

REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: 3AEY

Product name(s): Mevalone

Chemical active substances:

Eugenol 33 g/L

Geraniol 66 g/L

Thymol 66 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorization for Mevalone product)

Applicant: Eden Research plc

Submission date: 15/07/2021

Update date: 21/12/2021

MS Finalisation date: April 2022 (initial Core Assessment)

November 2022 (final Core Assessment)

Version history

When	What
July 2021	Authorization of marketing in Central Zone of the plant protection product Mevalone on grapes and pome fruits
December 2021	Addition of 4.2. Procedures for cleaning application equipment
April 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 .
November 2022	Final report (Core Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded .

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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substances.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

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1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

The product contains eugenol (33.0 g/L), geraniol (66.0 g/L) and thymol (66.0 g/L).

1.2.3.1 Eugenol

Eugenol min. 990 g/kg

Relevant impurities

Methyleugenol max. 1 g/kg

Details of significant impurities are provided in Part C.

1.2.3.2 Geraniol

Geraniol min. 980 g/kg

Details of significant impurities are provided in Part C.

1.2.3.3 Thymol

Thymol min. 990 g/kg

Details of significant impurities are provided in Part C.

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Mevalone
Company code number: Mevalone / 3AEY

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance	Declared content of the pure active substance (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (% w/w)
Eugenol (pure)	33.0	29.7 – 36.3	-	-
As eugenol technical (990 g/kg)	-	30.0 – 36.6	33.3	3.24
Geraniol (pure)	66.0	59.4 – 72.6	-	-
As geraniol technical (980 g/kg)	-	60.6 – 74.1	67.3	6.54
Thymol (pure)	66.0	59.4 – 72.6	-	-
As thymol technical (990 g/kg)	-	60.0 – 73.3	66.7	6.48

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

** Based on the nominal density of the formulation = 1.029 [The nominal density of the product is 1.029 and the recipe composition is based on this density. This is slightly different to the measured value of 1.035 found in the phys chem study by White 2007 (Report No. J16537).]

Table 1.4-2: Safener and synergists

The product does not contain any safener nor synergist.

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L)
Methyleugenol	0.033

* Based on the maximum 1 g/kg content declared for registration in the active substance dossier

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-4: Information on active substances

Type	Name/Code Number
ISO common name	Eugenol
CAS No.	97-53-0
EC No.	202-589-1
CIPAC No.	967
Salt, ester anion or cation present	No

Type	Name/Code Number
ISO common name	Geraniol
CAS No.	106-24-1
EC No.	Not available
CIPAC No.	968
Salt, ester anion or cation present	No

Type	Name/Code Number
ISO common name	Thymol
CAS No.	89-83-8
EC No.	201-944-8
CIPAC No.	969
Salt, ester anion or cation present	No

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Capsule Suspension

[Code: CS]

1.6 Function (KCP 1.6)

Fungicide.

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product 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.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Classification:

The product is not classified for physical hazards.

Labelling:

As the product is a plant protection product, the specific statement EUH401 must appear on the label:
EUH401: To avoid risks to human health and the environment, comply with the instructions for use.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

As the product is not classified for physical hazards, no hazard or precautionary statements are required.

Compliance with FAO specifications:

The product Mevalone complies with FAO specifications.

Formulation used for tests

This document contains full summaries of studies, which were available at the time of the first EU inclusion of Mevalone and also studies that have not previously been evaluated during the first EU review. In order to facilitate discrimination between new and original information, the original information is shaded in grey. All the studies in this submission have been found acceptable in previous evaluations. For all studies, detailed summaries are provided in this dossier.

The following tests have been performed by GLP-certified laboratories on Mevalone (named as 3AEY in the studies) batch n°YPOA3Y424-1.1, batch n°70618 and batch n°53161-022.

Batch n°YPOA3Y424-1.1 contains 3.23% w/w eugenol, 6.47% w/w geraniol, and 6.56% w/w thymol (White G.A. report n°J16313).

Batch n°70618 contains 3.17% w/w eugenol, 6.29% w/w geraniol, and 6.38% w/w thymol (White G.A. report n°J16537).

Batch n°53161-022 contains 3.47% w/w eugenol, 6.78% w/w geraniol, and 6.49% w/w thymol (White G.A. report n°J16537).

Table 2-1.6-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual inspection, Odour committee	3AEY Batch no. YPOA3Y424-1.1 3.23% w/w eugenol 6.47% w/w geraniol 6.56% w/w thymol	Light cream coffee brown (beige), viscous liquid with an odour typical of a mixture of the three active ingredients but predominantly clove oil. Following storage at ambient temperature for 2 years: Light cream coffee brown, viscous liquid with an odour typical of a mixture of the three active ingredients but predominantly clove oil. Some oil noticed on surface and a little sediment – easily homogenised on shaking	Y	KCP 2.1/01	The results are still valid and acceptable.
		3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	Dark cream (beige), viscous liquid with an odour typical of a mixture of the three active ingredients but predominantly clove oil. Following accelerated storage at 54°C for 14 days: Slightly darker cream/ beige than initial sample, otherwise, no change from initial sample Following after freeze / thaw cycle: No change from initial sample.	Y	KCP 2.1/02	The results are still valid and acceptable.
		3AEY Batch n°53161-022 3.47% w/w eugenol 6.78% w/w geraniol 6.49% w/w thymol	Light cream coffee brown (beige), viscous liquid with an odour typical of a mixture of the three active ingredients but predominantly clove oil. Following accelerated storage at 54°C for 14 days: As initial except colouration of liquid slightly darker brown.	Y	KCP 2.1/03	Accepted.
			Light brown, slightly viscous mobile liquid. No separation (homogenous). No signs of contamination. Characteristic odour. Following storage at ambient temperature for 2 years: No change from initial sample.	Y	KCP 2.1/04	Accepted.
Explosive properties (KCP 2.2.1)	ASTM E537-02 (DSC)	3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	Samples were heated in sealed, high-pressure, stainless steel capsules at a heating rate of 10°C/minute over the range 30°C to 400°C, in a test chamber environment of nitrogen at a purge rate of approximately 20 mL/minute. No significant exothermic event was noted in any of the samples examined. In addition, the oxygen balance for the three active ingredients are all below -240 and hence Mevalone presents no realistic possibility to be an explosion hazard.	Y	KCP 2.1/02	The results are still valid and acceptable.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Oxidizing properties (KCP 2.2.2)	EEC A.17	3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	In a 2:1 Mevalone: Cellulose cone test, the cone started singing slightly after 7 minutes, then started smoking after 16 minutes and was fully carbonised after 37 minutes. Mevalone presents no realistic possibility to be an oxidation hazard.	Y	KCP 2.1/02	The results are still valid and acceptable.
Flash point (KCP 2.3.1)	EEC A.9	3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	Pensky Martens Closed Cup: no flash up to 100°C. At temperatures above 100°C, the sample boiled over and extinguished the flame.	Y	KCP 2.1/02	The results are still valid and acceptable.
Flammability (KCP 2.3.2)	-	-	Not required since Mevalone is neither a solid nor a gas	-	-	-
Self-heating (KCP 2.3.3)	EEC A.15	3AEY Batch no. YPOA3Y424-1.1 3.23% w/w eugenol 6.47% w/w geraniol 6.56% w/w thymol	The sample did not auto-ignite below 400°C.	Y	KCP 2.1/01	The results are still valid and acceptable.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT75	3AEY Batch no. YPOA3Y424-1.1 3.23% w/w eugenol 6.47% w/w geraniol 6.56% w/w thymol	pH = 5.58 (neat) Following storage at ambient temperature for 2 years: pH = 5.32 (neat) Acidity or alkalinity is not required since Mevalone does not have a pH <4 or > 10	Y	KCP 2.1/01	The results are still valid and acceptable.
		3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	pH = 5.72 (neat) Following accelerated storage at 54°C for 14 days: pH = 5.69 (neat) Following after freeze / thaw cycle: pH = 5.69 (neat) Acidity or alkalinity is not required since Mevalone does not have a pH <4 or > 10	Y	KCP 2.1/02	The results are still valid and acceptable.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT75	3AEY Batch no. YPOA3Y424-1.1 3.23% w/w eugenol	pH = 5.74 (1% w/v solution in water) Following storage at ambient temperature for 2 years: pH = 6.16 (1% w/v solution in water)	Y	KCP 2.1/01	The results are still valid and acceptable.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																													
		6.47% w/w geraniol 6.56% w/w thymol																																	
		3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	pH = 5.85 (1% w/v solution in water) Following accelerated storage at 54°C for 14 days: pH = 5.87 (1% w/v solution in water) Following after freeze / thaw cycle: pH = 5.84 (1% w/v solution in water)	Y	KCP 2.1/02	The results are still valid and acceptable.																													
Viscosity (KCP 2.5.1)	OECD 114	3AEY Batch no. YPOA3Y424-1.1 3.23% w/w eugenol 6.47% w/w geraniol 6.56% w/w thymol	3mm ISO Cup at 20 and 40 ± 0.5°C: flow time > 30 seconds. Mevalone does not present an aspiration hazard. Brookfield RVT Viscometer with n°2 spindle: <table border="1"> <thead> <tr> <th rowspan="2">Speed (rpm)</th> <th colspan="2">Viscosity</th> </tr> <tr> <th>20°C</th> <th>40°C</th> </tr> </thead> <tbody> <tr> <td>0.5</td> <td>4800</td> <td>4000</td> </tr> <tr> <td>1.0</td> <td>3200</td> <td>2400</td> </tr> <tr> <td>2.5</td> <td>1744</td> <td>1280</td> </tr> <tr> <td>5</td> <td>1112</td> <td>840</td> </tr> <tr> <td>10</td> <td>728</td> <td>560</td> </tr> <tr> <td>20</td> <td>520</td> <td>400</td> </tr> <tr> <td>50</td> <td>352</td> <td>272</td> </tr> <tr> <td>100</td> <td>286</td> <td>217</td> </tr> </tbody> </table> The product is a non-newtonian liquid.	Speed (rpm)	Viscosity		20°C	40°C	0.5	4800	4000	1.0	3200	2400	2.5	1744	1280	5	1112	840	10	728	560	20	520	400	50	352	272	100	286	217	Y	KCP 2.1/01	The results are still valid and acceptable.
Speed (rpm)	Viscosity																																		
	20°C	40°C																																	
0.5	4800	4000																																	
1.0	3200	2400																																	
2.5	1744	1280																																	
5	1112	840																																	
10	728	560																																	
20	520	400																																	
50	352	272																																	
100	286	217																																	
Surface tension (KCP 2.5.2)	EEC A.5	3AEY Batch no. YPOA3Y424-1.1 3.23% w/w eugenol 6.47% w/w geraniol 6.56% w/w thymol	The average of duplicate measurements over the course of 30 minutes varied between 38.4 and 39.3 mN/m. The overall surface tension was 38.9 mN/m at 20 ± 0.5°C.	Y	KCP 2.1/01	The results are still valid and acceptable.																													
Relative density (KCP 2.6.1)	CIPAC MT 3.3.2	3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	1.035	Y	KCP 2.1/02	The results are still valid and acceptable.																													
Bulk density (KCP 2.6.2)	-	-	Not required since Mevalone is neither a powder nor a granule	-	-	-																													

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	Stable throughout the test period of 14 days at 54 ± 2°C with respect to appearance (product and packaging), active substances content (free, encapsulated and total), pH, persistence of foaming, spontaneity of dispersion, suspensibility, wet sieve and pourability. The data demonstrates that the commercial packaging (HDPE bottles – refer to section 4.4 of this document) is resistant to the product during the period of storage. No adverse effects were observed for the packaging following the accelerated storage of the product. Please see Table 2.1.6-2 below for details of accelerated storage stability.	Y	KCP 2.1/02	The results are still valid and acceptable.
		3AEY Batch n°53161-022 3.47% w/w eugenol 6.78% w/w geraniol 6.49% w/w thymol	Stable throughout the test period of 14 days at 54 ± 2°C with respect to appearance (product and packaging), impurity content, and pH. The data demonstrates that the commercial packaging (HDPE bottles – refer to section 4 of this document) is resistant to the product during the period of storage. No adverse effects were observed for the packaging following the accelerated storage of the product. Please see Table 2.1.6-3 below for details of accelerated storage stability.	Y	KCP 2.1/04	Accepted. The product showed no significant physical changes after accelerated storage. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE.
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required since Mevalone is not heat sensitive	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	14 days at 54°C	3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	No appreciable changes were observed after 14 days of storage at 54°C for active substances content (free, encapsulated and total). Please see Table 2.1.6-2 below for details of accelerated storage stability.	Y	KCP 2.1/02	The results are still valid and acceptable.
	14 days at 54°C	3AEY Batch n°53161-022 3.47% w/w eugenol 6.78% w/w geraniol 6.49% w/w thymol	No appreciable changes were observed after 14 days of storage at 54°C for impurity content. Please see Table 2.1.6-3 below for details of accelerated storage stability.	Y	KCP 2.1/04	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	Stable throughout the test period (cycling comprised 16 hours at <-10°C followed by 8 hours at 25 ± 2°C (65 ± 4% rh) for a total of 7 cycles) with respect to appearance (product and packaging), active substances content (free, encapsulated and total), pH, persistence of foaming, spontaneity of dispersion, suspensibility, wet sieve and pourability. The data demonstrates that the commercial packaging (HDPE bottles – refer to section 4 of this document) is resistant to the product during the period of storage. No adverse effects were observed for the packaging following the accelerated storage of the product. Please see table 2.1.6-4 below for details of cold storage stability.	Y	KCP 2.1/02	The results are still valid and acceptable.
Ambient temperature shelf life (KCP 2.7.5)	CropLife International Technical Monograph n°17	3AEY Batch no. YPOA3Y424-1.1 3.23% w/w eugenol 6.47% w/w geraniol 6.56% w/w thymol	Stable throughout the test period of 2 year at 20 ± 2°C with respect to appearance (product and packaging), active substances content (free, encapsulated and total), pH, persistence of foaming, spontaneity of dispersion, suspensibility, wet sieve and pourability. The data demonstrates that the commercial packaging (HDPE bottles – refer to section 4 of this document) is resistant to the product during the period of storage. No adverse effects were observed for the packaging following the accelerated storage of the product. Please see Table 2.1.6-5 below for details of ambient shelf-life.	Y	KCP 2.1/01	The results are still valid and acceptable.
		3AEY Batch n°53161-022 3.47% w/w eugenol 6.78% w/w geraniol 6.49% w/w thymol	Stable throughout the test period of 2 year at 20 ± 2°C with respect to appearance (product and packaging), impurity content, and pH. The data demonstrates that the commercial packaging (HDPE bottles – refer to section 4 of this document) is resistant to the product during the period of storage. No adverse effects were observed for the packaging following the accelerated storage of the product. Please see Table 2.1.6-6 below for details of ambient shelf-life.	Y	KCP 2.1/03	Study accepted. The HDPE container showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product. Period of validity: 2 years
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Since the storage stability at ambient temperature is not less than 2 years (see point IIIA 2.7.5), shelf life study in months is not required.	-	-	-
Wettability (KCP 2.8.1)	-	-	Not required for CS formulation.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.1	3AEY Batch no. YPOA3Y424-1.1 3.23% w/w eugenol 6.47% w/w geraniol 6.56% w/w thymol	For a 0.4% v/v aqueous suspension: 0mL after 1 min Following storage at ambient temperature for 2 years: No change from initial sample.	Y	KCP 2.1/01	The results are still valid and acceptable.
		3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	For a 0.4% v/v aqueous suspension: 0mL after 1 min Following accelerated storage at 54°C for 14 days: No change from initial sample. Following after freeze / thaw cycle: No change from initial sample.	Y	KCP 2.1/02	The results are still valid and acceptable.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 161	3AEY Batch no. YPOA3Y424-1.1 3.23% w/w eugenol 6.47% w/w geraniol 6.56% w/w thymol	For a 0.4% v/v aqueous suspension: 99.1% of eugenol 99.5% of geraniol 99.9% of thymol Following storage at ambient temperature for 2 years: 100.4% of eugenol 100.3% of geraniol 100.5% of thymol	Y	KCP 2.1/01	The results are still valid and acceptable.
		3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	For a 0.4% v/v aqueous suspension: 99.1% of eugenol 99.5% of geraniol 99.9% of thymol Following accelerated storage at 54°C for 14 days: 98.9% of eugenol 99.9% of geraniol 100.0% of thymol Following after freeze / thaw cycle: 99.2% of eugenol 99.5% of geraniol 100.0% of thymol	Y	KCP 2.1/02	The results are still valid and acceptable.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	3AEY Batch no. YPOA3Y424-	For a 0.4% v/v aqueous suspension: 100.2% of eugenol	Y	KCP 2.1/01	The results are still valid and acceptable.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		1.1 3.23% w/w eugenol 6.47% w/w geraniol 6.56% w/w thymol	100.7% of geraniol 100.7% of thymol Following storage at ambient temperature for 2 years: 100.5% of eugenol 100.7% of geraniol 100.5% of thymol			
		3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	For a 0.4% v/v aqueous suspension: 100.2% of eugenol 100.7% of geraniol 100.7% of thymol Following accelerated storage at 54°C for 14 days: 100.0% of eugenol 99.8% of geraniol 100.5% of thymol Following after freeze / thaw cycle: 100.2% of eugenol 100.6% of geraniol 100.7% of thymol	Y	KCP 2.1/02	The results are still valid and acceptable.
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for CS formulation.	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for CS formulation.	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required for CS formulation.	-	-	-
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 59.3	3AEY Batch no. YPOA3Y424-1.1 3.23% w/w eugenol 6.47% w/w geraniol 6.56% w/w thymol	% Retained on 75 µm Sieve: < 0.01% Following storage at ambient temperature for 2 years: % Retained on 75 µm Sieve: < 0.01%	Y	KCP 2.1/01	The results are still valid and acceptable.
		3AEY	For a 0.4% v/v aqueous suspension:	Y	KCP 2.1/02	The results are still valid

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	% Retained on 75 µm Sieve: < 0.01% Following accelerated storage at 54°C for 14 days: % Retained on 75 µm Sieve: < 0.01% Following after freeze / thaw cycle: % Retained on 75 µm Sieve: < 0.01%			and acceptable.
Dust content (KCP 2.8.5.2.1)	-	-	Not required for CS formulation.	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for CS formulation.	-	-	-
Attrition (KCP 2.8.5.3)	-	-	Not required for CS formulation.	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for CS formulation.	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for CS formulation.	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	Not required for CS formulation.	-	-	-
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required for CS formulation.	-	-	-
Flowability (KCP 2.8.7.1)	-	-	Not required for CS formulation.	-	-	-
Pourability (KCP 2.8.7.2)	CIPAC MT 59.3 Method MT 148	3AEY Batch no. YPOA3Y424-1.1 3.23% w/w eugenol 6.47% w/w geraniol 6.56% w/w thymol	Residue: 1.46% Rinsed residue: 0.208% Following storage at ambient temperature for 2 years: Residue: 2.48% Rinsed residue: 0.206%	Y	KCP 2.1/01	The results are still valid and acceptable.
		3AEY Batch no. 70618 3.17% w/w eugenol 6.29% w/w geraniol 6.38% w/w thymol	Residue: 1.46% Rinsed residue: 0.208% Following accelerated storage at 54°C for 14 days: Residue: 2.06%	Y	KCP 2.1/02	The results are still valid and acceptable.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Rinsed residue: 0.211% Following after freeze / thaw cycle: Residue: 1.52% Rinsed residue: 0.163%			
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for CS formulation.	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not applicable. Tank-mixes with Mevalone are not recommended	-	-	Tank-mixes with Mevalone are not proposed.
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not applicable. Tank-mixes with Mevalone are not recommended	-	-	Tank-mixes with Mevalone are not proposed.
Adhesion to seeds (KCP 2.10.1)	-	-	Not applicable. Mevalone is not a seed treatment	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not applicable. Mevalone is not a seed treatment	-	-	-
Other/special studies (KCP 2.11)	-	-	None.	-	-	-

Table 2.1.6-2: Detailed results of the accelerated storage stability study – White, G.A., J16537, 2007

Test and Annex Point	Method	Results before Storage	Results after storage at 54 ± 2°C for two weeks
Appearance (CP 2.1)	Visual Inspection	Formulation: Dark cream/ beige, viscous liquid with an odour typical of a mixture of the three active ingredients but predominantly clove oil Packaging: 1 litre, white plastic bottle with a screw cap. No further seals. Structural integrity intact. No signs of leaks, distortion or damage.	Formulation: Slightly darker cream/ beige than initial sample, otherwise, no change from initial sample Packaging: 1 litre, white plastic bottle with a screw cap. No further seals. Structural integrity intact. No signs of leaks, distortion or damage. No change from initial sample.

Test and Annex Point	Method	Results before Storage				Results after storage at 54 ± 2°C for two weeks			
Active Ingredient Content	Internally validated method M619	% w/w	Geraniol	Thymol	Eugenol	% w/w	Geraniol	Thymol	Eugenol
		Total	6.29	6.38	3.17	Total	6.28	6.38	3.16
		Free active ingredient	0.098	0.113	0.082	Free active ingredient	0.099	0.113	0.082
		Encapsulated active ingredient	6.19	6.27	3.09	Encapsulated active ingredient	6.18	6.27	3.08
pH of a 1% dilution, emulsion or dispersion (CP 2.4.2)	CIPAC MT 75.3	Determination	pH neat	pH 1% w/v dil.		Determination	pH neat	pH 1% w/v dil.	
		1	5.71	5.83		1	5.69	5.86	
		2	5.73	5.86		2	5.69	5.88	
		Average	5.72	5.85		Average	5.69	5.87	
Persistence of foaming (CP 2.8.2)	CIPAC MT 47.1	Time	Volume of foam (0.4% v/v aqueous suspension)			Time	Volume of foam (0.4% v/v aqueous suspension)		
		10 secs	0 mL			10 secs	0 mL		
		1 min	0 mL			1 min	0 mL		
		3 min	0 mL			3 min	0 mL		
		12 min	0 mL			12 min	0 mL		
Spontaneity of dispersion (CP 2.8.3)	CIPAC MT 160	Spontaneity of dispersion %			Spontaneity of dispersion %				
		Geraniol	Thymol	Eugenol	Geraniol	Thymol	Eugenol		
		100.7	100.7	100.2	99.9	100.0	98.9		
Suspensibility (CP 2.8.3)	CIPAC MT 161	Suspensibility % (0.4% v/v aqueous suspension)			Suspensibility % (0.4% v/v aqueous suspension)				
		Geraniol	Thymol	Eugenol	Geraniol	Thymol	Eugenol		
		99.5	99.9	99.1	99.8	100.5	100.0		
Wet sieve test (CP 2.8.5.1)	CIPAC MT 59.3	% Retained on 75 µm Sieve: < 0.01%				% Retained on 75 µm Sieve: < 0.01%			

Test and Annex Point	Method	Results before Storage	Results after storage at 54 ± 2°C for two weeks
Pourability (CP 2.8.7)	CIPAC MT 148	Residue: 1.46% Rinsed residue: 0.208%	Residue: 2.06% Rinsed residue: 0.211%

Table 2.1.6-3:– Detailed results of the accelerated storage stability study – Gates, G.J.D., J19052, 2012

Test and Annex Point	Method	Results before Storage	Results after storage at 54 ± 2°C for two weeks
Appearance (CP 2.1)	Visual Inspection	Formulation: Light cream coffee brown, viscous liquid with an odour typical of a mixture of the three active ingredients but predominantly clove oil. Packaging; 250 ml, transparent, HDPE, bottle with transparent lid. No further seals. Structural integrity intact. No signs of leaks, distortion or damage.	Formulation: As initial except colouration of liquid slightly darker brown. Packaging; 250 ml, transparent, HDPE, bottle with transparent lid. No further seals. Structural integrity intact. No signs of discoloration, panelling (concave pack walls), blowing (convex pack walls), softening (loss of rigidity), hardening (loss of plasticity), cracking, frosting, or crazing. No evidence of Pack/Preparation interactions. No change from initial sample.
Impurity Content	Internally validated method M737	7.74 mg/kg (ppm) of methyleugenol	7.16 mg/kg (ppm) of methyleugenol

Table 2.1.6-4: Detailed results of the cold storage stability study – White, G.A., J16537, 2007

The freeze/thaw specimen was cycled between -10 ± 2°C and 25 ± 2°C (65 ± 4% rh) over the period of eight days. Cycling comprised 16 hours at <-10°C followed by 8 hours at 25 ± 2°C (65 ± 4% rh) for a total of 7 cycles.

Test and Annex Point	Method	Results before Storage	Results after freeze / thaw cycle
Appearance (CP 2.1)	Visual Inspection	Formulation; Dark cream/ beige, viscous liquid with an odour typical of a mixture of the three active ingredients but predominantly clove oil Packaging: 1 litre, white plastic bottle with a screw cap. No further seals. Structural integrity intact. No signs of leaks, distortion or damage.	Formulation; Dark cream/ beige, viscous liquid with an odour typical of a mixture of the three active ingredients but predominantly clove oil. No change from initial sample Packaging: 1 litre, white plastic bottle with a screw cap. No further seals. Structural integrity intact. No signs of leaks, distortion or damage. No change from initial sample.
Active Ingredient Content	Internally validated method M619	% w/w	% w/w
		Total	Total
		Free active ingredient	Free active ingredient
		Encapsulated active ingredient	Encapsulated active ingredient
pH of a 1% dilution, emulsion or dispersion (CP 2.4.2)	CIPAC MT 75.3	Determination	Determination
		1	1

Geraniol	Thymol	Eugenol
6.29	6.38	3.17
0.098	0.113	0.082
6.19	6.27	3.09

Geraniol	Thymol	Eugenol
6.31	6.40	3.18
0.085	0.098	0.074
6.22	6.30	3.11

pH neat	pH 1% w/v dil.
5.71	5.83

pH neat	pH 1% w/v dil.
5.68	5.83

Test and Annex Point	Method	Results before Storage			Results after freeze / thaw cycle		
		2	5.73	5.86	2	5.69	5.85
		Average	5.72	5.85	Average	5.69	5.84
Persistence of foaming (CP 2.8.2)	CIPAC MT 47.1	Time	Volume of foam (0.4% v/v aqueous suspension)		Time	Volume of foam (0.4% v/v aqueous suspension)	
		10 secs	0 mL		10 secs	0 mL	
		1 min	0 mL		1 min	0 mL	
		3 min	0 mL		3 min	0 mL	
		12 min	0 mL		12 min	0 mL	
Spontaneity of dispersion (CP 2.8.3)	CIPAC MT 160	Spontaneity of dispersion %			Spontaneity of dispersion %		
		Geraniol	Thymol	Eugenol	Geraniol	Thymol	Eugenol
		100.7	100.7	100.2	100.6	100.7	100.2
Suspensibility (CP 2.8.3)	CIPAC MT 161	Suspensibility % (0.4% v/v aqueous suspension)			Suspensibility % (0.4% v/v aqueous suspension)		
		Geraniol	Thymol	Eugenol	Geraniol	Thymol	Eugenol
		99.5	99.9	99.1	99.5	100.0	99.2
Wet sieve test (CP 2.8.5.1)	CIPAC MT 59.3	% Retained on 75 µm Sieve: < 0.01%			% Retained on 75 µm Sieve: < 0.01%		
Pourability (CP 2.8.7)	CIPAC MT 148	Residue: 1.46% Rinsed residue: 0.208%			Residue: 1.52% Rinsed residue: 0.163%		

Table 2.1.6-5: Detailed results of the ambient storage stability study – White, G.A., J16313, 2011

Test and Annex Point	Method	Results before Storage	Results after storage at ambient temperature for 24 months
Appearance (CP 2.1)	Visual Inspection	<p>Formulation: Dark cream/ beige, viscous liquid with an odour typical of a mixture of the three active ingredients but predominantly clove oil</p> <p>Packaging: 1 litre, white plastic bottle with a screw cap. No further seals. Structural integrity intact. No signs of leaks, distortion or damage.</p>	<p>Formulation: Light cream coffee brown, viscous liquid with an odour typical of a mixture of the three active ingredients but predominantly clove oil. Some oil noticed on surface and a little sediment – easily homogenised on shaking</p> <p>Packaging: 1 litre, white plastic bottle with a screw cap. No further seals. Structural integrity intact. No signs of leaks, distortion or damage. No change from Initial Sample.</p> <p>No signs of discoloration, panelling (concave pack walls), blowing (convex pack walls), softening (loss of rigidity), hardening (loss of plasticity), cracking, frosting, or crazing. - No evidence of Pack/Preparation interactions.</p>

Test and Annex Point	Method	Results before Storage				Results after storage at ambient temperature for 24 months			
		% w/w	Geraniol	Thymol	Eugenol	% w/w	Geraniol	Thymol	Eugenol
Active Ingredient Content	Internally validated method M619	Total	6.47	6.56	3.23	Total	6.47	6.54	3.16
		Free active ingredient	0.113	0.131	0.090	Free active ingredient	0.145	0.160	0.102
		Encapsulated active ingredient	6.36	6.43	3.14	Encapsulated active ingredient	6.33	6.38	3.06
pH of a 1% dilution, emulsion or dispersion (CP 2.4.2)	CIPAC MT 75.3	Determination	pH neat	pH 1% w/v dil.	Determination	pH neat	pH 1% w/v dil.		
		1	5.57	5.73	1	5.31	6.15		
		2	5.59	5.74	2	5.32	6.17		
		Average	5.58	5.74	Average	5.32	6.16		
Persistence of foaming (CP 2.8.2)	CIPAC MT 47.1	Time	Volume of foam (0.4% v/v aqueous suspension)		Time	Volume of foam (0.4% v/v aqueous suspension)			
		10 secs	0 mL		10 secs	0 mL			
		1 min	0 mL		1 min	0 mL			
		3 min	0 mL		3 min	0 mL			
		12 min	0 mL		12 min	0 mL			
Spontaneity of dispersion (CP 2.8.3)	CIPAC MT 160	Spontaneity of dispersion %			Spontaneity of dispersion %				
		Geraniol	Thymol	Eugenol	Geraniol	Thymol	Eugenol		
		97.2	97.9	96.5	100.7	100.5	100.5		
Suspensibility (CP 2.8.3)	CIPAC MT 161	Suspensibility % (0.4% v/v aqueous suspension)			Suspensibility % (0.4% v/v aqueous suspension)				
		Geraniol	Thymol	Eugenol	Geraniol	Thymol	Eugenol		
		100.5	100.4	100.2	100.3	100.5	100.4		
Wet sieve test (CP 2.8.5.1)	CIPAC MT 59.3	% Retained on 75 µm Sieve: < 0.01%				% Retained on 75 µm Sieve: < 0.01%			
Pourability (CP 2.8.7)	CIPAC MT 148	Residue: 1.92% Rinsed residue: 0.166%				Residue: 2.48% Rinsed residue: 0.206%			

Table 2.1.6-6: Detailed results of the ambient storage stability study – Gates, G.J.D., J19053, 2014

Test and Annex Point	Method	Results before Storage	Results after storage at ambient temperature for 24 months
Appearance (CP 2.1)	Visual Inspection	<p>Formulation: Light brown, slightly viscous mobile liquid. No separation (homogenous). No signs of contamination. Characteristic odour.</p> <p>Packaging: 250 mL, transparent HDPE bottle with transparent screw top lid. No further seals. Structural integrity intact. No signs of leaks, distortion or damage. No signs of discolouration, panelling (concave pack walls), blowing (convex pack walls), softening (loss of rigidity), hardening (loss of plasticity), cracking, frosting or crazing. No evidence of Pack/Preparation interactions.</p>	<p>Formulation: Light brown, slightly viscous mobile liquid. No separation (homogenous). No signs of contamination. Characteristic odour. No change from initial sample.</p> <p>Packaging: 250 mL, transparent HDPE bottle with transparent screw top lid. No further seals. Structural integrity intact. No signs of leaks, distortion or damage. No signs of discolouration, panelling (concave pack walls), blowing (convex pack walls), softening (loss of rigidity), hardening (loss of plasticity), cracking, frosting or crazing. No evidence of Pack/Preparation interactions. No change from initial sample.</p>
Impurity Content	Internally validated method M737	8.19 mg/kg (ppm) of methyleugenol	6.59 mg/kg (ppm) of methyleugenol

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Comments of zRMS:	The results of the accelerated storage stability study and 2 years at ambient temperature stability study indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Extrapolation from HDPE to HDPE/PA is acceptable.
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Table 4.1-1: Packaging information for 5 liter jerry cans

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	Square dimmensions: 140 mm x 190 mm Height: 313 mm
Opening:	63 mm diameter
Closure:	Screw cap
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-2: Packaging information for 10 liter jerry cans

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	Square dimmensions: 165 mm x 230 mm Height: 375 mm
Opening:	63 mm diameter
Closure:	Screw cap
Manner of construction	Extruded
UN/ADR	Compliant

Suitability of the packaging and closures: strength; leakproofness; resistance to normal transport and handling

Problems with the suitability of packaging are not expected. Accelerated storage stability (14 days at 54°C), low temperature storage and long term storage (24 months at 20°C) studies have indicated no problems with 1-L HDPE packaging in terms of leakage, distortion or damage.

Resistance of the packaging material to its contents

Accelerated storage stability (14 days at 54°C), low temperature storage and long-term storage (24 months at 20°C) studies have indicated no problems with the packaging.

4.2 Procedures for Cleaning Application Equipment

4.2.1 Procedures for cleaning application equipment and protective clothing

Comments of zRMS:	Taking in to account the results of the pourability study double rinsing with tap water is recommended.
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Ensure suitable protective clothing is worn. Avoid contact with the skin, eyes or clothing. Ensure adequate ventilation.

In case the material is released or spilled, the product should be absorbed onto an inert absorbent material (e.g. sand, earth, sawdust). Prevent spills from entering waterways by diking with absorbent clay. If

contamination of drainage systems is unavoidable, immediately inform the appropriate authorities.
Mop up spills on hard surfaces and transfer to the original container. Adsorb with sand or earth and then transfer to a suitable container. After cleaning, flush traces away with water.
Dispose of waste via an authorised waste disposal facility according to local, state or national regulations.

4.2.2 Effectiveness of the cleaning procedures

No data provided. The procedures detailed above are standard approved procedures.

Appendix 1 Lists of data considered in support of the evaluation

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1/03	Bates G.J.D.	2014	Ambient storage stability trial for the 3AEY formulation Report n°J19053, G.C. Laboratories Ltd GLP Unpublished	N	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	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	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	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	Eden Research plc

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Eugenol

None.

A 2.2 Geraniol

None.

A 2.3 Thymol

None.