

REGISTRATION REPORT

Part A

Risk Management

Product code: 3AEY

Product name(s): Mevalone

Chemical active substances:

Eugenol, 33 g/L

Geraniol, 66 g/L

Thymol, 66 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

Applicant: Eden Research plc

Submission date: July 2021

Updated date: December 2021

MS Finalisation date: July 2022 (initial National Assessment)

December 2022 (final National Assessment)

Version history

When	What
July 2021	Initial dRR – Eden Research plc
December 2021	Update – Eden Research plc: <ul style="list-style-type: none">- The authorizations obtained on pome fruits in France- Pome fruits example in § Application background- The GAP table- Addition of storage stability for grapes and apples- List of data with final reports
July 2022	Initial zRMS assessment In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and the product label are highlighted in grey, while not agreed use pattern is struck through and shaded .
December 2022	Final report (National 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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PART A

RISK MANAGEMENT

1 Details of the application

This dossier is proposed for an application according to Article 33 of Regulation (EC) N° 1107/2009 of the product Mevalone. This evaluation is for first approval in the Central Zone.

Mevalone has already been authorized on grapes and other various crops in several countries of the Southern Zone and in non-EU countries. Application on pome fruits has also been authorized at a national level in France.

This application dossier is proposed for the following field crops for Mevalone:

- Grapes against grey mould (*Botrytis cinerea*),
- Pome fruits, against post-harvest storage diseases (e.g. *Phytophthora spp.*, *Botrytis cinerea*).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Reports, Part B Sections 1-10 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review.

1.1 Application background

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.

Eugenol, geraniol and thymol 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. The EU approval for the active substances will expire on November 30th, 2023. The supplementary dossiers have been submitted for renewal authorization on February 28th, 2021 (AIR 5 programme), the product Mevalone being the representative product. The zRMS is Spain and co-RMS is Greece.

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

Mevalone has already been authorized on grapes and other various crops in several Southern Europe countries (Albania, Bulgaria, Cyprus, France, Greece, Italy, Malta, Portugal, Romania and Spain) and in non-EU countries. Application on pome fruits has also been authorized in France.

This present dossier is for application in the Central Zone, with Poland as zRMS.

The concerned MS are **Austria, Belgium, Czech Republic, Germany, Hungary, the Netherlands, Luxembourg, Romania, Slovakia, Slovenia and the Republic of Ireland.**

1.2 Letters of Access

Letter of access is provided where appropriate.

1.3 Justification for submission of tests and studies

No new studies have been conducted for this application dossier.

Considering that the new data obtained for the AIR Renewal dossiers of the active substances are

under evaluation and therefore not yet peer-reviewed and agreed, previous peer-reviewed endpoints and newly obtained data for new requirements or to fulfil previous data gaps are presented in this application dossier.

1.4 Data protection claims

Eden Research plc has claimed protection of plant protection product data for the registration of Mevalone in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in 0.

2 Details of the authorization decision

2.1 Product identity

Product code	3AEY
Product name in MS	Mevalone
Authorization number	Not available
Function	Fungicide
Applicant	Eden Research plc
Active substance(s) (incl. content)	Eugenol 33 g/L Geraniol 66 g/L Thymol 66 g/L
Formulation type	Capsule suspension (CS)
Packaging	Professional user: 1L, 2L, 5L, 10L HDPE; 1L, 2L, 5L and 10L HDPE/PA (coex) jerry cans; 1L, 2L, 5L, 10L HDPE/EVOH.
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identity	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

The evaluation of the application for 3AEY / Mevalone resulted in the decision to grant the authorization.

All uses applied for were authorised except for the use in *Pyrus communis*, *Cydonia oblonga*, *Malus sylvestris*, *Eryobotria japonica*, *Mespilus germanica*, *Pyrus pyrifolia* – due to no efficacy data. These uses can not be registered under article 33 of 1107/2009 regulation. *Pyrus communis*, *Cydonia oblonga*, *Malus sylvestris*, *Mespilus germanica*, *Pyrus pyrifolia* are minor crops in Poland and can be registered under article 51 of 1107/2009 regulation.

2.3 Substances of concern for national monitoring

Not applicable. The plant protection product Mevalone does not contain any substance of concern for national monitoring.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin Sensitisation – Category 1 Serious eye damage / Eye irritation – Category 2
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	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+338 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. P501: Dispose of contents/containers in accordance with local/regional/national/international regulations (to be specified)
Additional labelling phrases:	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]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

Not applicable	
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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
Not applicable	Work wear, protective gloves and eye protection worn when mix/loading. Work wear (only) when applying the diluted product.
Worker protection:	
Not applicable	Gloves and work wear are to be worn during crop re-entry activities.
Integrated pest management (IPM)/sustainable use:	
Not applicable	-
Environmental protection	
SPe 3	To protect aquatic organisms respect an vegetated filter strip of 10 m to surface water bodies.
Other specific restrictions	
Not applicable	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
Not applicable	

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
Not applicable		
Environmental protection:		Relevant for use no.
Not applicable		

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	Mevalone / 3AEY	Formulation type:	GAP rev. 1, date: 2022-07 CS ^(a, b)
Active substance 1:	Eugenol	Conc. of as 1:	33 g/L ^(c)
Active substance 2:	Geraniol	Conc. of as 2:	66 g/L ^(c)
Active substance 3:	Thymol	Conc. of as 3:	66 g/L ^(c)
Safener:	-	Conc. of safener:	--
Synergist:	-	Conc. of synergist:	--
Applicant:	Eden Research plc	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Central ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	Yes		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14*							
Use- No.	Me- mber stat e(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (day s)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Groundwater	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
1	PL	Grape (<i>Vitis vinifera</i> VITV)	F	Grey mould (<i>Botrytis cinerea</i> BOTRCI)	Foliar. Tractor-mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 60-89	a) 1 b) 4 (7 days)	a) 1-6 2.0 –4.0 L/ha b) 6-4 8.0 –16 L/ha	a) 52-8 66 – 132 (E) 106 132 – 264 (G) 106 132 – 264 (T) b) 211 264 – 528 (E) 422 528 – 1056 (G) 422 528 – 1056 (T)	400 500 – 1000	7	The product is applied so that the concentration in g a.s./hL is kept constant at 13.2 (eugenol), 26.4 (geraniol), 26.4 (thymol) g a.s / hectolitre of spray water volume. Therefore, the higher application rate is diluted in the higher water volume. Apply at max. 3.0 - 3.2 L/ha LWA Dose rate range and water volume have been changed after efficacy evaluation.	A	A	A	A	A	R Aquatics A Remaining species	A	A Acceptabl e dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA)
2	PL	Apple <i>Malus domestica</i> MABSD, pear <i>Pyrus communis</i> PYUCO, quince <i>Cydonia oblonga</i> CYDOB, crab-apple <i>Malus sylvestris</i> MABSY, loquat <i>Eryobotria japonica</i> EIOJA, medlar <i>Mespilus germanica</i> MSPGE, Nashi pear <i>Pyrus pyrifolia</i> var. <i>culta</i> PYUPC	F	Post-harvest storage diseases	Foliar. Tractor-mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 75-87	a) 1 b) 4 (7 days)	a) 2-4 – 4.0 L/ha b) 9-6 – 16 L/ha	a) 79-2 132 (E) 158 264 (G) 158 264 (T) b) 317 – 528 (E) 634 – 1056 (G) 634 – 1056 (T)	600 – 1000	1	The product is applied so that the concentration in g a.s./hL is kept constant at 13.2 (eugenol), 26.4 (geraniol), 26.4 (thymol) g a.s / hectolitre of spray water volume. Therefore, the higher application rate is diluted in the higher water volume. Apply at 3.0 - 3.2 L/ha LWA Examples of pathogens causing post-harvest storage diseases: <i>Phytophthora</i> spp. PHYTSP (mainly <i>P. cactorum</i> PHYTCC or <i>P. syringae</i> PHYTSY), <i>Alternaria</i> spp. ALTESP, <i>Botrytis cinerea</i> BOTRCI Dose rate range and water volume have been changed after efficacy evaluation	A	A	A	A	A	R Aquatics A Remaining species	A	A MABSD N PYUCO CYDOB MABSY MSPGE PYUPC (possible registration under art. 51) N EIOJA

Remarks	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR), capsule suspension (CS)	(d)	Select relevant
table heading:	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPS in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
columns:	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
			13	PHI - minimum pre-harvest interval
			14	Overall conclusions

*** Explanation for column 14 "Overall conclusions"**

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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product Mevalone is that of light cream coffee brown (beige), viscous liquid, with a typical odour. It is not explosive, has no oxidising properties. The product is surface active and has non-newtonian properties. The product has no flash point up to 100°C. It has no self-ignition temperature up to 400°C. In aqueous solution (1% w/v suspension), it has a pH value around 5.8 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after freeze/thaw specimen cycle (between -10°C and 25°C (65 ± 4% rh) over the period of eight days) and 14 days at 54°C, neither the active substances content, the impurity content nor the technical properties were significantly changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging. Its technical characteristics are acceptable for a suspension concentrate formulation.

The intended concentration of use is 0.4 L Mevalone per 100 L of spray, equivalent to 0.4% v/v.

The product is not intended for use in any positive tank mixture.

3.2 Efficacy (Part B, Section 3)

This draft Registration Report summarizes the biological activity of biofungicide 3AEY (Mevalone) containing the active substances: eugenol (33 g/L), geraniol (66 g/L) and thymol (66 g/L) on *Botrytis cinerea* in grapevine and pathogens causing storage diseases in pome fruits. All the data regarding the efficacy and selectivity of the Mevalone have been submitted in dRR B-Section 3 and detailed in the Biological Assessment Dossier (BAD).

3.3 Efficacy data

The efficacy evaluation was based on 35 valid field efficacy trials carried out in the years 2006-2019 in grapevine (18 trials), and apple (17 trials) and 1 laboratory study carried out in 2018. The trials were conducted in 4 EPPO zones: Maritime (AT, CZ, DE, FR), North-East (PL), South-East (HU, RO, SL) and Mediterranean (FR).

Efficacy of Mevalone was assessed, when applied according to the requested GAP for the control of:

- ✓ *Botrytis cinerea* in grapes,
- ✓ Storage diseases (*Gloeosporium* sp., *Botrytis* sp., *Penicillium* sp., *Alternaria mali*, *Phytophthora* sp. and *Fusarium oxysporum*) in apples.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Mevalone is a biofungicide containing 33 g eugenol/L, 66 g geraniol/L and 66 g thymol/L. All three active ingredients belong to the same group of compounds, commonly known as terpenes, and have the same fungicidal mode of action. However, the primary effects on the cell membrane and other cell structures are considered to be from general activity on lipid components, rather than from activity at a very specific site. Based on this, it is highly unlikely that fungi would develop resistance to the action of the terpenes on the cell membrane.

As the mode of action of the terpenes involves the non-specific breakdown of lipids in membranes it is considered unlikely that fungi would be able to modify the target site or biosynthetic pathway in order

to develop resistance.

In addition, no specific resistance management guidelines are proposed by FRAC. Mevalone has a low risk for the development of resistance.

3.3.2 Adverse effects on treated crops

In a total of 26 efficacy trials on grapevine and 19 practical value trials on apple, including 14 trials in which it was applied at the 2N dose, Mevalone demonstrated a high crop safety. Yield was tested in 1 trial on grapes and 6 trials on apples.

• Phytotoxicity to host crops

No phytotoxicity was observed in any efficacy trials.

• Effects on total yield

No adverse effect on qualitative features of the harvested product was observed in any trials and no adverse effect is expected after application of the product according to the recommendations of the GAP table.

• Effects on qualitative features of the harvested products

~~No adverse effect on qualitative features of the harvested product is expected after application of the product according to the recommendations of the GAP table.~~ Mevalone applied close to harvest, may affect the taste of raisins produced from treated crops.

• Effects on transformation processes

No adverse effect on transformation processes of the harvested product is normally expected after application of the product according to the recommendations of the GAP table.

• Effects on propagation purposes

No adverse effect on treated plants or plant products to be used for propagation is normally expected after application of the product according to the recommendations of the GAP table.

3.3.3 Observations on other undesirable or unintended side-effects

In a total of 26 efficacy trials on grapevine and 19 practical value trials on apple, including 14 trials in which it was applied at the 2N dose, MEVALONE demonstrated a high crop safety.

Besides, no adverse effects on succeeding crops, other plants, including adjacent crops are expected, when Mevalone is used according to GAP and label recommendations.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Total eugenol, geraniol and thymol are determined and quantified in Mevalone after dilution in methanol using gas chromatography with a flame-ionisation detector and 1-nonanol as internal standard.

Free eugenol, geraniol and thymol are determined and quantified in Mevalone after extraction in hexane using gas chromatography with a flame-ionisation detector and 1-nonanol as internal standard.

The validation of the method for analysis of eugenol, geraniol and thymol in Mevalone has already been evaluated at EU level. It was performed under GLP according to Guideline SANCO/3030/99 rev.4 and was successfully validated. Validation also complies with SANCO/3030/99 rev.5.

3.4.2 Analytical methods for residues

For pre-authorisation, suitable validated methods were submitted to cover the intended uses and to support toxicity, ecotoxicity and e-fate studies.

For post-authorization control and monitoring purposes, it is proposed that eugenol, geraniol and thymol are included into Annex IV to Regulation (EC) No. 396/2005 and so a residue definition for plant and animal matrices would not be required.

For other matrices, all of these methods will be reviewed at EU level for renewal of active substances.

According to the EFSA Journal 2012;10(11):2914-2916 the data gap is identified for methods of analysis for soil, water and air for eugenol, geraniol and thymol.

New analytical methods for the determination of

- eugenol and methyl-eugenol residues in plant matrices,
- eugenol and methyl-eugenol residues in animal matrices,
- eugenol and methyl-eugenol residues in water,
- eugenol and methyl-eugenol residues in air,
- eugenol and methyl-eugenol residues in body fluids and tissues,
- geraniol residues in plant matrices,
- geraniol residues in animal matrices,
- geraniol residues in water,
- geraniol residues in air,
- geraniol residues in body fluids and tissues,
- thymol residues in plant matrices,
- thymol residues in animal matrices,
- thymol residues in water,
- thymol residues in air,
- thymol residues in body fluids and tissues

have been provided by Applicant. These data are currently under evaluation for the renewal of approval of the active substances. For the detailed evaluation of new studies it is referred to Appendix 2 of Part B5. The studies are acceptable.

According to the SANCO/825/00 rev.8.1 and the guidance document SANTE/2020/12830 rev.1 “A validation of the primary monitoring method in an independent laboratory (ILV) is required for the determination of residues in food of plant and animal origin and in drinking water. The ILV shall confirm the LOQ of the primary method, or at least cover the lowest MRL.” It should be noted that no definition of residue or MRL has been set for the active substance eugenol, geraniol and thymol in food and feed of animal origin, so the analytical methods and ILV for plant and animal matrices are not required.

Study of ILV for the determination of eugenol, methyl-eugenol, geraniol and thymol residues in water is on-going and will be submitted as part of the renewal of approval of active substances.

3.5 Mammalian toxicology (Part B, Section 6)

A modern, guideline compliant 6 pack is available. Mevalone was the representative formulation in the EU review of eugenol, geraniol and thymol. The acute toxicity studies for Mevalone were evaluated during the review and were considered adequate. Mevalone is of low acute oral, dermal and inhalation toxicity. It is sensitising and is a mild skin irritant and is irritating to eyes.

Based on the results of the acute toxicity studies and non-dietary risk assessments conducted with Mevalone, the following personal protective equipment (PPE)/risk management measures (RMM) are recommended:

Operator: Work wear, protective gloves and eye protection worn when mix/loading. Work wear (only)

when applying the diluted product.

Worker: Gloves and work wear are to be worn during crop re-entry activities.

3.5.1 Acute toxicity

The acute toxicity of Mevalone has been determined in a series of acute toxicity studies. The Table below summarises the acute toxicity of Mevalone.

Type of test, species, model system (Guideline)	Result	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (OECD 423)	> 2000 mg/kg bw	None	XXXX
LD ₅₀ dermal, rat (OECD 402)	> 2000 mg/kg bw	None	XXXX
LC ₅₀ inhalation, rat (OECD 403)	LC ₅₀ > 2.28 mg/L air (maximum achievable)	None	XXXX
Skin irritation, rabbit (OECD 404)	Mild Irritant	None	XXXX
Eye irritation, rabbit (OECD 405)	Irritant	H319	XXXX
Skin sensitisation, mouse (OECD 429, LLNA)	Sensitising	H317	XXXX

For further details, please refer to Part B, Section 6.3 of this submission.

Mevalone is of low acute oral, dermal and inhalation toxicity. It is sensitising and is a mild skin irritant and is irritating to eyes. Taking into account all submitted data and the labelling of the active substances, Mevalone should be labelled as, H319: Cause serious eye irritation and, H317: May cause an allergic skin reaction”, according to Regulation (EC) 1272/2008.

3.5.2 Operator exposure

The estimated levels of exposure to eugenol, thymol and geraniol in operators applying Mevalone to pome fruits or grapes using vehicle mounted sprayers are within the respective AOELs when adequate work clothing is worn. Exposure to eugenol, thymol and geraniol is also within acceptable limits when applying Mevalone to grapes and/or pome fruits using a knapsack sprayer whilst wearing adequate work wear.

The predicted combined exposure (sum of component exposures to eugenol, thymol and geraniol) for operators applying Mevalone to pome fruits or grapes using vehicle mounted sprayers is within acceptable limits when typical work clothing is worn. The combined level of exposure is also within acceptable limits when applying Mevalone to grapes or pome fruits using a knapsack sprayer whilst wearing adequate work wear.

3.5.3 Worker exposure

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

The predicted combined exposure (sum of component exposures to eugenol, thymol and geraniol) 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 fruits uses).

3.5.4 Bystander and resident exposure

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

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

3.6 Residues and consumer exposure (Part B, Section 7)

3.6.1 Residues

Eugenol, geraniol and thymol are provisionally included into Annex IV to Regulation (EC) No. 396/2005 and therefore MRLs are not necessary.

Residue trials have been conducted in the northern residue zone on grapes and apples, as the representative crop for pome fruits.

For grapes, the PHI is 7 days. Residues of eugenol and methyl-eugenol were not detectable at harvest. Residues of thymol were either not detectable or below the LOQ. For geraniol, natural background concentrations were found in the control grape samples and at harvest residues were identical to the natural background concentrations. Thus, the trials demonstrated that there was no increase in residues above natural background concentrations.

For pome fruits, the PHI is 1 day. Residues of eugenol, methyl-eugenol and geraniol were not detectable and residues of thymol were below the LOQ at harvest.

Storage stability studies have been conducted on grapes and apples, which were stored under the same conditions as in the residue trials. A detailed assessment of the data indicated that the residues would be stable for the duration of storage and that the results of the residue trials could be relied upon.

Rotational crop studies are not relevant, since grapes and pome fruits are not grown in rotation.

Livestock metabolism and magnitude of the residue studies are not necessary, due to the natural occurrence of eugenol, geraniol and thymol in a variety of fruits, vegetables, herbs and spices. Furthermore, livestock dietary intake calculations demonstrate that the dietary intake of all 3 actives is below the trigger of 0.004 mg/kg bw/day.

3.6.2 Consumer exposure

Eugenol, geraniol and thymol are all naturally occurring in a wide variety of fruit, vegetables, herbs and spices and as such there is already considerable natural exposure.

Dietary intake calculations were performed using EFSA PRIMo 3.1, using default input values of 0.01* mg/kg for all residues. This is worst-case since residues were either not detectable, below the LOQ or identical to natural background concentrations. Nevertheless, the TMDI was equal to 0.1%, 0.2% and 4% of the ADI for eugenol, geraniol and thymol respectively and the IESTI was 2% of the ARfD for thymol (ARfD not set for eugenol and geraniol).

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

Soil exposure for eugenol, geraniol and thymol was calculated using approach described in respective FOCUS guidance for the intended uses of Mevalone. For all compounds, EU agreed data were taken into account. Soil exposure for the formulated product was also calculated. Obtained PEC_{SOIL} values were used in the risk assessment for soil organisms.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The leaching behaviour of eugenol, geraniol and thymol was assessed using FOCUS leaching models FOCUS PEARL v. 4.4.4, FOCUS PELMO v. 5.5.3 and MACRO 5.5.4 on the basis of the EU agreed input parameters and intended use pattern of Mevalone.

Performed calculations resulted with PEC_{GW} values <0.1 µg/L in all relevant Polish scenarios, demonstrating that no unacceptable leaching of these compounds is expected when Mevalone is used according to recommendations.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The surface water exposure was estimated using the respective FOCUS models. EU agreed endpoints and intended use pattern of Mevalone were considered. The surface water exposure to the formulated product was calculated using Spray Drift Calculator. Obtained PEC_{SW} values were used in the risk assessment for aquatic organisms.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The fate and behaviour in air of eugenol, geraniol and thymol was evaluated during the Annex I renewal. No additional studies are necessary. The Annex I review concluded that the active substance is not expected to form significant concentrations in air due to rapid degradation in air.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds

Acceptable acute and long-term risk to birds is concluded at the screening step from the proposed uses of Mevalone in vineyards and pome fruit. The risk from secondary poisoning and drinking water is also considered to be acceptable.

It should be, however, noted that in absence of the EU agreed avian reproductive toxicity studies, the long-term risk assessment was performed with consideration of the surrogate LD₅₀/10 value and should be rather considered as illustrative. Nevertheless, in opinion of the zRMS, based on results of the performed calculations, rapid dissipation of active compounds due to volatilisation and degradation as well as natural occurrence of eugenol, methyl-eugenol, geraniol and thymol in various food items of birds, no unacceptable risk to birds is anticipated from uses of Mevalone in line with the Polish GAP. Further evaluation will be performed once final and firm conclusions are taken at the EU level following the ongoing renewal process of all three active compounds.

Mammals

Acceptable acute and long-term risk to mammals is concluded at the screening step or first-tier for the proposed uses of Mevalone in vineyards and pome fruit. The risk from secondary poisoning and drinking water is also considered to be acceptable.

It should be, however, noted that in absence of the EU agreed mammalian reproductive toxicity studies for geraniol and thymol, the long-term risk assessment was performed with consideration of the provisional long-term toxicity endpoints derived by the zRMS with consideration of information available in the DAR (May 2011) for both active compounds. Nevertheless, in opinion of the zRMS, based on results of the performed calculations, rapid dissipation of active compounds due to volatilisation and degradation as well as natural occurrence of eugenol, methyl-eugenol, geraniol and thymol in various food items of mammals, no unacceptable risk to mammals is anticipated from uses of Mevalone in line with the Polish GAP. Further evaluation will be performed once final and firm conclusions are taken at the EU level following the ongoing renewal process of all three active compounds.

3.8.2 Effects on aquatic species

An acceptable risk to aquatic organisms following the proposed uses of Mevalone in Poland (including the three active substances eugenol, geraniol and thymol) is concluded provided that In order to protect aquatic organisms a vegetated filter strip of 10 metres to surface water bodies is respected during application in both crops.

It should be noted that due to measured concentrations of geraniol in aged test solutions being <LOD/LOQ, the evaluation performed for geraniol is provisional and further evaluation will be performed once decision on acceptability of the study is taken at the EU level following the ongoing renewal process.

3.8.3 Effects on bees

Based on the performed evaluation, acceptable risk to bees from the intended uses of Mevalone in Poland may be concluded.

3.8.4 Effects on other arthropod species other than bees

Based on the performed evaluation, acceptable risk to non-target arthropods from the intended uses of Mevalone in Poland may be concluded with no need for risk mitigation measures.

3.8.5 Effects on soil organisms

The risk to earthworms and *Folsomia candida* from exposure of Mevalone and the three active substances eugenol, geraniol and thymol, was demonstrated to be acceptable when the maximum predicted soil concentration was considered.

No significant effects (<25%) on soil micro-organisms were shown for Mevalone (including eugenol, geraniol and thymol) at concentrations greater than the maximum predicted environmental concentrations in soil. The risk to soil micro-organisms from the proposed uses of Mevalone in Poland is therefore considered to be acceptable.

3.8.6 Effects on non-target terrestrial plants

The risk assessment for non-target plants was considered to be acceptable using the maximum

application rate of Mevalone and the screening data reported in DAR. No adverse effects are expected at 4 L/ha x 4 applications of Mevalone. No risk mitigation measures are deemed necessary.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Additional data on other terrestrial organisms are not considered necessary based on the acceptable risk demonstrated for terrestrial organisms.

No further assessments are considered necessary.

3.9 Relevance of metabolites (Part B, Section 10)

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

Therefore, no relevance assessment is required.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not applicable as the active substance are not listed as candidates for substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, pozostałości, toksykologii i istotności toksykologicznej metabolitów, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym kolorem.

Zakres zmian jest następujący:

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008 r. nie jest wymagane.
2. Okres ważności: 2 lata w opakowaniach wykonanych z HDPE na podstawie wyników 2-letnich badań stabilności. Zgodnie z zapisami wytycznej Ministerstwa Rolnictwa i Rozwoju Wsi w sprawie zasad zatwierdzania opakowań środków ochrony roślin z dnia 18/10/2021 możliwa jest ekstrapolacja wyników badań stabilności wykonanych dla środka przechowywanego w HDPE na HDPE/PA i HDPE/EVOH. W związku z powyższym, wszystkie opakowania wymienione, w punktach 2.1 dokumentu A i 4.1 Sekcji 1 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania oraz sporządzania cieczy użytkowej.
4. Brak uwag do zapisów nazw grup chemicznych, do których przyporządkowano substancje czynne oraz ich zawartości (zawartości substancji czynnych wyrażone w procentach obliczono w oparciu o gęstość środka ochrony roślin 1.029 g/ml zgodnie z danymi zawartymi w punkcie 1.2.1 dokumentu C).
5. Zgodnie z informacjami zawartymi w punktach IIIA 2.9.1 i IIIA 2.9.2 Sekcji 1,2,4 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania.

Sekcja skuteczność:

1. Na podstawie przedłożonych przez wnioskodawcę badań możliwa jest rejestracja fungicydu 3AEY / Mevalone w trybie art. 33 rozporządzenia 1107/2009 do ochrony winorośli przed sprawcą szarej pleśni oraz jabłoni przed patogenami powodującymi choroby przechowalnicze.
2. Tabela GAP uwzględnia dodatkowo rejestrację środka w następujących uprawach: grusza pospolita, pigwa, jabłoń płonka, nieśplik japoński, nieszpuka zwyczajna, grusza azjatycka w trybie art. 33 rozporządzenia 1107/2009. Z uwagi na brak jakichkolwiek badań skuteczności wykonanych w tych uprawach, nie można ich zarejestrować w trybie artykułu 33. Z uwagi na to, że grusza pospolita, pigwa, jabłoń płonka, nieszpuka zwyczajna, grusza azjatycka są wpisane na listę upraw małoobszarowych w rozporządzeniu Ministra Rolnictwa i Rozwoju Wsi z dnia 18 września 2019 r. zmieniającym rozporządzenie w sprawie zastosowań małoobszarowych środka ochrony roślin, można zarejestrować te uprawy w trybie art. 51 rozporządzenia 1107/2009.
3. Z uwagi na to, że w jabłoni środek Mevalone bez dodatku adjuwantu stosowany był jedynie w dawce 4,0 l/ha oraz biorąc pod uwagę uzyskany poziom skuteczności (<60%) dla tej dawki, uznano że dawka 4,0 l/ha jest jedyną dawką, która może zostać wpisana do etykiety środka z jednoczesną uwagą o ograniczeniu występowania chorób przechowalniczych. Biorąc pod uwagę badania skuteczności wykonane w strefie EPPO północno-wschodniej, jako przykładowe patogeny powodujące choroby przechowalnicze do polskiej etykiety można wpisać jedynie *Botrytis* sp. oraz *Gloeosporium* sp. (po 2 badania przedłożone dla każdego patogenu). Nie uwzględniono wyników badań z krajów sąsiednich z uwagi na bardzo niską skuteczność <40% odnotowaną dla *Penicilium expansum* czy *Fusarium oxysporum* oraz brak wyników badań z Niemiec czy Czech dla *Phytophthora* sp., *Alternaria* sp.. W związku z powyższym zmieniono zapisy w etykiecie środka dla jabłoni tj. usunięto przedział dawek 2,4-4,0 l/ha pozostawiając jedynie dawkę 4,0 l/ha. Jednocześnie, celem zachowania stężenia cieczy użytkowej 0,4%, zmieniono zakres wody z 400-1000 l/ha na 1000 l/ha. Usunięto z etykiety patogeny: *Phytophthora* sp., *Alternaria* sp., *Penicilium*, *Fusarium oxysporum*. Wprowadzono także uwagę o ograniczeniu występowania chorób przechowalniczych.
4. Podczas oceny skuteczności środka w zwalczaniu *Botrytis cinerea* w winorośli, z uwagi na brak badań skuteczności ze strefy EPPO północno-wschodniej, uwzględniono wyniki badań z Niemiec. Jest to zgodne z zapisem ustaleń harmonizacyjnych, pozwalających na wykorzystanie badań z krajów sąsiednich w sytuacji, gdy nowe substancje czynne są zakwalifikowane do stosowania w rolnictwie ekologicznym. (eugenol, geraniol i tymol są wymienione w rozporządzeniu 2019/2164 z dnia 17 grudnia 2019 r. zmieniającym

rozporządzenie (WE) nr 889/2008 ustanawiającym szczegółowe zasady wdrażania rozporządzenia Rady (WE) nr 834/2007 w sprawie produkcji ekologicznej i znakowania produktów ekologicznych w odniesieniu do produkcji ekologicznej, znakowania i kontroli. Jednocześnie, biorąc pod uwagę odnotowany niski poziom skuteczności środka dla dawki <2,0 L/ha, zmieniono zakres dawek dla zastosowania środka w winorośli z 1,6-4,0 L/ha na 2,0-4,0 L/ha. Wprowadzono uwagę o stosowaniu niższej z zalecanych dawek w warunkach niskiego nasilenia występowania choroby. Jednocześnie, celem zachowania stężenia cieczy użytkowej 0,4%, zmieniono zakres wody z 400-1000 L/ha na 500-1000 L/ha. Wprowadzono także uwagę o średnim poziomie zwalczania choroby.

5. Dopisano informację o konieczności prowadzenia monitoringu pod kątem ewentualnego wystąpienia odporności patogenów.
6. Wprowadzono uwagę o możliwym wpływie środka Mevalone, stosowanego krótko przed zbiorem na smak rodzynek.

Sekcja metody analityczne:

1. Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W części dotyczącej klasyfikacji zagrożeń zmodyfikowano zwrot P280 zgodnie z zasadami CLP.
2. W części dotyczącej środków ostrożności dla osób stosujących środek odpowiedni zapis zmodyfikowano zgodnie z wymaganiami harmonizacyjnymi (Min Rol wer 26.10.2021).

Sekcja pozostałości:

1. Zapisy dotyczące roślin następczych nie dotyczą proponowanych zastosowań, ze względu na to, że drzewa owocowe i winorośl nie są uprawiane w płodozmianie.
2. Okresy karencji dla jabłoni i winorośli są zaakceptowane.

Sekcja los i zachowanie w środowisku:

1. Brak uwag.

Sekcja ekotoksykologia:

1. Poprawiono zwroty dotyczące zarządzania ryzykiem..

Posiadacz zezwolenia:

Eden Research plc, 67C Innovation Drive, Milton Park, Oxfordshire, Zjednoczone Królestwo Wielkiej Brytanii i Irlandii Północnej, OX4 4RQ, Tel.: +44 1258 359 555

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Sumi Agro Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa, tel.: +48 22 637 32 37, fax: +48 22 637 32 38, www.sumiagro.pl; e-mail: biuro@sumiagro.pl

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

.....

MEVALONE

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

eugenol (związek z grupy pochodnych terpenów) – 33 g/l (3,2%)
geraniol (związek z grupy pochodnych terpenów) – 66 g/l (6,4%)
tymol (związek z grupy pochodnych terpenów) – 66 g/l (6,4%)

Zezwolenie MRiRW nr R- .../2021 z dnia2021 r.



Uwaga	
H317 H319	Może powodować reakcję alergiczną skóry. Działa drażniąco na oczy.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
EUH208	Zawiera eugenol i geraniol. Może powodować wystąpienie reakcji alergicznej.
P280 P302 + P352	Stosować rękawice ochronne/ odzież ochronną /ochronę oczu/ochronę twarzy. W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody /mydłem.
P305+P351+P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P333 + P313	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/ zgłosić się pod opiekę lekarza.
P337 + P 313	W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

OPIS DZIAŁANIA

FUNGICYD w formie zawiesiny kapsuł w cieczy do sporządzania zawiesiny wodnej przeznaczonym do stosowania zapobiegawczego i interwencyjnego w zwalczaniu chorób.

Środek zawiera trzy substancje czynne z grupy terpenów: wg FRAC grupa BM 01 (wcześniej F7) – substancje powodujące uszkodzenie błony komórkowej, ściany komórkowej patogenów oraz indukujące mechanizmy obronne roślin. Dotychczas nie stwierdzono żadnej odporności patogenów na substancje czynne z tej grupy. Niezbędny jest ciągły monitoring sytuacji i zaraportowanie każdego ewentualnego przypadku wystąpienia odporności w przyszłości.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych i sadowniczych oraz opryskiwaczy ręcznych.

Jabłoń

Choroby przechowalnicze powodowane przez: *Botrytis sp.*, *Phytophthora sp.*, *Alternaria sp.*, *Penicillium*, *Fusarium oxysporum*, *Gloeosporium sp.* (ograniczenie występowania chorób)

Maksymalna dawka dla jednorazowego zastosowania: 4,0 l/ha.

Zalecana dawka dla jednorazowego zastosowania: ~~2,4~~ 4,0 l/ha lub 3,0-3,2 l/ha powierzchni ściany liściowej.

Termin stosowania: Środek stosować od fazy, gdy owoce osiągają połowę typowej wielkości do fazy zbioru owoców przestrzegając okresu karencji (BBCH 75-87).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 4.

Minimalny odstęp między zabiegami: 7 dni.

Zalecana ilość wody: ~~600~~ 1000 l/ha.

Należy zachować końcowe stężenie cieczy roboczej 400 ml środka Mevalone / 100 l wody.

Zalecane opryskiwanie: średniokropliste.

Winorośl

Szara pleń (średni poziom zwalczania choroby)

Maksymalna dawka dla jednorazowego zastosowania: 4,0 l/ha.

Zalecana dawka dla jednorazowego zastosowania: ~~1,6~~ 2,0 - 4,0 l/ha lub ~~3,0~~ 1,7-3,2 l/ha powierzchni ściany liściowej.

Niższą z zalecanych dawek stosować jedynie w warunkach niskiego nasilenia występowania choroby.

Termin stosowania: Środek stosować od fazy początk u kwitnienia tj., gdy pierwsze kwiaty rozchylają się do fazy zbioru owoców przestrzegając okresu karencji (BBCH 60-89).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 4.

Minimalny odstęp między zabiegami: 7 dni.

Zalecana ilość wody: ~~400~~ 500-1000 l/ha.

Należy zachować końcowe stężenie cieczy roboczej 400 ml środka Mevalone / 100 l wody.

Zalecane opryskiwanie: średniokropliste.

Uwaga: Mevalone stosowany krótko przed zbiorem może wpływać na smak rodzynek.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Jabłoń - 1 dzień.

Winorośl - 7 dni.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po dodaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Rozproszenie rozcieńczonej cieczy użytkowej i wody po myciu aparatury wykonywać dopiero po obesznięciu opryskiwanych roślin, obniżając ciśnienie robocze oraz zwiększając prędkość roboczą opryskiwacza.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

Nie jeść, nie pić ani nie palić podczas używania produktu.

~~Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.~~

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

Unikać wdychania pyłu/rozpylonej cieczy.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W przypadku obu upraw w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 metrów od zbiorników i cieków wodnych.

W celu ochrony pszczoł i innych owadów zapylających środek stosować wieczorem po zakończeniu oblotu roślin przez pszczoły i inne gatunki zapylające.

W celu ochrony stawonogów oraz roślin niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie od zbiorników i cieków wodnych strefy ochronnej o szerokości 1 m w przypadku stosowania środka w uprawie jabłoni i winorośli.~~

~~W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie od terenów nieużytkowanych rolniczo strefy ochronnej o szerokości 1 m w przypadku stosowania środka w uprawie jabłoni i winorośli.~~

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0 - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W przypadku połknięcia: Skontaktować się z ośrodkiem zatruc lub lekarzem.

W przypadku dostania się na skórę: umyć dużą ilością wody z mydłem.

W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Appendix 4 Lists of data considered for national authorization (Master reference list)

List of data submitted by the applicant and relied on

These studies have been submitted within the AIR dossier of active substances (RMS: Spain) 28th February 2021 (except for KCP 6.2. Efficacy data)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1/03 KCP 5.1.2/18	Bates G.J.D.	2014	Ambient storage stability trial for the 3AEY formulation Report n°J19053, G.C. Laboratories Ltd GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 2.1/04	Bates G.J.D.	2012	Accelerated storage stability trial for the 3AEY formulation Report n°J19052, G.C. Laboratories Ltd GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.1.1/02	Wronska, L.	2020a	Validation of Analytical Method TS20010-1 for the determination of Active Ingredient Content in Cedroz and Mevalone Formulations Battelle UK Ltd. Report No. TS/20/010/1 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.1.1/06	Wronska, L.	2020b	Validation of an Analytical Method TS21001-1 for the determination of Impurity Methy-Eugenol in Mevalone Formulations Battelle UK Ltd. Report No. TS/21/001/1 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.1.2/03 KCA 4.1.2/03 (eugenol) KCA 4.1.2/03 (geraniol) KCA 4.1.2/05 (thymol)	Cheshire A.	2008	To determine the magnitude of geraniol, eugenol and thymol residues at harvest in the raw agricultural commodity grapes resulting from sequential applications of 3AEY, in Southern and Northern France, 2007 Agrisearch UK Ltd Report No. AF/12268/ED GLP Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/05 KCA 4.1.2/05 (eugenol/ geraniol) KCA 4.1.2/08 (thymol)	Chadwick G.	2021a	Determination of residues of eugenol, methyl eugenol, geraniol and thymol after 4 foliar applications of Mevalone (3AEY / EDN-004) to grapevine, 3 trials in N EU (3 x DEC) and 3 trials in S EU (3 x DEC), 2020 Eurofins Agrosience Services Report No. S20-06337 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.1.2/06 KCA 4.1.2/06 (eugenol/ geraniol) KCA 4.1.2/09 (thymol)	Chadwick G.	2021b	Determination of residues of eugenol, methyl eugenol, geraniol and thymol after 4 foliar applications of Mevalone (3AEY / EDN-004) to apple, 3 trials in N EU (3 x DEC) and 3 trials in S EU (3 x DEC), 2020 Eurofins Agrosience Services Report No. S20-06361 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCA 4.1.2/21 (eugenol)	Egeler P	2021a	Eugenol : A Study on the Chronic Toxicity to <i>Daphnia magna</i> - Analysis of Test Solutions - ECT Oekotoxikologie GmbH Report No. 20GC3DB GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCA 4.1.2/42 (geraniol)	Schrag K.	2021	A Study on the Chronic Toxicity to <i>Daphnia magna</i> - Analysis of Test Solutions – CIP GmbH report n°20GC1DB GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCA 4.1.2/44 (geraniol)	Seidel U., Emnet P.	2021	Geraniol: Toxicity to <i>Pseudokirchneriella subcapitata</i> in an Algal Growth Inhibition Test CIP GmbH report No 155771210 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCA 4.1.2/21 (thymol)	Egeler P.	2021b	A Study on the Chronic Toxicity to <i>Daphnia magna</i> ECT GmbH Report No. 20GC2DB GLP Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/12 KCA 4.1.2/23 (eugenol) KCA 4.1.2/45 (geraniol) KCA 4.1.2/23 (thymol)	Aversa S.	2019	Validation of an analytical method for the determination of eugenol, geraniol and thymol in water stock solution and in sugar feeding solution treated with test item ARAW (according to SANCO 3029/99/rev.4 guidance document) BioTecnologie BT S.r.l. Report No. BT081/19 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.1.2/13	Pecorari F.	2019a	Chronic oral effects of ARAW on adult worker honeybees <i>Apis mellifera</i> L., 10-day feeding laboratory test BioTecnologie BT S.r.l. Report No. BT059/19 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.1.2/14	Pecorari F.	2019b	Effects of ARAW on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure BioTecnologie BT S.r.l. Report No. BT060/19 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCA 4.2/01 (geraniol/ thymol)	Wiesner F., Breyer N.	2017	Validation of an Analytical Method for the Determination of Residues of Geraniol and Thymol in Tomato, Cucumber and Strawberry Eurofins GmbH Report No. S16-03357 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCA 4.1.2/25 (eugenol)	Lingott J.	2020a	Partition coefficient of Eugenol (Shake-Flask Method) Eurofins GmbH Report No. S20-06643 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCA 4.1.2/47 (geraniol)	Lingott J.	2020b	Partition coefficient of Geraniol (Shake-Flask Method) Eurofins GmbH Report No. S20-06645 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.2/25 (thymol)	Lingott J.	2020	Partition coefficient of Thymol (Shake-Flask Method) Eurofins Agroscience Services EcoChem GmbH Report No. S20-06644 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.2/01 KCA 4.2/01 (eugenol) KCA 4.2/02 (geraniol/ thymol)	Driss F	2021a	Validation of residue method for the determination of eugenol, geraniol, thymol and methyl-eugenol in grape Eurofins Agroscience Services Chem SAS Report No. S20-06528 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.2/02 KCA 4.2/02 (eugenol) KCA 4.2/03 (geraniol/ thymol)	Driss F.	2021b	Storage Stability of Eugenol, Geraniol, Thymol and Methyl Eugenol in Grape under Deep Frozen Conditions Eurofins Agroscience Services Report No. S20-06526 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.2/05 KCA 4.2/05 (eugenol) KCA 4.2/06 (geraniol/ thymol)	Driss F	2021c	Validation of the residue method for the determination of eugenol, geraniol, thymol and methyl-eugenol in apple Eurofins Agroscience Services Chem SAS Report No. S20-06529 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.2/06 KCA 4.2/06 (eugenol) KCA 4.2/07 (geraniol/ thymol)	Driss F	2021d	Storage Stability of Eugenol, Methyl Eugenol, Geraniol and Thymol in apple under Deep Frozen Conditions Eurofins Agroscience Services Report No. S20-06527 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.2/07 KCA 4.2/10 (eugenol) KCA 4.2/11 (geraniol/ thymol)	Driss F	2021e	Validation of the residue method for the determination of eugenol, geraniol, thymol and methyl-eugenol in body fluid (blood and urine) Eurofins Agroscience Services Chem SAS Report No. S20-06626 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/08 KCA 4.2/11 (eugenol) KCA 4.2/12 (geraniol/thymol)	Driss F	2021f	Validation of the residue method for the determination of eugenol, geraniol, thymol and methyl-eugenol in body tissue (meat and liver) Eurofins Agrosience Services Chem SAS Report No. S20-06625 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.2/10 KCA 4.2/07 (eugenol) KCA 4.2/08 (geraniol/thymol)	Chambers J.	2020a	Thymol, Eugenol, Methyl Eugenol and Geraniol: Method Validation in Surface Water Report number TS/19/001 Battelle UK GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 5.2/11 KCA 4.2/09 (eugenol) KCA 4.2/10 (geraniol/thymol)	Chambers J.	2020b	Thymol, Eugenol, Methyl Eugenol and Geraniol: Method Validation in Air – amended report Report number TS/19/003 Battelle UK GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6	Anonym	2021	BAD of Mevalone - Central zone – Core assessment (authorization for Mevalone product) Staphyt Regulatory Report n°: N/A GEP: N/A Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /01 <i>Also cited in KCP 6.4</i>	Sutherland J. Sipos P.	2018	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine, 1 site South-east zone, 2018 Eurofins Agrosience Services Report n°: S18-05195-01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /02 <i>Also cited in KCP 6.4</i>	Sutherland J. Sipos P.	2018	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine, 1 site South-east zone, 2018 Eurofins Agrosience Services Report n°: S18-05195-02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /03 <i>Also cited in</i>	Sutherland J. Sipos P.	2018	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine, 1 site South-east zone, 2018	N	Y	Data/study report never submitted before to	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4			Eurofins Agrosience Services Report n°: S18-05195-03 GEP Unpublished			Poland	
KCP 6.2 /04 Also cited in KCP 6.4	Sutherland J. Leitner A.	2018	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine, 1 site Maritime zone, 2018 Eurofins Agrosience Services Report n°: S18-05195-04 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /05 Also cited in KCP 6.4	Sutherland J. Karrasch H.	2018	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine, 1 site Maritime zone, 2018 Eurofins Agrosience Services Report n°: S18-05195-05 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /06 Also cited in KCP 6.4	Sutherland J. Hubner H.	2018	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine, 1 site Maritime zone, 2018 Eurofins Agrosience Services Report n°: S18-05195-06 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /07 Also cited in KCP 6.4	Sutherland J. Sipos P.	2019	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine OUTDOOR 2019 Eurofins Agrosience Services Report n°: S19-20334-01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /08 Also cited in KCP 6.4	Sutherland J. Sipos P.	2019	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine OUTDOOR 2019 Eurofins Agrosience Services Report n°: S19-20334-02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2 /09 Also cited in KCP 6.4	Sutherland J. Alexandru A.	2019	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine OUTDOOR 2019 Eurofins Agrosience Services Report n°: S19-20334-03 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /10 Also cited in KCP 6.4	Sutherland J. Beber M.	2019	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine OUTDOOR 2019 Eurofins Agrosience Services Report n°: S19-20334-04 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /11 Also cited in KCP 6.4	Sutherland J. Beber M.	2019	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine OUTDOOR 2019 Eurofins Agrosience Services Report n°: S19-20334-05 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /12 Also cited in KCP 6.4	Sutherland J. Beber M.	2019	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine OUTDOOR 2019 Eurofins Agrosience Services Report n°: S19-20334-06 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /13 Also cited in KCP 6.4	Sutherland J. Hubner H.	2019	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine OUTDOOR 2019 Eurofins Agrosience Services Report n°: S19-20334-07 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /14 Also cited in KCP 6.4	Sutherland J. Karrasch H.	2019	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine OUTDOOR 2019 Eurofins Agrosience Services Report n°: S19-20334-08 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2 /15 <i>Also cited in KCP 6.4</i>	Cheshire A.	2008	Determination of Efficacy and Crop Safety of 3Trisopren (3AEY) against Grey Mould in Vines, 3 sites in Germany 2008 Eurofins Agrosience Services Report n°: S08-02271 (including 3 trials: S08-02271-01, S08-02271-02 and S08-02271-03) GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Cheminova A/S
KCP 6.2 /16 <i>Also cited in KCP 6.4</i>	Hilweg M.	2006	Fungicides based on terpens for disease control in grapevines Stähler International GmbH & Co. KG Report n°: 06WF08_Eden terpen (including 6 trials: 06WF232C58, 06WF232C59, 06WF232C513, 06WF232C514, 06WF08-A3 and 06WF08-A4) GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.2 /17 <i>Also cited in KCP 6.4</i>	Matkin M. Harrison C.	2007	Field study to evaluate the efficacy of 3 AEY when applied at a range of rates for the control of grey mould (<i>Botryotinia fuckeliana</i>) on vines in Germany, 2007 Eurofins Agrosience Services Report n°: AF/12263/CN (including 3 trials AF/12263/CN/1, AF/12263/CN/2, AF/12263/CN/3) GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Cheminova A/S
KCP 6.2 /18 <i>Also cited in KCP 6.4</i>	Pesteil L. Curti M.	2016	Study of practical value of fungicide programs against conservation diseases and apple scab if necessary in an apple orchards Raison'Alpes Report n°: 16-Fa-Pm-13 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /19 <i>Also cited in KCP 6.4</i>	Touche M.	2017	Study of the practical value of fungicide programmes on apple in storage diseases management (and scab management, if relevant) Raison'Alpes Report n°: 17-Fa-Pm-14 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /20 <i>Also cited in</i>	Pesteil L. Curti M.	2018	Study of the effectiveness of several fungicides applied before harvest against storage diseases on apple	N	Y	Data/study report never submitted before to	SUMI AGRO

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4			Raison'Alpes Report n°: 18-Fa-Pm-11 GEP Unpublished			Poland	
KCP 6.2 /21 Also cited in KCP 6.4	Motais F.	2018	Comparison of the Efficacy of different fungicides combinations applied pre-harvest in Apple against storage diseases, France, 2018. Eurofins Agrosience Services Report n°: S18-06188-01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /22 Also cited in KCP 6.4	Motais F.	2019	Comparison of the Efficacy of different fungicides combinations applied pre-harvest in Apple against storage diseases, 2019-2020 Eurofins Agrosience Services Report n°: S19-20999-01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /23 Also cited in KCP 6.4	Essing M.	2018	Comparison of the Efficacy of different fungicides combinations applied pre-harvest in Apple against storage diseases, Germany, 2018 Eurofins Agrosience Services GmbH Report n°: S18-06150-01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /24 Also cited in KCP 6.4	Motais F.	2019	Comparison of the Efficacy of different fungicides combinations applied pre-harvest in Apple against storage diseases, 2019-2020 Eurofins Agrosience Services Report n°: S19-20999-02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /25 Also cited in KCP 6.4	Kloutvorová J.	2017	Comparison of the efficacy of different fungicide combinations in apple against late scab and different storage diseases. VŠÚO Holovousy s.r.o. Report n°: SUMI-F-2017-HOL03 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2 /26 <i>Also cited in KCP 6.4</i>	Kolník M.	2018	Comparison of the efficacy of different fungicide combinations applied preharvest in apple against storage diseases. InTec Agro Trials Report n°: F-19-O-502-01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /27 <i>Also cited in KCP 6.4</i>	Kolnik M.	2019	Comparison of the efficacy of different fungicide combinations applied preharvest in apple against storage diseases Intec Agro Trials Report n°: F-20-O-501-01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /28 <i>Also cited in KCP 6.4</i>	Kussinszky T.	2018	Comparison of the efficacy of different fungicide combinations applied pre-harvest in apple against storage diseases 2018-2019. Eurofins Agrosience Services Kft. Report n°: S18-06194-01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /29 <i>Also cited in KCP 6.4</i>	Kussinszky T.	2018	Comparison of the efficacy of different fungicide combinations applied pre-harvest in apple against storage diseases 2018-2019. Eurofins Agrosience Services Kft. Report n°: S18-06194-02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /30 <i>Also cited in KCP 6.4</i>	Motais F.	2019	Comparison of the Efficacy of different fungicides combinations applied pre-harvest in Apple against storage diseases, 2019-2020 Eurofins Agrosience Services Report n°: S19-20999-03 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /31 <i>Also cited in KCP 6.4</i>	Biniszewska A.	2017	Comparison of the efficacy of different fungicide combinations in apple against late scab and different storage diseases Staphyt Report n°: AB5-17-31410-PL01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2 /32 <i>Also cited in KCP 6.4</i>	Biniszewska A.	2017	Comparison of the efficacy of different fungicide combinations in apple against late scab and different storage diseases Staphyt Report n°: AB5-17-31410-PL02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /33 <i>Also cited in KCP 6.4</i>	Biniszewska A.	2018	Comparison of the efficacy of different fungicide combinations applied pre-harvest in apple against storage diseases Staphyt Report n°: AB5-19-36737-PL01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /34 <i>Also cited in KCP 6.4</i>	Biniszewska A.	2018	Comparison of the efficacy of different fungicide combinations applied pre-harvest in apple against storage diseases Staphyt Report n°: AB5-19-36737-PL02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /35 <i>Also cited in KCP 6.4</i>	Szrama K.	2019	Comparison of the efficacy of different fungicides combinations applied pre-harvest in apple against storage diseases. Poland 2019, GEP Trial Staphyt Report n°: KSA-19-41935-PL01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /36 <i>Also cited in KCP 6.4</i>	Szrama K.	2019	Comparison of the efficacy of different fungicides combinations applied pre-harvest in apple against storage diseases. GEP Trial Staphyt Report n°: KSA-19-41936-PL01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	SUMI AGRO
KCP 6.2 /37	Dr. Kuntz S.	2018	Efficacy of 3AEY against Botrytis cinerea (grey mould), Penicillium expansum (blue mould), Neofabraea alba (Gloeosporium), Monilia sp. (brown rot), Phytophthora cactorum in apple wounds and Stemphylium vesicarium in pear wounds Bio-Protect GmbH Report n°: 30.01.2019; Dr. Stefan Kunz	N	Y	Data/study report never submitted before to Poland	SUMI AGRO

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP: N/A Unpublished				
KCP 6.4/01	Bailey, A	2008	Field study to evaluate the crop safety of 3AEY when applied at a range of rates to grapevine and to generate specimens for vinification and subsequent taint testing in Spain, Portugal and Greece AGRISEARCH UK LIMITED, Slade Lane, Wilson, Melbourne, Derbyshire, DE73 8AG, UK Eden Research plc Report No.: AF/10726/ED GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.4/02	Cheshire, A	2008	Field study to generate specimens of grape for transformation processes and taint testing following multiple applications of 3AEY to grapevine in Greece AGRISEARCH UK LIMITED, Slade Lane, Wilson, Melbourne, Derbyshire, DE73 8AG, UK Eden Research plc Report No.: AF/12265/ED GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 6.4/03	Cheshire, A	2007	Field study to generate specimens of grape for vinification and subsequent taint testing following multiple applications of 3AEY to grapevine in France, Germany and Spain AGRISEARCH UK LIMITED, Slade Lane, Wilson, Melbourne, Derbyshire, DE73 8AG, UK Eden Research plc Report No.: AF/12267/ED GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 8.1/01	Brown, D.	2012	To determine the stability of thymol, eugenol and geraniol residues in grape specimens following storage at ca. -18°C for 0, 1, 3, 7, 14 and 28 days, 3, 6 and 12 months after treatment with 3AEY (6.4% w/w geraniol, 3.2% w/w eugenol and 6.4% w/w thymol) Eurofins Agrosience Services Report No. AF/12351/ED GLP Unpublished	N	Y	Data/study report never submitted before to Poland Interim report already evaluated in DAR IIA 6.1.1	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.1/02	Driss, F.	2021a	Storage Stability of Eugenol, Geraniol, Thymol and Methyl Eugenol in Grape under Deep Freeze Conditions Eurofins Agrosience Services Report No. S20-06526 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 8.1/03	Driss, F.	2021b	Storage Stability of Eugenol, Methyl Eugenol, Geraniol and Thymol in Apple under Deep Freeze Conditions Eurofins Agrosience Services Report No. S20-06527 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 8.3/01	Chadwick, G.	2021a	Determination of residues of eugenol, methyl eugenol, geraniol and thymol after 4 foliar applications of Mevalone (3AEY / EDN-004) to grapevine, 3 trials in N EU (3 x DEC) and 3 trials in S EU (3 x DEC), 2020 Eurofins Agrosience Services Report No. S20-06337 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 8.3/02	Chadwick, G.	2021b	Determination of residues of eugenol, methyl eugenol, geraniol and thymol after 4 foliar applications of Mevalone (3AEY / EDN-004) to apple, 3 trials in N EU (3 x DEC) and 3 trials in S EU (3 x DEC), 2020 Eurofins Agrosience Services Report No. S20-06361 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 9.2.4	H. Walshaw	2021a	Mevalone: Predicted Environmental Concentrations of Eugenol, Geraniol, and Thymol in Groundwater Following Application to Vines and Apples, Using FOCUS-MACRO, FOCUS-PEARL and FOCUS-PELMO Source: Staphyt Regulatory Company Report No 21/14 GLP: N/A Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.5	H. Walshaw	2021b	Mevalone: Predicted Environmental Concentrations of Eugenol, Geraniol, and Thymol in Surface Water following application to vines and apples, Using FOCUS-STEPS 1-3 Source: Staphyt Regulatory Company Report No 21/13 GLP: N/A Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 10.2.1/01	Egeler, P.	2021a	Eugenol: A Study on the Chronic Toxicity to <i>Daphnia magna</i> Company Report No 20GC3DB IBACON GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 10.2.1/02	Egeler, P.	2021b	Geraniol: A Study on the Chronic Toxicity to <i>Daphnia magna</i> Company Report No 20GC1DB IBACON GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 10.2.1/03	Egeler, P.	2021c	Thymol: A Study on the Chronic Toxicity to <i>Daphnia magna</i> Company Report No 20GC2DB IBACON GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 10.2.1/04	Siedel, U., Emnet, P.	2021	Geraniol: Toxicity to <i>Pseudokirchneriella subcapitata</i> in an Algal Growth inhibition Test. Company Report No 155771210 IBACON GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 10.3.1.2/01	Pecorari, F.	2019a	Chronic oral effects of ARAW on adult worker honeybees <i>Apis mellifera</i> L., 10-day feeding laboratory test Report No. BT059/19 BioTecnologie BT S.r.l., Italy GLP Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.3/01	Pecorari, F.	2019b	Effects of ARAW on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure Report No. BT060/19 BioTecnologie BT S.r.l., Italy GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 10.4.1.1/01	Straube, D.	2021	Mevalone: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil Company Report No 155781022 IBACON Gmbh, Rossdorf, Germany GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc
KCP 10.4.2/01	Straube, D.	2020	Mevalone: Effects on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil Company Report No 15578101 IBACON Gmbh, Rossdorf, Germany GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Eden Research plc

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1/01	White G.A.	2011	3AEY Formulation storage stability trial and physical / chemical tests Final report (24 months storage) Report n°J16313, G.C. Laboratories Ltd GLP Unpublished	N	N	Already evaluated in DAR IIIA 2.1/02	Eden Research plc
KCP 2.1/02	White G.A.	2007	3AEY Formulation accelerated and cold storage temperature storage stability trials and physical / chemical tests Report n°J16537, G.C. Laboratories Ltd GLP Unpublished	N	N	Already evaluated in DAR IIIA 2.1/01	Eden Research plc
KCP 5.1.1/01	White G.A.	2007d	Validation of Analytical Method M619, Gas chromatographic determination of free and encapsulated thymol, eugenol and geraniol in formulations, for the 3AEY formulation G.C. Laboratories Ltd Report No. J16312 GLP Unpublished	N	N	Already evaluated in DAR IIIA 5.2.1/01	Eden Research plc
KCP 5.1.1/03	Kant A.	2008	Terpene Release from Encapsulated Formulation 3AEY, Appendix 4 - RFM039_ExtVal: Determination of free and encapsulated terpenes in formulation 3AEY: Validation of extraction and GC-MS methods Flavometrix Report No. RFM039_MainPhase Not GLP Unpublished	N	N	Already evaluated in DAR IIIA 2.15/01, IIIA 5.9/02, IIIA 9.10.1/01	Eden Research plc
KCP 5.1.1/04	Kant A.	2008	Terpene Release from Encapsulated Formulation 3AEY, Appendix 5 - RFM039_APcIMSval: Validation of the APcI-MS Headspace Analysis Method Flavometrix Report No. RFM039_MainPhase Not GLP Unpublished	N	N	Already evaluated in DAR IIIA 2.15/01, IIIA 5.9/01, IIIA 9.10.1/01	Eden Research plc
KCP 5.1.1/05	Bates G.J.D.	2012a	Validation of Analytical Method M737, Gas chromatographic determination of methyl eugenol in formulations, for low levels of methyl eugenol in the 3AEY formulation G.C. Laboratories Ltd Report No. J19055	N	N	TBC	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCA 4.1.2/01 (thymol)	Brice A., Heslop D.	2009	Validation for the Determination of Thymol in Dietary Formulation, Mouse Plasma and Rat Plasma Covance Laboratories Ltd Report No. 8201847-D2149 GLP Unpublished	N	N	TBC	Eden Research plc
KCA 4.1.2/02 (thymol)	Wilcox A	2009	Thymol: Oral (Gavage) Administration Pharmacokinetic Study in the Mouse Covance Laboratories Ltd Report No. 8202028 GLP Unpublished	N	N	TBC	Eden Research plc
KCA 4.1.2/03 (thymol)	Bowen D	2009	Induction of chromosome aberrations in the bone marrow of treated rats Covance Laboratories Ltd Report No. 8201846 GLP Unpublished	N	N	TBC	Eden Research plc
KCP 5.1.2/01 KCA 4.1.2/01 (eugenol/ geraniol) KCA 4.1.2/04 (thymol)	Bailey A.	2007	To determine the magnitude of geraniol, eugenol and thymol residues at harvest in the raw agricultural commodity grapes resulting from sequential applications of 3AEY, in Southern Europe (2006 – 2007) Agriseach UK Ltd Report No. AF/10728/ED GLP Unpublished	N	N	Already evaluated in DAR IIA 4.3/02	Eden Research plc
KCP 5.1.2/02 KCA 4.1.2/02 (eugenol) KCA 4.1.2/03 (geraniol) KCA 4.1.2/06 (thymol)	Bailey A.	2008	To determine the magnitude of geraniol, eugenol and thymol residues on the surface of grapes by deposit analysis resulting from sequential applications of 3AEY, in Southern Europe (2006) Agriseach UK Ltd Report No. AF/11125/ED GLP Unpublished	N	N	Already evaluated in DAR IIA 4.3/01	Eden Research plc
KCP 5.1.2/04 KCA	Jones S.	2012	Determination of natural background level residues of thymol, eugenol and geraniol in grapes Eurofins Agrosience Services Report No. S11-03787	N	N	TBC	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
4.1.2/04 (eugenol/ geraniol) KCA 4.1.2/07 (thymol)			GLP Unpublished				
KCP 5.1.2/07	Martin K.H., Nixon W.B.	2007	Analytical method verification for the determination of 3 AEY (thymol/geraniol/eugenol mixture) in avian diet Wildlife International Ltd Report No. 648C-101 GLP Unpublished	N	N	Already evaluated in DAR IIA 8.1.2/01	Eden Research plc
KCP 5.1.2/08	Hubbard P.M, Martin K.H, Beavers J.B.	2007	3AEY (Thymol/Geraniol/Eugenol Mixture): a dietary LC50 study with the northern bobwhite Wildlife International Ltd Report No. 648-102 GLP Unpublished	N	N	Already evaluated in DAR IIA 8.1.2/01	Eden Research plc
KCA 4.1.2/18 (eugenol)	Grossmann R., Wydra V.	2008a	Acute Toxicity of EUGENOL to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a 96-hour Semi-static Test Ibacon GmbH Report No. 37984230 GLP Unpublished	N	N	Already evaluated in DAR IIA 8.2.1.1/01	Eden Research plc
KCA 4.1.2/19 (eugenol)	Grossmann R., Wydra V.	2008b	Acute Toxicity of EUGENOL to Zebra Fish (<i>Danio rerio</i>) in a 96-hour Semi-static Test Ibacon GmbH Report No. 37983230 GLP Unpublished	N	N	Already evaluated in DAR IIA 8.2.1.2/01	Eden Research plc
KCA 4.1.2/20 (eugenol)	Pavié B., Wydra V.	2008	Acute Toxicity of EUGENOL to <i>Daphnia magna</i> in a Static 48-hour Immobilization Test Ibacon GmbH Report No. 37982220 GLP Unpublished	N	N	Already evaluated in DAR IIA 8.3.1.1/01	Eden Research plc
KCA 4.1.2/22 (eugenol)	Meister Werner A., Wydra V.	2008	Toxicity of EUGENOL to <i>Pseudokirchneriella subcapitata</i> in an Algal Growth Inhibition Test Ibacon GmbH Report No. 37981210 GLP Unpublished	N	N	Already evaluated in DAR IIA 8.4/01	Eden Research plc
KCA 4.1.2/39	Grade R., Wydra V.	2008d	Acute Toxicity of GERANIOL to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a 96-hour Semi-static Test	N	N	Already evaluated in DAR IIA 8.2.1.1/01	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
(geraniol)			Ibacon GmbH Report No. 34291230 GLP Unpublished				
KCA 4.1.2/40 (geraniol)	Grade R., Wydra V.	2008e	Acute Toxicity of GERANIOL to Zebra Fish (Danio rerio) in a 96-hour Semi-static Test Ibacon GmbH Report No. 34292230 GLP Unpublished	N	N	Already evaluated in DAR IIA 8.2.1.2/01	Eden Research plc
KCA 4.1.2/41 (geraniol)	Grade R., Wydra V.	2007a	Acute Toxicity of GERANIOL to Daphnia magna in a Static 48-hour Immobilization Test Ibacon GmbH Report No. 34293220 GLP Unpublished	N	N	Already evaluated in DAR IIA 8.3.1.1/01	Eden Research plc
KCA 4.1.2/43 (geraniol)	Grade R., Wydra V.	2008f	Acute toxicity of GERANIOL to Pseudokirchneriella subcapitata in an Algal growth Inhibition Test Ibacon GmbH Report No. 34294210 GLP Unpublished	N	N	Already evaluated in DAR IIA 8.4/01	Eden Research plc
KCA 4.1.2/18 (thymol)	Grade R., Wydra V.	2008g	Acute Toxicity of THYMOL CRYSTALS to Rainbow Trout (Oncorhynchus mykiss) in a 96-hour Semi-static Test Ibacon GmbH Report No. 34281230 GLP Unpublished	N	N	Already evaluated in DAR IIA 8.2.1.1/01	Eden Research plc
KCA 4.1.2/19 (thymol)	Grade R., Wydra V.	2008h	Acute Toxicity of THYMOL CRYSTALS to Zebra Fish (Danio rerio) in a 96-hour Semi-static Test Ibacon GmbH Report No. 34282230 GLP Unpublished	N	N	Already evaluated in DAR IIA 8.2.1.2/01	Eden Research plc
KCA 4.1.2/20 (thymol)	Grade R., Wydra V.	2007b	Acute Toxicity of THYMOL CRYSTALS to Daphnia magna in a Static 48-hour Immobilization Test Ibacon GmbH Report No. 34283220 GLP Unpublished	N	N	Already evaluated in DAR IIA 8.3.1.1/01	Eden Research plc
KCA 4.1.2/22 (thymol)	Grade R., Wydra V. (Hoffmann K, Wydra V. amended report)	2008c, 2011	Toxicity of THYMOL CRYSTALS to Pseudokirchneriella subcapitata in an Algal growth Inhibition Test Ibacon GmbH Report No. 34284210 GLP Unpublished	N	N	Already evaluated in DAR IIIA 8.4/01	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/09	Grade R., Wydra V.	2008a	Acute Toxicity of 3AEY to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a 96-hour Semi-static Test Ibacon GmbH Report No. 34301230 GLP Unpublished	N	N	Already evaluated in DAR IIIA 10.2.2.1/01	Eden Research plc
KCP 5.1.2/10	Grade R., Wydra V.	2008b	Acute Toxicity of 3AEY to <i>Daphnia magna</i> in a Static 48-hour Immobilization Test Ibacon GmbH Report No. 34302220 GLP Unpublished	N	N	Already evaluated in DAR IIIA 10.2.2.2/01	Eden Research plc
KCP 5.1.2/11	Grade R., Wydra V.	2008c	Toxicity of 3AEY to <i>Pseudokirchneriella subcapitata</i> in an Algal Growth Inhibition Test Ibacon GmbH Report No. 34303210 GLP Unpublished	N	N	Already evaluated in DAR IIIA 10.2.2.3/01	Eden Research plc
KCP 5.1.2/15	White G.A.	2011	3AEY Formulation storage stability trial and physical / chemical tests Final report (24 months storage) G.C. Laboratories Ltd Report No. J16313 GLP Unpublished	N	N	TBC	Eden Research plc
KCP 5.1.2/16	White G.A.	2007c	3AEY Formulation accelerated and cold storage temperature storage stability trials and physical chemical tests G.C. Laboratories Ltd Report No. J16537 GLP Unpublished	N	N	Already evaluated in DAR IIIA 2.1/01	Eden Research plc
KCP 5.2/03 KCA 4.2/03 (eugenol) KCA 4.2/04 (geraniol/thymol)	Brown D	2007	To determine the stability of thymol, eugenol and geraniol residues in grape specimens following storage at ca. -18° for 0, 1, 3, and 6 months (2006-2007) Eurofins Agrosience Services Report No. AD/11145/ED GLP Unpublished	N	N	Already evaluated in DAR IIA 6.1.1/01	Eden Research plc
KCP 5.2/04 KCA 4.2/04 (eugenol) KCA 4.2/05 (geraniol/thymol)	Brown D	2012	To determine the stability of thymol, eugenol and geraniol residues in grape specimens following storage at ca. -18° for 0, 1, 3, 7, 14 and 28 days, 3, 6 and 12 months after treatment with 3AEY (6.4% w/w geraniol, 3.2% w/w eugenol and 6.4% w/w thymol) Eurofins Agrosience Services Report No. AD/12351/ED GLP Unpublished	N	N	Already evaluated in DAR IIA 6.1.1/02	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.1/01	XXXX	2007a	Acute oral toxicity study of product 3AEY in rats Jai Research Foundation Eden Research plc Report No.: 6733 GLP, Unpublished	Y	N	Already evaluated in DAR IIIA 7.1.1	Eden Research plc
KCP 7.1.2/01	XXXX	2007b	Acute dermal toxicity study of product 3AEY in rats Jai Research Foundation Eden Research plc Report No.: 6734 GLP, Unpublished	Y	N	Already evaluated in DAR IIIA 7.1.2	Eden Research plc
KCP 7.1.3/01	XXXX	2007	Acute inhalation toxicity study of product 3AEY in rats Jai Research Foundation Eden Research plc Report No.: 6735 GLP, Unpublished	Y	N	Already evaluated in DAR IIIA 7.1.3	Eden Research plc
KCP 7.1.4/01	XXXX	2007c	Acute dermal irritation study of product 3AEY in rats Jai Research Foundation Eden Research plc Report No.: 6736 GLP, Unpublished	Y	N	Already evaluated in DAR IIIA 7.1.4	Eden Research plc
KCP 7.1.5/01	XXXX	2007d	Acute eye irritation study of product 3AEY in rats Jai Research Foundation Eden Research plc Report No.: 6737 GLP, Unpublished	Y	N	Already evaluated in DAR IIIA 7.1.5	Eden Research plc
KCP 7.1.6/01	XXXX	2007	3AEY: Local lymph node assay in the mouse Safepharm Laboratories Limited Eden Research plc Report No.: 2408/0001 GLP, Unpublished	Y	N	Already evaluated in DAR IIIA 7.1.6	Eden Research plc
KCP 10.1.1.1/01	XXXX.	2007	3AEY (thymol/geraniol/eugenol mixture): An acute oral toxicity study with the Northern Bobwhite Report No. 648-101 Wildlife International, Ltd, USA GLP Unpublished	Y	N	Already evaluated in DAR B.9.1.1	Eden Research plc
KCP 10.2.1/01	XXXX.	2008a	Acute toxicity of 3AEY to rainbow trout (<i>Oncorhynchus mykiss</i>) in a 96-hour semi-static test	Y	N	Already evaluated in DAR B.9.2.1.1	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No. 34301230 IBACON GmbH, Germany GLP Unpublished				
KCP 10.2.1/02	Grade, R., Wydra, V.	2008a	Acute toxicity of 3AEY to <i>Daphnia magna</i> in a static 48-hour immobilization test Report No. 34302220 IBACON GmbH, Germany GLP Unpublished	N	N	Already evaluated in DAR B.9.2.1.2	Eden Research plc
KCP 10.2.1/03	Grade, R.; Wydra, V.	2008c	Toxicity of 3AEY to <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test Report No. 34303210 IBACON GmbH, Germany GLP Unpublished	N	N	Already evaluated in DAR B.9.2.1.3	Eden Research plc
KCP 10.3.1.1.1/01	Schmitzer, S.	2007	Effects of 3AEY (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory Report No. 34304035 IBACON GmbH, Germany GLP Unpublished	N	N	Already evaluated in DAR B.9.4.1	Eden Research plc
KCP 10.3.2.1/01	Moll, M.	2007a	Effects of 3AEY on the Predatory Mite <i>Typhlodromus pyri</i> in the Laboratory - Dose Response Test Report No. 34306063 IBACON GmbH, Germany GLP Unpublished	N	N	Already evaluated in DAR B.9.5.1	Eden Research plc
KCP 10.3.2.1/02	Moll, M.	2007b	Effects of 3AEY on the Parasitoid <i>Aphidius rhopalosiphi</i> in the Laboratory - Dose Response Test Report No. 34305001 IBACON GmbH, Germany GLP Unpublished	N	N	Already evaluated in DAR B.9.5.1	Eden Research plc
KCP 10.4.1.1/01	Lühns, U.	2007	Acute toxicity (14 days) of 3AEY to the earthworm <i>Eisenia fetida</i> in artificial soil Report No. 34307021 IBACON GmbH, Germany GLP Unpublished	N	N	Already evaluated in DAR B.9.6.1	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.5/01	Reis, K.H.	2007	Effects of 3AEY on the activity of the soil microflora in the laboratory Report No. 34308080 IBACON GmbH, Germany GLP Unpublished	N	N	Already evaluated in DAR B.9.8.1	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-

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

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