorption of the product	70.00%		
Dermal absorption of the in-use dilution	70.00%		
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.396	µg a.s./cm ²	
Working hours	8	hr	
Dermal transfer coefficient - Total potential exposure	30000	cm ² /hr	
Dermal transfer coefficient - arms, body and legs covered	10100	cm ² /hr	
Dermal transfer coefficient - hands, arms, body and legs covered	660	cm ² /hr	
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}	
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}	
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}	
1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	66.5280000	22.3977600	1.4636160
Total systemic exposure per kg body weight (mg/kg bw/day)	1.1088000	0.3732960	0.0243936
% of RVNAS	110.88%	37.33%	2.44%

A 3.2.2 Calculations for geraniol

Worker re-entry exposure to geraniol– Application to pome fruit

Substance name	Geraniol
Product name	Mevalone (3AEY) - Geraniol
Reference value non acutely toxic active substance (RVNAS)	0.5 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Pome fruit
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Worker exposure from residues on foliage for Mevalone (3AEY) - Geraniol			
Crop type	Pome fruit		
Indoor or outdoor	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Searching, reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0.264	kg a.s./ha	
Number of applications	1		
Interval between multiple applications	365	days	
Half-life of active substance	30	days	
Multiple application factor	1.0		
Dermal absorption of the product	25.00%		
Dermal absorption of the in-use dilution	70.00%		
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.792	µg a.s./cm ²	
Working hours	8	hr	
Dermal transfer coefficient - Total potential exposure	22500	cm ² /hr	
Dermal transfer coefficient - arms, body and legs covered	4500	cm ² /hr	
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm ² /hr	
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}	
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}	
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}	
1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	99.7920000	19.9584000	9.9792000
Total systemic exposure per kg body weight (mg/kg bw/day)	1.6632000	0.3326400	0.1663200
% of RVNAS	332.64%	66.53%	33.26%

Worker re-entry exposure to geraniol – Application to grape

Substance name	Geraniol
Product name	Mevalone (3AEY) - Geraniol
Reference value non acutely toxic active substance (RVNAS)	0.5 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Grapes
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Worker exposure from residues on foliage for Mevalone (3AEY) - Geraniol			
Crop type	Grapes		
Indoor or outdoor	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Hand harvesting		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0.264	kg a.s./ha	
Number of applications	1		
Interval between multiple applications	365	days	
Half-life of active substance	30	days	
Multiple application factor	1.0		
Dermal absorption of the product	25.00%		
Dermal absorption of the in-use dilution	70.00%		
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.792	µg a.s./cm ²	
Working hours	8	hr	
Dermal transfer coefficient - Total potential exposure	30000	cm ² /hr	
Dermal transfer coefficient - arms, body and legs covered	10100	cm ² /hr	
Dermal transfer coefficient - hands, arms, body and legs covered	660	cm ² /hr	
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}	
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}	
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}	
1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	133.0560000	44.7955200	2.9272320
Total systemic exposure per kg body weight (mg/kg bw/day)	2.2176000	0.7465920	0.0487872
% of RVNAS	443.52%	149.32%	9.76%

A 3.2.3 Calculations for thymol

Worker re-entry exposure to thymol – Application to pome fruit

Substance name	Thymol
Product name	Mevalone (3AEY) -Thymol
Reference value non acutely toxic active substance (RVNAS)	0.4 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Pome fruit
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Worker exposure from residues on foliage for Mevalone (3AEY) -Thymol			
Crop type	Pome fruit		
Indoor or outdoor	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Searching, reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0.264	kg a.s./ha	
Number of applications	1		
Interval between multiple applications	365	days	
Half-life of active substance	30	days	
Multiple application factor	1.0		
Dermal absorption of the product	25.00%		
Dermal absorption of the in-use dilution	70.00%		
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.792	µg a.s./cm ²	
Working hours	8	hr	
Dermal transfer coefficient - Total potential exposure	22500	cm ² /hr	
Dermal transfer coefficient - arms, body and legs covered	4500	cm ² /hr	
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm ² /hr	
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}	
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}	
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}	
1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	99.7920000	19.9584000	9.9792000
Total systemic exposure per kg body weight (mg/kg bw/day)	1.6632000	0.3326400	0.1663200
% of RVNAS	415.80%	83.16%	41.58%

Worker re-entry exposure to thymol – Application to grape

Substance name	Thymol
Product name	Mevalone (3AEY) -Thymol
Reference value non acutely toxic active substance (RVNAS)	0.4 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Grapes
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10-3Pa and 10-2Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Worker exposure from residues on foliage for Mevalone (3AEY) -Thymol			
Crop type	Grapes		
Indoor or outdoor	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Hand harvesting		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0.264	kg a.s./ha	
Number of applications	1		
Interval between multiple applications	365	days	
Half-life of active substance	30	days	
Multiple application factor	1.0		
Dermal absorption of the product	25.00%		
Dermal absorption of the in-use dilution	70.00%		
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.792	µg a.s./cm ²	
Working hours	8	hr	
Dermal transfer coefficient - Total potential exposure	30000	cm ² /hr	
Dermal transfer coefficient - arms, body and legs covered	10100	cm ² /hr	
Dermal transfer coefficient - hands, arms, body and legs covered	660	cm ² /hr	
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}	
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}	
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}	
1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	133.0560000	44.7955200	2.9272320
Total systemic exposure per kg body weight (mg/kg bw/day)	2.2176000	0.7465920	0.0487872
% of RVNAS	554.40%	186.65%	12.20%

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for eugenol

Resident & bystander exposure to eugenol input parameters and results – pome fruit

Substance name	Eugenol
Product name	Mevalone (3AEY) - Eugenol
Reference value non acutely toxic active substance (RVNAS)	1 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Pome fruit
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.132 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	70.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Resident exposure for Mevalone (3AEY) - Eugenol					
Croptype	Pome fruit				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip	5 m				i_Buffer
Application rate of the product	0.132 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0.132 g a.s./l				d_ConcAS
Dermal absorption of product	70.00%				i_AbsorpProduct
Dermal absorption of in-use dilution	70.00%				i_Absorplnuse
Oral absorption	100.00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.396 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	moderately volatile substances with a vapour pressure between 5*10-3Pa and 10-2Pa				i_Volat
Concentration in air	2Pa				
Resident dermal spray drift exposure 75th percentile - adult	0.015 mg/m³				d_AirCon
Resident dermal spray drift exposure 75th percentile - child	5.63 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	1.689 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00210 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.00164 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	3.68 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	1.11 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00170 ml spray dilution/person				
Exposure duration dermal	0.00133 ml spray dilution/person				
Exposure duration inhalation	2 hours				d_ReExpDur
Exposure duration entry into treated crops	24 hours				d_ReExpDurInhal
Light clothing adjustment factor	0.25 hours				d_ExpDurTreatCrop
Breathing rate adult	18.0%				d_ClothAF
Breathing rate child (1-3 year old)	0.23 m³/day/kg				d_BreathRAD
Drift percentage on surface (75th percentile)	1.07 m³/day/kg				d_BreathRCh
Drift percentage on surface (mean)	15.79%				
Turf transferable residues percentage	11.69%				
Transfer coeff. of surface deposits-adult	5.00%				d_Turf
Transfer coeff. of surface deposits-child (1-3 year old)	7300 cm²/hour				d_ReTCAd
Saliva extraction percentage	2600 cm²/hour				d_ReTCCh
Surface area of hands mouthed	50.00%				d_SalExt
Frequency of hand to mouth activity	20 cm²				d_AreaHM
Ingestion rate for mouthing of grass per day	9.5 events/hour				d_ReFreqHM
Dislodgeable residues percentage transferability for object to mouth	25 cm²				d_MouthGrass
Transfer coefficient for entry into treated crops (75th percentile) - adult	20.00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - child	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - adult	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - child	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1281891	0.1605000	0.0409561	0.1559250	0.3994238
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0128189	0.0160500	0.0040956	0.0155925	0.0399424
% of RVNAS	1.28%	1.61%	0.41%	1.56%	3.99%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.4268510	0.2070000	0.1065067	0.5197500	0.9793160
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0071142	0.0034500	0.0017751	0.0086625	0.0163219
% of RVNAS	0.71%	0.35%	0.18%	0.87%	1.63%

Resident & bystander exposure to eugenol input parameters and results – grapes

Substance name	Eugenol
Product name	Mevalone
Reference value non acutely toxic active substance (RVNAS)	1 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Grapes
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.132 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	70.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Resident exposure for Mevalone					
Croptype			Grapes		
Application method			Upward spraying		
Application equipment			Vehicle-mounted		<i>l_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				<i>l_FormVal</i>
Buffer strip			5 m		<i>l_Buffer</i>
Application rate of the product			0.132 kg a.s./ha		<i>l_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)			0.132 g a.s./l		<i>d_ConcAS</i>
Dermal absorption of product			70.00%		<i>l_AbsorpProduct</i>
Dermal absorption of in-use dilution			70.00%		<i>l_Absorpinuse</i>
Oral absorption			100.00%		<i>l_AbsorpOrallnuse</i>
Dislodgeable foliar residue (i_AppRate*i_DFR)			0.396 µg a.s./cm²		<i>d_DFR</i>
Vapour pressure of in-use dilution	moderately volatile substances with a vapour pressure between 5*10-3Pa and 10-2Pa				<i>l_Volat</i>
Concentration in air			0.015 mg/m³		<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult			5.63 ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child			1.689 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult			0.00210 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child			0.00164 ml spray dilution/person		
Resident dermal spray drift exposure mean - adult			3.68 ml spray dilution/person		
Resident dermal spray drift exposure mean - child			1.11 ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult			0.00170 ml spray dilution/person		
Resident inhal. spray drift exposure mean - child			0.00133 ml spray dilution/person		
Exposure duration dermal			2 hours		<i>d_ReExpDur</i>
Exposure duration inhalation			24 hours		<i>d_ReExpDurinhal</i>
Exposure duration entry into treated crops			0.25 hours		<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor			18.0%		<i>d_ClothAF</i>
Breathing rate adult			0.23 m³/day/kg		<i>d_BreathRAAd</i>
Breathing rate child (1-3 year old)			1.07 m³/day/kg		<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)			3.07%		
Drift percentage on surface (mean)			2.32%		
Turf transferable residues percentage			5.00%		<i>d_Turf</i>
Transfer coeff. of surface deposits-adult			7300 cm²/hour		<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)			2600 cm²/hour		<i>d_ReTCCh</i>
Saliva extraction percentage			50.00%		<i>d_SolExt</i>
Surface area of hands mouthed			20 cm²		<i>d_AreaHM</i>
Frequency of hand to mouth activity			9.5 events/hour		<i>d_ReFreqHM</i>
Ingestion rate for mouthing of grass per day			25 cm²		<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth			20.00%		<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - ad			7500 cm²/h		<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - chi			2250 cm²/h		<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult			5980 cm²/h		<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child			1794 cm²/h		<i>d_TcEntryCh</i>
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1281891	0.1605000	0.0079630	0.1559250	0.3751199
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0128189	0.0160500	0.0007963	0.0155925	0.0375120
% of RVNAS	1.28%	1.61%	0.08%	1.56%	3.75%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.4268510	0.2070000	0.0207078	0.5197500	0.9161135
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0071142	0.0034500	0.0003451	0.0086625	0.0152686
% of RVNAS	0.71%	0.35%	0.03%	0.87%	1.53%

A. 3.3.2 Calculations for geraniol

Resident and bystander exposure to geraniol input parameters and results – pome fruit

Substance name	Geraniol
Product name	Mevalone
Reference value non acutely toxic active substance (RVNAS)	0.5 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Grapes
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10-3Pa and 10-2Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Resident exposure for Mevalone (3AEY) - Geraniol					
Croptype	Pome fruit				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	5 m				
Application rate of the product	0.264 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.264 g a.s./l				
Dermal absorption of product	25.00%				
Dermal absorption of in-use dilution	70.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.792 µg a.s./cm²				
Vapour pressure of in-use dilution	moderately volatile substances with a vapour pressure between 5*10-3Pa and 10-1Pa				
Concentration in air	0.015 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	5.63 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	1.689 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00210 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00164 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	3.68 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	1.11 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00170 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00133 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0.25 hours				
Light clothing adjustment factor	18.0%				
Breathing rate adult	0.23 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	15.79%				
Drift percentage on surface (mean)	11.69%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2563782	0.1605000	0.0819122	0.3118500	0.6383476
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0256378	0.0160500	0.0082	0.0311850	0.0638348
% of RVNAS	5.13%	3.21%	1.64%	6.24%	12.77%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.8537021	0.2070000	0.2130134	1.0395000	1.7516321
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0142284	0.0034500	0.0035502	0.0173250	0.0291939
% of RVNAS	2.85%	0.690%	0.71%	3.47%	5.84%

Resident and bystander exposure to geraniol input parameters and results – grapes

Substance name	Geraniol
Product name	Mevalone
Reference value non acutely toxic active substance (RVNAS)	0.5 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Grapes
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10-3Pa and 10-2Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Resident exposure for Mevalone					
Croptype		Grapes			
Application method		Upward spraying			
Application equipment		Vehicle-mounted			<i>l_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				<i>l_FormVal</i>
Buffer strip		5 m			<i>l_Buffer</i>
Application rate of the product		0.264 kg a.s./ha			<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)		0.264 g a.s./l			<i>d_ConcAS</i>
Dermal absorption of product		25.00%			<i>l_AbsorpProduct</i>
Dermal absorption of in-use dilution		70.00%			<i>l_Absorpnuse</i>
Oral absorption		100.00%			<i>i_AbsorpOralnuse</i>
Dislodgeable foliar residue (i_AppRate*i_DFR)		0.792 µg a.s./cm²			<i>d_DFR</i>
Vapour pressure of in-use dilution	moderately volatile substances with a vapour pressure between 5*10-3Pa and 10-2Pa	Pa			<i>l_Volat</i>
Concentration in air		0.015 mg/m³			<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult		5.63 ml spray dilution/person			
Resident dermal spray drift exposure 75th percentile - child		1.689 ml spray dilution/person			
Resident inhal. spray drift exposure 75th percentile - adult		0.00210 ml spray dilution/person			
Resident inhal. spray drift exposure 75th percentile - child		0.00164 ml spray dilution/person			
Resident dermal spray drift exposure mean - adult		3.68 ml spray dilution/person			
Resident dermal spray drift exposure mean - child		1.11 ml spray dilution/person			
Resident inhal. spray drift exposure mean - adult		0.00170 ml spray dilution/person			
Resident inhal. spray drift exposure mean - child		0.00133 ml spray dilution/person			
Exposure duration dermal		2 hours			<i>d_ReExpDur</i>
Exposure duration inhalation		24 hours			<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops		0.25 hours			<i>d_ExpDurTreatCrap</i>
Light clothing adjustment factor		18.0%			<i>d_ClothAF</i>
Breathing rate adult		0.23 m³/day/kg			<i>d_BreathRAd</i>
Breathing rate child (1-3 year old)		1.07 m³/day/kg			<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)		3.07%			
Drift percentage on surface (mean)		2.32%			
Turf transferable residues percentage		5.00%			<i>d_Turf</i>
Transfer coeff. of surface deposits-adult		7300 cm²/hour			<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)		2600 cm²/hour			<i>d_ReTCCh</i>
Saliva extraction percentage		50.00%			<i>d_SalExt</i>
Surface area of hands mouthed		20 cm²			<i>d_AreaHM</i>
Frequency of hand to mouth activity		9.5 events/hour			<i>d_ReFreqHM</i>
Ingestion rate for mouthing of grass per day		25 cm²			<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth		20.00%			<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - ad		7500 cm²/h			<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - chi		2250 cm²/h			<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult		5980 cm²/h			<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child		1794 cm²/h			<i>d_TcEntryCh</i>
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2563782	0.1605000	0.0159259	0.3118500	0.5897398
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0256378	0.0160500	0.0015926	0.0311850	0.0589740
% of RVNAS	5.13%	3.21%	0.32%	6.24%	11.79%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.8537021	0.2070000	0.0414155	1.0395000	1.6252270
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0142284	0.0034500	0.0006903	0.0173250	0.0270871
% of RVNAS	2.85%	0.69%	0.14%	3.47%	5.42%

A 3.3.3 Calculations for thymol

Resident & bystander exposure to thymol input parameters and results – pome fruit

Substance name	Thymol
Product name	Mevalone (3AEY) -Thymol
Reference value non acutely toxic active substance (RVNAS)	0.4 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Pome fruit
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Resident exposure for Mevalone (3AEY) -Thymol					
Croptype	Pome fruit				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip	5 m				i_Buffer
Application rate of the product	0.264 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0.264 g a.s./l				d_ConcAS
Dermal absorption of product	25.00%				i_AbsorpProduct
Dermal absorption of in-use dilution	70.00%				i_Absorplnuse
Oral absorption	100.00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.792 µg a.s./cm ²				d_DFR
Vapour pressure of in-use dilution	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻¹ Pa				i_Volat
Concentration in air	0.015 mg/m ³				d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	5.63 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	1.689 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00210 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00164 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	3.68 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	1.11 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00170 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00133 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ReExpDur
Exposure duration inhalation	24 hours				d_ReExpDurInhal
Exposure duration entry into treated crops	0.25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%				d_ClothAF
Breathing rate adult	0.23 m ³ /day/kg				d_BreathRAD
Breathing rate child (1-3 year old)	1.07 m ³ /day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	15.79%				
Drift percentage on surface (mean)	11.69%				
Turf transferable residues percentage	5.00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm ² /hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour				d_ReTCCh
Saliva extraction percentage	50.00%				d_SalExt
Surface area of hands mouthed	20 cm ²				d_AreaHM
Frequency of hand to mouth activity	9.5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm ²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2563782	0.1605000	0.0819122	0.3118500	0.6383476
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0256378	0.0160500	0.0081912	0.0311850	0.0638348
% of RVNAS	6.41%	4.01%	2.05%	7.80%	15.96%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.8537021	0.2070000	0.2130134	1.0395000	1.7516321
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0142284	0.0034500	0.0035502	0.0173250	0.0291939
% of RVNAS	3.56%	0.863%	0.89%	4.33%	7.30%

Resident & bystander exposure to thymol input parameters and results – grapes

Substance name	Thymol
Product name	Mevalone
Reference value non acutely toxic active substance (RVNAS)	0.4 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Grapes
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Resident exposure for Mevalone					
Croptype	Grapes				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				<i>l_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				<i>l_FormVal</i>
Buffer strip	5 m				<i>l_Buffer</i>
Application rate of the product	0.264 kg a.s./ha				<i>l_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	0.264 g a.s./l				<i>d_ConcAS</i>
Dermal absorption of product	25.00%				<i>l_AbsorpProduct</i>
Dermal absorption of in-use dilution	70.00%				<i>l_Absorplnuse</i>
Oral absorption	100.00%				<i>l_AbsorpOrallnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.792 µg a.s./cm ²				<i>d_DFR</i>
Vapour pressure of in-use dilution	moderately volatile substances with a vapour pressure between 5*10-3Pa and 10-2Pa				<i>l_Volat</i>
Concentration in air	0.015 mg/m ³				<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult	5.63 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	1.689 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00210 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00164 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	3.68 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	1.11 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00170 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00133 ml spray dilution/person				
Exposure duration dermal	2 hours				<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours				<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0.25 hours				<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18.0%				<i>d_ClothAF</i>
Breathing rate adult	0.23 m ³ /day/kg				<i>d_BreathRAd</i>
Breathing rate child (1-3 year old)	1.07 m ³ /day/kg				<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	3.07%				
Drift percentage on surface (mean)	2.32%				
Turf transferable residues percentage	5.00%				<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm ² /hour				<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour				<i>d_ReTCCh</i>
Saliva extraction percentage	50.00%				<i>d_SalExt</i>
Surface area of hands mouthed	20 cm ²				<i>d_AreaHM</i>
Frequency of hand to mouth activity	9.5 events/hour				<i>d_ReFreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm ²				<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20.00%				<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm ² /h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm ² /h				<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h				<i>d_TcEntryCh</i>
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2563782	0.1605000	0.0159259	0.3118500	0.5897398
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0256378	0.0160500	0.0015926	0.0311850	0.0589740
% of RVNAS	6.41%	4.01%	0.40%	7.80%	14.74%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.8537021	0.2070000	0.0414155	1.0395000	1.6252270
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0142284	0.0034500	0.0006903	0.0173250	0.0270871
% of RVNAS	3.56%	0.86%	0.17%	4.33%	6.77%

Resident & bystander exposure– EFSA (2022) OPEX version 0.3.22

Use : Orchards

Scenario 1 : Outdoor, early season

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 1000 l			
Number of applications and application rate: 1 x 0.132 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Eugenol			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.01	1.3
	Vapour (75th perc.)	0.01	1.2
	Deposits (75th perc.)	0.004	0.4
	Re-entry (75th perc.)	0.02	1.6
	Sum (mean)	0.04	3.6
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.007	0.7
	Vapour (75th perc.)	0.004	0.4
	Deposits (75th perc.)	0.002	0.2
	Re-entry (75th perc.)	0.009	0.9
	Sum (mean)	0.02	1.7
Number of applications and application rate: 1 x 0.264 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Thymol			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.03	6.4
	Vapour (75th perc.)	0.01	3
	Deposits (75th perc.)	0.008	2
	Re-entry (75th perc.)	0.03	7.8
	Sum (mean)	0.06	14.9
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.01	3.6
	Vapour (75th perc.)	0.004	1
	Deposits (75th perc.)	0.004	0.9
	Re-entry (75th perc.)	0.02	4.3
	Sum (mean)	0.03	7.4

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Geraniol	Number of applications and application rate: 1 x 0.264 kg a.s./ha		
	Dermal absorption: 70 %		
	DFR: 3 µg/cm ² foliage per kg a.s./ha		
	DT50: 30 days		
	Drift (75th perc.)	0.03	5.1
Resident child Body weight: 10 kg	Vapour (75th perc.)	0.01	2.4
	Deposits (75th perc.)	0.008	1.6
	Re-entry (75th perc.)	0.03	6.2
	Sum (mean)	0.06	12
	Drift (75th perc.)	0.01	2.8
Resident adult Body weight: 60 kg	Vapour (75th perc.)	0.004	0.8
	Deposits (75th perc.)	0.004	0.7
	Re-entry (75th perc.)	0.02	3.5
	Sum (mean)	0.03	6
Combined exposure			Hazard index
Resident child Body weight: 10 kg	Drift (75th perc.)		0.1
	Vapour (75th perc.)		0.07
	Deposits (75th perc.)		0.04
	Re-entry (75th perc.)		0.2
	Sum (mean)		0.3
Resident adult Body weight: 60 kg	Drift (75th perc.)		0.07
	Vapour (75th perc.)		0.02
	Deposits (75th perc.)		0.02
	Re-entry (75th perc.)		0.09
	Sum (mean)		0.2

Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not applicable.

A 3.3.1 Calculations for eugenol

Resident & bystander exposure to eugenol input parameters and results

Substance name	Eugenol
Product name	Mevalone (3AEY) - Eugenol
Reference value non acutely toxic active substance (RVNAS)	1 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Pome fruit
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.132 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	70.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Resident exposure for Mevalone (3AEY) - Eugenol					
Croptype	Pome fruit				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip	5 m				i_Buffer
Application rate of the product	0.132 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0.132 g a.s./l				d_ConcAS
Dermal absorption of product	70.00%				i_AbsorpProduct
Dermal absorption of in-use dilution	70.00%				i_Absorplnuse
Oral absorption	100.00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.396 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	moderately volatile substances with a vapour pressure between 5*10-3Pa and 10-2Pa				i_Volat
Concentration in air	0.015 mg/m³				d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	5.63 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	1.689 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00210 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00164 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	3.68 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	1.11 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00170 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00133 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ReExpDur
Exposure duration inhalation	24 hours				d_ReExpDurInhal
Exposure duration entry into treated crops	0.25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%				d_ClothAF
Breathing rate adult	0.23 m³/day/kg				d_BreathRAD
Breathing rate child (1-3 year old)	1.07 m³/day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	15.79%				
Drift percentage on surface (mean)	11.69%				
Turf transferable residues percentage	5.00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCh
Saliva extraction percentage	50.00%				d_SalExt
Surface area of hands mouthed	20 cm²				d_AreaHM
Frequency of hand to mouth activity	9.5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1281891	0.1605000	0.0409561	0.1559250	0.3994238
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0128189	0.0160500	0.0040956	0.0155925	0.0399424
% of RVNAS	1.28%	1.61%	0.41%	1.56%	3.99%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.4268510	0.2070000	0.1065067	0.5197500	0.9793160
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0071142	0.0034500	0.0017751	0.0086625	0.0163219
% of RVNAS	0.71%	0.35%	0.18%	0.87%	1.63%

A 3.3.2 Calculations for geraniol

Resident and bystander exposure to geraniol input parameters and results

Substance name	Geraniol
Product name	Mevalone (3AEY) - Geraniol
Reference value non acutely toxic active substance (RVNAS)	0.5 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Pome fruit
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Resident exposure for Mevalone (3AEY) - Geraniol					
Croptype	Pome fruit				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip	5 m				i_Buffer
Application rate of the product	0.264 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0.264 g a.s./l				d_ConcAS
Dermal absorption of product	25.00%				i_AbsorpProduct
Dermal absorption of in-use dilution	70.00%				i_Absorplnuse
Oral absorption	100.00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.792 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	moderately volatile substances with a vapour pressure between 5*10-3Pa and 10- Pa				i_Volat
Concentration in air	2Pa				
Resident dermal spray drift exposure 75th percentile - adult	0.015 mg/m³				d_AirCon
Resident dermal spray drift exposure 75th percentile - child	5.63 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	1.689 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00210 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.00164 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	3.68 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	1.11 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00170 ml spray dilution/person				
Exposure duration dermal	0.00133 ml spray dilution/person				
Exposure duration inhalation	2 hours				d_ReExpDur
Exposure duration entry into treated crops	24 hours				d_ReExpDurInhal
Light clothing adjustment factor	0.25 hours				d_ExpDurTreatCrop
Breathing rate adult	18.0%				d_ClothAF
Breathing rate child (1-3 year old)	0.23 m³/day/kg				d_BreathRAD
Drift percentage on surface (75th percentile)	1.07 m³/day/kg				d_BreathRCh
Drift percentage on surface (mean)	15.79%				
Turf transferable residues percentage	11.69%				
Transfer coeff. of surface deposits-adult	5.00%				d_Turf
Transfer coeff. of surface deposits-child (1-3 year old)	7300 cm²/hour				d_ReTCAd
Saliva extraction percentage	2600 cm²/hour				d_ReTCCh
Surface area of hands mouthed	50.00%				d_SalExt
Frequency of hand to mouth activity	20 cm²				d_AreaHM
Ingestion rate for mouthing of grass per day	9.5 events/hour				d_ReFreqHM
Dislodgeable residues percentage transferability for object to mouth	25 cm²				d_MouthGrass
Transfer coefficient for entry into treated crops (75th percentile) - adult	20.00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - child	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - adult	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - child	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2563782	0.1605000	0.0819122	0.3118500	0.6383476
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0256378	0.0160500	0.0082	0.0311850	0.0638348
% of RVNAS	5.13%	3.21%	1.64%	6.24%	12.77%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.8537021	0.2070000	0.2130134	1.0395000	1.7516321
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0142284	0.0034500	0.0035502	0.0173250	0.0291939
% of RVNAS	2.85%	0.690%	0.71%	3.47%	5.84%

A 3.3.3 Calculations for thymol

Resident & bystander exposure to thymol input parameters and results

Substance name	Thymol
Product name	Mevalone (3AEY) -Thymol
Reference value non acutely toxic active substance (RVNAS)	0.4 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	mg/kg bw/day
Crop type	Pome fruit
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	1000 L/ha
Maximum application rate of active substance	0.264 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption of active substance	100.00%
Inhalation absorption of active substance	100.00%
Vapour pressure of active substance	moderately volatile substances with a vapour pressure between 5*10 ⁻³ Pa and 10 ⁻² Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Buffer strip	5 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Resident exposure for Mevalone (3AEY) -Thymol					
Croptype	Pome fruit				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip	5 m				i_Buffer
Application rate of the product	0.264 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0.264 g a.s./l				d_ConcAS
Dermal absorption of product	25.00%				i_AbsorpProduct
Dermal absorption of in-use dilution	70.00%				i_Absorplnuse
Oral absorption	100.00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.792 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	moderately volatile substances with a vapour pressure between 5*10-3Pa and 10- Pa				i_Volat
Concentration in air	2Pa 0.015 mg/m³				d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	5.63 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	1.689 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00210 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00164 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	3.68 ml spray dilution/person				
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Resident inhal. spray drift exposure mean - adult	0.00170 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00133 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ReExpDur
Exposure duration inhalation	24 hours				d_ReExpDurInhal
Exposure duration entry into treated crops	0.25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%				d_ClothAF
Breathing rate adult	0.23 m³/day/kg				d_BreathRAD
Breathing rate child (1-3 year old)	1.07 m³/day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	15.79%				
Drift percentage on surface (mean)	11.69%				
Turf transferable residues percentage	5.00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCh
Saliva extraction percentage	50.00%				d_SalExt
Surface area of hands mouthed	20 cm²				d_AreaHM
Frequency of hand to mouth activity	9.5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h				d_TcEntryCh
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Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2563782	0.1605000	0.0819122	0.3118500	0.6383476
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0256378	0.0160500	0.0081912	0.0311850	0.0638348
% of RVNAS	6.41%	4.01%	2.05%	7.80%	15.96%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.8537021	0.2070000	0.2130134	1.0395000	1.7516321
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0142284	0.0034500	0.0035502	0.0173250	0.0291939
% of RVNAS	3.56%	0.863%	0.89%	4.33%	7.30%

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not applicable.