

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: 3AEY

Product name(s): Mevalone

Chemical active substances:

Eugenol, 33 g/L

Geraniol, 66 g/L

Thymol, 66 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Eden Research plc

Submission date: July 2021

Updated date: December 2021

MS Finalisation date: July 2022 (initial Core Assessment)

December 2022 (final Core 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 in France and Romania- The intended uses of grapes in the Benelux and Republic of Ireland- the GAP table
July 2022	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey . Not agreed or not relevant information are struck through and shaded for transparency .
December 2022	Final report (Core Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow . Information no longer relevant is struck through and shaded .

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This dossier is proposed for an application according to Article 33 of Regulation (EC) N° 1107/2009 of the product Mevalone (product code 3AEY). This evaluation is for first approval in the Central Zone.

Mevalone (product code 3AEY) is a 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.

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 (*Phytophthora spp.* and *Botrytis cinerea*).

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	Not applicable	Not applicable
Central zone	zRMS for Mevalone: Poland	cMS for Mevalone: - Austria, Belgium, Czech Republic, Germany, Hungary, the Netherlands, Luxembourg, Romania, Slovakia, Slovenia and the Republic of Ireland
Southern zone	Not applicable	Not applicable
Inter-zonal	Not applicable	Not applicable

0.1.3 Regulatory history of the active(s)

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.

0.1.3.1 Eugenol

Table 0.1-2: Summary of regulatory history of CAS No: 97-53-0

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 546/2013 of 14 June 2013
RMS	SP, co-RMS: GR (former RMS: UK)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.12.2013
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	-
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	30.11.2023
Low risk substance or Candidate for Substitution?	Not applicable

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate;
- the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;
- the risk to aquatic organisms;
- the risk to insectivorous birds.

Conditions of use shall include risk mitigation measures, where appropriate.

The SANCO report for eugenol (SANCO/10577/2013 rev.3 17 May 2013) is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

An EFSA Scientific Report was made available on 11 October 2012 (EFSA Journal 2012; 10(11):2914).

Table 0.1-3: Information on minimum purity of eugenol

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
≥ 990 g/kg Relevant impurity: methyleugenol maximum 0.1% of the technical material	Not applicable

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Active Substance	
	EU agreed endpoint from EFSA scientific report	Endpoint used *
Toxicology	EFSA Journal 2012;10(11):2914 EFSA Supporting publication 2017:EN-1165	Refer to section B8
Environnement fate		Refer to section B9
Ecotoxicology		Refer to section B10

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

0.1.3.2 Geraniol

Table 0.1-4: Summary of regulatory history of CAS No: 106-24-1

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 570/2013 of 17 June 2013
RMS	SP, co-RMS: GR (former RMS: UK)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.12.2013
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	-
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	30.11.2023
Low risk substance or Candidate for Substitution?	Not applicable

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate;
- the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;
- the risk to aquatic organisms;
- the risk to birds and mammals.

Conditions of use shall include risk mitigation measures, where appropriate.

The SANCO report for geraniol (SANCO/10579/2013 rev 3, 17 May 2013) is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

An EFSA Scientific Report was made available on 11 October 2012 (EFSA Journal 2012;10(11):2915).

Table 0.1-5: Information on minimum purity of geraniol

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
≥ 980 g/kg	Not applicable

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Active Substance	
	EU agreed endpoint from EFSA scientific report	Endpoint used *
Toxicology	EFSA Journal 2012;10(11):2915 EFSA Supporting publication 2017:EN-1163	Refer to section B8
Environnement fate		Refer to section B9
Ecotoxicology		Refer to section B10

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

0.1.3.3 Thymol

Table 0.1-6: Summary of regulatory history of CAS No: 89-83-8

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 568/2013 of 18 June 2013
RMS	SP, co-RMS: GR (former RMS: UK)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.12.2013
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	-
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	30.11.2023
Low risk substance or Candidate for Substitution?	Not applicable

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate;

- the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;
- the risk to aquatic organisms;
- the risk to birds and mammals.

Conditions of use shall include risk mitigation measures, where appropriate.

The SANCO report for thymol (SANCO/10581/2013 rev 3, 17 May 2013) is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

An EFSA Scientific Report was made available on 11 October 2012 (EFSA Journal 2012;10(11):2916).

Table 0.1-7: Information on minimum purity of thymol

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
≥ 990 g/kg	Not applicable

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Active Substance	
	EU agreed endpoint from EFSA scientific report	Endpoint used *
Toxicology	EFSA Journal 2012;10(11):2916	Refer to section B8
Environnement fate	EFSA Supporting publication 2017:EN-1162	Refer to section B9
Ecotoxicology		Refer to section B10

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

0.1.4 Regulatory history of the product

The product Mevalone (product code 3AEY) was the representative product at the first inclusion of the active substances and in the AIR Renewal dossier submitted on February 28th, 2021.

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-8: Summary of regulatory history of the product Mevalone

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
3AEY	Mevalone	France	2161080	05 Jan 2017	
3AEY	Mevalone	Cyprus	3333	15 Feb 2017	
3AEY	Araw	Spain	ES-00108	23 Jun 2016	
3AEY	Mevalone	Greece	60467	17 Jul 2015	
3AEY	3logy	Italy	16480	16 Mar 2016	
3AEY	Mevalone	Malta	2015-05-18 P02	18 Feb 015	

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
3AEY	Araw	Portugal	1012	14 Sep 2017	
3AEY	Mevalone	Albania	650	15 Dec 2016	
3AEY	Mevalone	Bulgaria	01354-PPP-1/15.02.2016	15 Feb 2016	
3AEY	Mevalone	Romania	684C	22 Apr 2021	

0.2 zRMS conclusion

Authorisation of the product 3AEY / Mevalone is recommended to the control of *Botrytis cinerea* in grapevine and pathogens causing storage diseases in pome fruits. For pome fruits, Member States will need to make their own decision based on the available efficacy data and extrapolation possibility according to their national requirements.

Uses to be considered safe on the basis of EU methodology:

See column 14 of the GAP table presented in Appendix 1 of this document.

Uses to be considered non-safe on the basis of EU methodology:

See column 14 of the GAP table presented in Appendix 1 of this document.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

See column 14 of the GAP table presented in Appendix 1 of this document.

Appendix 1 ALL intended uses

PPP (product name/code):	Mevalone / 3AEY	Formulation type:	CS ^(a, b)	GAP rev. 1, date: 2022-04
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 Ne			
Field of use:	Fungicide			

1	2	3	4	5	6	7	8	9	10	11	12	13	14*															
													Overall conclusions								Phys-chem	Analytical methods	Toxicology	Residues	Groundwater	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
													Use -No.	Member state (s)	Crop and/or situation (crop destination / purpose of crop)	FG or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application		Application rate								
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																							
1	PL	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey mould (<i>Botrytis cinerea</i> BOTRCI)	Foliar. Tractor-mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 60-89	a) 1 b) 4 (7 days)	a) 1-6 2.0-4.0 L/ha b) 5-4 8.0-16 L/ha	a) 52-8 66-132 (E) 106 132-264 (G) b) 144 264-528 (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	C Birds, mammals, bees R Aquatics D3, D5, D6, R2, R3 A Aquatics D4,R1, R4 A Remaining species	A	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA)								
1	AT	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey mould (<i>Botrytis cinerea</i> BOTRCI)	Foliar. Tractor-mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 60-89	a) 1 b) 4 (7 days)	a) 1-6 2.0-4.0 L/ha b) 5-4 8.0-16 L/ha	a) 52-8 66-132 (E) 106 132-264 (G) b) 144 264-528 (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	C Birds, mammals, bees R Aquatics D3, D5, D6, R2, R3 A Aquatics D4,R1, R4 A Remaining species	A	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA)								
1	BE	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey mould (<i>Botrytis cinerea</i> BOTRCI)	Foliar. Tractor-mounted air blast	BBCH 60-89	a) 1 b) 4 (7 days)	a) 1-6 2.0-4.0 L/ha b) 5-4 8.0-16 L/ha	a) 52-8 66-132 (E) 106 132-264 (G)	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 /	A	A	A	A	A	C Birds, mammals, bees	A	A Acceptable								

1	2	3	4	5	6	7	8	9	10	11	12	13	14*							
													Overall conclusions							
													Phys-chem	Analytical methods	Toxicology	Residues	Grundwater	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Use -No.	Member state (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 (days)	Remarks:	Phys-chem	Analytical methods	Toxicology	Residues	Grundwater	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy	
					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
					sprayer. Hand-held knapsack sprayer.				b) 264 – 528 (E) 528 – 1056 (G) 528 – 1056 (T)		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						R Aquatics D3, D5, D6, R2, R3 A Aquatics D4,R1, R4 A Remaining species		e dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA)	
1	CZ	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey mould (<i>Botrytis cinerea</i> BOTRCI)	Foliar. Tractor-mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 60-89	a) 1 b) 4 (7 days)	a) 2.0 – 4.0 L/ha b) 8.0 – 16 L/ha	a) 66- 132 (E) 132- 264 (G) 132- 264 (T) b) 264 – 528 (E) 528 – 1056 (G) 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	C Birds, mammals, bees R Aquatics D3, D5, D6, R2, R3 A Aquatics D4,R1, R4 A Remaining species	A	Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA)
1	DE	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey mould (<i>Botrytis cinerea</i> BOTRCI)	Foliar. Tractor-mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 60-89	a) 1 b) 4 (7 days)	a) 2.0 – 4.0 L/ha b) 8.0 – 16 L/ha	a) 66- 132 (E) 132- 264 (G) 132- 264 (T) b) 264 – 528 (E) 528 – 1056 (G) 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	A	A	A	A	A	C Birds, mammals, bees R Aquatics D3, D5, D6, R2, R3	A	Acceptable dose rate range is 2.0 – 4.0 L/ha

1	2	3	4	5	6	7	8	9	10	11	12	13	14*							
													Overall conclusions							Phys-chem
Use -No.	Member state (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 (days)	Remarks:								
1	LU	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey mould (<i>Botrytis cinerea</i> BOTRC1)	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) 214 264 – 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	C Birds, mammals, bees R Aquatics D3, D5, D6, R2, R3 A Aquatics D4,R1, R4 A Remaining species	A	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA)
1	SK	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey mould (<i>Botrytis cinerea</i> BOTRC1)	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) 214 264 – 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	C Birds, mammals, bees R Aquatics D3, D5, D6, R2, R3 A Aquatics D4,R1, R4 A Remaining species	A	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA)
1	SI	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey mould (<i>Botrytis cinerea</i> BOTRC1)	Foliar. Tractor-mounted air blast	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)	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 /	A	A	A	A	A	C Birds, mammals, bees	A	A Acceptable dose rate

1	2	3	4	5	6	7	8	9	10	11	12	13	14*							
													Overall conclusions							
Use -No.	Member state (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 (days)	Remarks:	Phys-chem	Analytical methods	Toxicology	Residues	Grundwater	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
					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										
																	R Aquatics All scenarios		art. 51)	
													A	A	A	A	A	A Remaining species	A	N EIOJA
2	AT	Apple <i>Malus domestica</i> MABSD, pear <i>Pyrus communis</i> PYUCO, quince	F	Post-harvest storage diseases	Foliar. Tractor-mounted air blast sprayer. Hand-held knapsack	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)	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	A	A	A	A	A	C Birds, mammals, bees	A	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14*							
													Overall conclusions							
													Phys-chem	Analytical methods	Toxicology	Residues	Grundwater	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Use -No.	Member state (s)	Crop and/or situation (crop destination / purpose of crop)	FG or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application		Application rate			PHI (days)	Remarks:									
2	DE	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 <u>Dose rate range and water volume have been changed after efficacy evaluation.</u>	A	A	A	A	A	C Birds, mammals, bees	A	C
2	HU	Apple <i>Malus domestica</i> MABSD, pear <i>Pyrus communis</i> PYUCO, quince	F	Post-harvest storage diseases	Foliar. Tractor-mounted air blast sprayer. Hand-held knapsack	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)	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	A	A	A	A	A	C Birds, mammals, bees	A	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14*							
													Overall conclusions							Phys-chem
Use -No.	Member state (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 (days)	Remarks:									
					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								
		<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			sprayer.				634– 1056 (T)		e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures 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.						R Aquatics All scenarios			
2	NL	Apple <i>Malus domestica</i> MABSD, pear <i>Pyrus communis</i> PYUCO, quince <i>Cydonia oblonga</i> CYDOB, crab-apple <i>Malus sylvestris</i> MABSY,	F	Post-harvest storage diseases	Foliar. Tractor-mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 75-87	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) 417– 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),	A	A	A	A	A	C Birds, mammals, bees	A	C
																	R Aquatics All scenarios			

1	2	3	4	5	6	7	8	9	10	11	12	13	14*							
													Overall conclusions							
													Phys-chem	Analytical methods	Toxicology	Residues	Groundwater	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Use -No.	Member state (s)	Crop and/or situation (crop destination / purpose of crop)	FG or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application		Application rate			PHI (days)	Remarks:									
2	SK	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. <i>Therefore, the higher application rate is diluted in the higher water volume.</i> 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 <u>Dose rate range and water volume have been changed after efficacy evaluation.</u>	A	A	A	A	A	C Birds, mammals, bees	A	C
2	SI	Apple <i>Malus domestica</i> MABSD, pear <i>Pyrus communis</i> PYUCO, quince	F	Post-harvest storage diseases	Foliar. Tractor-mounted air blast sprayer. Hand-held knapsack	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)	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. <i>Therefore, the higher application rate is diluted in the higher water</i>	A	A	A	A	A	C Birds, mammals, bees	A	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14*								
													Overall conclusions							Phys-chem	Analytical methods
Use -No.	Member state (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 (days)	Remarks:										
					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									
		<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			sprayer.				634– 1056 (T)		e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures 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.						R Aquatics All scenarios				
2	IE	Apple <i>Malus domestica</i> MABSD, pear <i>Pyrus communis</i> PYUCO, quince <i>Cydonia oblonga</i> CYDOB, crab-apple <i>Malus sylvestris</i> MABSY,	F	Post-harvest storage diseases	Foliar. Tractor-mounted air blast sprayer. Hand-held knapsack sprayer.	BBCH 75-87	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) 417– 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),	A	A	A	A	A	C Birds, mammals, bees	A	C	
																	R Aquatics All scenarios				

1	2	3	4	5	6	7	8	9	10	11	12	13	14*						
													Overall conclusions						
													Phys-chem	Analytical methods	Toxicology	Residues	Grundwater	Ecotoxicology	Relevance of metabolites in groundwater
Use -No.	Member state (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 (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	-	-	-	-	-	-	-
					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									
2	GB	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) 2.1—4.0 L/ha b) 9.6—16 L/ha	a) 79.2—132 (E) 158—264 (G) 158—264 (T) b) 417—528 (E) 634—1056 (G) 634—1056 (T)	600-1000	4	The product is applied so that the concentration in g a.s./hl is kept constant at 13.2 (eugenol), 26.4 (geraniol), 26.4 (thymol) g a.s./ hectolitre of spray water volume. Therefore, the higher application rate is diluted in the higher water volume. Apply at 3.0—3.2 L/ha LWA Example of 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	-	-	-	-	-	-	-

Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR), capsule suspension (CS) (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008 (c) g/kg or g/l	(d) Select relevant (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 (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 columns:	1 Numeration necessary to allow references 2 Use official codes/nomenclatures of EU Member States 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) 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 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. 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.	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 8 The maximum number of application possible under practical conditions of use must be provided. 9 Minimum interval (in days) between applications of the same product 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. 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). 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