

REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

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: April 2022 (initial Core Assessment)

November 2022 (final Core Assessment)

Version history

When	What
July 2021	Initial dRR – Eden Research plc
December 2021	Update of the GAP table – Eden Research plc
April 2022	<p>Initial zRMS assessment</p> <p>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.</p>
November 2022	<p>Final report (Core Assessment updated following the commenting period).</p> <p>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.</p>

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

Comments of zRMS:

Conclusions from the evaluation were prepared using grey commenting boxes placed at the end of each chapter. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are also visibly marked with the grey font.

3.1. Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS:

This application has been submitted for authorization of the biofungicide Mevalone (3AEY) containing 3 active substances of natural origin: 33 g/L eugenol, 66 g/L geraniol and 66 g/L thymol (terpenes, FRAC BM 01; previously F7). Eugenol, geraniol and thymol are listed in Annex II of Commission Regulation (EU) 2019/2164 of 17 December 2019 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control. Mevalone is intended to be used in grapevine to the control of: *Botrytis cinera* (BOTRCI) and in pome fruits to the control of pathogens causing storage diseases (e.g. *Botrytis cinera* (BOTRCI), *Altrnarnia mali* (ALTEMA); *Gloesporium* sp. (GLOESP), *Penicilium expansum* (PENIEX), *Phytophthora cactorum* (PHYTCC), *Fusarium oxysporum* (FUSAOX)).

Efficacy

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). Based on the submitted efficacy trial results it can be concluded, that biofungicide Mevalone at dose rates of 2.0-4.0 L/ha ~~or 3.0~~ (1.7– 3.2 L/ha LWA), depending on disease pressure, dose rate tested and kind of assessment (PESSEV or PESINC) is moderately effective in the control of *Botrytis cinerea* or only reduces disease severity or disease incidence in grapevine in Maritime and South-East EPPO zone. The information about moderate efficacy/ reducing storage disease occurrence should be considered to be added on the national labels of Mevalone. Due to limited efficacy data (for PESSEV) or low efficacy (for PESINC) noted for MAR zone and due to no efficacy data available for SE zone for Mevalone applied at dose rates < 2.0 L/ha, in the opinion of zRMS it is not acceptable to recommend dose rates lower than 2.0 L/ha. Mevalone applied at dose rate of 4.0 L/ha (approx. 3.0-3.2 L/ha LWA) reduces storage disease incidence in apple fruits in NE zone. Mevalone applied at dose rate of 3.0 L/ha with an adjuvant (Slippa or Heliosol) is moderately effective or reduces storage diseases incidence. As no efficacy trials have been submitted to support the use of Mevalone without adjuvant at dose rates < 4.0 L/ha, the acceptable dose rate for Mevalone for NE EPPO zone in apple protection is 4.0 L/ha or 3.0-3.2 L/ha LWA. Mevalone applied at dose rate of 4.0 L/ha or applied at dose rate of 3.0 L/ha with adjuvant (Heliosol) only reduces storage diseases incidence on a very low level, based on the trials carried out in MAR and SE EPPO zone. Due to low efficacy results achieved in MAR and SE zone and due to limited efficacy data from SE zone, the concerned MSs are kindly advised to consider possibly efficacy trial results from NE zone and make a decision concerning acceptance of this use on the national level. As no efficacy trials are available for Mevalone applied without adjuvant at dose rates lower than 4.0 L/ha and due to efficacy results (below 40%) achieved for dose rate of 4.0 L/ha, in the opinion of zRMS dose rate of 4.0 L/ha is the only dose rate that can be considered for this claimed use.

As no efficacy trials have been submitted for *Pyrus communis*, *Cydonia oblonga*, *Malus sylvestris*, *Eryobotria japonica*, *Mespilus germanica* and *Pyrus pyrifolia* var. *culta* listed in GAP table, the concerned MSs are kindly advised to consider individually possible extrapolation of efficacy trial results from *Malus domestica*, according to the national requirements and make a decision concerning acceptance of this use on the national level.

Phytotoxicity, yield, transformation processes, germination, succeeding crops and adjacent crops

No phytotoxicity was observed after application of Mevalone in the course of the efficacy trials presented in support of the submission. No negative impact on the yield was observed after application of Mevalone in several trials, where a yield assessment was carried out.

It can be also concluded that no adverse effect on yield ~~quality, transformation~~ **vinification** processes, plant products used for propagation, succeeding crops, adjacent crops is expected after application of Mevalone.

On the label, the mention “when applied close to harvest Mevalone may affect the taste of raisins produced from treated crops” is recommended to be added.

Resistance management strategy

As terpenes have no activity at a very specific site, it is considered unlikely that fungi would develop resistance to these compounds. Resistance risk to terpenes has been considered as low. Target pathogens: *Botrytis cinerea*, *Penicillium* spp. belongs to high risk of resistance pathogens, *Monilia* spp. is a medium risk of resistance pathogen and *Alternaria* spp., *Fusarium* spp., *Phytophthora* spp are classified as low risk of resistance development pathogens. The overall fungicide/pathogen combined risk of resistance for Mevalone is considered as medium.

Due to no cases of resistance to terpenes, no expectations of resistance development because of no specific site of action, no specific management strategy for Mevalone has been proposed. This is acceptable, until any reports of resistance occurrence will be recorded. Monitoring and reporting of any occurrence of resistance is necessary.

GAP table – intended uses

The intended uses for Mevalone (product code 3AEY) are presented in the table thereafter.

Table 1.01-1: Acceptability of intended uses

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop-destination / purpose-of-crop)	F, Fn, Fnp G, Gn, Gnp or I**	Pests or Group of pests con- trolled (additionally: developmental stages-of-the-pest or-pest-group)	Application				Application-rate			PHI (days)	Remarks: e.g.-g safener/-syner- gist per-ha; other dose-rate-expression; dose-range (min- max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage-of crop-& season	Max. num- ber a)-per-use b)-per-crop/ season	Min. inter- val-between applications (days)	kg-or-L product / ha a)-max. rate per-appl. b)-max. total rate-per crop/season	g-or-kg-as/ha a)-max. rate per-appl. b)-max. total rate-per crop/season	Water L/ha min-/ max			
Zonal-uses (field-or-outdoor-uses, certain-types of protected-crops)														
1	Central-Zone IE, GB, NL, BE, LU, DE, CZ, AT, SI, SK, HU, PL	Grape (<i>Vitis vinifera</i> VITVI)	F	Grey-mould (<i>Botrytis cinerea</i> BOTRCI)	Foliar. Trac- tor-mounted air-blast sprayer. Hand-held knapsack sprayer.	BBCH-60- 89	a)-1 b)-4	7	a)-1.6—4.0 L/ha b)-6.4—16 L/ha	a) 52.8—132 (E) 106—264 (G) 106—264 (T) b) 211—528 (E) 422—1056 (G) 422—1056 (T)	400-1000	7	The-product-is-ap- plied-so-that-the concentration-in-g a.s./hL-is kept con- stant-at-13.2 (euge- nol), 26.4 (geraniol), 26.4 (thymol)-g a.s./ hectolitre-of-spray water-volume. Therefore, the higher application-rate-is diluted-in-the-higher water-volume. Apply at 3.0–3.2 L/ha-LWA	
2	Central-Zone IE, GB, NL, BE, LU, DE, CZ, AT, SI, SK, HU, RO, PL	Apple- <i>Malus domestica</i> -MABSD; pear- <i>Pyrus communis</i> -PYUCO; quince- <i>Cydonia oblonga</i> -CYDOB; crab-apple- <i>Malus sylvestris</i> -MABSY; loquat- <i>Eryobotria japonica</i> -EIOJA; medlar- <i>Mespilus germanica</i> -MSPGE; Nashi-pear- <i>Pyrus</i>	F	Post-harvest storage-diseases	Foliar. Trac- tor-mounted air-blast sprayer. Hand-held knapsack sprayer.	BBCH-75- 87	a)-1 b)-4	7	a)-1.6—4.0 L/ha b)-6.4—16 L/ha	a) 52.8—132 (E) 106—264 (G) 106—264 (T) b) 211—528 (E) 422—1056 (G) 422—1056 (T)	400-1000	7	The-product-is-ap- plied-so-that-the concentration-in-g a.s./hL-is kept con- stant-at-13.2 (euge- nol), 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.	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. ※	Member state(s)	Crop and/ or situation (crop-destination/ purpose-of-crop)	F, Fn, Fnp G, Gn, Gnp or I.※※	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest-group)	Application				Application-rate			PHI (days)	Remarks: e.g.-g-safener/-syner- gist per-ha, other dose-rate-expression; dose-range (min- max)	zRMS Conclusion (efficacy)
					Method-/ Kind	Timing-/ Growth stage-of crop-& season	Max.-num- ber a)-per-use b)-per-crop/ season	Min.-inter- val-between applications (days)	kg-or-L product-/ha a)-max.-rate per-appl. b)-max.-total rate-per crop/season	g-or-kg-as/ha a)-max.-rate per-appl. b)-max.-total rate-per crop/season	Water L/ha min-/ max			
		<i>pyrifolia</i> var. <i>culta</i> PYUPC											Apply at 3.0–3.2 L/ha-LWA Example or post- harvest storage diseases: <i>Phy-</i> <i>tophthora</i> spp. PHYTSP (mainly <i>P.</i> <i>cactorum</i> PHYTCC or <i>P. syringae</i> PHYTSY), <i>Alter-</i> <i>naria</i> spp. ALTESP, <i>Botrytis cinerea</i> BOTRCI	

※ Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

※※ F: professional field use, Fn: non-professional field use, Fnp: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gnp: professional and non-professional greenhouse use, I: indoor application

Table 1.01-2: Acceptability of intended uses

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			P H I (d a y s)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	kg, L prod- uct / 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) 6-4 8.0 – 16 L/ha	a) 52-8 66- 132 (E) 106-132 132- 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	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA) Acceptable water volume range is 500-1000 L/ha
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) 6-4 8.0 – 16 L/ha	a) 52-8 66- 132 (E) 106-132 132- 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	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA) Acceptable water volume range is 500-1000 L/ha

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			P H I (d a y s)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	kg, L prod- uct / 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	BE	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) 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	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA) Acceptable water volume range is 500-1000 L/ha
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) 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	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA) Acceptable water volume range is 500-1000 L/ha
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) 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	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA) Acceptable water volume range is 500-1000 L/ha

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			P H I (d ay s)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	kg, L prod- uct / 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	HU	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) 6-4 8.0 – 16 L/ha	a) 52-8 66- 132 (E) 106-132 132- 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	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA) Acceptable water volume range is 500-1000 L/ha
1	NL	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) 6-4 8.0 – 16 L/ha	a) 52-8 66- 132 (E) 106-132 132- 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	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA) Acceptable water volume range is 500-1000 L/ha
1	LU	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) 6-4 8.0 – 16 L/ha	a) 52-8 66- 132 (E) 106-132 132- 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	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA) Acceptable water volume range is 500-1000 L/ha

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I (additionally: developmen- tal stages of the pest or pest group)	Pests or Group of pests con- trolled (additionally: developmen- tal stages of the pest or pest group)	Application			Application rate			P H I (d ay s)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	kg, L prod- uct / 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	SK	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) 6-4 8.0 – 16 L/ha	a) 52-8 66- 132 (E) 106-132 132- 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	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA) Acceptable water volume range is 500-1000 L/ha
1	SI	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) 6-4 8.0 – 16 L/ha	a) 52-8 66- 132 (E) 106-132 132- 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	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA) Acceptable water volume range is 500-1000 L/ha
1	IE	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) 6-4 8.0 – 16 L/ha	a) 52-8 66- 132 (E) 106-132 132- 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	A Acceptable dose rate range is 2.0 – 4.0 L/ha (1.7-3.2 L/ha LWA) Acceptable water volume range is 500-1000 L/ha

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I	Pests or Group of pests con- trolled (additionally: developmen- tal stages of the pest or pest group)	Application			Application rate			P H I (d ay s)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	kg, L prod- uct / 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	GB	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—4.0 L/ha b) 6.4—16 L/ha	a) 52.8—132 (E) 106—264 (G) 106—264 (T) b) 211—528 (E) 422—1056 (G) 422—1056 (T)	400- 1000	7	The product is applied so that the concentration in g a.s./hL is kept constant at 13.2 (eugenol), 26.4 (geraniol), 26.4 (thymol) g a.s / hectolitre of spray water volume. Therefore, the higher application rate is diluted in the higher water volume. Apply at 3.0 – 3.2 L/ha LWA	
2	PL	Apple <i>Malus domestica</i> MABSD, pear <i>Pyrus communis</i> PYUCO, quince <i>Cydonia</i> <i>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 dis- eases	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. syrin-</i> <i>gae</i> PHYTSY), <i>Alternaria</i> spp. ALTESP, <i>Botrytis cinerea</i> BOTRCI	A MABSD Dose rate 4.0 L/ha and water volume 1000 L/ha is acceptable N PYUCO, CYDOB, MABSY, MSPGE, PYUPC (possible registration under art. 51) N EIOJA

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I (additionally: developmen- tal stages of the pest or pest group)	Pests or Group of pests con- trolled (additionally: developmen- tal stages of the pest or pest group)	Application			Application rate			P H I (d a y s)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	kg, L prod- uct / 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	AT	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 dis- eases	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. syrin- gae</i> PHYTSY), <i>Alternaria</i> spp. ALTESP, <i>Botrytis cinerea</i> BOTRCI	C This claimed use is to be confirmed by cMS. Dose rate and water vol- ume have been changed after evaluation – to be confirmed by cMS

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I (additionally: developmental stages of the pest or pest group)	Pests or Group of pests controlled	Application			Application rate			P H I (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (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			
2	BE	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	C This claimed use is to be confirmed by cMS. Dose rate and water volume have been changed after evaluation – to be confirmed by cMS

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I (additionally: developmental stages of the pest or pest group)	Pests or Group of pests controlled	Application			Application rate			P H I (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (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			
2	CZ	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	C This claimed use is to be confirmed by cMS. Dose rate and water volume have been changed after evaluation – to be confirmed by cMS

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I (additionally: developmental stages of the pest or pest group)	Pests or Group of pests controlled	Application			Application rate			P H I (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (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			
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	C This claimed use is to be confirmed by cMS. Dose rate and water volume have been changed after evaluation – to be confirmed by cMS

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Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I (additionally: developmental stages of the pest or pest group)	Pests or Group of pests controlled	Application			Application rate			P H I (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (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			
2	HU	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	C This claimed use is to be confirmed by cMS. Dose rate and water volume have been changed after evaluation – to be confirmed by cMS

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Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I (additionally: developmen- tal stages of the pest or pest group)	Pests or Group of pests con- trolled (additionally: developmen- tal stages of the pest or pest group)	Application			Application rate			P H I (d ay s)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	kg, L prod- uct / 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	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, 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 dis- eases	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. syrin- gae</i> PHYTSY), <i>Alternaria</i> spp. ALTESP, <i>Botrytis cinerea</i> BOTRCI	C This claimed use is to be confirmed by cMS. Dose rate and water vol- ume have been changed after evaluation – to be confirmed by cMS

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I (additionally: developmental stages of the pest or pest group)	Pests or Group of pests controlled	Application			Application rate			P H I (d a y s)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	kg, L prod- uct / 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	LU	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 dis- eases	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	C This claimed use is to be confirmed by cMS. Dose rate and water vol- ume have been changed after evaluation – to be confirmed by cMS

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Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I (additionally: developmental stages of the pest or pest group)	Pests or Group of pests controlled	Application			Application rate			P H I (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (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			
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. 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	C This claimed use is to be confirmed by cMS. Dose rate and water volume have been changed after evaluation – to be confirmed by cMS

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Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I (additionally: developmental stages of the pest or pest group)	Pests or Group of pests controlled	Application			Application rate			P H I (d a y s)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	kg, L prod- uct / 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	SI	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 dis- eases	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. syrin- gae</i> PHYTSY), <i>Alternaria</i> spp. ALTESP, <i>Botrytis cinerea</i> BOTRCI	C This claimed use is to be confirmed by cMS. Dose rate and water vol- ume have been changed after evaluation – to be confirmed by cMS

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I (additionally: developmental stages of the pest or pest group)	Pests or Group of pests controlled	Application			Application rate			P H I (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (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			
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, 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	C This claimed use is to be confirmed by cMS. Dose rate and water volume have been changed after evaluation – to be confirmed by cMS

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I (additionally: developmental stages of the pest or pest group)	Pests or Group of pests controlled	Application			Application rate			P H I (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (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			
2	RO	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	C This claimed use is to be confirmed by cMS. Dose rate and water volume have been changed after evaluation – to be confirmed by cMS

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G o r I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			P H I (d a y s)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	kg, L prod- uct / 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</i> <i>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 dis- eases	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 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</i> <i>cinerea</i> BOTRCI	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Column 14: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by CMS
N	Not acceptable / evaluation not possible

Comments of zRMS on:

Table 1.01-3: Acceptability of intended uses (GAP)

As GAP table contained in Part B Section 3 differed from GAP table contained in Part B Section 0 and in other sections, for the sake of documents consistency, GAP from Part B Section 0 has been moved to Part B Section 3. The previous GAP from Part B Section 3 has been visibly removed.

3.2 Efficacy data (KCP 6)

Introduction

The product Mevalone (product code 3AEY) is a biofungicide product belonging to the category of natural substances containing eugenol (33 g/L), geraniol (66 g/L) and thymol (66 g/L) (CS formulation). Mevalone helps therefore to reduce the number of treatments with synthetic chemicals. It is already registered in South European member states under several trade names as a fungicide against *Botrytis cinerea* in grapevine and a range of other crops.

The purpose of this document is to present efficacy and crop safety data, in support of the initial authorisation in the countries of the Central zone, for Mevalone as a fungicide against *Botrytis cinerea* in grapevine and against storage diseases on pome fruits.

This document summarises the information related to the efficacy of the product Mevalone containing the substances: eugenol, geraniol and thymol, which were included into Annex I of the Regulation (EC) No 1107/2009, repealing directive 91/414/EEC. The SANCO reports for eugenol (SANCO/10577/2013 rev 3), geraniol (SANCO/10579/2013 rev 3) and thymol (SANCO/10581/2013 rev 3) are considered to provide the relevant review information or a reference to where such information can be found.

The Annex I Inclusion Directive for eugenol, geraniol and thymol (2009/11/EC) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation:

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the eugenol, geraniol and thymol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17/05/2013 shall be taken into account. In this overall assessment:

Member States shall pay particular attention to the:

- 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;
- the risk to insectivorous birds.

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

Compatibility with the current reduction of synthetic chemicals

Mevalone contains the active substances eugenol, geraniol and thymol, which are terpene compounds found naturally occurring in certain plants species and as constituents of essential oils. They are considered to have both curative and protectant fungicidal activity.

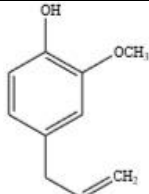
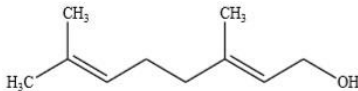
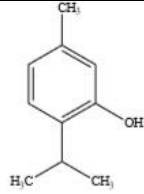
Like the few other biofungicide products already available for the control of apple storage disease in Europe, Mevalone is a useful alternative to synthetic chemical substances and may contribute to the reduction of the risk of resistance to these substances. Considering the multi-site mode of action of the product and the absence of existing cases of resistance to terpenes, the risk of resistance to the active substances of Mevalone can be considered as low.

Another important aspect is the political context of reduction of the number of treatments applied in the crops (Sustainable Use Directive). As a biocontrol product (natural substances category), Mevalone will help reducing the number of synthetic chemical treatments. In addition, biocontrol products such as Mevalone are in line with the European Green Deal and the target of 50% reduction in synthetic chemicals by 2030. Moreover, the terpenes are Annex II approved organic inputs and the European Green Deal has a target of 25% organic agriculture by 2030.

Description of the active substances

Mevalone contains 3 active substances: eugenol, geraniol and thymol. These 3 active substances are used together. They act as a fungicide.

Table 3.2-1: Details of the active substances

Common name (ISO)	Eugenol	Geraniol	Thymol
Chemical name (IU-PAC)	4-allyl-2-methoxyphenol	(E) 3,7-dimethyl-2,6-octadien-1-ol	5-methyl-2-propan-2-yl-phenol
Chemical name (CA)	2-methoxy-4-(2-propenyl)phenol	(E) 3,7-dimethyl-2,6-octadien-1-ol	5-methyl-2-propan-2-yl-phenol
CIPAC N°	967	968	969
CAS N°	97-53-0	106-24-1	89-83-8
Molecular formula	C ₁₀ H ₁₂ O ₂	C ₁₀ H ₁₈ O	C ₁₀ H ₁₄ O
Molecular mass	164.20 g/mol	154.25 g/mol	150.22 g/mol
Structural formula			

Sources: SANCO reports for Eugenol (SANCO/10577/2013 rev 3), Geraniol (SANCO/10579/2013 rev 3) and Thymol (SANCO/10581/2013 rev 3).

Mode of action

Terpene compounds such as eugenol, geraniol and thymol generally possess antifungal activity and it is believed that they have a single mode of action that is very similar to that of benzyl alcohol, phenol and polyphenols. From widespread research carried out on terpenes, it is evident that eugenol, geraniol and thymol all have the same mode of action against fungi, having effects on spore germination, hyphal penetration, mycelial growth and hyphal growth.

All terpene compounds are reported to have direct effects on cell walls, membranes, which is associated with the capability of the compounds to dissolve lipids and results in leakage of cellular substances leading to cell death. Studies have confirmed that cyclic terpene hydrocarbons accumulate in the cell membrane causing a loss of membrane integrity, with associated changes in composition of fatty acids and phospholipids. This is thought to occur as a result of lesion formation in the cytoplasmic membrane with reductions in ergosterol content due to the disruption of biosynthesis.

Due to these effects on membranes, there is also thought to be an impact on processes involving ATP and active transport of molecules across membranes, leading to depletion of the ATP pool and leakage of cellular substances, with impairment of energy metabolism. Mitochondrial structure disorganization may occur and the effects on membranes have been shown to cause partial dissipation of the pH gradient and electrical potential.

Terpenes have also been observed to cause changes in the hyphal wall. Some effects on enzyme activity have also been reported, including interference with respiratory enzymes and enzymes responsible for cell wall synthesis.

Description of the plant protection product

Mevalone is a capsule suspension formulation (CS) containing eugenol (33 g a.s./L), geraniol (66 g a.s./L) and thymol (66 g a.s./L). Eugenol, geraniol and thymol are all terpene compounds found naturally occurring in certain plant species and as constituents of essential oils. They are considered to have both curative and protectant fungicidal activity.

The product is registered for use as a fungicide in countries of Southern Europe under several commercial names.

The table below gives an overview of the current uses authorised for Mevalone in Europe.

Table 3.2-2: List of currently authorised uses with Mevalone

Country	Trade name Registration n°	Company	Crop	Target / use	Dose L/ha	Max nb of application	PHI
Malta	Mevalone 2015-05-18 P02	Eden Research plc	Grape (wine)	<i>Botrytis cinerea</i>	4	4	3
			Grape (table)	<i>Botrytis cinerea</i>	4	4	7
France	Mevalone 2161080	Sumi Agro France	Grape (wine)	<i>Botrytis cinerea</i>	4	4	3
			Grape (table)	<i>Botrytis cinerea</i>	4	4	7
Spain	Araw ES-00108	Sipcam Iberia	Grape (wine)	Botrytis	4	4	3
			Grape (table)	Botrytis	4	4	7
			Grape (wine)	Powdery mildew	4	4	3
			Grape (table)	Powdery mildew	4	4	7
			Fruit bushes	Botrytis	2 - 4	1	1
				Powdery mildew	2 - 3	1	1
				Rust	2 - 3	1	1
			Aubergine	Botrytis	2 - 4	5	1
				Powdery mildew	2 - 3	5	1
			Courgette	Powdery mildew	2 - 3	5	1
			Pumpkin	Powdery mildew	2 - 3	5	1
			Strawberry	Botrytis	2 - 4	4	1
				Powdery mildew	2 - 3	4	1
			Fresh herbs and edible flowers	Botrytis	2 - 4	2	1
				Powdery mildew	2 - 3	2	1
				Sclerotinia	2 - 4	2	1
			Lettuce and simila	Botrytis	2 - 4	5	1
				Powdery mildew	2 - 3	5	1
				Sclerotinia	2 - 4	5	1
			Melon	Powdery mildew	2 - 3	5	1
			Gherkin	Powdery mildew	2 - 3	5	1
			Cucumber	Powdery mildew	2 - 3	5	1
			Pepper	Botrytis	2 - 4	5	1
				Powdery mildew	2 - 3	5	1
			Watermelon	Powdery mildew	2 - 3	5	1
			Tomato	Botrytis	2 - 4	5	1
				Powdery mildew	2 - 3	5	1
			Pomegranate	<i>Botrytis cinerea</i>	2 - 4	1	2
			Fava bean	Botrytis	2 - 4	5	1
			Fig	Botrytis	2 - 4	1	2
			Fennel	Sclerotinia	2 - 4	5	1
			Brassica vegetables	Botrytis	2 - 4	5	1
				Sclerotinia	2 - 4	5	1
			Hop	Powdery mildew	2 - 4	5	1
			Tobacco	Botrytis	2 - 4	5	1
				Powdery mildew	2 - 3	5	1
Italy	3logy 16480	Sipcam Italia SpA	Grape (wine)	<i>Botrytis cinerea</i>	4	4	3
			Grape (table)	<i>Botrytis cinerea</i>	4	4	7

Country	Trade name Registration n°	Company	Crop	Target / use	Dose L/ha	Max nb of application	PHI
Portugal	Mevalone 1012	Eden Research plc	Grape (wine)	<i>Botrytis cinerea</i>	4	4	3
			Grape (table)	<i>Botrytis cinerea</i>	4	4	7
Greece	Mevalone 60467	Eden Research plc	Grape (wine)	<i>Botrytis cinerea</i>	4	4	3
			Grape (table)	<i>Botrytis cinerea</i>	4	4	7
			Aubergine	<i>Botrytis cinerea</i>	4	4	3
			Pomegranate	<i>Botrytis cinerea</i>	4	4	3
			Spring onion	<i>Botrytis cinerea</i>	4	4	3
			Kiwi	<i>Botrytis cinerea</i>	4	4	3
			Tomato	<i>Sclerotium rolfsii</i> *, <i>Athelia rolfsii</i> *	4	2	7
			Olive	<i>Colletotrichum spp</i> *	4	2	7
Cyprus	Mevalone 3333	Eden Research plc	Grape (wine)	<i>Botrytis cinerea</i>	4	4	3
			Grape (table)	<i>Botrytis cinerea</i>	4	4	7
			Aubergine	<i>Botrytis cinerea</i>	4	4	3
			Pomegranate	<i>Botrytis cinerea</i>	4	4	3
			Spring onion	<i>Botrytis cinerea</i>	4	4	3
			Kiwi	<i>Botrytis cinerea</i>	4	4	3
			Tomato	<i>Sclerotium rolfsii</i> *, <i>Athelia rolfsii</i> *	4	2	7
			Olive	<i>Colletotrichum spp</i> *	4	2	7
Albania	Mevalone 650	K&N Efthymiadis	Grape (wine)	<i>Botrytis cinerea</i>	4	4	3
			Grape (table)	<i>Botrytis cinerea</i>	4	4	7
			Aubergine	<i>Botrytis cinerea</i>	4	4	3
			Pomegranate	<i>Botrytis cinerea</i>	4	4	3
			Spring onion	<i>Botrytis cinerea</i>	4	4	3
			Kiwi	<i>Botrytis cinerea</i>	4	4	3
Bulgaria	Mevalone 01354 - PPP-1 / 15.02.2016	K&NE Certis	Grape (wine)	<i>Botrytis cinerea</i>	4	4	3
			Grape (table)	<i>Botrytis cinerea</i>	4	4	7
Romania	Mevalone Authorized but waiting for certifi- cate	K&NE Certis	Grape	<i>Botrytis cinerea</i>	4	4	7

* Minor uses

Mevalone is requested for use against *Botrytis cinerea* in grapevine and storage diseases in pome fruits as follows:

Table 3.2-3: Simplified table of requested uses for Mevalone

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Grape	Grey mould (<i>Botrytis cinerea</i>)	SI, SK, HU, DE, AT, CZ, PL, BE, NL, LU, IE	3.0-3.2 L/ha LWA, max. rate of 4.0 L/ha	max. 4 applications per season - 7 days interval
Pome fruits	Post-harvest storage diseases	IE, NL, BE, LU, DE, CZ, AT, SI, SK, HU, RO, PL, BE, NL, LU, IE	3.0-3.2 L/ha LWA, max. rate of 4.0 L/ha	max. 4 applications per season - 7 days interval

Description of the target pests

The pests mentioned in this document are listed in the following table:

Table 3.2-4: Glossary of pests mentioned in the document

EPPO code	Scientific name
ALTEMA	<i>Alternaria mali</i>
IGLOEG	Gloeosporium (anamorphic genus)
IPHYTG	Phytophthora (anamorphic genus)
BOTRCI	<i>Botrytis cinerea</i>
BOTRSP	<i>Botrytis sp.</i>
FUSAOX	<i>Fusarium oxysporum</i>
GLOESP	<i>Gloeosporium sp.</i>
MONIFG	<i>Monillia fructigena</i>
MONISP	<i>Monilinia sp.</i>
MUCOSP	<i>Mucor sp.</i>
PENIEX	<i>Penicillium expansum</i>
PENISP	<i>Penicillium sp.</i>
PEZIAL	<i>Gloeosporium album</i> = <i>Pezicula alba</i> = <i>Neofabraea alba</i>
PHYTCC	<i>Phytophthora cactorum</i>
VENTIN	<i>Venturia inaequalis</i>

Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Grape	SI*, SK, HU, GB, DE, AT, CZ, PL	PL	<i>Botrytis cinerea</i>	SI, SK, HU, GB, DE, AT, CZ, PL	-
Pome fruits	GB, NL, BE, DE, CZ, AT, HU, RO, PL**	IE, LU, SK, SI	Storage diseases	IE, GB, NL, BE, LU, DE, CZ, AT, SI, SK, HU, RO, PL	-

*table grape minor in Slovenia

** concerns apple only

***Botrytis cinerea* in grape**

Description: Botrytis bunch rot is caused by the fungus *Botrytis cinerea*. This fungus is very common in nature and causes diseases on a variety of unrelated crops. It's one of the most important diseases of grapes in the world, which can cause serious losses in grape yields. Losses result from the rotting of berries in the field or in storage. The fungus can occur anytime during the growing season, but infections occur most commonly at flowering and near the harvest time. Symptoms become evident in ripe berries.

Symptoms and biology: Infection of flowers or ripe berries is the most common and destructive phase of this disease. First infected berries become soft and watery, which under high relative humidity and moisture become covered with the grey sporulating growth of the fungus. The berries of white cultivars become brown, and those of purple cultivars develop a reddish color. Rotted berries generally shrivel with time and drop to the ground as hard mummies. The fungus also can cause a blossom blight that can result in significant crop loss early in the season. The fungus overwinters in grape mummies, dead grape tissues, and other plant hosts. In spring, the fungus germinates from small structures known as sclerotia. In late spring, a fungus can infect young shoots, blossoms, and leaves. Birds, insects, hail, or powdery mildew that cause wounds on berries, increase the possibility of infection with Botrytis. Also wet and humid environmental conditions increase the disease development.

Control: Promote good air circulation and light penetration by proper pruning, controlling weeds and suckers. Prevent wounding by controlling insects, birds, and other grape diseases. Fungicides applied at appropriate times during the growing season provide significant control.

***Botrytis cinerea* in pome fruit**

Description: *B. cinerea* are the major post-harvest diseases of apple, especially in North of France. It can cause significant losses. The fungus readily develops at storage temperatures and forms large nests of rots in long-term stored fruit.

Symptoms and biology³: The symptoms on apple are variable depending on the variety and the source of infection. *B. cinerea* associated with wounds is regular in shape, pale-mid brown in colour often with darker areas around the calyx and lenticels. *B. cinerea* associated with calyx infections varies in colour and is irregular in shape, often appearing as fingers of rot extending down from the calyx. The disease cycle and epidemiology involves spores (conidia) being spread by wind and rain at any time of the year. Spores are produced during wet weather throughout the year and colonise dying flower parts during bloom. These infections either develop into dry-eye rot visible in the orchard or remain as latent infection and subsequently develop during storage.

Control⁴: Pre-harvest chemical controls are available that will help reduce both pre-harvest and storage diseases. Some general management techniques can reduce postharvest fruit rots (handle fruit carefully during harvest, minimize inoculum source in the orchard, keep fruit cool after harvest, etc).

³<https://apples.ahdb.org.uk/botrytis-rot.asp>

⁴<http://www.omafra.gov.on.ca/english/crops/hort/news/orchnews/2016/on-0816a5.htm>

***Gloeosporium* sp. in pome fruit**

Description¹: Gloeosporium rots are the major post-harvest diseases of apple in Western Europe, causing crop losses in the context of long-term storage. Incorrectly called Gloeosporium, there are actually several species responsible, although only one of them is dominant in France: *Gloeosporium alba*, currently called *Neofabraea alba*. Gloeosporium can be important causes of rotting in a number of apple varieties and both have increased in incidence in recent years causing significant losses.

Symptoms and biology²: The fungus usually enters the fruit via a lenticel producing a cheek rot, but it may also occur around the stalk or calyx where it enters via a wound or small crack. The rot is brown, circular, forms concentric zones of different colours as the tissue is invaded. Cream-coloured slimy pustules may be produced during storage.

Gloeosporium over-winter in the orchard as cankers on dead twigs, leaves or on mummified fruit. Spores produced on these in wet weather during the growing season infect fruit from blossom to harvest. Infection remains latent and subsequently develops during storage usually after December.

Control: Control is based on an integrated approach combining cultural measures of inoculum removal in the orchard with chemical control where a risk has been identified. Only fruit of the correct mineral composition should be stored long-term.

¹http://www.ctifl.fr/ecophytopic/infos_ctifl/infos%20285/285p21-29.pdf

²<https://apples.ahdb.org.uk/gloeosporium-rot.asp> / <https://apples.ahdb.org.uk/gloeosporium-rot-additional.asp>

***Phytophthora* rot (*Phytophthora syringae*; *Phytophthora cactorum*)⁵ in pome fruit**

All apple varieties appear to be susceptible to infection. Both *P. cactorum* and *P. syringae* are responsible for fruit rot. Its relative importance is dependent on the incidence of rainfall pre-harvest.

Symptoms and biology: The characteristic symptoms are a firm rot, mid-dark brown in colour and often marbled or blotchy. Symptoms vary according to the variety. The rot is usually firm and the skin easily peeled away.

The life cycle and epidemiology of this soil-borne fungus involves survival in the soil as resting spores (oospores). These germinate in wet weather releasing swimming spores (zoospores) which splash onto low hanging fruit causing rotting. Infection occurs via lenticels. Symptomless infected fruit are picked and stored and initiate rotting and spread during storage.

Control: The risk of rotting during storage can be reduced by a combination of cultural and chemical control measures including mulching the soil surface, selectively picking only fruits above knee-height for storage and/or fungicide sprays.

⁵<https://apples.ahdb.org.uk/phytophthora-rot.asp>

***Alternaria* spp.^{6,7} (*Alternaria alternata* & *Alternaria mali*) in pome fruit**

In the literature there are currently three apple diseases referred to as being caused by *Alternaria* species. *Alternaria* leaf blotch and *Alternaria* fruit spot (caused by *A. mali*) and *Alternaria* core rot, induced by *A. alternata*, usually present a postharvest problem, although infection most likely occurs in the field.

Common injuries that can lead to *Alternaria* rot include mechanical or chemical injury, sunscald, or chilling injury.

Symptoms and biology: The disease affects most apple varieties but is particularly evident in those varieties with an open calyx. Disease symptoms include mold growth in the core region of the fruit. Sometimes the rot does not spread into the flesh, and can be seen only when the fruit is cut open. Diseased fruits have irregular-shaped brown to black spots. Under a humid atmosphere the surface of the fruit is covered with a brown-greenish mold.

The fungus is soil borne and primary infection occurs by spores surviving in the soil. Warm weather and high humidity favour the development of diseases.

⁶https://rwdf.cra.wallonie.be/sites/default/files/linked_docs/Fruits/6-Maladies-ravageurs/Maladies_conservation/maladies_conservation_pommes.pdf

⁷<http://vikaspedia.in/agriculture/crop-production/integrated-pest-managment/ipm-for-fruit-crops/ipm-strategies-for-apple/apple-diseases-and-symptoms>

***Penicillium* rot (*Penicillium expansum*)⁸ in pome fruit**

Penicillium rot is one of the most common post-harvest rots of apple. It produces a mycotoxin, patulin, which occurs in *Penicillium*-rotted fruit and subsequently in fruit juice produced from reject fruit.

Symptoms and biology: The fungus is ubiquitous and infection will always occur if a fruit is damaged or not handled correctly. It causes a pale green to dark brown circular soft rot which spreads rapidly over the fruit surface and into the flesh. Mature lesions are covered in brilliant white pustules which quickly turn blue. *P. expansum* survives on mummified fruit or fruit bits stuck on bulk bins or lying around in the storage room. Most wound infections during storage result from water borne spores in post-harvest drench solutions (e.g. anti-scald agents) or in water flumes used to grade fruit.

Control: Control or prevention of *Penicillium* rot is mainly dependent on cultural methods based on good hygiene, particularly of bins, and of good supervision at harvest to minimise damage to fruit. Pre-harvest fungicide treatment is generally ineffective against *Penicillium* as rot incidence is related to fruit damage. Cultural methods of control are equally applicable and effective in organic production, provided only best quality fruit is stored.

⁸<https://apples.ahdb.org.uk/Penicillium-rot.asp>

General information on crops tested in this document - Grape and Apple

Grape: *Vitis vinifera* (the common grape vine) is a species of the genus *Vitis*, native to the Mediterranean region, Central Europe, and southwestern Asia. There are currently between 5,000 and 10,000 varieties of *Vitis vinifera* grapes though only a few are of commercial significance for wine and table grape production. The grape is eaten fresh, processed to make wine, vinegar or juice, or dried to produce raisins. Cultivars of *Vitis vinifera* form the basis of the majority of wines produced around the world. All of the familiar wine varieties belong to *Vitis vinifera*, which is cultivated on every continent except for Antarctica, and in all the major wine regions of the world.

V. vinifera contains many phenolic compounds. Red cultivars are rich in anthocyanins that impart their colour to the berries (generally in the skin).

The European Union is the largest grape producer in the world. Within the Union, Italy, Spain and Greece are the largest producers by far.

The production of grapes in the member states of the central zone is summarized in the following table:

Country	Area harvested (ha)	Production (tonnes)	Yield (hg/ha)
Austria	48 645	367 131	75 471
Czech Republic	15 941	103 704	65 056
Germany	100 182	1 403 597	140 105
Hungary	65 712	539 940	82 168
Poland	730	3 920	53 699
Romania	173 685	1 144 305	65 884
Slovakia	8 013	52 418	65 416
Slovenia	15 630	126 958	81 227
United Kingdom	580	587	10 111

Source: <http://www.fao.org/faostat/>, 4 March 2020 - Data from 2018

Apple: Apple is an edible fruit produced by an apple tree (*Malus domestica*) originated in Central Asia. Apple trees are cultivated worldwide and are the most widely grown species in the genus *Malus*. There are currently more than 7,500 known cultivars of apples, resulting in a range of characteristics. Trees and fruits are prone to a number of fungal, bacterial and pest problems, which can be controlled by a number of organic and non-organic means.

Commercially, apples can be stored for some months in controlled atmosphere chambers to delay ethylene-induced ripening. Apples are commonly stored in chambers with higher concentrations of carbon dioxide and high air filtration. This prevents ethylene concentrations from rising to higher amounts and preventing ripening from occurring too quickly.

The largest apple producers in the EU are Poland, Italy and France.

The production of apples in the member states of the central zone is summarized in the following table:

Country	Area harvested (ha)	Production (tonnes)	Yield (hg/ha)
Austria	nc	387 954	nc
Belgium	5 985	273 950	457 728
Czech Republic	7 250	151 528	208 990
Germany	33 978	1 198 517	352 733
Hungary	31 799	674 525	212 121
Ireland	713	20 100	281 907
Luxembourg	269	2 077	77 212
Netherlands	6 599	269 000	407 638
Poland	161 790	3 999 523	247 205
Romania	53 939	643 856	119 367
Slovakia	2 137	43 929	205 564
Slovenia	2 328	86 587	371 937
United Kingdom	16 163	502 700	311 019

Source: <http://www.fao.org/faostat/>, 4 March 2020 - Data from 2018

Compliance with the Uniform Principles

The preparation Mevalone complies with the Uniform Principles.

- **Guidelines:** Trials were conducted under GEP guidelines and followed method recommendations published by EPPO. No significant deviation to guidelines was reported.
- **Testing facility or organisation:** All trials were carried out by testing facilities officially recognised as competent to carry out efficacy testing in accordance with the requirements of Directive 93/71/EEC, and in accordance with the principles of GEP. Copies of certificates are given under point 3.7.
- **Sites:** Trials were located in areas considered to be either representative of the range of agricul-

tural, plant health and environmental conditions (including climatic conditions) likely to be encountered in practice in the area of proposed use, or of a more severe nature of those conditions.

- **Meteorological information:** Trials included a range of climatic conditions representative of those where crops are grown commercially. Data describing the climatic conditions at application are presented in individual trial reports. In all cases, conditions were within the normal range for the areas in which the trials were conducted for the duration of the study, or were considered to have represented a more severe nature of those conditions.
- **Experimental details:** In all trials, crops were managed according to local agronomical best practices. There were no significant deviations from the specified testing methods in any trial. Trials were conducted in order to investigate the effectiveness of Mevalone as a fungicide against several fungi of economical importance in grape and storage diseases in apple, in order to assess its efficacy under the conditions in which it will be applied.

Information on trials submitted (3.2 Efficacy data)

The table below gives an overview of the trials used in section **3.2 Efficacy data** of this document.

Table 3.2-6: Presentation of trials

Table 3.2-6. Presentation of trials									
Crop	Target	Country	Years	Type of trial*	Number of trials (number of valid trials)				GEP, non- GEP, official**
					Mediterranean zone	Maritime zone	South-East zone	North-East zone	
Grape	<i>Botrytis cinerea</i>	AT	2006	E	-	2 (2)	-	-	GEP
			2018	MED, E	-	1 (1)	-	-	GEP
			2019	MED, E	-	2 (2)	-	-	GEP
		DE	2007	MED, E	-	3 (3)	-	-	GEP
			2008	MED, E	-	3 (3)	-	-	GEP
			2018	MED, E	-	2 (1)	-	-	GEP
			2019	MED, E	-	2 (1)	-	-	GEP
		HU	2018	MED, E	-	-	3 (2)	-	GEP
			2019	MED, E	-	-	2 (1)	-	GEP
		SL	2019	MED, E	-	-	1 (1)	-	GEP
		RO	2019	MED, E	-	-	1 (1)	-	GEP
SW	2006	E	-	4 (4)	-	-	GEP		
Total Grape					-	19 (17)	7 (5)	-	
					26 (22)				
Apple	Storage diseases	FR	2016	PV	1 (1)	-	-	-	GEP
			2017	PV	1 (1)	-	-	-	GEP
			2018	PV	1 (1)	1 (1)	-	-	GEP
			2019	PV	-	1 (1)	-	-	GEP
		DE	2018	PV	-	1 (1)	-	-	GEP
			2019	PV	-	1 (1)	-	-	GEP
		CZ	2017	PV	-	1 (1)	-	-	GEP
			2018	PV	-	1 (1)	-	-	GEP
			2019	PV	-	1 (1)	-	-	GEP
		HU	2018	PV	-	-	2 (2)	-	GEP
			2019	PV	-	-	1 (1)	-	GEP
		PL	2017	PV	-	-	-	2 (2)	GEP
			2018	PV	-	-	-	2 (2)	GEP
			2019	PV	-	-	-	2 (2)	GEP
DE	2018	E (study in laboratory)	-	1 (1)	-	-	non GEP		
Total Apple					3 (3)	8 (8)	3 (3)	6 (6)	
					20 (20)				

* P = preliminary trial, MED = minimum effective dose, E = efficacy trial, PV = practical value.

** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Justification for the use of data from several climatic zones:

Trials were carried out from 2006 to 2019 under various conditions, in 9 countries and 4 climatic zones (Mediterranean, Maritime, South-East and North-East zones).

In the case of fungicides against storage diseases, results from several climatic zones can be considered as relevant for the evaluation of the product in the given countries for several reasons:

- In the case of a fungicide with post-storage effect, the cultural differences that can be encountered between countries only have limited impact.
- As the product is intended to be applied close to harvest (max. 30 days before harvest) climatic conditions also have limited effect.
- Climatic conditions at application (air temperature and relative hygrometry) were globally homogeneous from a climatic zone to another (see Appendix 4).
- Conditions during cold storage are the same in every climatic zone or country.

The trials are thus fully representative of all conditions that can be encountered in all the countries where Mevalone is intended to be used and are thus fully relevant to assess Mevalone efficacy in countries of the Central zone.

Reference products

Reference products and adjuvants used in the fungicide programs are presented in the following tables:

Table 3.2-7: Presentation of reference standards used in trials in grape

Reference standard	Countries where the product is registered	Authorization number	Active substance(s)	Formulation		Registered application rate	Application rate in trials (per treatment)
				Type	Concentration of a.s.		
Frupica	Austria	2805-0	Mepanipyrim	WP	500 g/kg	1.2 L/ha (0.12%)	1.2 L/ha (0.12%)
Frupica SC	Swiss	W-5498	Mepanipyrim	SC	440 g/kg	1.2 L/ha	1.2 L/ha (0.12%)
Scala	Germany	024225-00	Pyrimethanil	SC	400 g/L	0.5 - 2 L/ha*	1 - 2 L/ha
Switch = Switch 62.5 WG	Austria Germany Hungary Slovenia Romania	2619 034419-00 04.2/2876/1/2017 U34330-10/14/19 1760/12.11.1996	cyprodinil + fludioxonil	WG	375 g/kg + 250 g/kg	0.96 kg/ha 0.96 kg/ha 0.8-1 kg/ha 1 kg/ha 0.6 kg/ha	0.96 kg/ha 0.48- 0.96 kg/ha 0.96-1 kg/ha 1 kg/ha 1 kg/ha
Teldor WG	Swiss	W-5751	Fenhexamid	WG	500 g/kg	1.5 kg/ha	1.5 L/ha (0.15%)

* Basic dose: 0,5L/ha - BBCH 75: 2 L/ha - BBCH 71: 1,5 L/ha - BBCH 61: 1 L/ha

Table 3.2-8: Presentation of reference standards used in trials in apple

Reference standard	Countries where the product is registered	Authorization number	Active substance(s)	Formulation		Registered application rate	Application rate in trials (per treatment)
				Type	Concentration of a.s.		
Reference products							
Merpan 80 WDG	France Germany Czech Rep. Hungary Poland	9300108 024519-00 3982 04.2/7170-2/2016 R-105/2013	Captan	WG	80%	1.9 kg/ha 0.75 kg/ha* 1.5 kg/ha (stone fruits) 1.25-2.0 kg/ha 1.9 kg/ha	1.9 kg/ha 1.9 kg/ha 1.5-1.9 kg/ha 1.9 kg/ha 1.9 kg/ha
Bellis	France Germany Czech Rep. Hungary Poland	2080070 006767-00 5004 04.2/2596-1/2012 R-48/2011	Pyraclostrobin Boscalid	WG	128 g/kg 252 g/kg	0.08 kg/hl 0,267kg/ha* 0.8 kg/ha (stone fruits) 0.8 kg/ha 0.8 kg/ha	0.8 kg/ha 0.8 kg/ha 0.8 kg/ha 0.8 kg/ha 0.8 kg/ha
Geoxe	France Germany Czech Rep. Hungary Poland	2110147 007606-00 5254 Not registered R-120/2014	Fludioxonil	WG	50%	0.4 kg/ha 0.15 kg/ha* 0.45 kg/ha Not registered 0.45 kg/ha	0.4 kg/ha 0.4 kg/ha 0.4-0.45 kg/ha 0.4 kg/ha 0.4-0.45 kg/ha
Cuprozin progress	Germany	006895-00	Kupferhydroxid	SC	383 g/L	4 L/ha in 500 L/ha	0.8%
Adjuvants							
Héliosol	France Germany Czech Rep. Hungary Poland	7200313 8243-00 1777 04.2/1034-1/2017 **	Terpenic alcohols	EC	665 g/L	0.2% 0.2% 0.2% 0.5 L/ha (wheat) **	0.2% 1.2 L/ha 0.2% or 2 L/ha 1.2 L/ha 0.2%
Slippa	Poland	**	Organosilicone/linear alcohol	EC	650 g/L	**	0.15% or 0.2 L/ha

* per meter crown height

** Adjuvants are not officially registered in Poland. Thus no authorization number / registered application rate are available.

Dose expression per hectare Leaf Wall Area (LWA) in vertical crops

In order to harmonize the PPP evaluation at EU level, the LWA approach has been implemented. In grapevine and apple, as sprayers deliver the spray liquid containing the product to a predominantly vertical area, the product dose rate can be expressed in relation to the treated leaf wall area.

As a result, the treated LWA m² per hectare is calculated as follows:

$$\text{Treated LWA (m}^2\text{)} = 2 \times \text{Treated Canopy height (m)} \times 10000 \text{ m}^2 / \text{Row Spacing (m)}$$

At the time of writing this dossier, the countries of the Central administrative zone already adopted the LWA area dose expression approach, but not the countries of the Southern administrative zone.

For implementation of the field efficacy trials for this product submission, the approach taken was to express the rate in relation to the ground area (/ha). This approach might not be sufficient to evaluate the expected efficacy level in detail. Therefore, the tested dose rates in L/ha ground were converted into L/ha LWA as follows:

$$\text{Rate/ha LWA} = \text{rate/ha ground area} \times 10000 / \text{treated LWA}$$

Trials in grape

Despite the tested dose rates in L/ha LWA were globally heterogeneous from a trial to another, the

LWA approach is followed in this document.

For recent trials (2018-2019) the LWA was given in the individual reports. For older trials (2006-2008) the LWA was calculated according to the row spacing and the treated crop height. When data was not available, the average LWA value of the country where the trial was implemented is used.

The treated LWA m² per hectare and the tested rates (per ha ground and per ha of LWA) in the 26 field efficacy trials presented in this document is given in the 26 field efficacy trials presented in this document is given in Table 3.2 9.

Table 3.2-9: Treated LWA m² per hectare and tested rates applied in trials in grapevine

Trials with LWA in individual report - Trials 2018-2019														
Trial ID	EPPO zone	Country	Treated LWA (m²/ha)	Rates applied (L/ha ground)					Rates applied (L/ha LWA)					
S19-20334-01	SE	HU	9333	2.0	-	4.0	8.0	2.1	-	4.3	8.6			
S19-20334-02	SE	HU	10714	2.0	-	4.0	8.0	1.9	-	3.7	7.5			
S19-20334-03	SE	RO	12000	2.0	-	4.0	8.0	1.7	-	3.3	6.7			
S19-20334-04	SE	SL	12500	2.0	-	4.0	8.0	1.6	-	3.2	6.4			
S19-20334-05	MAR	AT	10000	2.0	-	4.0	8.0	2.0	-	4.0	8.0			
S19-20334-06	MAR	AT	11200	2.0	-	4.0	8.0	1.8	-	3.6	7.1			
S19-20334-07	MAR	DE	13636	2.0	-	4.0	8.0	1.5	-	2.9	5.9			
S19-20334-08	MAR	DE	17500	2.0	-	4.0	8.0	1.1	-	2.3	4.6			
S18-051950-01	SE	HU	8571	2.0	3.0	4.0	8.0	2.3	3.5	4.7	9.3			
S18-051950-02	SE	HU	13636	2.0	3.0	4.0	8.0	1.5	2.2	2.9	5.9			
S18-051950-03	SE	HU	10000	2.0	3.0	4.0	8.0	2.0	3.0	4.0	8.0			
S18-051950-04	MAR	AT	10400	2.0	3.0	4.0	8.0	1.9	2.9	3.8	7.7			
S18-051950-05	MAR	DE	15000	2.0	3.0	4.0	8.0	1.3	2.0	2.7	5.3			
S18-051950-06	MAR	DE	15000	2.0	3.0	4.0	8.0	1.3	2.0	2.7	5.3			
Trials with missing data to calculate LWA - Trials 2006-2008														
Trial ID	EPPO zone	Country	Treated LWA* (m²/ha)	Rates applied (L/ha ground)					Rates applied (L/ha LWA)					
S08-02271-01	MAR	DE	15000*	1.8	3.0	3.6	7.2	-	-	1.2	2.0	2.4	4.8	-
S08-02271-02	MAR	DE	15000*	1.2	2.0	2.4	4.8	-	-	0.8	1.3	1.6	3.2	-
S08-02271-03	MAR	DE	15000*	2.4	4.0	4.8	9.6	-	-	1.6	2.7	3.2	6.4	-
AF/12263/CN/1	MAR	DE	15000*	0.2	0.4	0.8	1.6	3.2	6.4	0.1	0.3	0.5	1.1	2.1
AF/12263/CN/2	MAR	DE	15000*	0.2	0.4	0.8	1.6	3.2	6.4	0.1	0.3	0.5	1.1	2.1
AF/12263/CN/3	MAR	DE	15000*	0.2	0.4	0.8	1.6	3.2	6.4	0.1	0.3	0.5	1.1	2.1
06WF232C58	MAR	SW	12444*	4.8	-	-	-	-	-	3.9	-	-	-	-
06WF232C59	MAR	SW	12444*	4.8	-	-	-	-	-	3.9	-	-	-	-
06WF232C513	MAR	SW	12444*	4.8	-	-	-	-	-	3.9	-	-	-	-
06WF232C514	MAR	SW	12444*	4.8	-	-	-	-	-	3.9	-	-	-	-
06WF08-A3	MAR	AT	9333*	4.0	8.0	-	-	-	-	4.3	8.6	-	-	-
06WF08-A4	MAR	AT	9333*	4.0	8.0	-	-	-	-	4.3	8.6	-	-	-

* Row spacing and/or treated canopy height values missing - Average LWA value for a given country according to "Doserateexpressionin vertical growingcrops– Needforharmonisationfromtheperspectiveof the PlantProtectionProduct Industry", An IndustryProposalof Adama, BASF, Bayer CS, Dow AS, DuPont AS and Syngenta
MAR= Maritime, SE= South-East

Trials in apple

The tested dose rates in L/ha LWA were globally heterogeneous from a trial to another. In addition, the treated canopy height was available in only 2 out of 14 trials. When not available, the treated canopy height was calculated by subtracting 50 cm of trunk height by default from the crop height, which is considered on average the typical trunk height in apple orchards of the Central zone.

For the 3 trials implemented in Mediterranean EPPO zone, the crop height was not available. Thus no LWA could be calculated. These data are therefore presented as complementary data.
For the 6 trials implemented in 2019, the treated LWA value was calculated in the individual reports.

Table 3.2-10: Treated LWA m² per hectare and tested rates applied in trials in apple

Trial ID	EPPO zone	Country	Treated LWA (m ² /ha)	Rates applied (L/ha ground)		Rates applied (L/ha LWA)	
AB5-1817-31410-PL01	NE	PL	11053*	3.0	-	2.7	-
AB5-1817-31410-PL02	NE	PL	9600*	3.0	-	3.1	-
AB5-19-36737-PL01	NE	PL	11579*	3.0	4.0	2.6	3.5
AB5-19-36737-PL02	NE	PL	15429*	3.0	4.0	1.9	2.6
KSA-19-41935-PL01	NE	PL	15789	3.0	4.0	1.9	2.5
KSA-19-41936-PL01	NE	PL	14286	3.0	4.0	2.1	2.8
F-19-O-502-01	MAR	CZ	10857*	3.0	4.0	2.8	3.7
SUMI-F-2017-HOL03	MAR	CZ	8889*	3.0	-	3.4	-
F-20-O-501-01	MAR	CZ	11429	3.0	4.0	2.6	3.5
S18-06150-01	MAR	DE	14545* 13879	3.0	4.0	2.1 2.2	2.8 2.9
S19-20999-02	MAR	DE	14971	3.0	4.0	2.0	2.7
S18-06188-01	MAR	FR	14300*	3.0	4.0	2.1	2.8
S19-20999-01	MAR	FR	17653	3.0	4.0	1.7	2.3
S18-06194-01	SE	HU	11000*	3.0	4.0	2.7	3.6
S18-06194-02	SE	HU	14286*	3.0	4.0	2.1	2.7 2.8
S19-20999-03	SE	HU	16757	3.0	4.0	1.8	2.4
16-Fa-Pm-13	Med.	FR	No data	3.0	-	No data	-
17-Fa-Pm-14	Med.	FR	No data	3.0	-	No data	-
18-Fa-Pm-11	Med.	FR	No data	3.0	4.0	No data	-

* Calculated as follows Treated crop height = (crop height - 50 cm trunk).

MAR= Maritime, SE= South-East, NE= North-East, Med= Mediterranean

3.2.1 Preliminary tests (KCP 6.1)

No preliminary range-finding tests are available as eugenol, geraniol and thymol are well-known active substances.

Comments of zRMS on: Preliminary tests (3.2.1)

Lack of preliminary testing is acceptable if eugenol, geraniol and thymol are known active substances. Mevalone (Araw, 3logy) is currently authorised in Albania, Bulgaria, Cyprus, Greece, France, Italy, Malta, Portugal, Romania and Spain in grapevine and many other crops (see table 3.2-2).

3.2.2 Minimum effective dose tests (KCP 6.2)

Minimum effective dose in grape

A total of 20 trials tested several dose rates to evaluate the minimum effective dose rate of Mevalone against *Botrytis cinerea*. Results focussed on the last efficacy assessment on pest severity (% of bunch area infected). Only relevant results are considered (at least 3% of pest severity in the untreated control plots). The selected dose rates range from 1.6 to 9.6 L/ha ground (i.e. 1.1 to 7.1 L/ha LWA) as rates lower than 1 L/ha were only tested in 2 trials.

Results are thus presented from the following 8 trials:

Table 3.2-11: Trials used to evaluate the minimum effective dose on grape - Rates tested

EPPO zone	Country	Year	Trial ID	Rates L/ha ground	Rates L/10000m ² LWA
Maritime	Austria	2019	S19-20334-06	2.0 ; 4.0 ; 8.0	1.8 ; 3.6 ; 7.1
Maritime	Germany	2007	AF/12263/CN/3	1.6 ; 3.2	1.1 ; 2.1
Maritime	Germany	2008	S08-02271-01	1.8 ; 3.0 ; 3.6 ; 7.2	1.2 ; 2.0 ; 2.4 ; 4.8
Maritime	Germany	2008	S08-02271-03	2.4 ; 4.0 ; 4.8 ; 9.6	1.6 ; 2.7 ; 3.2 ; 6.4
Maritime	Germany	2019	S19-20334-07	2.0 ; 4.0 ; 8.0	1.5 ; 2.9 ; 5.9
South-East	Hungary	2018	S18-05195-01	2.0 ; 3.0 ; 4.0 ; 8.0	2.3 ; 3.5 ; 4.7 ; 9.3
South-East	Hungary	2019	S19-20334-02	2.0 ; 4.0 ; 8.0	1.9 ; 3.7 ; 7.5
South-East	Romania	2019	S19-20334-03	2.0 ; 4.0 ; 8.0	1.7 ; 3.3 ; 6.7

Full details regarding trials implementation are given in the next part 6.2.3 *Efficacy tests*.

Tables are made according to recommendations of the Austrian Authorities for presenting minimum effective dose results according to the new LWA approach. Results are presented in Table 3.2-12 (means of all trials) and Table 3.2-13 (means per EPPO zone).

Table 3.2-12: Efficacy results sorted by L/10000m² LWA rate (only trials where different dose rates were tested, excluding dose rates <1L/10000m² LWA and excluding all trials with infection rates <3% in untreated plots) - Mean per L/10000m² LWA group

Mean per group		Mean per group		Mean per group	
53.7	1.1-1.7 L/10000m ² LWA Mean: 1.4	55.7	1.1-1.9 L/10000m ² LWA Mean: 1.5	53.7	1.1-1.7 L/10000m ² LWA Mean: 1.4
52.0	1.8-2.4 L/10000m ² LWA Mean: 2.1		2.0-2.7 L/10000m ² LWA Mean: 2.3	50.8	1.8-2.7 L/10000m ² LWA Mean: 2.2
63.0	2.7-3.5 L/10000m ² LWA Mean: 3.1	66.9	2.9-3.7 L/10000m ² LWA Mean: 3.4	66.9	2.9-3.7 L/10000m ² LWA Mean: 3.4
65.0	3.6-4.7 L/10000m ² LWA Mean: 4.0		4.7-9.3 L/10000m ² LWA Mean: 6.5	68.4	4.7-6.4 L/10000m ² LWA Mean: 5.4
67.7	6.7-7.4 L/10000m ² LWA Mean: 7.1	67.4		66.3	6.7-9.3 L/10000m ² LWA Mean: 7.7

Table 3.2-13: Efficacy results sorted by L/10000m² LWA rate (only trials where different dose rates were tested, excluding dose rates <1L/10000m² LWA and excluding all trials with infection rates <3% in untreated plots) - Mean per L/10000m² LWA group for each EPPO zone

EPPO zone	Mean per group		Mean per group	
MAR	50.5	1.1-1.6 L/10000m ² LWA Mean: 1.3	50.5	1.1-1.6 L/10000m ² LWA Mean: 1.3
	51.5	1.8-2.7 L/10000m ² LWA Mean: 2.2	53.5	1.8-2.4 L/10000m ² LWA Mean: 2.1
	76.1	2.9-3.6 L/10000m ² LWA Mean: 3.2	68.0	2.7-3.6 L/10000m ² LWA Mean: 3.1
	74.7	4.8-7.1 L/10000m ² LWA Mean: 6.1	74.7	4.8-7.1 L/10000m ² LWA Mean: 6.1

EPPO zone	Mean per group	
SE	47.6	1.7-1.9 L/10000m ² LWA Mean: 1.8
	60.6	2.3-3.7 L/10000m ² LWA Mean: 3.2
	60.0	4.7-9.3 L/10000m ² LWA Mean: 7.0

Conclusion

Considering all EPPO zones (Table 3.2-12), with the mean values of trials no dose response is observed between ~~1.5~~ 1.4 and ~~2~~ 2.3 L/ha LWA. A clear dose response is observed between ~~2~~ 2.3 and ~~3~~ 3.1 L/ha LWA, whatever the grouping of the rates. No clear dose response is noticed between ~~3~~ 3.1 L/ha LWA and upper rates (4 to 7.7 L/ha LWA). The same conclusions can be drawn considering the average values in the Maritime EPPO zone and in the South-east EPPO zone as well (Table 3.2-13).

Results of the 8 trials show that applying a dose rate of approx. 3 L/ha LWA (on average from 3.1 to 3.4 L/ha LWA depending on the grouping of results) gives a satisfactory control of *Botrytis cinerea* in grape (on average an efficacy from ~~63 to 67%~~ 61 to 76% depending on the grouping of results). A higher rate does not give significant better results (on average an efficacy from ~~65 60~~ to ~~68%~~ 75% depending on the grouping of results).

It can be concluded that a dose rate of approx. 3 L/ha LWA is the minimum effective dose to control *Botrytis cinerea* in grape.

Based on the available results, the proposed LWA rate range for Mevalone is 3.0-3.2 L/ha LWA.

Minimum effective dose in pome fruits

No trials were established in order to determine the minimum effective dose for the control of storage diseases in pome fruits. Application rates are based on the experience gained with the uses of Mevalone against botrytis in grape. All trials were practical trials in apple, testing the product within a fungicide program, applied with or without adjuvant. In most of the trials Mevalone was applied with adjuvant at 3.0 L/ha and without adjuvant at 4.0 L/ha, depending on the tested fungicide programs. Mevalone is already registered on vine against various diseases and in practice it can be considered that the use of the product at 3.0 L/ha with an adjuvant gives comparable results to the full dose rate of 4.0 L/ha without adjuvant.

For grapes a dose rate of 3.0-3.2 L/ha LWA is claimed against *B. cinerea*. These results could be extrapolated to apple and pome fruits and thus a dose rate of 3.0-3.2 L/ha LWA is claimed against

storage disease in pome fruits.

All results are shown in the following part **3.2.3 Efficacy tests**.

Comments of zRMS on:

Minimum effective dose tests (3.2.2)

Minimum effective dose (MED) was determined based on the trials carried out in grapevine against *Botrytis cinerea*. Results from 8 efficacy trials have been presented to determine MED for Mevalone. MED trials were carried out in Austria (1), Germany (4), Hungary (2) and Romania (1) in the years 2007-2019. Mevalone at a range of dose rates 1.6-9.6 L/ha (1.1 to 7.1 L/ha LWA) was applied in grapevine against *Botrytis cinerea*. Pest severity (% of bunch area infected) was assessed to determine MED.

Mevalone applied at dose rate of approx. 3 L/ha LWA was effective on a moderate level (showing average efficacy from 61 to 76%). No significant higher efficacy (average efficacy from 60 to 75%) was noted for higher dose rates. A visible dose response was noted comparing dose rate of approx. 3 L/ha with lower dose rates (an average efficacy from 46.9-55.7% for lower dose rates).

Based on the trials results it can be concluded that dose rate of approx. 3 L/ha LWA is the MED for Mevalone in the control of *Botrytis cinerea* in grapevine. The proposed LWA rate range for Mevalone: 3.0-3.2 L/ha LWA is acceptable. Data to justify MED for use on pome fruits against pathogens causing storage diseases was not submitted. The same LWA rate range 3.0-3.2 L/ha LWA is proposed by the applicant for pome fruits protection against pathogens causing storage diseases, based on the experience gained with the uses of Mevalone against *Botrytis cinerea* in grape. If Mevalone in most of the trials conducted in apple was tested at dose rate of 4.0 L/ha (approx. 3.0-3.2 L/ha LWA) (see table 3.2-10), the proposed LWA rate range for Mevalone: 3.0-3.2 L/ha LWA is acceptable also for pome fruits protection.

3.2.3 Efficacy tests (KCP 6.2)

3.2.3.1 Efficacy tests on grape

A total of 26 efficacy trials were carried out with the test product Mevalone to control *Botrytis cinerea* (BOTRCI) in grape. Trials were set up between 2006 and 2019 in the Maritime EPPO zone: Germany (10), Austria (5), Switzerland (4), and in the South-East EPPO zone: Hungary (5), Romania (1) and Slovenia (1).

The vineyards were selected based on varieties sensitive to *Botrytis cinerea* and all trials were carried out according to Good Experimental Practices (GEP).

An overview of all available trials per country and per year is provided in the table below.

Table 3.2-14: List of efficacy trials testing the efficacy of Mevalone in grape

Trial No.	EPPO zone	Country	Year	Testing facility	Trial status	Disease* Y/N
06WF08-A3	MAR	Austria	2006	Stähler International GmbH	GEP	Y
06WF08-A4	MAR	Austria	2006	Stähler International GmbH	GEP	Y
S18-05195-04	MAR	Austria	2018	Eurofins Agrosience Services	GEP	Y
S19-20334-05	MAR	Austria	2019	Eurofins Agrosience Services	GEP	Y
S19-20334-06	MAR	Austria	2019	Eurofins Agrosience Services	GEP	Y
AF/12263/CN/1	MAR	Germany	2007	Eurofins Agrosience Services	GEP	Y
AF/12263/CN/2	MAR	Germany	2007	Eurofins Agrosience Services	GEP	Y
AF/12263/CN/3	MAR	Germany	2007	Eurofins Agrosience Services	GEP	Y
S08-02271-01	MAR	Germany	2008	Eurofins Agrosience Services	GEP	Y
S08-02271-02	MAR	Germany	2008	Eurofins Agrosience Services	GEP	Y
S08-02271-03	MAR	Germany	2008	Eurofins Agrosience Services	GEP	Y
S18-05195-05	MAR	Germany	2018	Eurofins Agrosience Services	GEP	N
S18-05195-06	MAR	Germany	2018	Eurofins Agrosience Services	GEP	Y
S19-20334-07	MAR	Germany	2019	Eurofins Agrosience Services	GEP	Y
S19-20334-08	MAR	Germany	2019	Eurofins Agrosience Services	GEP	N
06WF232C58	MAR	Switzerland	2006	Stähler International GmbH	GEP	Y
06WF232C59	MAR	Switzerland	2006	Stähler International GmbH	GEP	Y
06WF232C513	MAR	Switzerland	2006	Stähler International GmbH	GEP	Y
06WF232C514	MAR	Switzerland	2006	Stähler International GmbH	GEP	Y
S18-05195-01	SE	Hungary	2018	Eurofins Agrosience Services	GEP	Y
S18-05195-02	SE	Hungary	2018	Eurofins Agrosience Services	GEP	N
S18-05195-03	SE	Hungary	2018	Eurofins Agrosience Services	GEP	Y
S19-20334-01	SE	Hungary	2019	Eurofins Agrosience Services	GEP	N
S19-20334-02	SE	Hungary	2019	Eurofins Agrosience Services	GEP	Y
S19-20334-03	SE	Romania	2019	Eurofins Agrosience Services	GEP	Y
S19-20334-04	SE	Slovenia	2019	Eurofins Agrosience Services	GEP	Y

* Relevant disease infestation at least at single assessment

MAR= Maritime, SE= South-East

Trials where no relevant disease development was observed are described hereafter but efficacy results are not presented. These trials are used for selectivity purpose only and corresponding phytotoxicity results are presented in section 6.4.1 *Phytotoxicity to host crop*.

Material and methods

Trial sites and application details are summarised in Appendix 4 of BAD document.

Details on trial methodology are summarized next table 3.2-15.

Table 3.2-15: Details on trial methodology - Efficacy trials in grape

Guidelines	General guidelines	EPPO: PP 1/135(2-4), 1/152(2-4), 1/181(2-4) (all trials)
	Specific guidelines	EPPO: PP 1/17(2) (all trials)
Experimental design	Plot design	RCB (26 trials)
	Plot size	9-50.4 m ²
	Number of rep.	6 replications (14), 4 replications (10 trials) 3 replications (2 trials)
Crop	Trials per crop	Grape (26)
	Varieties per crop	Blauburger (1), Gamay (2), Juhfark (1), Kadarka (1), Muscat blanc (1), Müller-Thurgau (3), Olaszrizling (1), Pinot blanc (1), Pinot noir (2), Riesling (1), Riesling Sylvaner (1), Rózsakő (1), Sämbling (1), Scheurebe (1), Schwarzriesling (2), Schwarzriesling/ Pinot Meunier (2), Traminer Roz (1), Weißburgunder (2), Welschriesling (1)
	Planting period	1972-2015 (23), nc (3)
Application	Number of appl. Intervals	4 (22 trials), 3 (4 trials) Interval: 6-8 days in 14 trials 2018-2019 (7 days interval), 10-42 days in 12 trials 2006-2008 (treatments according to crop developmental stages)
	Crop stage (BBCH) at application	Application A: BBCH 61-85 Application B: BBCH 70-87 Application C: BBCH 77-88 Application D: BBCH 79-89
	Timing of application	<u>Trials 2018-2019</u> (14 trials): A = at growth stage BBCH 60-88 73-85 dependent upon infection risk B = 7+/- 1 Ddays after application A C = 7+/- 1 Ddays after application B D = 7+/- 1 Ddays after application C <u>Trial series S08-02271 and AF/12263/CN</u> (6 trials): A = at growth stage BBCH 69-73, end of flowering to the stage when bunches begin to sag B = at growth stage BBCH 77-79, berries begin to touch - berry touch complete C = at growth stage BBCH 81-83, beginning of ripening - berries brightening D = 3 weeks before normal harvest <u>Trial serie 06WF08</u> (6 trials): A = at growth stage BBCH 65-69 61-71, mid to end beginning of flowering to the beginning of berries development B = at growth stage BBCH 70-77, beginning of berries development to bunch closure C = at growth stage BBCH 81-85, beginning of coloring of grapes to the softness of the berries D = when first symptoms of Grey mold are visible
	Spray volumes	300-1600 L/ha (26 trials)
Assessment	Assessment types	-Phytotoxicity as % of total leaf area affected by symptom or according to a EWRS scale (1-9 scale where 1= no damage to 9 = total kill) -Crop vigour on a 0-100 or 0-10 linear scale, where 0 = no crop and 10 or 100 = the most vigorous plot within the trial area -Pest incidence: % of infected bunches (sample = 50-100 bunches per plot) -Pest severity: % area infected (sample = 50-100 bunches per plot) -Weight of fallen bunches in case of high infection (2 trials)
	Statistical analysis	Analysis of variances: ANOVA Statistical letters on means: Student-Newman-Keuls test probability of no significant difference between means = 5%
	Assessment dates	Depending on trials 0 to 61 days after last application
Other relevant information	Infestation	Natural infestation (26 trials)
	Field / greenhouse	Vineyard (26 trials)

Trials location is illustrated on the map below.

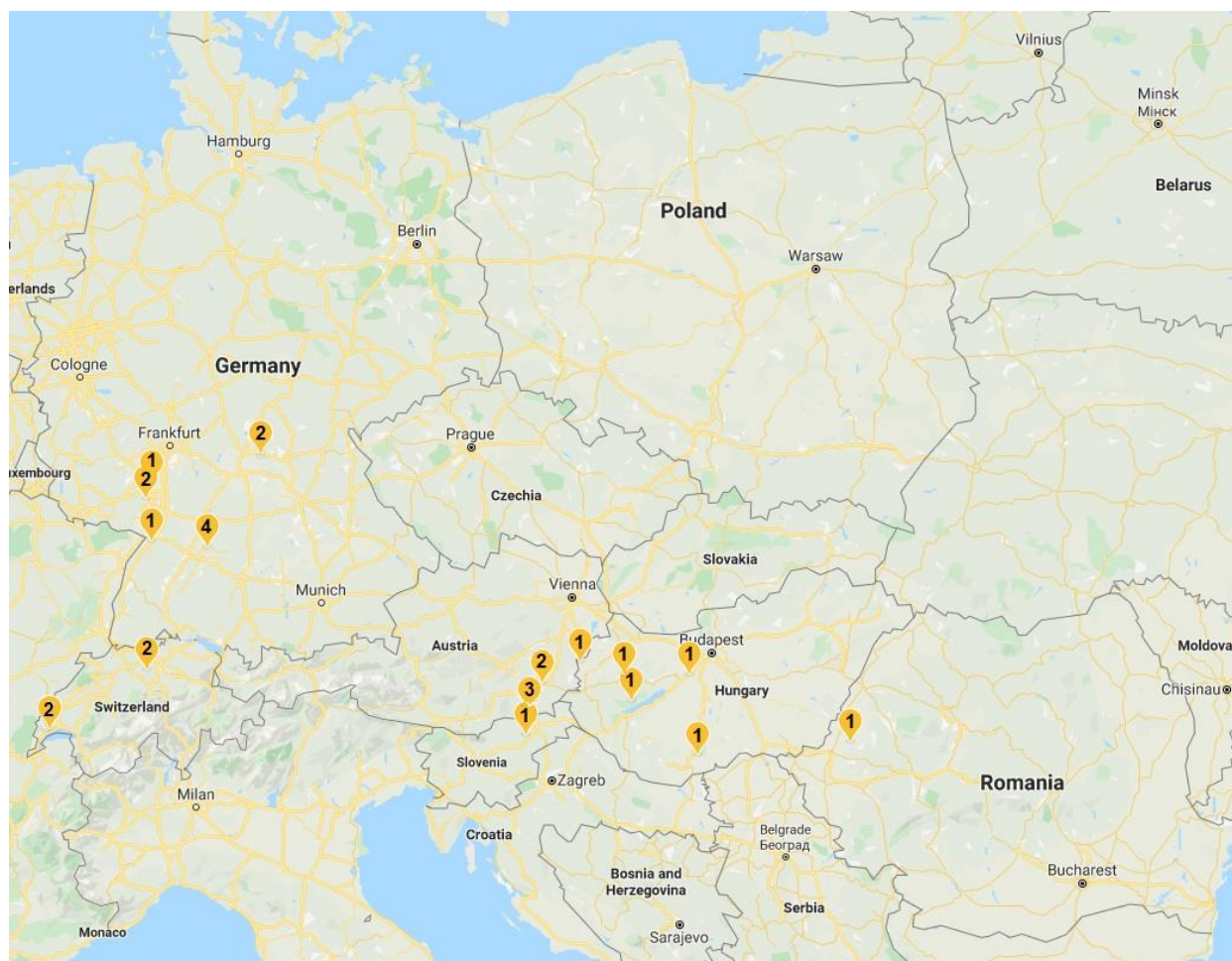


Figure 1: Locations of the 26 efficacy trials in Germany, Austria, Switzerland, Hungary, Romania and Slovenia

Standard methods

The following EPPO guidelines were followed:

- **PP 1/135(2/4)** Phytotoxicity assessment
- **PP 1/152(2/4)** Design and analysis of efficacy evaluation trials
- **PP 1/181(2/4)** Conduct and reporting of efficacy evaluation trials including GEP
- **PP 1/17(2)** *Botrytis cinerea* on grapevine (replaced by **PP 1/17 (3)** *Botryotinia fuckeliana* on grapevine)

Treatments

Mevalone was applied 3 or 4 times and compared to a reference fungicide product: FRUPICA (Mepanipyrim), SCALA (Pyrimethanil), SWITCH (Cyprodinil + fludioxonil) and FRUPICA (Mepanipyrim) + TELDOR (Fenhexamid) - See Table 3.2-7.

Efficacy results of Mevalone at 8 L/ha are not presented (2N rate tested for selectivity purpose only).

Products were applied according to the timing recommendations in the trial protocols. In some old trials only 3 instead of 4 applications were made. In the old trials the product was applied only according to crop developmental stages. In the new trials the first application was based on disease

risk and all further applications were done in a 7 days interval after the first application, independent on crop developmental stage.

Assessment details

The % control was calculated according to Abbott formula.

Only results of the relevant diseases infection (i.e. with at least a total of 4 % of pest incidence and at least 3% of pest severity in the untreated plots) are taken into consideration.

In all trials, phytotoxicity and crop vigour was also assessed. Yield was calculated in trial AF/12263/CN/2. Crop safety and yield results are presented in Point 3.4 of this document.

Statistical analysis

Data were then analysed using a two-way ANOVA on untransformed or transformed data. The probability of non-significant differences occurring between treatment means is calculated as the F probability value $p(F)$. Student-Newman-Keuls multiple comparison test was applied to separate any significant treatment differences that may be implied by the ANOVA and these are indicated by a letter: treatment means with at least one letter in common are not significantly different according to the test initiated at the 95% confidence level.

In trial serie 06WF232C (4 trials) no statistical analysis was made.

Presentation of the results

Results are first presented for efficacy on pest severity (PESSEV = area of bunch infected) and then for pest incidence (PESINC = % of infected bunches).

Both LWA and ground area approaches are investigated.

Application rates selected for mean calculations according to the LWA approach: Based on a Minimum effective dose range of 3.0-3.2 L/10000m² LWA all trials with dose rates of 2.4 - 3.8 L/10000m² LWA are used for the calculation of efficacy, considering that +/- 20% deviation from the target dose range is acceptable.

Application rates selected for mean calculations according to L/ha ground approach: Based on a dose range of 1.6-4.0 L/ha all trials based on a L/ha dose are used for the calculation of efficacy. (~~doses used: 2.4 – 4.0 L/ha~~).

- Pest severity on bunches:

According to the LWA approach (See Table 3.2-16), data from 8 relevant trials are taken into consideration (5 trials from Maritime zone and 3 trials from South-East zone).

With the mean values of 8 trials, Mevalone applied from 2.4 to 3.6 L/ha LWA gave 60.2% of efficacy whereas the reference product SWITCH gave 83.1% of efficacy. Individually, the difference was statistically significant in 2 out of 8 trials in favour of the reference product. The same trend was observed in both EPPO zones.

With the mean values of 3 trials Mevalone applied from 2.4 to 3.2 L/ha LWA gave 49.1% of efficacy whereas the reference product SCALA gave 69.8% of efficacy. Individually, the difference was statistically significant in 1 out of 3 trials in favour of the reference product.

To support registration of Mevalone in NE EPPO zone (PL), data from 2 German trials (with infection level > 5% pest severity) have been presented separately in the table 3.2.16. Mevalone applied from 2.4 to 2.7 L/ha LWA achieved 29% efficacy, whereas the reference product SWITCH gave 75.3% efficacy and reference product Scala gave 57.2% efficacy. Individually, the difference was statistically significant in 1 out of 2 trials in favour of the reference products.

According to the L/ha ground approach (See Table 3.2-17), data from 11 relevant trials are taken into consideration (8 trials from Maritime zone and 3 trials from South-East zone).

With the mean values of 9 trials, Mevalone applied from 2.4 to 4.0 L/ha ground gave ~~64.5%~~ 63.7% of efficacy whereas the reference product SWITCH gave 84.5% of efficacy. Individually, the difference was statistically significant in ~~1~~ 2 out of 9 trials in favour of the reference product. The same trend was observed in both EPPO zones.

With the mean values of 4 trials Mevalone applied from 2.4 to 4.0 L/ha ground gave ~~61.4%~~ 59.6% of efficacy whereas the reference product SCALA gave 71.8% of efficacy. Individually, the difference was statistically significant in favour of the reference product in 1 out of 4 trials and in favour of Mevalone in 1 out of 4 trials.

To support registration of Mevalone in NE EPPO zone (PL), data from 3 German trials (with infection level > 5% pest severity) have been presented separately in the table 3.2.17. Mevalone applied from 3.6 to 4.0 L/ha achieved 29% of efficacy, whereas the reference product SWITCH gave 75.3% efficacy based on the results from 2 trials. Mevalone applied from 3.2 to 4.0 L/ha achieved 52.1% efficacy, whereas the reference product Scala gave 57.2% efficacy based on the results from 3 trials. Individually, the difference was statistically significant in 1 out of 3 trials in favour of the reference products and in favour of Mevalone in 1 out of 3 trials.

According to the GAP table the dose rate range claimed for Mevalone is 1.6-2.0 L/ha. Additional tables 3.2.17 a-3.2.17h have been added by zRMS to show detailed efficacy data for all tested dose rates from all the trials submitted by the applicant. Results from these trials are discussed in the zRMS commenting box at the end of this chapter.

- Pest intensity on bunches:

According to the LWA approach (See Table 3.2-18), data from 12 relevant trials are taken into consideration (7 trials from Maritime zone and 5 trials from South-East zone).

With the mean values of 12 trials, Mevalone applied from 2.4 to ~~3.9~~ 3.8 L/ha LWA gave 49.6% of efficacy whereas the reference product SWITCH gave 66.7% of efficacy. Individually, the difference was statistically significant in 3 out of 12 trials in favour of the reference product. The same trend was observed in both EPPO zones.

With the mean values of 3 trials Mevalone applied from 2.4 to 3.2 L/ha LWA gave ~~52.5%~~ 37.5% of efficacy whereas the reference product SCALA gave ~~68.9%~~ 58.8% of efficacy. Individually, the difference was statistically significant in 1 out of 3 trials in favour of the reference product.

To support registration of Mevalone in NE EPPO zone (PL) data from 4 German trials (with infection level > 5% pest incidence) have been presented separately in the table 3.2.18. Mevalone applied from 2.4 to 3.2 L/ha LWA achieved 50.1% efficacy, whereas the reference product SWITCH gave 70.2% efficacy based on the results from 4 trials. Mevalone applied from 2.4 to 3.2 L/ha LWA gave 37.5% efficacy, whereas the reference product Scala gave 58.8% efficacy based on the results from 3 trials. Individually, the difference was statistically significant in 2 out of 4 trials and in 1 out of 3 trials in favour of the reference product Switch and Scala respectively.

According to the L/ha ground approach (See Table 3.2-19), data from ~~19~~ 17 relevant trials are taken into consideration (~~13~~ 12 trials from Maritime zone and ~~6~~ 5 trials from South-East zone).

With the mean values of 13 trials, Mevalone applied from 2.4 to 4.0 L/ha ground gave 53.8% of efficacy whereas the reference product SWITCH gave 68.3% of efficacy. Individually, the difference was statistically significant in 4 out of 13 trials in favour of the reference product. The same trend was observed in both EPPO zones.

With the mean values of 6 trials Mevalone applied from 2.4 to 4.0 L/ha ground gave 48.1% of efficacy whereas the reference product SCALA gave 53.5% of efficacy. Individually, the difference was statistically significant in favour of the reference product in 2 out of 6 trials and in favour of Mevalone in 1 out of 6 trials.

To support registration of Mevalone in NE EPPO zone (PL), data from 7 German trials (with infection level > 5% pest incidence) have been presented separately in the table 3.2.19. Mevalone applied from

2.4 to 4.0 L/ha achieved 48.2% of efficacy, whereas the reference product SWITCH gave 70.2% efficacy based on the results from 4 trials. Mevalone applied from 2.4 to 4.0 L/ha achieved 48.1% efficacy, whereas the reference product Scala gave 53.5% efficacy based on the results from 6 trials. Individually, the difference was statistically significant in 2 out of 4 trials and in 2 out of 6 trials in favour of the reference product Switch and Scala respectively and in favour of Mevalone in 1 out of 6 trials. According to the GAP table the dose rate range claimed for Mevalone is 1.6-4.0 L/ha. Additional tables 3.2.19 a-3.2.19h have been added by zRMS to show detailed efficacy data for all tested dose rates from all the trials submitted by the applicant. Results from these trials are discussed in the zRMS commenting box at the end of this chapter.

Table 3.2-16: Efficacy on the pest severity - LWA approach: all trials with dose rates of 3.0-3.2 L/10000m² LWA +/- 20% are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
All trials – Reference product Switch:	Mean:	13.6	60.2	83.1	69.8	3.6-4.8	2.4-3.7
	Max:	56.1	89.2	100.0	95.0		
	Min:	3.8	14.5	50.5	33.2		
	n	8	8	8	3		
EPPO Maritime – Reference product Switch:	Mean:	16.7	61.8	86.5	-	3.6-4.8	2.4-3.6
	Max:	56.1	89.2	100.0	-		
	Min:	3.8	14.5	50.5	-		
	n	5	5	5	-		
EPPO Maritime – Reference product Scala:	Mean:	25.0	49.1	-	69.8	3.6-4.8	2.4-3.2
	Max:	56.1	89.2	-	95.0		
	Min:	4.0	14.5	-	33.2		
	n	3	3	-	3		
EPPO South-East – Reference product Switch:	Mean:	8.6	57.7	77.3	-	3.0-4.0	3.3-3.7
	Max:	13.9	65.1	88.7	-		
	Min:	5.7	50.4	64.5	-		
	n	3	3	3	-		
EPPO Maritime (DE) – Reference product Switch or Scala:	Mean:	35.6	29.0	75.3	57.2	3.6-4.0	2.4-2.7
	Max:	56.1	43.5	100.0	81.1		
	Min:	15.0	14.5	50.5	33.2		
	n	2	2	2	2		

Table 3.2-17: Efficacy on the pest severity - L/ha ground approach: all trials with dose rates of 2.4-4.0 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
All trials – Reference product Switch :	Mean :	12.4	63.7	84.5	-	-	2.4-4.0	1.6-4.7
	Max :	56.1	89.1	100.0	-	-		
	Min :	2.8	14.5	50.5	-	-		
	n	9	9	9	-	-		
EPPO Maritime – Reference product Switch:	Mean:	14.4	64.3	88.1	-	-	2.4-4.0	1.6-4.3 3.6
	Max:	56.1	89.1	100.0	-	-		
	Min:	2.8	14.5	50.5	-	-		
	n	6	6	6	-	-		
EPPO Maritime – Reference product Scala:	Mean:	25.6	59.6	-	71.8	-	2.4-4.0	1.6-2.7
	Max:	56.1	98.2	-	95.0	-		
	Min:	4.0	14.5	-	33.2	-		
	n	4	4	-	4	-		
EPPO Maritime – Reference product Frupica:	Mean:	35.1	53.4	-	-	51.9	4.0	4.3
	n	1	1	-	-	1		
EPPO South-East – Reference product Switch:	Mean:	8.6	62.6	77.3	-	-	4.0	3.3-4.7
	Max:	13.9	65.1	88.7	-	-		
	Min:	5.7	57.5	64.5	-	-		
	n	3	3	3	-	-		
EPPO Maritime (DE)– Reference product Switch :	Mean :	35.6	29.0	75.3	-	-	3.6-4.0	2.4-2.7
	Max :	56.1	43.5	100.0	-	-		
	Min :	15.0	14.5	50.5	-	-		
	n	2	2	2	-	-		
EPPO Maritime (DE)– Reference product Scala:	Mean:	32.9	52.1	-	64.0	-	3.2-4.0	2.1-2.7
	Max:	56.1	98.2	-	81.1	-		
	Min:	15.0	14.5	-	33.2	-		
	n	3	3	-	3	-		

Table 3.2-17a: Efficacy on the pest severity - L/ha ground approach: all trials with dose rate of 1.6 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
EPPO Maritime (DE)– Reference product Scala:	Mean:	27.5	91.1	-	77.8	-	1.6	1.1
	n	1	1	-	1	-		

Table 3.2-17b: Efficacy on the pest severity - L/ha ground approach: all trials with dose rate of 1.8 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
EPPO Maritime (DE)– Reference product Scala:	Mean:	56.1	5.8	50.5	33.2	-	1.8	1.2
	n	1	1	1	1	-		

Table 3.2-17c: Efficacy on the pest severity - L/ha ground approach: all trials with dose rate of 2.0 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
All trials – Reference product Switch :	Mean :	5.8	70.5	87.1	-	-	2.0	1.3-2.3
	Max :	13.9	92.5	98.1	-	-		
	Min :	2.8	28.6	64.5	-	-		
	n	7	7	7	-	-		
EPPO Maritime – Reference product Switch:	Mean:	3.8	82.2	94.5	-	-	2.0	1.3-2.0
	Max:	4.5	92.5	98.1	-	-		
	Min:	2.8	71.7	90.9	-	-		
	n	4	4	4	-	-		
EPPO Maritime – Reference product Scala:	Mean:	4.0	84.0	-	95.0	-	2.0	1.3
	n	1	1	-	1	-		
EPPO South-East – Reference product Switch:	Mean:	8.6	54.9	77.3	-	-	2.0	1.7-2.3
	Max:	13.9	69.5	88.7	-	-		
	Min:	5.7	28.6	64.5	-	-		
	n	3	3	3	-	-		

Table 3.2-17d: Efficacy on the pest severity - L/ha ground approach: all trials with dose rate of 2.4 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
EPPO Maritime (DE) – Reference product Switch and Scala:	Mean:	9.5	57.8	99.1	88.1	-	2.4	1.6
	Max:	4.0	82.2	100.0	95.0	-		
	Min:	15.0	33.3	98.1	81.1	-		
	n	2	2	2	2	-		

Table 3.2-17e: Efficacy on the pest severity - L/ha ground approach: all trials with dose rate of 3.0 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
All trials – Reference product Switch :	Mean :	30.9	29.7	69.6	-	-	3.0	2.0-3.5
	Max :	56.1	50.4	88.7	-	-		
	Min :	5.7	8.9	50.5	-	-		
	n	2	2	2	-	-		
EPPO Maritime (DE)– Reference product Switch and Scala:	Mean:	56.1	8.9	50.5	33.2	-	3.0	2.0
	n	1	1	1	1	-		
EPPO South-East – Reference product Switch:	Mean:	5.7	50.4	88.7	-	-	3.0	3.5
	n	1	1	1	-	-		

Table 3.2-17f: Efficacy on the pest severity - L/ha ground approach: all trials with dose rate of 3.2 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
EPPO Maritime (DE) – Reference product Scala:	Mean:	27.5	98.2	-	77.8	-	3.2	2.1
	n	1	1	-	1	-		

Table 3.2-17g: Efficacy on the pest severity - L/ha ground approach: all trials with dose rate of 3.6 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
EPPO Maritime (DE) – Reference product Switch and Scala:	Mean:	56.1	14.5	50.5	33.2	-	3.6	2.4
	n	1	1	-	1	-		

Table 3.2-17h: Efficacy on the pest severity - L/ha ground approach: all trials with dose rate of 4.0 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
All trials – Reference product Switch :	Mean :	12.4	68.1	87.4	-	-	4.0	2.7-4.7
	Max :	35.1	89.1	100.0	-	-		
	Min :	2.8	43.5	64.5	-	-		
	n	7	7	7	-	-		
EPPO Maritime – Reference product Switch:	Mean:	6.5	72.3	95.0	-	-	4.0	2.7-4.0
	Max:	15.0	89.2	100.0	-	-		
	Min:	2.8	14.5	90.9	-	-		
	n	4	4	4	-	-		
EPPO Maritime (DE) – Reference product Switch and Scala:	Mean:	15.0	43.5	100.0	81.1	-	4.0	2.7
	n	1	1	1	1	-		
EPPO Maritime – Reference product Frupica:	Mean:	35.1	53.4	-	-	51.9	4.0	4.3
	n	1	1	-	-	1		
EPPO South-East – Reference product Switch:	Mean:	8.6	62.6	77.3	-	-	4.0	3.3-4.7
	Max:	13.9	65.1	88.7	-	-		
	Min:	5.7	57.5	64.5	-	-		
	n	3	3	3	-	-		

Table 3.2-18: Efficacy on the pest incidence - LWA approach: all trials with dose rates of 3.0-3.2 L/10000m² LWA+/- 20% are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
All trials:	Mean:	39.4	49.6	66.7	58.8	3.0-4.8	2.4-3.9 3.8
	Max:	99.8	100.0	100.0	96.7		
	Min:	4.2	0.0	7.9	6.0		
	n	12	12	12	3		
EPPO Maritime – Reference product Switch:	Mean:	48.1	52.5	68.9	-	3.6-4.8	2.4-3.9 3.8
	Max:	99.8	100.0	100.0	-		
	Min:	4.2	3.0	7.9	-		
	n	7	7	7	-		
EPPO Maritime – Reference product Scala:	Mean:	79.2	37.5	-	58.8	3.6-4.8	2.4-3.2
	Max:	99.8	61.9	-	96.7		
	Min:	52.3	3.0	-	6.0		
	n	3	3	-	3		
EPPO South-East – Reference product Switch:	Mean:	27.1	45.5	63.5	-	3.0-4.0	3.0-3.7
	Max:	39.6	78.7	86.7	-		
	Min:	12.5	0.0	30.8	-		
	n	5	5	5	-		
EPPO Maritime (DE) – Reference product Switch:	Mean:	64.3	50.1	70.2	-	3.6-4.8	2.4-3.2
	Max:	99.8	87.9	100	-		
	Min:	19.3	3.0	7.9	-		
	n	4	4	4	-		

EPPO Maritime (DE) – Reference product Scala:	Mean:	79.2	37.5	-	58.8	3.6-4.8	2.4-3.2
	Max:	99.8	61.9	-	96.7		
	Min:	52.3	3.0	-	6.0		
	n	3	3	-	3		

Table 3.2-19: Efficacy on the pest incidence - L/ha ground approach: all trials with dose rates of 2.0-4.0 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone	
		%Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
All trials – Reference product Switch:	Mean :	37.5	53.8	68.3	-	-	2.4-4.0	1.6-4.7
	Max :	99.8	100.0	100.0	-	-		
	Min :	4.2	3.0	18.8 7.9	-	-		
	n	13	13	13	-	-		
EPPO Maritime – Reference product Switch:	Mean:	44.0	54.1	71.4	-	-	2.4-4.0	1.6- 4.3 4.0
	Max:	99.8	100.0	100.0	-	-		
	Min:	4.2	3.0	7.9	-	-		
	n	8	8	8	-	-		
EPPO Maritime – Reference product Scala:	Mean:	60.5	48.1	-	53.5	-	2.4-4.0	1.6-2.7
	Max:	99.8	91.4	-	96.7	-		
	Min:	16.1	3.0	-	6.0	-		
	n	6	6	-	6	-		
EPPO Maritime – Reference product Frupica:	Mean:	52.0	48.3	-	-	65.1 50.3	4.0	4.3
	n	1	1	-	-	1		
EPPO South-East – Reference product Switch:	Mean:	27.1	53.2	63.5	-	-	4.0	3.2-4.7
	Max:	39.6	78.7	86.7	-	-		
	Min:	12.5	15.4	30.8	-	-		
	n	5	5	5	-	-		
EPPO Maritime (DE)– Reference product Switch:	Mean:	64.3	48.2	70.2	-	-	2.4-4.0	1.6-2.9
	Max:	99.8	87.9	100.0	-	-		
	Min:	19.3	3.0	7.9	-	-		
	n	4	4	4	-	-		
EPPO Maritime (DE)– Reference product Scala:	Mean:	60.5	48.1	-	53.5	-	2.4-4.0	1.6-2.7
	Max:	99.8	91.4	-	96.7	-		
	Min:	16.1	3.0	-	6.0	-		
	n	6	6	-	6	-		

Table 3.2-19a: Efficacy on the pest incidence - L/ha ground approach: all trials with dose rate of 1.6 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
EPPO Maritime (DE)– Reference product Scala:	Mean :	41.7	35.1	-	48.1	-	1.6	1.1
	Max :	86.3	65.3	-	27.4	-		
	Min :	16.1	0.0	-	69.6	-		
	n	3	3	-	3	-		

Table 3.2-19b: Efficacy on the pest incidence - L/ha ground approach: all trials with dose rate of 1.8 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
EPPO Maritime (DE) – Reference product Switch and Scala:	Mean:	99.8	0.0	7.9	6.0	-	1.8	1.2

Table 3.2-19c: Efficacy on the pest incidence - L/ha ground approach: all trials with dose rate of 2.0 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
All trials – Reference product Switch :	Mean :	27.5	54.7	70.9	-	-	2.0	1.3-2.3
	Max :	58.5	100.0	100.0	-	-		
	Min :	4.2	6.6	18.8	-	-		
	n	11	11	11	-	-		
EPPO Maritime – Reference product Switch:	Mean:	27.8	64.3	77.2	-	-	2.0	1.3-2.0
	Max:	58.5	100.0	100.0	-	-		
	Min:	4.2	6.6	18.8	-	-		
	n	6	6	6	-	-		
EPPO Maritime (DE) – Reference product Scala:	Mean:	52.3	57.2	-	73.8	-	2.0	1.3
	n	1	1	-	1	-		
EPPO Maritime (DE) – Reference product Switch:	Mean:	35.8	63.5	86.4	-	-	2.0	1.3-1.5
	Max:	52.3	69.8	89.7	-	-		
	Min:	19.3	57.2	83.0	-	-		
	n	2	2	2	-	-		
EPPO South-East – Reference product Switch:	Mean:	27.1	43.3	63.5	-	-	2.0	1.6-2.3
	Max:	39.6	65.3	86.7	-	-		
	Min:	12.5	11.9	30.8	-	-		
	n	5	5	5	-	-		

Table 3.2-19d: Efficacy on the pest incidence - L/ha ground approach: all trials with dose rate of 2.4 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
EPPO Maritime (DE)– Reference product Switch and Scala:	Mean :	69.0	38.4	91.5	85.3	-	2.4	1.6
	Max :	85.6	54.2	100.0	96.7	-		
	Min :	52.3	22.6	83.0	73.8	-		
	n	2	2	2	2	-		

Table 3.2-19e: Efficacy on the pest incidence - L/ha ground approach: all trials with dose rate of 3.0 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
All trials – Reference product Switch :	Mean :	45.2	28.0	46.2	-	-	3.0	2.0-3.5
	Max :	99.8	100.0	100.0	-	-		
	Min :	4.2	0.0	7.9	-	-		
	n	5	5	5	-	-		
EPPO Maritime – Reference product Switch:	Mean:	54.2	38.3	42.2	-	-	3.0	2.0-2.9
	Max:	99.8	100.0	100.0	-	-		
	Min:	4.2	0.8	7.9	-	-		
	n	3	3	3	-	-		
EPPO Maritime (DE) – Reference product Switch or Scala:	Mean:	99.8	0.8	7.9	6.0	-	3.0	2.0
	n	1	1	1	1	-		
EPPO South-East – Reference product Switch:	Mean:	31.7	12.7	52.1	-	-	3.0	3.0-3.5
	Max:	39.6	25.4	73.4	-	-		
	Min:	23.8	0.0	30.8	-	-		
	n	2	2	2	-	-		

Table 3.2-19f: Efficacy on the pest incidence - L/ha ground approach: all trials with dose rate of 3.2 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
EPPO Maritime (DE)– Reference product Scala:	Mean :	41.7	61.3	-	48.1	-	3.2	2.1
	Max :	86.3	91.4	-	69.6	-		
	Min :	16.1	24.1	-	27.4	-		
	n	3	3	-	3	-		

Table 3.2-19g: Efficacy on the pest incidence - L/ha ground approach: all trials with dose rate of 3.6 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
EPPO Maritime (DE) – Reference product Switch and Scala:	Mean:	99.8	3.0	7.9	6.0	-	3.6	2.4

Table 3.2-19h: Efficacy on the pest incidence - L/ha ground approach: all trials with dose rate of 4.0 L/ha are used for the calculation

Grouping	Rating Type	Untreated check	Mevalone	Reference product 1	Reference product 2	Reference product 3	Mevalone dose rates	
		% Infection	Eff %	Eff %	Eff %	Eff %	Dose rate L/ha	Dose rate L/ha LWA
All trials – Reference product Switch :	Mean :	30.5	58.4	72.5	-	-	4.0	2.7-4.7
	Max :	85.6	100.0	100.0	-	-		
	Min :	4.2	5.7	18.8	-	-		
	n	11	11	11	-	-		
EPPO Maritime – Reference product Switch:	Mean:	33.4	62.7	80.0	-	-	4.0	2.7-4.0
	Max:	85.6	100.0	100.0	-	-		
	Min:	4.2	5.7	18.8	-	-		
	n	6	6	6	-	-		
EPPO Maritime (DE) – Reference product Scala:	Mean:	85.6	47.5	-	96.7	-	4.0	2.7
	n	1	1	-	1	-		
EPPO Maritime – Reference product Frupica:	Mean:	52.0	48.3	-	-	50.3	4.0	4.3
	n	1	1	-	-	1		
EPPO Maritime (DE) – Reference product Switch:	Mean:	52.5	67.7	94.9	-	-	4.0	2.7-2.9
	Max:	85.6	87.9	100.0	-	-		
	Min:	19.3	47.5	89.7	-	-		
	n	2	2	2	-	-		
EPPO South-East – Reference product Switch:	Mean:	27.1	53.2	63.5	-	-	4.0	3.2-4.7
	Max:	39.6	78.7	86.7	-	-		
	Min:	12.5	15.4	30.8	-	-		
	n	5	5	5	-	-		

Conclusion on the efficacy of Mevalone against *Botrytis cinerea* in grape:

A total of 18 relevant field trials implemented in the Maritime EPPO zone (5 trials in Austria and 8 trials in Germany) and in the South-east EPPO zone (3 trials in Hungary, 1 in Romania and 1 in Slovenia) were used to evaluate the target registration rate of Mevalone (max. 4.0 L/ha ground, or 3.0 - 3.2 L/ha LWA), for the control of *Botrytis cinerea* on grapes. Mevalone was compared to the reference products SWITCH (cyprodinil + fludioxonil), SCALA (Pyrimethanil), FRUPICA (Mepanipyrim) and TELDOR WG (Fenhexamid).

Summary of overall efficacy based on pest incidence and pest severity at the last relevant assessment (0 to 61 days after last application) are provided in the following tables.

Table 3.2-20: Summary of efficacy - L/ha LWA approach: all trials with dose rates of 3.0-3.2 L/10000m2 LWA+/- 20%

	EPPO zone	Nb of trials	Untreated %PESSEV or % PESINC		% Efficacy - L/ha ground approach						Number of trials where 3AEY is >, =, < compared to	
					3AEY 2.4-3.8 L/ha LWA		Reference product 1		Reference product 2			
			Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	RP1	RP2
PESSEV	All	8	13.6	3.8 - 56.1	60.2	14.5 - 89.2	83.1	50.5 - 100.0	-	-	6= ; 2<	-
	MAR	5	16.7	3.8 - 56.1	61.8	14.5 - 89.2	86.5	50.5 - 100.0	-	-	4= ; 1<	-
	SE	3	8.6	5.7 - 13.9	57.7	50.4 - 65.1	77.3	64.5 - 88.7	-	-	2= ; 1<	-
	MAR	3	25.0	4.0 - 56.1	49.1	14.5 - 89.2	-	-	69.8	33.2 - 95.0	-	2= ; 1<
	MAR (DE)	2	35.6	15.0 - 56.1	29.0	14.5 - 43.5	75.3	50.5 - 100.0			1= ; 1<	
	MAR (DE)	2	35.6	15.0 - 56.1	29.0	14.5 - 43.5			57.2	33.2 - 81.1		1= ; 1<
PESINC	All	12	39.4	4.2 - 99.8	49.6	0.0 - 100.0	66.7	7.9 - 100.0	-	-	9= ; 3<	-
	MAR	7	48.1	4.2 - 99.8	52.5	3.0 - 100.0	68.9	7.9 - 100.0	-	-	5= ; 2<	-
	SE	5	27.1	12.5 -	45.5	0.0 -	63.5	30.8 -	-	-	4= ; 1<	-

			39.6		78.7		86.7				
MAR	3	79.2	52.3 - 99.8	37.5	3.0 - 61.9	-	-	58.8	6.0 - 96.7	-	2= ; 1<
MAR (DE)	4	64.3	19.3 – 99.8	50.1	3.0 – 87.9	70.2	7.9 – 100.0			2= ; 2<	
MAR (DE)	3	79.2	52.3 – 99.8	37.5	3.0 – 61.9			58.8	6.0 – 96.7		2= ; 1<

Table 3.2-21: Summary of efficacy - L/ha ground approach: all trials with dose rates of 2.0-2.4-4.0 L/ha

	EPPO zone	Nb of trials	Untreated %PESSEV or % PESINC		% Efficacy - L/ha ground approach								Number of trials where 3AEY is >, =, < compared to		
					3AEY 2.0-2.4-4.0 L/ha		Reference product 1		Reference product 2		Reference product 3				
			Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	RP1	RP2	RP3
PESSEV	All	9	12.4	2.8 - 56.1	64.5 63.7	14.5 - 89.2 89.1	84.5	50.5 - 100.0	-	-	-	-	8.7=; 1< 2<	-	-
	MAR	6	14.4	2.8 - 56.1	65.5 64.3	14.5 - 89.2 89.1	88.1	50.5 - 100.0	-	-	-	-	5.4=; 1< 2<	-	-
	SE	3	8.6	5.7 - 13.9	62.6	57.5 - 65.1	77.3	64.5 - 88.7	-	-	-	-	3=	-	-
	MAR	4	25.6	4.0 - 56.1	61.4 59.6	14.5 - 98.2	-	-	78.1 71.8	33.2 - 95.0	-	-	-	1>; 2=; 1<	-
	MAR	1	35.1	-	53.4	-	-	-	-	-	72.2 51.9	-	-	-	1=
	MAR (DE)	2	35.6	15.0 - 56.1	29.0	14.5 - 43.5	75.3	50.5 - 100.0					1>; 1<		
	MAR (DE)	3	32.9	15.0 - 56.1	52.1	14.5 - 98.2			64.0	33.2 - 81.1			1>; 1=; 1<		
PESINC	All	13	37.5	4.2 - 99.8	53.8	3.0 - 100.0	68.3	7.9 - 100.0	-	-	-	-	9=; 4<	-	-
	MAR	8	44.0	4.2 - 99.8	54.1	3.0 - 100.0	71.4	7.9 - 100.0	-	-	-	-	5=; 3<	-	-
	SE	5	27.1	12.5 - 39.6	53.2	15.4 - 78.7	63.5	30.8 - 86.7	-	-	-	-	4=; 1<	-	-
	MAR	6	60.5	16.1 - 99.8	48.1	3.0 - 91.4	-	-	53.5	6.0 - 96.7	-	-	-	1>; 3=; 2<	-
	MAR	1	52	-	48.3	-	-	-	-	-	65.1 50.3	-	-	-	1=
	MAR (DE)	4	64.3	19.3 - 99.8	48.2	3.0 - 87.9	70.2	7.9 - 100.0					2=; 2<		
	MAR (DE)	6	60.5	16.1 - 99.8	48.1	3.0 - 91.4			53.5	6.0 - 96.7			1>; 3=; 2<		

MAR= Maritime, SE= South-East

Results from the presented trials demonstrated that Mevalone applied at the recommended dose rate of 2.0-2.4-4.0 L/ha (L/ha approach) (or 3.0-3.2 L/ha LWA +/-20%) (LWA approach) provided moderate levels of control (about 50-55% on pest incidence and about 60-65% on pest severity).

Results were comparable in both EPPO zones Maritime and South-East.

Numerically the tested reference products showed a better control, but no clear statistical difference was demonstrated in most cases.

According to the GAP table the dose rate range claimed for Mevalone is 1.6-4.0 L/ha. Additional summary tables 3.2.21a-3.2.21h have been added by zRMS to show detailed efficacy data for all tested dose rates from all the trials submitted by the applicant. Results from these trials are discussed in the zRMS commenting box at the end of this chapter.

Table 3.2-21a: Summary of efficacy - L/ha ground approach: all trials with dose rate of 1.6 L/ha

	EPPO zone	Nb of trials	Untreated %PESSEV or % PESINC		% Efficacy - L/ha ground approach								Number of trials where 3AEY is >, =, < compared to		
					3AEY 1.6 L/ha		Reference product 1		Reference product 2		Reference product 3				
			Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	RP1	RP2	RP3
PESSEV	MAR (DE)	1	27,5	-	91.1	-	-	-	77,8	-	-	-		1>	-
PESINC	MAR (DE)	3	41.7	16.1 – 86.3	35.1	0.0 – 65.3	-	-	48.1	27.4 – 69.6	-	-	-	1=; 1<; 1>	-

Table 3.2-21b: Summary of efficacy - L/ha ground approach: all trials with dose rate of 1.8 L/ha

	EPPO zone	Nb of trials	Untreated %PESSEV or % PESINC		% Efficacy - L/ha ground approach								Number of trials where 3AEY is >, =, < compared to		
					3AEY 1.8 L/ha		Reference product 1		Reference product 2		Reference product 3				
			Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	RP1	RP2	RP3
PESSEV	MAR (DE)	1	56.1	-	5.8	-	50.5	-	33,2	-	-	-	1<	1=	-
PESINC	MAR (DE)	1	99.8	-	0.0	-	7.9	-	6.0	-	-	-	1<	1<	-

Table 3.2-21c: Summary of efficacy - L/ha ground approach: all trials with dose rate of 2.0 L/ha

	EPPO zone	Nb of trials	Untreated %PESSEV or % PESINC		% Efficacy - L/ha ground approach								Number of trials where 3AEY is >, =, < compared to		
					3AEY 2.0 L/ha		Reference product 1		Reference product 2		Reference product 3				
			Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	RP1	RP2	RP3
PESSEV	All	7	5.8	2.8 – 13.9	70.5	28.6 – 92.5	87.1	64.5 – 98.1	-	-	-	-	6= ; 1<	-	-
	MAR	4	3.8	2.8 – 4.5	82.2	71.7 – 92.5	94.5	90.9 – 98.1	-	-	-	-	3=; 1<	-	-
	MAR	1	4.0	-	84.0	-	-	-	95.0	-	-	-	-	1=	-
	SE	3	8.6	5.7 – 13.9	54.9	28.6 – 69.5	77.3	64.5 – 88.7	-	-	-	-	3=	-	-
PESINC	All	11	27.5	4.2 – 58.5	54.7	6.6 – 100.0	70.9	18.8 – 100.0	-	-	-	-	8= ; 3<	-	-
	MAR	6	27.8	4.2 – 58.5	64.3	6.6 – 100.0	77.2	18.8 – 100.0	-	-	-	-	4= ; 2<	-	-
	MAR	1	52.3	-	57.2	-	-	-	73.8	-	-	-	-	1<	-
	MAR (DE)	2	35.8	19.3 – 52.3	63.5	57.2 – 69.8	86.4	83.0 – 89.7	-	-	-	-	1= ; 1<	-	-
	MAR (DE)	1	52.3	-	57.2	-			73.8	-	-	-	-	1<	-
	SE	5	27.1	12.5 – 39.6	43.3	11.9 – 65.3	63.5	30.8 – 86.7	-	-	-	-	4= ; 1<	-	-

Table 3.2-21d: Summary of efficacy - L/ha ground approach: all trials with dose rate of 2.4 L/ha

Table 3.2.2.1d: Summary of efficacy - L/ha ground approach: all trials with dose rate of 2.4 L/ha															
	EPPO zone	Nb of trials	Untreated %PESSEV or % PESINC		% Efficacy - L/ha ground approach								Number of trials where 3AEY is >, =, < compared to		
					3AEY 2.4 L/ha		Reference product 1		Reference product 2		Reference product 3				
			Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	RP1	RP2	RP3
PESSEV	MAR (DE)	2	9.5	4.0 – 15.0	57.8	33.3 – 82.2	99.1	98.1 – 100.0	88.1	81.1 – 95.0	-	-	2<	1= ; 1<	-
PESINC	MAR (DE)	2	69.0	52.3 – 85.6	38.4	22.6 – 54.2	91.5	83.0 – 100.0	85.3	73.8 – 96.7	-	-	2<	2<	-

Table 3.2-21e: Summary of efficacy - L/ha ground approach: all trials with dose rate of 3.0 L/ha

	EPPO zone	Nb of trials	Untreated %PESSEV or % PESINC		% Efficacy - L/ha ground approach								Number of trials where 3AEY is >, =, < compared to		
					3AEY 3.0 L/ha		Reference product 1		Reference product 2		Reference product 3				
			Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	RP1	RP2	RP3
PESSEV	All	2	30.9	5.7 – 56.1	29.7	8.9 – 50.4	69.6	50.5 – 88.7	-	-	-	-	2<	-	-
	MAR (DE)	1	56.1	-	8.9	-	50.5	-	33.2	-	-	-	1<	1=	-
	SE	1	5.7	-	50.4	-	88.7	-	-	-	-	-	1<	-	-
PESINC	All	5	45.2	4.2 – 99.8	28.0	0.0 – 100.0	46.2	7.9 – 100.0	-	-	-	-	4= ; 1<	-	-
	MAR	3	54.2	4.2 – 99.8	38.3	0.8 – 100.0	42.2	7.9 – 100.0	-	-	-	-	3=	-	-
	MAR	1	99.8	-	0.8	-	-	-	6.0	-	-	-	-	1=	-
	MAR (DE)	1	99.8	-	0.8	-	7.9	-	6.0	-	-	-	1=	1=	-
	SE	2	31.7	23.8 – 39.6	12.7	0.0 – 25.4	52.1	30.8 – 73.4	-	-	-	-	1= ; 1<	-	-

Table 3.2-21f: Summary of efficacy - L/ha ground approach: all trials with dose rate of 3.2 L/ha

Table 3.2.2.11: Summary of efficacy - L/ha ground approach, all trials with dose rate of 3.2 L/ha															
	EPPO zone	Nb of trials	Untreated %PESSEV or % PESINC		% Efficacy - L/ha ground approach								Number of trials where 3AEY is >, =, < compared to		
					3AEY 3.2 L/ha		Reference product 1		Reference product 2		Reference product 3				
			Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	RP1	RP2	RP3
PESSEV	MAR (DE)	1	27.5	-	98.2	-	-	-	77.8	-	-	-	-	1>	-
PESINC	MAR (DE)	3	41.7	16.1 – 86.3	61.3	24.1 – 91.4	-	-	48.1	27.4 – 69.6	-	-	-	2= ; 1>	-

Table 3.2-21g: Summary of efficacy - L/ha ground approach: all trials with dose rate of 3.6 L/ha

Table 3.12.215: Summary of efficacy - L/ha ground approach: all trials with dose rate of 3.6 L/ha															
	EPPO zone	Nb of trials	Untreated %PESSEV or % PESINC		% Efficacy - L/ha ground approach								Number of trials where 3AEY is >, =, < compared to		
					3AEY 3.6 L/ha		Reference product 1		Reference product 2		Reference product 3				
			Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	RP1
PESSEV	MAR (DE)	1	56.1	-	14.5	-	50.5	-	33.2	-	-	-	1<	1=	-
PESINC	MAR (DE)	1	99.8	-	3.0	-	7.9	-	6.0	-	-	-	1=	1=	-

Table 3.2-21h: Summary of efficacy - L/ha ground approach: all trials with dose rate of 4.0 L/ha

	EPPO zone	Nb of trials	Untreated %PESSEV or % PESINC		% Efficacy - L/ha ground approach								Number of trials where 3AEY is >, =, < compared to		
					3AEY 4.0 L/ha		Reference product 1		Reference product 2		Reference product 3				
			Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	Mean	Min Max	RP1	RP2	RP3
PESSEV	All	7	12.4	2.8 – 35.1	68.1	43.5 – 89.1	87.4	64.5 – 100.0	-	-	-	-	6= ; 1<	-	-
	MAR	4	6.5	2.8 – 15.0	72.3	14.5 – 89.2	95.0	90.9 – 100.0	-	-	-	-	3=; 1<	-	-
	MAR	1	15.0	-	43.5	-	-	-	81.1	-	-	-	-	1<	-
	MAR	1	35.1	-	53.4	-	-	-	-	-	51.9	-	-	-	1=
	MAR (DE)	1	15.0	-	43.5	-	100.0	-	81.1	-	-	-	1<	1<	-
	SE	3	8.6	5.7 – 13.9	62.6	57.5- 65.1	77.3	64.5 – 88.7	-	-	-	-	3=	-	-
PESINC	All	11	30.5	4.2 – 85.6	58.4	5.7 – 100.0	72.5	18.8 – 100.0	-	-	-	-	8= ; 3<	-	-
	MAR	6	33.4	4.2 – 85.6	62.7	5.7 – 100.0	80.0	18.8 – 100.0	-	-	-	-	4= ; 2<	-	-
	MAR	1	85.6	-	47.5	-	-	-	96.7	-	-	-	-	1<	-
	MAR	1	52.0	-	48.3	-	-	-	-	-	50.3	-	-	-	1=
	MAR (DE)	2	52.5	19.3 – 85.6	67.7	47.5 – 87.9	94.9	89.7 – 100.0	-	-	-	-	1= ; 1<	-	-
	MAR (DE)	1	85.6	-	47.5	-			96.7	-	-	-	-	1<	-
	SE	5	27.1	12.5 – 39.6	53.2	15.4 – 78.7	63.5	30.8 – 86.7	-	-	-	-	4= ; 1<	-	-

3.2.3.2 Efficacy tests on apple

A total of 19 practical value trials were carried out with the test product Mevalone to control storage diseases in apple. Trials were set up between 2016 and 2019 in France (5), Germany (2), Czech Republic (3), Hungary (3) and Poland (6). All trials were carried out according to Good Experimental Practices (GEP).

An overview of all available trials per country and per year is provided in the table below.

Table 3.2-22: List of practical value trials testing the efficacy of Mevalone in pome fruits

Trial No.	EPPO zone*	Country	Year	Testing facility	Trial status
16-Fa-Pm-13	Med.	France	2016	Raison'Alpes	GEP
17-Fa-Pm-14	Med.	France	2017	Raison'Alpes	GEP
18-Fa-Pm-11	Med.	France	2018	Raison'Alpes	GEP
S18-06188-01	MAR	France	2018	Eurofins Agrosience Services	GEP
S19-20999-01	MAR	France	2019	Eurofins Agrosience Services	GEP
S18-06150-01	MAR	Germany	2018	Eurofins Agrosience Services GmbH	GEP
S19-20999-02	MAR	Germany	2019	Eurofins Agrosience Services GmbH	GEP
SUMI-F-2017-HOL03	MAR	Czech Republic	2017	VŠÚO Holovousy s.r.o.	GEP
F-19-O-502-01	MAR	Czech Republic	2018	InTec Agro Trials	GEP
F-20-O-501-01	MAR	Czech Republic	2019	InTec Agro Trials	GEP
S18-06194-01	SE	Hungary	2018	Eurofins Agrosience Services Kft.	GEP
S18-06194-02	SE	Hungary	2018	Eurofins Agrosience Services Kft.	GEP
S19-20999-03	SE	Hungary	2019	Eurofins Agrosience Services Kft.	GEP
AB5-17-31410-PL01	NE	Poland	2017	Staphyt	GEP
AB5-17-31410-PL02	NE	Poland	2017	Staphyt	GEP
AB5-19-36737-PL01	NE	Poland	2018	Staphyt	GEP
AB5-19-36737-PL02	NE	Poland	2018	Staphyt	GEP
KSA-19-41935-PL01	NE	Poland	2019	Staphyt	GEP
KSA-19-41936-PL01	NE	Poland	2019	Staphyt	GEP

* Med.= Mediterranean / MAR. = Maritime / NE = North-East / SE= South-East

Material and methods

Table 3.2-23: Details on trial methodology - Practical value trials

Guidelines	General guidelines	EPPO: PP 1/135(3/4), 1/152 (4), 1/181(3/4) (18 trials), 1/225(2) (4 trials), 1/223(2) (1 trial) CEB 225 (3 trials), MG012 (1 trial)
	Specific guidelines	EPPO: PP 1/18(3) (17 trials), PP 1/5(3) (+ 2 trials), CEB 14 (2 trials)
Experimental design	Plot design	Random complete blocks (19 trials)
	Plot size	3.8-44 14.8-45 m ² (16 trials) 5 trees (3 trials)
	Number of rep.	4 replications (19 trials)
Crop	Trials per crop	Apple (19 trials)
	Varieties per crop	Fuji (2), Gloster (1), Golden (1), Golden delicious (6), Granny Smith (1), Idared (1), Jumaní Junami (1), Melrose (1), Pink Lady (2), Pinova (1), Szampion (2)
	Planting period	1998-2013 (18 trials), nc (1 trial)
Application	Crop stage (BBCH) at application	Application A: BBCH 76-85 Application B: BBCH 78-87 Application C: BBCH 79-87 Application D: BBCH 81-87 Application E: BBCH 85-88
	Timing of application	A = 30 days before beginning of harvest B = 20 days before beginning of harvest C = 18 to 12 days before beginning of the harvest D = 10 days before beginning of the harvest E = 5 to 3 days before beginning of the harvest
	Number of appl. Intervals	5 (18 trials), 4 (1 trial) Interval: 3-12 days 3AEY applied without adjuvant: 4 (14 trials) 3AEY applied with adjuvant: 3 (7 trials) or 4 (12 trials) Interval: 3-4-12 days
	Spray volumes	400-1000 L/ha (17 trials), nc (2 trials)
Assessment	Assessment types	Number and/or % attacked fruits at harvest (200 to 250 fruits) Number and/or % attacked fruits after storage (125 to 250 fruits) % of fruit area with disease (125 to 250 fruits) Regular observations of phytotoxic effects/symptoms.
	Statistical analysis	Analysis of variances: ANOVA Statistical letters on means: Student-Newman-Keuls test probability of no significant difference between means = 5%
	Assessment dates	At harvest After 4-6 months of storage at 2-4°C After storage, every 7-14 days at ambient temperature
Other relevant information	Infestation	Natural infestation (19 trials)
	Field / greenhouse	Orchard selected based on varieties known to be more sensitive to storage diseases (19 trials)

Trials location is illustrated on the map thereafter.



Figure 2: Locations of the 19 trials in France, Germany, Czech Republic, Hungary & Poland

Standard methods

Depending on trials, the following EPPO guidelines and/or CEB methods were followed:

- **PP 1/135(3/4)** Phytotoxicity assessment
- **PP 1/152(4)** Design and analysis of efficacy evaluation trials
- **PP 1/181(3/4)** Conduct and reporting of efficacy evaluation trials including GEP
- **PP 1/5(3)** *Venturia inaequalis* and *V. pyrina*
- **PP 1/18(3)** Storage diseases of apples (pre-harvest application)
- **PP 1/223(2)** Introduction to the efficacy evaluation of plant protection products
- **PP 1/225(2)** Minimum effective dose
- **CEB n°225:** “Méthode d’essai de l’efficacité de préparations fongicides destinées à lutter contre les maladies de conservation des fruits à pépins, agrumes, actinidia”.
- **CEB n°14 :** “Méthode d’essai d’efficacité pratique de fongicides destinés à combattre les tavelures du pommier et du poirier, *Venturia inaequalis* et *Venturia pirina* », adaptée pour une étude de nuisibilité de la tavelure en phase de contaminations secondaires”
- **MG012:** “Principes généraux d’études de la sensibilité des cultures visà-vis d’une préparation herbicide, fongicide ou insecticide”.

Treatments

Mevalone was tested in several fungicide programs and compared to a reference fungicide program (MERPAN 80 WDG - BELLIS - GEOXE).

Depending on fungicide programs Mevalone was applied at 3 L/ha with an adjuvant (HELIOSOL or SLIPPA) and at 4 L/ha (requested dose rate) without adjuvant. Data show that Mevalone at 3 L/ha

applied with an adjuvant is comparable to Mevalone at 4 L/ha without adjuvant. In practice Mevalone can be applied with or without adjuvant.

Efficacy results of Mevalone at 8 L/ha are not presented (2N rate tested for selectivity purpose only).

Products were applied according to the timing recommendations:

- A = 30 days before beginning of harvest
- B = 20 days before beginning of harvest
- C = 18 to 12 days before beginning of the harvest
- D = 10 days before beginning of the harvest
- E = 5 to 3 days before beginning of the harvest,

In trial 17-Fa-Pm-14, the following timings were followed:

- A = 30 days before beginning of harvest
- B = 21 days before beginning of harvest
- C = 10 before beginning of the harvest
- D = 4 days before beginning of the harvest

This deviation had no incidence on the reliability of the trial.

Storage:

At harvest, 200 to 250 fruits were assessed and 125 to 250 non injured fruits were put in storage at 2-4°C during approximatively 4 to 6 months. No additional post-harvest treatment was made. After storage fruits were put at ambient temperature in the laboratory.

Assessment details

The achieved level of control was assessed by counting the number of diseased fruits.

125 to 250 fruits were assessed per plot. The % of diseased fruits was then calculated.

First assessment was made at the end of the storage and then every 7-14 days at ambient temperature if the disease pressure was significant. After each observation, all the diseased fruits were removed.

The severity of attack (% of diseased area) was also evaluated in several trials.

The % control was calculated according to Abbott formula.

Only results of the relevant storage diseases (i.e. with at least a total of 3 % of diseased fruits in the untreated plots) are taken into consideration.

In all trials, phytotoxicity was also assessed. Yield was calculated in 6 Polish trials. Crop safety and yield results are presented in Point 3.4..

Statistical analysis

Data were analysed using a two-way analysis of variance (ANOVA). The probability of no significant differences occurring between treatment means was calculated as the F probability value (pF). The Student-Newman-Keuls test was applied to separate any treatment differences that may be highlighted by the ANOVA test. These differences are indicated by a letter. Treatments with no letter in common are significantly different at 5% probability level.

In addition to the 19 practical value trials, a laboratory study was conducted in Germany in 2018. This trial is presented separately from practical value trials.

The presentation and the material & methods are given below.

Table 3.2-24: Laboratory study testing the efficacy of Mevalone in apple

Report No.	Year	EPPO zone	Country	Testing facility	Trial status
30.01.2019; Dr. Stefan Kunz	2018	Mar.	Germany	Bio-Protect GmbH	Non GEP

Table 3.2-25: Details on trial methodology - Laboratory study

Guidelines	General guidelines	None. Trial conducted under methods of the laboratory
Exp. design	Trial situation	Laboratory
	Number of rep.	12 apples
Crop	Crop	Apple
	Variety	Topaz
Infestation details	Infestation	Artificial inoculation
	Strains inoculated	<i>Botrytis cinerea</i> strain 12/4, <i>Neofabraea alba</i> strain N72, <i>Stemphylium vesicarium</i> strain EPS26 and <i>Phytophthora cactorum</i> strains G2f and PH2 and <i>Penicillium expansum</i> strain DSM62841, <i>Monilia</i> sp.
Application	Treatment type	Four equally-spaced wounds (0.3 cm in diameter) were made per fruit and two were inoculated with the conidial suspension mixed with water and two wounds were inoculated with the conidial suspension mixed with the test item.
	Incubation	Inoculated apples were incubated at 20°C until symptom diameter in the water treated control developed significantly.
Assessment	Assessment types	Symptoms of the fungal development were visible around the inoculated wounds and lesion diameter was measured for each wound. The average diameter was calculated for the water treated control and for the test item on each fruit, and the efficacy of the test item was calculated according to Abbott for each fruit. Efficacies of the test items on at least 12 fruits were averaged and compared to the water treated control and to the chemical standard.
	Assessment time	5 to 26 days after inoculation/treatment.
	Statistical analysis	A parametric, paired analyses of variance was done followed by the separation of the means of efficacies by Tukey's Multiple Comparison Test (p<0.05).

PRESENTATION OF THE RESULTS - Practical value trials

Efficacy results of Mevalone at 8 L/ha are not presented (2N rate tested for selectivity purpose only).

Results are presented first per trial. For each trial, only the percentage of diseased fruits (incidence) is presented because the percentage of diseased fruit area (severity) was often low and was not reported in all trials.

A total percentage of diseased fruits of < 3% is considered as not relevant.

These irrelevant data are presented for information only and are shaded in grey in the tables contained in BAD document. In a given trial, pest species with no relevant incidence in at least one assessment are not presented.

For each trial, only diseases with at least a relevant incidence throughout the course of the trial are presented.

Mean efficacy results for each pest species are then calculated per climatic zone for:

- the incidence at the end of storage
- the incidence 2-4 weeks after storage
- the total incidence (cumulative number of diseased fruits)

The following fungi were observed (only fungi with relevant incidence):

Pest species*	Nb of trials				
	All	Mediterranean zone	Maritime zone	SE zone	NE zone
<i>Gloeosporium sp.</i>	16	3	6	2	5
<i>Botrytis sp.</i>	5	1	2	-	2
<i>Penicillium sp.</i>	5	1	3	-	1
<i>Alternaria mali</i>	2	-	-	2	-
<i>Phytophthora sp.</i>	2	2	-	-	-
<i>Fusarium oxysporum</i>	2	-	2	-	-

*only fungi with relevant incidence of attack are presented in this table

Two trials had no relevant infestation (i.e. cumulative % of damaged fruits <5%). These trials are used for selectivity only.

Summary of the Mediterranean zone:

Only diseases observed in at least two trials are presented in the following table.

Table 3.2-26: Efficacy of Mevalone in Mediterranean zone - Efficacy on the total incidence in a summary form - 2 trials

Disease Pathogen code	Number of trial	UTC (% of diseased fruits)		MERPAN 80 WDG 1.9 kg/ha Mevalone 3 L/ha + adjuvant		Mevalone 3 L/ha + adjuvant		Reference program	
		21	4-38	28	16-39	27	21-32	34	14-53
GLOESP	2	21	4-38	28	16-39	27	21-32	34	14-53
All diseases pathogens	2	26	4-47	24	16-32	24	21-26	35	16-53

Remark: Statistical analysis was performed in 1 of 2 valid trials. No significant differences have been noted between 3AEY and reference program.

- Control of all diseases: Regarding the mean values of 2 trials, both treatments with Mevalone at 3L/ha + adjuvant had efficacy results comparable to the reference program (24%, vs 35%, respectively).
- Control of *Gloeosporium sp.*: Regarding the mean values of 2 trials, both treatments with Mevalone at 3L/ha + adjuvant had efficacy results comparable to the reference program (27-28%, vs 34%, respectively).
- Overall, treatments with Mevalone achieved control levels comparable to that of the reference program. The efficacy levels achieved should be considered cautiously as in 1 trial the assessments were made late: more than 1 month after storage whereas in practice the time between the end of cold storage and the sale or the consumption of the fruit does not exceed 3 to 4 weeks. Better efficacy levels are expected in practice.

Summary of the Maritime zone:

In all trials the last assessment (total infested fruits) was in line with the commercial practices (2 to 4 weeks after the end of the storage). As only a few relevant incidences were observed at the end of storage, only the efficacy on the cumulative incidences is presented in the table below.

Table 3.2-27: Efficacy of Mevalone in Maritime zone - Efficacy on the incidence 2 to 4 weeks after the end of storage in a summary form - 7 trials*

Timing Days after storage	Disease Pathogen code	Number of trial	UTC (% of diseased fruits)		Mevalone 4 L/ha (2.7-3.7 L/ha LWA)		Mevalone 3 L/ha (1.7- 3.4 L/ha LWA) + adjuvant		MERPAN 80 WDG - Mevalone 3 L/ha + adjuvant		Reference program		Number of trials where * is <, =, > compared to ref	
													Mevalone 4L/ha	Mevalone 3 L/ha +adj
Total 16-29 days	GLOESP	6	28 27	5-71	-	-	8	0-17	25	08- 46	59 57	41 32-80	-	3= ; 3<
		5	30	5-71	9	0-24	79	0-17	25 27	08- 46	62 61	43-80	1= ; 4<	2= ; 3<
	PENIEX	3	4	4-5	25	12-49	31	8-56	39	2-81	58	36-81	3=	3=
	BOTRCI	2	14	8-19	-	-	50	31-69	27	10-43 44	59	52-66 65	-	2=
		1	8	-	26	-	31	-	43	-	52	-	1=	1=
	FUSAOX	2	6	5-7	28	25-30	30	26-34	23	20-25	64	64-64	2=	2=
Total 16-29 days	All	7	32	5-79	-	-	16 17	0-41 6-38	26 28	012- 51	57 55	29-78	-	4= ; 3<
		6	32	5-79	89	0-22	12 14	06- 31	28 30	012- 51	57 56	29-78	3= ; 3<	3= ; 3<

- Control of all diseases: Regarding the mean values of all trials, the reference program had the best results (57 55% of efficacy). The most efficient Mevalone treatment was ‘MERPAN and Mevalone at 3 L/ha + adjuvant’ (26 28%). Mevalone applied alone at 4 L/ha or with an adjuvant at 3 L/ha gave comparable results.
- Control of *Gloeosporium sp.*: Regarding the mean values of 6 trials, the reference program had the best results (59 57% of efficacy). The most efficient Mevalone treatment was ‘MERPAN and Mevalone at 3 L/ha + adjuvant’ (25%). Mevalone applied alone at 4 L/ha or with an adjuvant at 3 L/ha gave comparable results.
- Control of *Penicillium expansum*: Regarding the mean values of 3 trials, the reference program had the best results (58% of efficacy). The most efficient Mevalone treatment was ‘MERPAN and Mevalone at 3 L/ha + adjuvant’ (39%). Mevalone applied alone at 4 L/ha or with an adjuvant at 3 L/ha gave comparable results.
- Control of *Botrytis sp.*: Regarding the mean values of 2 trials, the reference program had the best results (59% of efficacy). The most efficient Mevalone treatment was ‘Mevalone at 3 L/ha + adjuvant’ (50%). In 1 trial Mevalone applied alone at 4 L/ha or with an adjuvant at 3 L/ha had similar results.
- Control of *Fusarium oxysporum*: Regarding the mean values of 2 trials, the reference program had the best results (64% of efficacy). All treatment including Mevalone had moderate efficacy results below 40% (23-30%). Mevalone applied alone at 4 L/ha or with an adjuvant at 3 L/ha gave similar results.

Summary of the South-East zone:

Table 3.2-28: Efficacy of Mevalone in South-East zone - Efficacy on the incidence in a summary form - 2 trials

Timing : Days after storage	Disease Pathogen code	Number of trial	UTC (% of diseased fruits)		(A) MERPAN 80 WDG (BDE) Mevalone 4 L/ha		(ABDE) Mevalone 4 L/ha (2.8-3.6 L/ha LWA)		(A) MERPAN 80 WDG (BDE) Mevalone 3 L/ha + adjuvant		(ABDE) Mevalone 3 L/ha (2.1-2.7 L/ha LWA) + adjuvant		(ACE) Reference program		Number of trials where * is <, =, > compared to ref	
															*Mevalone 4L/ha	*Mevalone 3 L/ha +adj
21 days	GLOESP	2	21	13-30	23	1-45	24	13	23	3-42	18	8-28	26	5-46	2=	2=
	ALTEMA	2	31	12-50	27	9-44	30	19-41	30	27-32	28	14-42	32	23-41	2=	2=
Total 27-28 days	All	2	59	37-81	20	5-34	5	3-7	14	10-17	9	7-11	16	4-28	2=	2=

- Control of all diseases: Under moderate to very high disease pressure, the reference program gave low results (16% of efficacy) similar to those of both treatments including ‘MERPAN WDG and Mevalone’(14-20%).
- Control of *Gloeosporium sp.*: At the end of storage all programs including Mevalone had a moderate efficacy below 40% (13-23%), similar to that of the reference program (26%).
- Control of *Alternaria mali*: At the end of storage all programs including Mevalone had a moderate efficacy below 40% (27-30%), similar to that of the reference program (32%).

Summary of the North-East zone:

Table 3.2-29: Efficacy of Mevalone in North-East zone - Efficacy on the incidence in a summary form - 6 trials

Timing : Days after storage	Disease Pathogen code	Number of trial	UTC (% of diseased fruits)		Mevalone 4 L/ha (2.5-3.5 L/ha LWA)		Mevalone 3 L/ha (1.9-2.7 L/ha LWA) + Slippa		Reference program		Number of trials where * is <, =, > compared to ref	
											*Mevalone 4L/ha	*Mevalone 3 L/ha +adj
0 days	GLOESP	4	5	3-6	-	-	65	67	69	55-82	-	4=
		2	5	4-6	44	27-60	53	43-62	77	72-82	1<, 1=	2=
	BOTRSP	2	6	4-8	51	23-78	66	58-73	53	43-62	2=	2=
14 days	GLOESP	3	7	6-9	40	16-67	55	42-64	82	77-89	1<, 2=	3=
	BOTRSP	2	7	5-9	23	19-26	47	39-54	32	17-47	2=	2=
	PENIEX	1	11	-	33	-	67	-	70	-	1<	1=
TOTAL 0-35 days	all	6	24	3-53	-	-	66	49-88	65	49-84	-	-
		4	34	9-53	41	29-59	58	49-69	66	49-82	-	-

- Overall control of all diseases: Regarding the mean values of 6 trials, ‘Mevalone 3 L/ha + adjuvant’ was similar to the reference program. Based on the mean values of 4 trials, ‘Mevalone 4 L/ha’ showed lower results.
- Control of *Gloeosporium sp.*: At the end of storage ‘Mevalone 3 L/ha + adjuvant’ was similar effective as the reference program whereas ‘Mevalone 4 L/ha’ showed lower results. Two weeks after storage the same trends were observed.
- Control of *Botrytis sp.*: At the end of storage and 2 weeks after storage, both treatments with Mevalone gave results comparable to that of the reference program. Best results were achieved by ‘Mevalone 3 L/ha + adjuvant’.
- Control of *Penicillium expansum*: Two weeks after storage, Mevalone 3 L/ha + adjuvant’ was

similar effective as the reference program whereas ‘Mevalone 4 L/ha’ gave lower results.

Summary and conclusion of practical value trials in apple

Mevalone was included in several fungicide programs in 19 practical value trials carried out in France, Germany, Czech Republic, Hungary and Poland between 2016 and 2019. A total of 17 trials with relevant disease incidence was used to evaluate the control of Mevalone against storage diseases in apple.

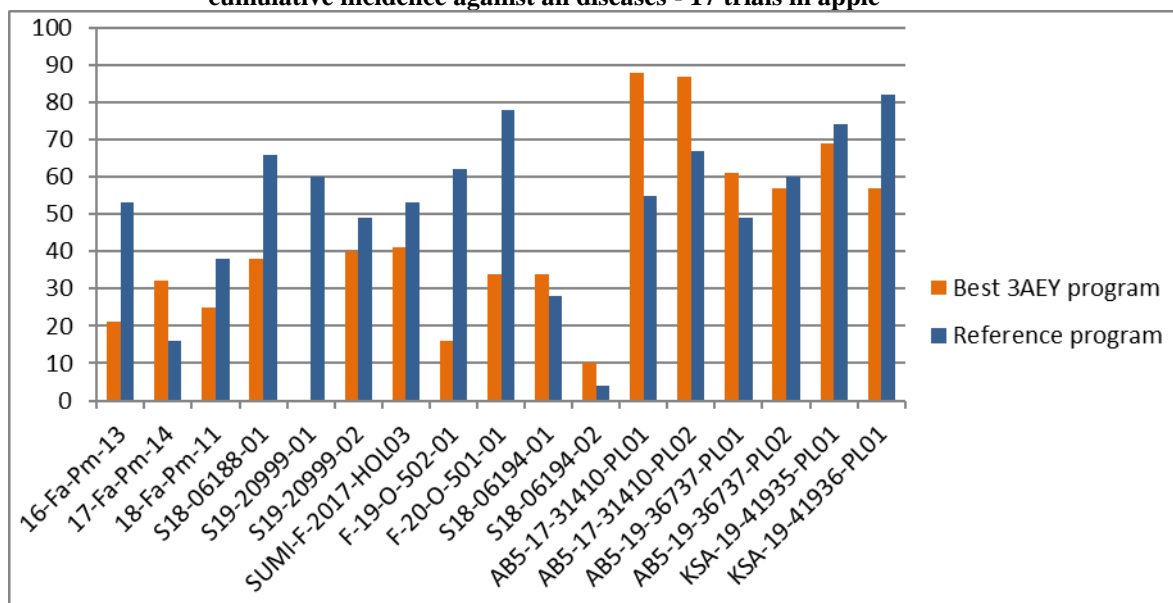
The following diseases were observed: (only disease with relevant incidence, i.e at least 3%)

- *Gloeosporium* sp. (16 trials)
- *Botrytis* sp. (5 trials)
- *Penicillium* sp. (5 trials)
- *Alternaria mali* (2 trials)
- *Phytophthora* sp. (2 trials)
- *Fusarium oxysporum* (2 trials)

As no post-harvest treatments were made, Mevalone only reduced disease incidence in most of the trials. Nevertheless, in 12 out of 17 trials (See Figure 3) several Mevalone fungicide programs had efficacy levels at least comparable to that of the reference program.

Results were heterogeneous from one trial to another, but the efficacy results of Mevalone applied at 3 L/ha with an adjuvant were globally comparable to that of Mevalone solo at 4 L/ha.

Figure 3: Efficacy of Mevalone programs compared to the reference program - % of efficacy on the cumulative incidence against all diseases - 17 trials in apple



Presentation of the results according to the LWA approach:

The following tables summarize the mean efficacy results against all pests at the end of the storage and at 2-4 weeks after the end of the storage.

Table 3.2-30: Efficacy of Mevalone against all pests at the end of the storage - LWA approach

		Untreated check	Mevalone		Reference	
		Infestation (%)	Infestation (%)	Abbott (%)	Infestation (%)	Abbott (%)
3 L/ha	Mean	7.7 7.1	4.6 4.1	46 51	2.3 2.3	67
	Min	2.3	0.4	0	0.8	52
	Max	24.0	12.3	83	7.2	84
	n	11 12	11 12	11 12	11 12	11 12
4 L/ha	Mean	8.5 8.0	7.3 7.0	30 29	2.6 2.5	68
	Min	2.3	0.6	0	0.8	52
	Max	24.0	24.7	81 78	7.2	81 84
	n	8 9	8 9	8 9	8 9	8 9
3.0-3.2 Lha/LWA +/- 20% (2.4 2.5 -3.7 L/ha LWA)	Mean	9.0 7.0	6.2 6.0	42 40	2.8 2.4	67 66
	Min	2.3	0.6	0	1.1	52
	Max	24.0	24.7	81 78	7.2	84
	n	13 11	13 11	13 11	13 11	13 11
3.0-3.2 Lha/LWA +/- 20% (2.5-3.7 L/ha LWA) – only trials with 3AEY without adjuvant	Mean	9.0	7.2	33	2.6	67
	Min	2.3	0.6	0	1.1	52
	Max	24.0	24.7	78	7.2	84
	n	8	8	8	8	8

Table 3.2-31: Efficacy of Mevalone against all pests at 2-4 weeks after the end of the storage - LWA approach

		Untreated check	Mevalone		Reference	
		Infestation (%)	Infestation (%)	Abbott (%)	Infestation (%)	Abbott (%)
3L/ha	Mean	47.7 33.3	45.4 26.8	24 27	34.3 16.4	49 53
	Min	4.9	3.4	6 6	3.5	4
	Max	80.6	74.6	61	77.3	78
	n	10 13	10 13	10 13	10 13	10 13
4L/ha	Mean	50.5 33.3	48.9 30.2	14 21	34.3 16.4	48 53
	Min	4.9	5.1 2.6	0	3.5 2.0	4
	Max	80.6	78.1	59 68	77.3	78 82
	n	9 12	9 12	9 12	9 12	9 12
3.0-3.2 Lha/LWA +/- 20% (2.4 2.5 -3.7 L/ha LWA)	Mean	50.7 35.0	49.9 30.6	20 24	32.3 17.4	50 53
	Min	4.9	5.1	0	3.5 2.0	4
	Max	80.6	78.1	61 68	77.3	78 82
	n	13 12	13 12	13 12	13 12	13 12
3.0-3.2 Lha/LWA +/- 20% (2.5-3.7 L/ha LWA) – only trials with 3AEY without adjuvant	Mean	35.1	31.5	23	17.4	53
	Min	4.9	5.1	0	2.0	4
	Max	80.6	78.1	68	77.3	82
	n	11	11	11	11	11

Regarding the ~~15~~ **13** relevant trials implemented in the Central zone (Maritime, South-east and North-East EPPO zones) where a LWA could be calculated, the rates tested in L/ha ranged from 1.7 to 3.7 L/ha LWA. No dose rate trend could be observed.

Taking into account the trials where 3.0-3.2 L/ha LWA (+/-20%) was tested (i.e. 2.4 2.5 to 3.7 L/ha LWA), the average efficacy at the end of the storage was 42 40% for 3AEY 3AEY (vs 67 66% with the reference products). The average efficacy at 2-4 weeks after the end of the storage was 20 24% for 3AEY 3AEY (vs 50 53% with the reference products).

Based only on the trials with Mevalone applied alone at 4.0 L/ha, the average efficacy at the end of the storage was 33% for 3AEY (vs 67% with the reference products). The average efficacy at 2-4 weeks after the end of the storage was 23% for 3AEY (vs 53% with the reference products).

Results from the presented trials demonstrated that Mevalone applied at the recommended dose rate of 3.0 L/ha (with adjuvant) or 4.0 L/ha (without adjuvant) (or 3.0-3.2 Lha/LWA +/- 20%) provided moderate levels of control reduces disease incidence at the end of the storage (about 45% on pest incidence) and low levels after 2-4 weeks after the end of storage (about 20% on pest incidence).

Based on trials with Mevalone applied without adjuvant at dose rate of 4.0 L/ha (or 3.0-3.2 L/ha/LWA +/- 20%), reducing disease incidence was noted (33% efficacy at the end of the storage and 23% efficacy 2-4 weeks after the end of the storage).

Numerically the tested reference products showed a better control but no clear statistical difference was demonstrated in most trials.

PRESENTATION OF THE RESULTS - Laboratory study

A specific study was conducted under controlled conditions (lab study) in order to evaluate the biological activity of MEVALONE and reference fungicides on five pathogens: *Botrytis cinerea*, *Monilia sp.*, *Neofabraea alba*, *Penicillium expansum* and *Phytophthora cactorum*.

The results of the % of efficacy are presented in the following table:

Table 3.2-32: Efficacy of Mevalone against storage diseases - Laboratory study under controlled conditions - Summary of efficacies - Reduction of the diameter of symptoms on fruits

Trial ID EPPO zone Country Year Variety	Disease	Time (day)	UTC Diameter (cm)	Test product	Reference products	
				Mevalone 0.4%	GEOXE 0.03%	CUPROZIN PROGRESS 0.8%
				(% of efficacy)		
30.01.2019; Dr. Stefan Kunz Mar. zone Germany 2018 Topaz	<i>Botrytis cinerea</i>	7	3.1	100.0 b	100.0 b	-
	<i>Monilia sp.</i>	5	4.5	95.8 b	100.0 b	-
	<i>Neofabraea alba</i> (Gloeosporium)	26	1.3	96.1 b	100.0 b	-
	<i>Penicillium expansum</i>	7	2.2	9.1 b	100.0 c	-
	<i>Phytophthora cactorum</i>	7	4.6	100 d	10.8 b	92.4 c

Lesion diameters in control wounds varied from 1.3 to 4.6 cm, depending on fungi.

The reference product GEOXE as well as Mevalone significantly reduced disease incidence of all tested fungi.

Considering *Botrytis cinerea*, *Monilia sp.* and *Neofabraea alba* (Gloeosporium), both Mevalone and GEOXE had an excellent efficacy (96-100%)

Penicillium expansum was significantly better controlled with GEOXE, whereas Mevalone totally controlled *Phytophthora cactorum*, significantly better than both reference products GEOXE and UP-ROZIN PROGRESS (100%, 11% and 92%, respectively).

In the conditions of this study Mevalone at 0.4% offered a reliable control against 4 out of the 5 storage diseases tested (*Botrytis cinerea*, *Monilia sp.*, *Neofabraea alba* = *Gloeosporium* and *Phytophthora cactorum*).

CONCLUSION on Efficacy part

A total of 18 relevant field trials implemented in Austria, Germany, Hungary, Romania and Slovenia were used to evaluate the target registration rate of Mevalone (max. 4.0 L/ha ground, or 3.0 – 3.2 L/ha LWA), for the control of *Botrytis cinerea* on grapes. Mevalone was compared to several reference products.

Results from the presented trials demonstrated that Mevalone applied at the recommended dose rate of 2.0-4.0 L/ha (or ~~3.0~~ 1.7-3.2 L/ha LWA ~~+/-20%~~) provided moderate levels of control, globally comparable to the reference products.

Efficacy results from ~~13~~ 17 practical value trials carried out in France, Germany, Czech Republic, Hungary and Poland between 2016 and ~~2018~~ 2019 demonstrated that Mevalone, mostly included in a fungicide program at 3.0 or 4.0 L/ha, ~~offered a significant control~~ reduced against several storage diseases incidence in apple such as *Gloeosporium sp.*, *Botrytis sp.*, *Alternaria mali*, *Phytophthora sp.* and *Penicillium sp.*

The control level of Mevalone was generally comparable to a reference fungicide program typically used by apple growers.

That was confirmed by a laboratory study carried out in Germany in 2018 on the same fungus species.

Like the other biocontrol products already available for the control of *Botrytis cinerea* on grapes or apple storage disease in Europe, Mevalone is a useful alternative to synthetic chemical substances and may contribute to the reduction of the risk of resistance to these substances. In addition, as a biocontrol product composed of active substances (natural substances category) exempted from MRL (Maximal Residue Limit) setting, Mevalone will contribute to reduce the number of residues found in grapes and apple fruits.

Therefore, the use of Mevalone is claimed at max. 4,0 L/ha ground, or 3,0 - 3,2 L/ha LWA alone or in a fungicide program to control *Botrytis cinerea* on grapes and storage diseases in pome fruits, with a maximum of 4 applications per year.

Comments of zRMS on:

Efficacy (3.2.3)

A total of 35 valid efficacy field trials carried out between 2006 and 2019 were considered for the evaluation of biofungicide Mevalone (3AEY) containing natural active substances: eugenol, geraniol and thymol. The trials were carried out in 4 EPPO zones: Mediterranean (FR), Maritime (AT, CZ, DE, FR), North-East (PL) and South-East (HU, RO, SL). All the efficacy field trials were carried out by the officially GEP-recognized testing units. Additionally 1 laboratory study has been submitted to support registration of Mevalone in the control of storage diseases. Mevalone is intended to be used for the control of *Botrytis cinerea* in grapevine, and pathogens causing storage diseases (e.g. *Gloeosporium* sp., *Botrytis* sp., *Penicillium* sp., *Alternaria mali*, *Phytophthora* sp., *Fusarium oxysporum*) in pome fruits. Mevalone is intended to be used within the crop stage ranging from BBCH 60-89 in grapevine and BBCH 75-87 in pome fruits. Conclusions from the evaluation have been summarized separately for individual claimed uses listed in the GAP table.

GRAPEVINE/ *Botrytis cinerea* – 18 valid trials [13 MAR (DE, AT) + 5 SE (HU, RO, SL); Tables: 3.2-16; 3.2-17; 3.2-17a-3.2-17h; 3.2-18; 3.2-19; 3.2-19a-3.2-19h; 3.2-20; 3.2-21; 3.2-21a-3.2-21h.

Efficacy datapackage includes 18 valid field trials carried out in grapevine in MAR and SE EPPO zone. No trials were conducted in NE EPPO zone. To support registration in PL, trial results from Germany have been separated by zRMS and presented in the tables 3.2-16-3.2-21h. Efficacy trials were conducted in the years 2006-2019. BBCH growth stage of the crop ranged from 61 to 89, which closely corresponds to the range proposed in the GAP table (BBCH 60-89). Mevalone was applied mainly 4 times (in 18 trials) and 3 times (in 4 trials). The maximum number of applications proposed for Mevalone is 4 per growth season. Range of dose rates 1.6-4.0 L/ha or 3.0-3.2 L/ha LWA is claimed, therefore both LWA and ground area approaches have been investigated. The trials contain data for efficacy on pest severity (PESSEV) and pest incidence (PESINC) and results from both types of assessment have been presented and discussed. According to the EPPO guideline PP 1/17 (3) “% bunch area infected and % of infected bunches should be assessed. In the case of low level of infection in the trial, only % of infected bunches should be assessed”. This explains more efficacy data presented for PESINC as compared with efficacy data presented for PESSEV (efficacy data from the trials with low infection level have been excluded from the evaluation).

Efficacy on PESSEV (area of bunch infected) (tables 3.2-16; 3.2-17; 3.2-17a-h; 3.2-20; 3.2-21; 3.2-21a-h)

Based on LWA approach, Mevalone at dose rates of approx. 3.0-3.2 L/ha LWA (MED determined for Mevalone in the chapter 3.2.2) was 61.8% effective and 49.1% effective in MAR zone based on 5 trials (comparison with reference product Switch – 86.5% effective) or 3 trials (comparison with reference product Scala – 69.8% effective) respectively. The average efficacy from 3 SE zone trials achieved 57.7% (reference product Switch was 77.3% effective). The average efficacy from 8 trials was 60.2% for Mevalone and 83.1% for standard Switch. No statistically significant differences in efficacy were noted between Mevalone and reference product Switch in the majority of trials (6). Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 2 of 8 trials. Statistically lower efficacy for Mevalone as compared with standard Scala was noted in 1 of 3 trials. Additionally results from 2 German trials may support registration in PL. The average efficacy from these trials was 29.0% for Mevalone, 75.3% for standard Switch and 57.2% for standard Scala. The difference was statistically significant in 1 of 2 trials in favour of the reference products.

Based on L/ha approach, Mevalone at dose rates of 2.4-4.0 L/ha was 64.3% effective, 59.6% effective and 53.4% effective in MAR zone based on 6 trials (comparison with reference product Switch – 88.1% effective), 4 trials (comparison with reference product Scala – 71.8% effective) and 1 trial (comparison with reference product Frupica – 51.9% effective) respectively. The average efficacy from 3 SE zone trials was 62.6% (reference product Switch was 77.3% effective). The average efficacy from 9 trials was 63.7% for Mevalone and 84.5% for standard Switch. No statistically significant differences in efficacy were noted between Mevalone and reference product Switch in the majority of trials (7). Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 2 of 9 trials. Statistically lower efficacy for Mevalone as compared with standard Scala was noted in 1 of 4 trials. Statistically higher efficacy for Mevalone as compared with standard Scala was noted in 1 of 4 trials. Additionally result from 3 German trials may support registration in PL. Mevalone at dose rates of 2.4-4.0 L/ha was 29.0% effective and 52.1% effective, based on 2 trials (comparison with reference product Switch – 75.3% effective) or 3 trials (comparison with reference product Scala – 64.0% effective). Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 1 of 2 trials. Statistically lower efficacy for Mevalone as compared with standard Scala was noted in 1 of 3 trials. Statistically higher efficacy for Mevalone as compared with standard Switch was noted in 1 of 2 trials. Statistically higher efficacy for Mevalone

as compared with standard Scala was noted in 1 of 3 trials.

Additional tables (3.2-17a-3.2-17h; 3.2-21a-3.2-21h) have been added by zRMS to present efficacy trial results for all dose rates tested in the trials. Dose rates lower than 2.0 L/ha were tested in only 2 trials carried out in Germany. Efficacy results from these trials are ambiguous (91.1% efficacy for Mevalone applied at **1.6 L/ha** and 5.8% efficacy for Mevalone applied at **1.8 L/ha**). It is worth adding that, the efficacy of reference product Scala was not statistically different as compared with Mevalone applied at dose rate of 1.8 L/ha. Additionally efficacy of Mevalone applied at dose rate of 1.6 L/ha was statistically higher than efficacy of standard Scala. Very low effectiveness was noted in the trial under infection level >50% disease severity.

According to zRMS, due to limited efficacy data submitted for MAR zone and no efficacy data available for SE zone for Mevalone applied at dose rates < 2.0 L/ha it is not acceptable to recommend dose rates lower than 2.0 L/ha.

Mevalone applied at dose rate of **2.0 L/ha** was 82.2% effective and 84% effective in MAR zone based on 4 trials (comparison with reference product Switch – 94.5% effective) or 1 trial (comparison with reference product Scala – 95.0% effective) respectively. The average efficacy from 3 SE zone trials was 54.9% (reference product Switch was 77.3% effective). The average efficacy from 7 trials was 70.5% for Mevalone and 87.1% for standard Switch. No statistically significant differences in efficacy were noted between Mevalone and reference product Switch in the majority of trials (6). Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 1 of 7 trials.

Mevalone applied at dose rate of **2.4 L/ha** was 57.8% effective based on 2 German trials (comparison with reference product Switch – 99.1% effective and reference product Scala – 88.1% effective). Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 2 trials. Statistically lower efficacy for Mevalone as compared with standard Scala was noted in 1 of 2 trials.

Mevalone applied at dose rate of **3.0 L/ha** was only 8.9% effective based on 1 German trial (comparison with reference product Switch – 50.5% effective and reference product Scala – 33.2% effective). It is worth adding that, the efficacy of reference product Scala was not statistically different as compared with Mevalone in this trial. Additionally very low effectiveness was noted under infection level >50% disease severity. The efficacy from 1 SE zone trial was 50.4% (reference product Switch was 88.7% effective). The average efficacy from 2 trials was 29.7% for Mevalone and 69.6% for standard Switch. Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 2 trials.

Mevalone was applied at dose rate of **3.2 L/ha** in 1 German trial, achieving 98.2% efficacy. The efficacy of standard Scala was statistically lower in this trial (77.8% efficacy).

Mevalone applied at dose rate of **3.6 L/ha** was 14.5% effective based on 1 German trial (comparison with reference product Switch – 50.5% effective and reference product Scala – 33.2% effective). It is worth adding that, the efficacy of reference product Scala was not statistically different as compared with Mevalone in this trial. Additionally very low efficacy was noted under infection level >50% disease severity.

Mevalone applied at dose rate of **4.0 L/ha** was 72.3% effective, 43.5% effective and 53.4% effective in MAR zone based on 4 trials (comparison with reference product Switch – 95.0% effective), 1 trial (comparison with reference product Scala – 81.1% effective) and 1 trial (comparison with reference product Frupica – 51.9% effective) respectively. The average efficacy from 3 SE zone trials was 62.6% (reference product Switch was 77.3% effective). The average efficacy from 7 trials was 68.1% for Mevalone and 87.4% for standard Switch. No statistically significant differences in efficacy were noted between Mevalone and reference product Switch in the majority of trials (9). Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 3 of 12 trials. Statistically lower efficacy for Mevalone as compared with standard Scala was noted in 1 trial. Additionally result from 1 German trial may support registration in PL. Mevalone at dose rate of 4.0 L/ha was 43.5% effective (comparison with reference product Switch – 100.0% effective and with the standard Scala – 81.1% effective). The difference was statistically significant in this trial in favour of the reference products.

Efficacy on PESINC (% of infected bunches) (tables 3.2-18; 3.2-19; 3.2-19a-h; 3.2-20; 3.2-21; 3.2-21a-h)

Based on LWA approach, Mevalone at dose rates of approx. 3.0-3.2 L/ha LWA (MED determined for Mevalone in the chapter 3.2.2) was 52.5% effective and 37.5% effective in MAR zone based on 7 trials (comparison with reference product Switch – 68.9% effective) or 3 trials (comparison with reference product Scala – 58.8% effective) respectively. The average efficacy from 5 SE zone trials was 45.5% (reference product Switch was 63.5% effective). The average efficacy from 12 trials was 49.6% for Mevalone and 66.7% for standard Switch. No statistically significant differences in efficacy were noted between Mevalone and reference product Switch in the majority of trials (9). Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 3 of 12 trials. Statistically lower efficacy for Mevalone as compared with standard Scala was noted in 1 of 3 trials. Additionally results from 4 German trials may support registration in PL. Mevalone at dose rates of approx. 3.0-3.2 L/ha LWA was 50.1% effective and 37.5% effective, based on 4 trials (comparison with refer-

ence product Switch – 70.2% effective) or 3 trials (comparison with reference product Scala – 58.8% effective). No statistically significant differences in efficacy between Mevalone and reference product was noted in 2 of 4 trials. Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 2 of 4 trials. Statistically lower efficacy for Mevalone as compared with standard Scala was noted in 1 of 3 trials.

Based on L/ha approach, Mevalone at dose rates of 2.4-4.0 L/ha was 54.1% effective, 48.1% effective and 48.3% effective in MAR zone based on 8 trials (comparison with reference product Switch – 71.4% effective), 6 trials (comparison with reference product Scala – 53.5% effective) and 1 trial (comparison with reference product Frupica – 50.3% effective) respectively. The average efficacy from 5 SE zone trials was 53.2% (reference product Switch was 63.5% effective). The average efficacy from 13 trials was 53.8% for Mevalone and 68.3% for standard Switch. No statistically significant differences in efficacy were noted between Mevalone and reference product Switch in the majority of trials (9). Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 4 of 13 trials. Statistically lower efficacy for Mevalone as compared with standard Scala was noted in 2 of 6 trials. Statistically higher efficacy for Mevalone as compared with standard Scala was noted in 1 of 6 trials. Additionally results from 6 German trials may support registration in PL. Mevalone at dose rates of 2.4-4.0 L/ha was 48.2% effective and 48.1% effective, based on 4 trials (comparison with reference product Switch – 70.2% effective) or 6 trials (comparison with reference product Scala – 53.5% effective). The difference was statistically significant in 2 out of 6 trials in favour of the reference product Switch. Similarly the difference was statistically significant in 2 out of 6 trials in favour of the reference product Scala. The difference was statistically significant in 1 out of 6 trials in favour of Mevalone comparing with standard Scala.

Additional tables (3.2-19a-3.2-19h; 3.2-21a-3.2-21h) have been added by zRMS to present efficacy trial results for all dose rates tested in the trials.

Mevalone applied at dose rate of **1.6 L/ha** was 35.1% effective based on 3 German trials. Standard Scala was 48.1% effective. No statistically significant difference in efficacy was noted between Mevalone and reference product Scala in 1 trial. The difference was statistically significant in 1 out of 3 trials in favour of the reference product Scala. The difference was statistically significant in 1 of 3 trials in favour of Mevalone comparing with standard Scala.

Mevalone applied at dose rate of **1.8 L/ha** was not effective in 1 German trial carried out under high infection close to 100% of disease incidence. Standard Switch was only 7.9% effective, standard Scala was only 6.0% effective in this trial. The difference was statistically significant in favour of the reference products.

According to zRMS, due to low efficacy results achieved for MAR zone and no efficacy data available for SE zone for Mevalone applied at dose rates < 2.0 L/ha it is not acceptable to recommend dose rates lower than 2.0 L/ha.

Mevalone applied at dose rate of **2.0 L/ha** was 64.3% effective and 57.2% effective in MAR zone based on 6 trials (comparison with reference product Switch – 77.2% effective) or 1 trial (comparison with reference product Scala – 73.8% effective) respectively. The average efficacy from 5 SE zone trials was 43.3% (reference product Switch was 63.5% effective). The average efficacy from 11 trials was 54.7% for Mevalone and 70.9% for standard Switch. No statistically significant differences in efficacy were noted between Mevalone and reference product Switch in the majority of trials (8). Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 3 of 11 trials. Statistically lower efficacy for Mevalone as compared with standard Scala was noted in 1 trial. Additionally results from 2 German trials may support registration in PL. Mevalone at dose rate of 2.0 L/ha was 63.5% and 57.2% effective based on 2 trials (comparison with reference product Switch – 86.4% effective) and 1 trial (comparison with reference product Scala – 73.8% effective). No statistically significant difference in efficacy between Mevalone and reference product Switch was noted in 1 of 2 trials. Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 1 of 2 trials. Statistically lower efficacy for Mevalone as compared with standard Scala was noted in 1 trial.

Mevalone applied at dose rate of **2.4 L/ha** was 38.4% effective based on 2 German trials (comparison with reference product Switch – 91.5% effective and reference product Scala – 85.3% effective). Statistically lower efficacy for Mevalone as compared with standards was noted in 2 trials.

Mevalone applied at dose rate of **3.0 L/ha** was 38.3% effective and no effective (efficacy 0.8%) in MAR zone based on 3 trials (comparison with reference product Switch – 42.2% effective) or 1 trial (comparison with reference product Scala – 6.0% effective) respectively. The average efficacy from 2 SE zone trials was only 12.7% (reference product Switch was 52.1% effective). The average efficacy from 5 trials was 28.0% for Mevalone and 46.2% for standard Switch. No statistically significant differences in efficacy were noted between Mevalone and reference product Switch in the majority of trials (4). Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 1 of 5 trials. No statistically significant difference in efficacy was noted between Mevalone and standard Scala in 1 trial. No efficacy of Mevalone was noted in 1 German trial carried out under high infection close to 100% disease incidence. It is worth adding that, the efficacy of reference products Switch and Scala was not statistically different as compared with Mevalone in this trial. It is recommended to add remark in the label of Mevalone to use lower dose rates under low disease pressure.

Mevalone applied at dose rate of **3.2 L/ha** was 61.3% effective based on 3 German trials (comparison with reference product Scala – 48.1% effective). Statistically higher efficacy for Mevalone as compared with standard Scala was noted in 1 trial. No statistically significant differences in efficacy between Mevalone and standard Scala were noted in 2 of 3 trials.

Mevalone applied at dose rate of **3.6 L/ha** was not effective (3.0% efficacy) based on 1 German trial (comparison with reference product Switch – 7.9% effective and reference product Scala – 6.0% effective). The efficacy of reference products Switch and Scala was not statistically different as compared with Mevalone in this trial. It is worth adding that very low effectiveness was noted under high infection close to 100% disease incidence.

Mevalone applied at dose rate of **4.0 L/ha** was 62.7% effective, 47.5% effective and 48.3% effective in MAR zone based on 6 trials (comparison with reference product Switch – 80.0% effective), 1 trial (comparison with reference product Scala – 96.7% effective) and 1 trial (comparison with reference product Frupica – 50.3% effective) respectively. The average efficacy from 5 SE zone trials was 53.2% (reference product Switch was 63.5% effective). The average efficacy from 11 trials was 58.4% for Mevalone and 72.5% for standard Switch. No statistically significant differences in efficacy were noted between Mevalone and reference product Switch in the majority of trials (8). Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 3 of 11 trials. Statistically lower efficacy for Mevalone as compared with standard Scala was noted in 1 trial. No statistically significant difference in efficacy was noted between Mevalone and reference product Frupica in 1 trial. Additionally results from 2 German trials may support registration in PL. Mevalone at dose rate of 4.0 L/ha was 67.7% effective, 47.5% effective based on 2 trials (comparison with reference product Switch – 94.9% effective) and 1 trial (comparison with reference product Scala – 96.7% effective) respectively. No statistically significant difference in efficacy was noted between Mevalone and reference product Switch in 1 trial. Statistically lower efficacy for Mevalone as compared with standard Switch was noted in 1 of 2 trials. Statistically lower efficacy for Mevalone as compared with standard Scala was noted in 1 trial.

POME FRUITS/storage diseases caused by: *Gloeosporium* sp., *Botrytis* sp., *Penicillium* sp., *Alternaria mali*, *Phytophthora* sp., *Fusarium oxysporum* : 17 valid trials [2 MED (FR) + 7 MAR (FR, CZ, DE) + 6 NE (PL) + 2 SE (HU)]; Tables 3.2-26 – 3.2-32.

Seventeen valid field efficacy trials have been considered for the evaluation of Mevalone against storage diseases in pome fruits. Trials were carried out in apple in 4 EPPO zones: MED, MAR, SE and NE in the years 2016-2019. BBCH growth stage of the crop ranged from 76 to 88, which closely corresponds to the range proposed in the GAP table (BBCH 75-87). Mevalone at dose rate of 4.0 L/ha, was applied 4 times in 14 trials. Mevalone at dose rate of 3.0 L/ha used with adjuvant (Heliosol of Slippa) was applied 3 times (in 6 trials) and 4 times (in 11 trials) at dose rate of 3.0 L/ha. Range of dose rates 2.4-4.0 L/ha or 3.0-3.2 L/ha LWA is claimed. Due to low disease pressure on pest severity noted in most of the trials, only efficacy trial results on pest incidence (PESINC) have been presented. This is in line with EPPO guideline PP 1/18 (3), which emphasizes the requirement to present data on pest incidence: “Storage rot: the number of fruits showing storage-rot symptoms should be recorded, together with the causal agent. The type and intensity of symptoms may also be described”

Efficacy on PESINC (% of infected fruits): MED zone (table 3.2-26).

Results from 2 valid trials presents data on efficacy of Mevalone applied at dose rate of 3.0 L/ha with an adjuvant. The average efficacy of Mevalone against *Gloeosporium* sp., from 2 trials achieved only 27% and was not statistically different as compared to reference program. The average efficacy for Mevalone recorded for all pathogens noted in these trials (*Gloeosporium* sp., *Phytophthora* sp.) was 24% and was not statistically different as compared to reference program.

Efficacy on PESINC (% of infected fruits): MAR zone (table 3.2-27).

Mevalone applied without adjuvant at dose rate of 4.0 L/ha (2.7-3.7 L/ha LWA) was:

- 9% effective against *Gloeosporium* sp. (statistically significant lower efficacy as compared with reference program noted in 4 of 5 trials),
- 25% effective against *Penicillium expansum* (no statistically significant differences in all trials as compared with reference program),
- 26% effective against *Botrytis* sp. (no statistically significant differences in the trial as compared with reference program),
- 28% effective against *Fusarium oxysporum* (no statistically significant differences in all trials as compared with reference program) and
- 9% effective against all pathogens noted in the trials (statistically significant lower efficacy as compared with reference program noted in 3 of 6 trials),

16-29 days after storage, based on 5; 3; 1; 2 and 6 trials respectively.

The average efficacy of Mevalone applied at dose rate of 3.0 L/ha (1.7-3.4 L/ha LWA) with adjuvant was:

- 25% in the control of *Gloeosporium sp.* (statistically significant lower efficacy as compared with reference program noted in 3 of 6 trials),
- 39% in the control of *Penicillium expansum* (no statistically significant differences in all trials as compared with reference program),
- 27% in the control of *Botrytis sp.* (no statistically significant differences in all trials as compared with reference program),
- 23% in the control of *Fusarium oxysporum* (no statistically significant differences in all trials as compared with reference program), and
- 28% in the control of all pathogens (statistically significant lower efficacy as compared with reference program noted in 3 of 7 trials),

16-29 days after storage based on 6; 3; 2; 2; and 7 trials respectively.

Based on the submitted trials results it can be concluded that Mevalone applied at dose rate of 4.0 L/ha or applied at dose rate of 3.0 L/ha with adjuvant only reduces storage diseases incidence on a very low level (average efficacy achieved 9%-39%) based on the trials carried out in MAR zone. Due to low efficacy results achieved in MAR EPPO zone, the concerned MSs are kindly advised to consider possibly efficacy trial results from NE zone and make a decision concerning acceptance of this use on the national level. As no efficacy trials are available for Mevalone applied without adjuvant at dose rates lower than 4.0 L/ha and due to efficacy results (below 40%) achieved for dose rate of 4.0 L/ha, in the opinion of zRMS dose rate of 4.0 L/ha is the only dose rate that can be considered for this claimed use.

Efficacy on PESINC (% of infected fruits): SE zone (table 3.2-28).

Results from 2 valid trials presents data on efficacy of Mevalone applied without adjuvant at dose rate of 4.0 L/ha (2.8-3.6 L/ha LWA) or applied at dose rate of 3.0 L/ha (2.1-2.7 L/ha LWA) with an adjuvant. The average efficacy of Mevalone at dose rate of 4.0 L/ha achieved only 13% against *Gloeosporium sp.* and 30% against *Alternaria mali* and was not statistically different as compared to reference program. Similarly, Mevalone at dose rate of 3.0 L/ha applied with adjuvant was 18% and 28% effective against *Gloeosporium sp.* and *Alternaria mali* respectively, 21 days after storage and no statistically significant differences have been noted. The average efficacy for Mevalone recorded for all pathogens noted in these trials was only 5% and 9% at 4.0 L/ha and 3.0 L/ha respectively, 27-38 days after storage and was not statistically different as compared to reference program

Based on the submitted trials results it can be concluded that Mevalone applied at dose rate of 4.0 L/ha or applied at dose rate of 3.0 L/ha with adjuvant only reduces storage diseases incidence on a very low level (average efficacy achieved 5%-30%) based on the trials carried out in SE zone. Due to limited efficacy data and low efficacy results achieved in SE EPPO zone, the concerned MSs are kindly advised to consider possibly efficacy trial results from NE zone and make a decision concerning acceptance of this use on the national level. As no efficacy trials are available for Mevalone applied without adjuvant at dose rates lower than 4.0 L/ha and due to efficacy results (below 40%) achieved for dose rate of 4.0 L/ha, in the opinion of zRMS dose rate of 4.0 L/ha is the only dose rate that can be considered for this claimed use.

Efficacy on PESINC (% of infected fruits): NE zone (table 3.2-29).

Mevalone applied without adjuvant at dose rate of 4.0 L/ha (2.5-3.5 L/ha LWA) was:

- 44% effective against *Gloeosporium sp.* at the end of the storage (statistically significant lower efficacy as compared with reference program noted in 1 of 2 trials),
- 51% effective against *Botrytis sp.* at the end of the storage (no statistically significant differences in 2 trials as compared with reference program),
- 40% effective against *Gloeosporium sp.* 14 days after storage (statistically significant lower efficacy as compared with reference program noted in 1 of 3 trials),
- 23% effective against *Botrytis sp.* 14 days after storage (no statistically significant differences in 2 trials as compared with reference program),
- 33% effective against *Penicillium expansum* 14 days after storage (no statistically significant differences in 1 trial as compared with reference program) and
- 41% effective against all pathogens noted in the trials, 0-35 days after storage (statistically differences were not determined).

Mevalone applied at dose rate of 3.0 L/ha (1.9-2.7 L/ha LWA) with adjuvant was:

- 67% effective against *Gloeosporium sp.* at the end of the storage (no statistically significant differences in 4 trials as compared with reference program),
- 66% effective against *Botrytis sp.* at the end of the storage (no statistically significant differences in 2 trials as compared with reference program),

- 55% effective against *Gloeosporium* sp. 14 days after storage (statistically significant lower efficacy as compared with reference program noted in 1 of 3 trials),
- 47% effective against *Botrytis* sp. 14 days after storage (no statistically significant differences in 2 trials as compared with reference program),
- 67% effective against *Penicillium expansum* 14 days after storage (no statistically significant differences in 1 trial as compared with reference program) and
- 66% effective against all pathogens noted in the trials, 0-35 days after storage (statistically differences were not determined).

Based on the submitted trials results from NE zone it can be concluded that Mevalone applied at dose rate of 4.0 L/ha reduces storage disease incidence (efficacy: 23-51%). Mevalone applied at dose rate of 3.0 L/ha with an adjuvant is moderately effective or reduces storage diseases incidence (efficacy: 47-67%). As no efficacy trials are available for Mevalone applied without adjuvant at dose rates lower than 4.0 L/ha and due to efficacy trials results achieving a level below 60% for dose rate of 4.0 L/ha, in the opinion of zRMS dose rate of 4.0 L/ha is the only acceptable dose rate for this claimed use.

Efficacy on PESINC (% of infected fruits): MAR, SE, NE zone, all pathogens, LWA approach.

The applicant presented additional tables with efficacy results for Mevalone in the control of all pathogens at the end of the storage and 2-4 weeks after the end of the storage, highlighting results for Mevalone applied at approximately 3.0-3.2 L/ha LWA +/-20% (2.5-3.7 L/ha LWA). Additionally zRMS has extracted results from the trials with Mevalone applied without adjuvant. Mevalone applied at dose rate of approx. 3.0-3.2 L/ha LWA was 40% effective and 33% effective at the end of the storage based on all trials or on trials without adjuvant respectively. 2-4 weeks after the storage the efficacy was 24% and 23% based on all trials or on trials without adjuvant.

Results from these trials confirm reducing storage diseases incidence by biofungicide Mevalone applied at dose rate of approx. 3.0-3.2 L/ha LWA. It is worth adding that tables 3.2.27-3.2.29 showing results presented for individual pathogens for individual EPPO zones also contained conversions of dose rate L/ha to L/ha LWA added by zRMS. It can be noticed that dose rate of 4 L/ha closely corresponds to 3.0-3.2 L/ha +/- 20% in all the trials.

Laboratory study

Additional laboratory study has been submitted by the applicant to support registration of Mevalone in the control of storage diseases in pome fruits. Results from this trial show high efficacy (close to 100%) of Mevalone applied at 0.4% in the control of *Botrytis cinerea*, *Monilia* sp., *Gloeosporium* and *Phytophthora cactorum* comparable to the reference products - Geoxe or Cuprozin Progress, tested in this trial (except efficacy results for *Phytophthora cactorum*, where statistically significant difference was noted in favour of Mevalone as compared with standard Geoxe). Only one tested pathogen *Penicillium expansum* was not satisfactorily controlled under laboratory conditions (efficacy: 9%). This trial provides additional data on concentration of Mevalone (0.4%), which may be of importance for the effectiveness of the treatment. Mevalone is recommended to be used at max. 4.0 L/ha and diluted in max. 1000 L water and this corresponds to concentration of 0.4%

SUMMARY

Based on the submitted trial results it can be concluded that Mevalone applied at dose rates of 2.0-4.0 L/ha or 3.0 – 3.2 L/ha LWA (corresponding mostly approximately with the highest recommended dose rate 4.0 L/ha in most of the efficacy trials), depending on disease pressure, dose rate tested and kind of assessment (PESSEV or PESINC) is moderately effective in the control of *Botrytis cinerea* or only reduces disease severity or incidence in grapevine in Maritime and South-East EPPO zone. The lower recommended doses <4.0 L/ha 2.0 L/ha, and corresponding to approximately 1.7 L/ha LWA can be recommended under conditions of low disease pressure. may be used in vineyards with a smaller leaf whole area to maintain the range of dose rates 3.0 – 3.2 L/ha LWA determined as the minimum effective dose rate. The information about moderate efficacy/ reducing storage disease occurrence should be considered to be added on the national labels of Mevalone. Due to limited efficacy data (for PESSEV) or low efficacy (for PESINC) noted for MAR zone and no efficacy data available for SE zone for Mevalone applied at dose rates < 2.0 L/ha in the opinion of zRMS it is not acceptable to recommend dose rates lower than 2.0 L/ha. Mevalone applied at dose rate of 4.0 L/ha (approx. 3.0-3.2 L/ha LWA) reduces storage disease incidence in apple fruits in NE zone. Mevalone applied at dose rate of 3.0 L/ha with an adjuvant (Slippa or Heliosol) is moderately effective or reduces storage diseases incidence in this zone. As no efficacy trials have been submitted to support the use of Mevalone without adjuvant at dose rates < 4.0 L/ha, the acceptable dose rate for Mevalone for NE EPPO zone in apple protection is 4.0 L/ha or 3.0-3.2 L/ha LWA. Mevalone ap-

plied at dose rate of 4.0 L/ha or applied at dose rate of 3.0 L/ha with adjuvant (Heliosol) only reduces storage diseases incidence on a very low level based on the trials carried out in MAR and SE EPPO zone. Due to low efficacy results achieved in MAR and SE zone and limited efficacy data from SE zone, the concerned MSs are kindly advised to consider possibly efficacy trial results from NE zone and make a decision concerning acceptance of this use on the national level. As no efficacy trials are available for Mevalone applied alone at dose rates lower than 4.0 L/ha and due to efficacy results below 40% achieved for dose rate of 4.0 L/ha, in the opinion of zRMS dose rate of 4.0 L/ha is the only dose rate that can be considered for this claimed use.

As no efficacy trials have been submitted for *Pyrus communis*, *Cydonia oblonga*, *Malus sylvestris*, *Eryobotria japonica*, *Mespilus germanica* and *Pyrus pyrifolia* var. *culta* listed in GAP table, the concerned MSs are kindly advised to consider individually possible extrapolation of efficacy trial results from *Malus domestica*, according to the national requirements and make a decision concerning acceptance of this use on the national level.

Additional/ supportive data

Calculation of dose rate 2.0 L/ha recommended for grapevine under low disease pressure, expressed in L/ha LWA, given by the applicant during commenting period is presented below:

“A minimum dose rate expressed in L/ha LWA can be calculated based on the minimum dose rate in L/ha applied in trials where the LWA rate was available in the individual report (see table below)

Table 3.2-9: Treated LWA m² per hectare and tested rates applied in trials in grapevine

Trials with LWA in individual report - Trials 2018-2019											
Trial ID	EPPO zone	Country	Treated LWA (m ² /ha)	Rates applied (L/ha ground)				Rates applied (L/ha LWA)			
S19-20334-01	SE	HU	9333	2.0	3.0	4.0	8.0	2.1	3.5	4.3	8.6
S19-20334-02	SE	HU	10714	2.0	3.0	4.0	8.0	1.9	3.2	3.7	7.5
S19-20334-03	SE	RO	12000	2.0	3.0	4.0	8.0	1.7	3.0	3.3	6.7
S19-20334-04	SE	SL	12500	2.0	3.0	4.0	8.0	1.6	2.9	3.2	6.4
S19-20334-05	Mar.	AT	10000	2.0	3.0	4.0	8.0	2.0	3.0	4.0	8.0
S19-20334-06	Mar.	AT	11200	2.0	3.0	4.0	8.0	1.8	2.9	3.6	7.1
S19-20334-07	Mar.	DE	13636	2.0	3.0	4.0	8.0	1.5	2.7	2.9	5.9
S19-20334-08	Mar.	DE	17500	2.0	3.0	4.0	8.0	1.1	2.3	2.3	4.6
S18-051950-01	SE	HU	8571	2.0	3.0	4.0	8.0	2.3	3.5	4.7	9.3
S18-051950-02	SE	HU	13636	2.0	3.0	4.0	8.0	1.5	2.2	2.9	5.9
S18-051950-03	SE	HU	10000	2.0	3.0	4.0	8.0	2.0	3.0	4.0	8.0
S18-051950-04	Mar.	AT	10400	2.0	3.0	4.0	8.0	1.9	2.9	3.8	7.7
S18-051950-05	Mar.	DE	15000	2.0	3.0	4.0	8.0	1.3	2.0	2.7	5.3
S18-051950-06	Mar.	DE	15000	2.0	3.0	4.0	8.0	1.3	2.0	2.7	5.3

The mean dose rate calculated from data in yellow is equal to 1.7 L/ha LWA.

Based on this, the proposed minimum dose rate for grapes is 1.7 L/ha LWA.

Therefore, the requested dose rate expressed in LWA for grapes is 1.7 - 3.2 L/ha LWA.”

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

This section was written taking into account the EPPO Standard PP 1/213 recommendations.

a) Mode of action

Mevalone is a capsule suspension formulation containing 33.0 g a.s./l eugenol, 66.0 g a.s./l geraniol and 66.0 g a.s./l thymol. Eugenol, geraniol and thymol are all terpene compounds naturally occurring in certain plants species and as constituents of essential oils. These types of compounds generally possess antifungal activity and it is believed that they have a multi-site mode of action that is very similar to that of benzyl alcohol, phenol and polyphenols. From widespread research carried out on terpenes,

it is evident that eugenol, geraniol and thymol have the same general mode of action against fungi, interacting with spore germination, hyphal penetration, mycelial growth and hyphal growth.

All terpene compounds are reported to have direct effects on cell walls, membranes and organelles of microorganisms. The primary mode of action is through the destruction of cell membranes, which is associated with the capability of the compounds to dissolve lipids and results in leakage of cellular substances leading to cell death. Studies have confirmed that cyclic terpene hydrocarbons accumulate in the cell membrane causing a loss of membrane integrity, with associated changes in composition of fatty acids and phospholipids. This is thought to occur as a result of lesion formation in the cytoplasmic membrane with reductions in ergosterol content due to the disruption of biosynthesis.

Due to these effects on membranes, there is also thought to be an impact on processes involving ATP and active transport of molecules across membranes, leading to depletion of the ATP pool and leakage of cellular substances, with impairment of energy metabolism. Mitochondrial structure disorganisation may occur and the effects on membranes have been shown to cause partial dissipation of the pH gradient and electrical potential.

Terpenes have also been observed to cause changes in the hyphal wall. Some effects on enzyme activity have also been reported, including interference with respiratory enzymes and enzymes responsible for cell wall synthesis. Terpenes are volatile, hydrophobic compounds and it is difficult to make stable aqueous formulations. Eden's unique encapsulation technology has enabled commercial formulations to become viable, without the use of solvents or polymers/microplastics.

b) Mechanism of resistance

Mevalone is a capsule suspension formulation containing 33.0 g a.s./l eugenol, 66.0 g a.s./l geraniol and 66.0 g a.s./l thymol. 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 and it was reported in the British Pharmacopoeia (1996 Edition) that microorganisms do not build up resistance to benzyl alcohol, phenols, polyphenols and similar products. 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.

There are currently no recorded cases of resistance of fungi or other microbes to any terpene, or related type compounds.

c) Evidence of resistance

There is no evidence of resistance of *Gloeosporium spp.*, *Phytophthora spp.*, *Alternaria spp.*, *Botrytis cinerea* or any other fungal or microbial pathogens to terpene compounds.

d) Cross resistance

The mode of action of eugenol, geraniol and thymol is different to that of any other existing group of pesticides and there is no known cross resistance.

e) Sensitivity data

No specific data on storage diseases are available.

f) Use pattern

The use pattern for Mevalone will be limited by factors other than the risk of resistance. Factors such as optimum application timings with respect to preventative and curative control and disease pressure will affect the use pattern for Mevalone. However, it is proposed that the likelihood of resistance de-

veloping to the terpene compounds, including eugenol, geraniol and thymol as the active ingredients of Mevalone, is low because of the relatively basic mode of action and low specificity of the site of action. Therefore, the proposed label usage instructions will dictate the optimum use pattern in the absence of resistance.

g) Resistance risk assessment of unrestricted use pattern

Botrytis cinerea (*Botryotinia fuckeliana*) and *Penicillium spp.* are rated as high risk in terms of the development of resistance to fungicides (EPPO 2002, FRAC Monograph No. 3, Russell, 2003). Terpenes are not yet widely used as fungicides in agricultural crops and as such they are not specifically included in the FRAC list of fungicide groups rated for risk of resistance developing. However, based on the mode of action and the absence of reported cases of resistance to terpenes or related compounds, it is proposed that the risk of resistance developing is low. Taking the resistance risk classification for the active substances in Mevalone to be low and the pathogen, that it controls, to be high, this gives an overall fungicide/pathogen combined resistance risk score for Mevalone against *Botrytis cinerea* (*Botryotinia fuckeliana*) and *Penicillium spp.* of 3. (Kuck K. H., “Fungicide Resistance Management in a New Regulatory Environment”, in the Proceedings of the Reinhardtbrunn Symposium 2004; Modern fungicides and antifungal agents, Dehne, Gisi, Kuck, Russell, eds., BCPC 2005). This equates to an ‘unrestricted use pattern’ posing a medium resistance risk.

Monilinia spp. is rated as medium risk in terms of the development of resistance to fungicides. This gives an overall fungicide/pathogen combined resistance risk score for Mevalone against *Monilinia spp.* of 2.

Alternaria spp., *Fusarium spp.* and *Phytophthora spp.* are rated as low risk in terms of the development of resistance to fungicides. This gives an overall fungicide/pathogen combined resistance risk score for Mevalone against those fungi of 1.

h) Acceptability of the resistance risk

The use pattern for Mevalone is restricted to that of a maximum of four applications per season at the proposed recommended rate of 4L/ha. Whilst the risk of resistance developing for *Botrytis cinerea* (*Botryotinia fuckeliana*) and *Penicillium spp.* is high, the likelihood of resistance developing to terpene compounds is low. Other storage disease pathogens have low or medium risk of resistance developing.

Therefore the overall risk of resistance developing is moderate and is considered acceptable.

i) Management strategy

The risk of resistance developing is acceptable and does not require a specific management strategy, other than the monitoring and reporting of changes in performance.

j) Monitoring, reporting and reaction to changes in performance

Eden Research plc / Sumi Agro France will inform the regulatory authorities of any confirmed occurrence of resistance regarding Mevalone.

Comments of zRMS on:

Information on the occurrence or possible occurrence of the development of resistance (3.3)

Biofungicide Mevalone contains 3 active substances of natural origin: eugenol (33.0 g/L), geraniol (66.0 g/L) and thymol (66.0 g/L) belonging to terpenes group (FRAC code: BM 01; previously F7). Terpenes have been described as biologicals (plant extracts) with multiple modes of action affecting on spore germination, hyphal penetration, mycelial growth and hyphal growth. These compounds affect on cell walls, membranes and organelles of microorganisms. The main action is destruction of cell membranes resulting in leakage of cellular substances leading to cell death. Currently, no cases of resistance have been described to terpenes. Due to no activity at a very specific site it is considered unlikely that fungi would develop resistance to terpenes. Resistance risk to terpenes has been considered as low. As target pathogens *Botrytis cinerea*, *Penicillium spp.* belongs to high risk

of resistance pathogens, *Monilia* spp. is a medium risk of resistance pathogen and *Alternaria* spp., *Fusarium* spp., *Phytophthora* spp are classified as low risk of resistance development pathogens, the overall fungicide/pathogen combined risk of resistance for Mevalone is considered as medium.

Due to no cases of resistance to terpenes, no expectations of resistance development because of no specific site of action, no specific management strategy for Mevalone has been proposed. This is acceptable until any reports of resistance occurrence will be recorded. Monitoring and reporting of any occurrence of resistance is necessary.

3.4 Adverse effects on treated crops (KCP 6.4)

No specific selectivity trials were carried out. In addition, Southern Zone data shows that Mevalone did not cause any phytotoxicity on any of the 26 efficacy trials, 3 processing or 4 vinification trials where observations and assessments were made. (Original EU dossier, submitted to Malta on 01/10/2013. Part B, Section 7).

Nevertheless, phytotoxic symptoms were regularly checked in all trials and yield was calculated in 1 trial in grape and in 4 trials in apple.

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Phytotoxicity to grape

The potential adverse effects towards grape of Mevalone applied up to 2 times were carried out in the 26 efficacy trials conducted from 2006 to 2019 in Austria, Germany, Switzerland, Hungary, Romania and Slovenia. Mevalone was applied from 0.2 to 9.6 L/ha (0.1 to 9.3 L/ha LWA). It was compared to the untreated control and to a reference fungicide. The 2N rate (8 L/ha ground) was tested in 16 trials.

The following 19 cultivars were tested:

Blauburger (1)	Gamay (2)	Juhfark (1)	Kadarka (1)	Muscat blanc (1)
Müller-Thurgau (3)	Olaszrizling (1)	Pinot blanc (1)	Pinot noir (2)	Riesling (1)
Rieseling Sylander (1)	Rózsakő (1)	Sämling (1)	Scheurebe (1)	Schwarzriesling (2)
Schwarzriesling/ Pinot Meunier (2)	Traminer Roz (1)	Weißburgunder (2)	Welschriesling (1)	

Throughout the field phase of all trials, the phytotoxicity on crop was assessed as a visual % of symptoms in comparison with the untreated control, Where 0% = no phyto and 100% = destruction of the crop.

In the 4 Swiss trials, phytotoxicity on crop was assessed using a EWRS 1-9 scale (where 1 = no damage; 2 = very mild symptoms; 3 = mild, but clearly recognizable symptoms; 4 = more severe symptoms, no effect on yield expected; 5 = severe symptoms, effect on yield; 6-9 = heavy damage to total kill).

Visual assessment of the crop vigor using a 0-10 scale or % was also made in several trials.

Results:

No symptoms of phytotoxicity were observed in any trials, at any assessment date and for any treatment. Results are thus not presented here.

Slight and consistent differences in crop vigor were observed throughout the season in 3 trials (S08-02271-02, S08-02271-03 and AF/12263/CN/3). These differences were due to field variation within the trial area and were not treatment related. Results are thus not presented here.

Detailed phytotoxicity assessments for each individual trial are presented in Appendix 5 of BAD document.

In conclusion Mevalone applied on grape according to the recommendations up to 4 L/ha (or 3.2 L/ha LWA) and max. 4 times per season is safe on grape.

Phytotoxicity to apple

The potential adverse effects towards apple of Mevalone applied up to 4 times were carried out in the 19 practical value trials conducted from 2016 to 2019 in France, Germany, Czech Republic, Hungary and Poland. Mevalone was applied within a fungicide program, with or without adjuvant from 3 L/ha to 8 L/ha. It was compared to the untreated control and to a reference fungicide program. The 2N rate was tested in 14 trials.

The following 11 cultivars that are likely to develop storage diseases were tested:

Fuji (2)	Golden (1)	Gloster (1)	Golden delicious (6)
Granny Smith (1)	Idared (1)	Junami (1)	Melrose (1)
Pink Lady (2)	Pinova (1)	Szampion (2)	

Throughout the field phase of all trials, the phytotoxicity on crop was assessed as a visual % of symptoms in comparison with the untreated control, Where 0% = no phyto and 100% = destruction of the crop.

Visual assessment of the crop vigor using a 0-10 scale was also made in several trials.

Russetting at harvest was also assessed in several trials. No russetting was observed.

Results:

No symptoms of phytotoxicity were observed in any trial, at any assessment date and for any fungicide program. Results are thus not presented here. Detailed phytotoxicity assessments for each individual trial are presented in Appendix 5 of BAD document.

In conclusion Mevalone applied on apples in a fungicide program according to the recommendations up to 4 L/ha and max. 4 times per season is safe for apple trees.

Comments of zRMS on:

Phytotoxicity to host crop (3.4.1)

As no phytotoxicity symptoms have been recorded in any efficacy trials carried out in grapevine and apple, it can be concluded that Mevalone can be safely used in these claimed crops.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Yield in Grapevine:

The yield of crop was evaluated in 1 trial carried out in Germany in 2007.

Mevalone was applied 4 times according to the recommendations and up to 1.6N the max. requested rate (i.e.6.4 L/ha).

Yield results are presented in the following table.

Table 0-1: Yield of grape in trial with Mevalone - Germany 2007

Rating Date Crop GS	Variable assessed (unit)	UTC	Test product			Ref product
			Mevalone 1,6 L/ha	Mevalone 3,2 L/ha	Mevalone 6,4 L/ha	SCALA 1 L/ha
21/09/2007 (24 DA last application) BBCH 89	Yield healthy bunches (T/ha)	6.79 a (100%)	7.83 a (115%)	7.65 a (113%)	7.49 a (110%)	7.45 a (110%)
	Yield damaged bunches (T/ha)	1.95 a (100%)	1.51 abc (77%)	0.62 c (32%)	0.45 c (23%)	0.85 bc (43%)
	Yield total (T/ha)	8.74 a (100%)	9.34 a (107%)	8.27 a (95%)	7.94 a (91%)	8.3 a (95%)

In this trial, Mevalone at proposed rates of 1.6 and 3.2 L/ha and at 6.4 L/ha (1.6N the max. requested rate) had no negative effect on total yield. The yield of healthy bunches increased in comparison with the untreated control, but the differences were not statistically significant. The yield of damaged bunches was significantly lower with all tested rates of Mevalone (from 23 to 77% of the untreated control).

Mevalone at all tested rates showed yield results comparable to that of the reference product SCALA. The differences were not statistically significant in any trial.

In conclusion Mevalone applied on grapes according to the recommendations up to 4 L/ha and max. 4 times per season has no negative impact on yield.

Yield in Apple:

The yield of crop was evaluated in 6 out of 19 practical value trials (Poland 2017 to 2019). The impact of Mevalone applied at twice the intended dose rate (8 L/ha) was tested in 4 trials. In all trials Mevalone was applied up to 4 times according to the recommendations.

Yield results are presented in the following table.

Table 0-2: Yield of apples in practical value trials with Mevalone - Poland 2017-2019

Trial ID EPPO zone Country	Year Variety	Date Days after last appl.	Variable assessed (unit)	UTC	Test programs			Reference program	
					(ABDE) Mevalone 3 L/ha + Héliosol 0,2%	(ABDE) Mevalone 3 L/ha + Slippa 0,15%	(A) MERPAN 80 WDG 1,9 kg/ha		
							(C) BELLIS 0,8 kg/ha		
							(E) GEOXE 0,4 kg/ha		
2 trials Mean Yield (%UTC) Min-max				24.0 14.9- 33.0	100% 95-105%	101% 100-102%	98% 96-99%		
Trial ID EPPO zone Country	Year Variety	Date Days after last appl.	Variable assessed (unit)	UTC	Test programs			Reference program	
					(ABDE or BDE) Mevalone 3 L/ha + Slippa 0,2%	(ABDE) Mevalone 4 L/ha	(ABDE) Mevalone 8 L/ha	(A) MERPAN 80 WDG 1,9 kg/ha	
								(C) BELLIS 0,8 kg/ha	
								(E) GEOXE 0,4 kg/ha	
4 trials Mean Yield (%UTC) Min-max				79.0 78.0 66.2- 97.0	103% 101-108%	102% 99-104%	101% 100- 102%	102% 96-111% 100-109% 105%	

In all 6 trials, Mevalone at 3 L/ha + adjuvant, at the proposed rate of 4 L/ha and at double rate of 8 L/ha had no negative effect on yield. Mevalone showed yield results comparable to that of the reference fungicide program. The differences were not statistically significant in any trial.

In conclusion Mevalone applied in a fungicide program on apples according to the recommendations up to 4 L/ha and max. 4 times per season has no negative impact on yield.

Comments of zRMS on:

Effect on the yield of treated plants or plant products (3.4.2)

Due to trial results presented for grapevine (1 trial) and apple (4 trials) it can be concluded that no negative effect of Mevalone on the yield is expected.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

From French agency ANSES conclusions Mevalone (MEVALONE brand) risk on vinification and taint is considered as acceptable. No additional quality and/or vinification trial was run since the submission of the zonal dossier.

In addition, previous results of several vine processing trials showed that Mevalone has no impact on the vine process after treatment on grapes against *Botrytis cinerea*.

As a product based on natural terpene compounds, Mevalone has no MRL (Maximal Residue Limit).

~~As a result, Mevalone applied according to recommendations for the control of storage diseases in apple and *Botrytis cinerea* in grapevine is not expected to have any impact on the quality of plants and plant products.~~

Taint testing

Introduction

Eleven trials in total were conducted during the 2006 and 2007 seasons to generate samples of grapes treated with 3AEY for taint testing and transformation processes.

Two trials were conducted in Greece (1 in 2006 and 1 in 2007) to generate samples of both fresh table grapes for taint testing and grapes for processing to juice and raisins for subsequent taint testing.

Two trials (1 in Portugal and 1 in Spain) were conducted in 2006 to generate samples of grapes for vinification and subsequent taint testing of the wine produced. Of these trials, the one in Spain (AF/10726/ED/2) was harvested by the grower before samples were taken and therefore produced no samples for vinification processes or taint data.

Seven trials (2 in Northern France, 2 in Southern France, 1 in Spain and 2 in Germany) were conducted in 2007 to generate samples of grapes for vinification and subsequent taint testing of the wine produced.

Materials and Methods

Testing facilities or organizations

Three trial series generated samples of grapes treated with 3AEY for taint testing and transformation processes.

All trials carried out in Spain and Portugal were conducted by AGRISEARCH IBERICA S.L, an organisation that was at the time of the trials officially recognised as competent to carry out efficacy testing in accordance with European Commission Directive 93/71/EEC by Orden Ministerial de 20 de septiembre de 1994 and Orden Ministerial de 11 de diciembre de 1995 in Spain and Decreto-Lei no 94/98 de 15 Abril in Portugal.

All trials carried out in France were conducted by AGRISEARCH FRANCE SARL, an organisation that was at the time of the trials officially recognised as competent to carry out efficacy testing in accordance with European Commission Directive 93/71/EEC by the Ministère de l'Agriculture, de la Pêche et de l'Alimentation, sous-direction de la Protection de Végétaux, in the categories of grandes cultures, arboriculture, viticulture, cultures légumières, triatement de semences et désherbage des zones non cultivées.

All trials carried out in Greece were conducted by AGROUNIT or AGROLAB, organisations that were at the time of the trials officially recognised as competent to carry out efficacy testing in accordance with European Commission Directive 93/71/EEC and 91/414/EEC, as it was embodied in to the Greek Legislation with the decision Π.Δ.115/97 (ΦΕΚ 104/30-5-97) and all updating amendments.

All trials carried out in Germany were conducted by GAB Biotechnologie GmbH, an organisation that was at the time of the trials officially recognised as competent to carry out efficacy testing in accordance with European Commission Directive 93/71/EEC by Regierungspräsidium Karlsruhe - Pflanzenschutzdienst.

The following Table 3.4-1 shows a complete list of all the trials used to generate samples of grapes treated with 3AEY for taint testing and transformation processes.

Table 3.4-1 Trial sites and application details in summary form for trials to generate samples of grapes treated with 3AEY for taint testing and transformation processes

Test report (year of trial)	Testing Unit	Trial location EPPO climatic zone	Test Methods Plot size Sample size	Application details			Remarks
				Method	Equipment	Crop GS (BBCH)	
AF/10726/ED/1 (2006)	AGRISEACH IBERICA S.L Zona Industrial da Lagoa, Cortes (porta 3), 4950-850 Monção, Portugal Tel: +35 251 654 403	Monção, Viana do Castelo, Portugal Post Code 3221 Latitude 42° 02' 19'' N, Longitude 08° 01' 38'' W Mediterranean zone	EPPO PP 1/152(2), PP 1/181(2), PP 1/242(1), CEB Method no. 143 3 x 60m (split into 3 sub-plots)	Directed spray applica- tion	Mistblower knapsack sprayer	A – 73-75 B – 75-77 C – 76-77 D – 78-79 E – 82-83 F – 83-84 G – 84-85 H – 85-87 I – 87-88 J – 88-89	Application volumes A – 729 l/ha B – 960 l/ha C – 978 l/ha D to J – 1000 l/ha Variety – Alvarinho (white wine production for taint testing)
AF/10726/ED/2 (2006)	AGRISEARCH IBERICA S.L Poligono de Malpica, Grupo Gregorio Quejido, C/F Oeste Nave 68, 50016 Zaragoza, Spain Tel: +34 976 588 585	Calatorao, Zaragoza, Spain Post Code 50280 Latitude 41° 31' 18'' N, Longitude 01° 20' 42'' W Mediterranean zone	EPPO PP 1/152(2), PP 1/181(2), PP 1/242(1), CEB Method no. 143 2.9 x 84m (split into 3 sub-plots)	As above	As above	A – 75-77 B – 77-79 C – 77-79 D – 79-81 E – 81 F – 81-83 G – 83 H – 83-85 I – 83-85 J – 83-85	Application volumes A to J – all 1000 l/ha Variety – Garnacha (red wine variety) Samples not taken and no taint data generated. Only crop safety data
AF/10726/ED/3 (2006)	AGROUNIT Co 1, Goula G.str Larissa 41222 Greece Tel: +30 2410 670 133	Tirnavos, Larissa, Greece Latitude 39° 42' 34'' N, Longitude 22° 18' 00'' W Mediterranean zone	EPPO PP 1/152(2), PP 1/181(2), PP 1/242(1), CEB Method no. 143 2 x 66m (split into 3 sub-plots)	As above	Hydraulic knapsack sprayer	A – 77 B – 79 C – 81 D – 81 E – 81 F – 83 G – 83 H – 83 I – 83 J – 85	Application volumes A to J – all 800 l/ha Variety – Moschato (table grape variety) Table grape, juice and raisin produced for taint testing
AF/12265/ED/1 (2007)	AGROLAB GR-570 22 Sindos Thessalonika Greece Tel: +30 2310 797 479	Kato Milia, Pieria, Greece Post Code GR-60100 Mediterranean zone	EPPO PP 1/152(3), PP 1/181(3), PP 1/242(1) 7.2 x 10.15m, 3 reps	As above	As above	A – 83 B – 85 C – 85 D – 87 E – 87-89	Application volumes A to J – all 1000 l/ha Variety – Muschat (table grape variety) Table grape, juice and raisin produced for taint testing
AF/12267/ED/1	AGRISEARCH FRANCE	Gertwiller, Alsace, France	EPPO	As above	Mistblower	A – 85	Application volumes

Test report (year of trial)	Testing Unit	Trial location EPPO climatic zone	Test Methods Plot size Sample size	Application details			Remarks
				Method	Equipment	Crop GS (BBCH)	
(2007)	SARL Les Herbonnes 82290 MEAUZAC France Tel: +33 563 31 51 85	Post code 67140 Latitude 48° 42' 11" N, Longitude 07° 46' 49" W Maritime zone	PP 1/152(3), PP 1/181(3), PP 1/242(1) CEB Method no. 143 3 x 10m, 3 reps		sprayer	B – 85 C – 85 D – 85-89 E – 85-89	A to E – all 120 l/ha Variety – Sylvaner (white wine production for taint testing). Treatments applied at 4 timings (A-D or B-E)
AF/12267/ED/2 (2007)	As above	Lue en Bugeois, Maine et Loire, France Post code 49140 Latitude 47° 31' 35" N, Longitude 00° 15' 21" W Maritime zone	EPPO PP 1/152(3), PP 1/181(3), PP 1/242(1) CEB Method no. 143 5.25 x 11m, 3 reps	As above	Knapsack sprayer	A – 81 B – 83 C – 85 D – 85 E – 87	Application volumes A to E – all 120 l/ha Variety – Cabernet franc (red wine production for taint testing). Treatments applied at 4 timings (A-D or B-E)
AF/12267/ED/3 (2007)	As above	Le Verdier, Tarn, France Post Code 81140 Latitude 44° 00' 24" N, Longitude 01° 49' 46" W Mediterranean zone	EPPO PP 1/152(3), PP 1/181(3), PP 1/242(1) CEB Method no. 143 4 x 10m, 3 reps	As above	Mistblower sprayer	A – 83 B – 83 C – 83 D – 85 E – 85	Application volumes A to E – all 120 l/ha Variety – Len de L'el (white wine production for taint testing). Treatments applied at 4 timings (A-D or B-E)
AF/12267/ED/4 (2007)	As above	Le Verdier, Tarn, France Post Code 81140 Latitude 43° 59' 56" N, Longitude 01° 49' 45" W Mediterranean zone	EPPO PP 1/152(3), PP 1/181(3), PP 1/242(1), CEB Method no. 143 6.9 x 10m, 3 reps	As above	As above	A – 83 B – 83 C – 85 D – 85 E – 85	Application volumes A to E – all 120 l/ha Variety – Cabernet (red wine production for taint testing). Treatments applied at 4 timings (A-D or B-E)
AF/12267/ED/5 (2007)	Agriseach IBERICA S.L Poligono de Malpica Grupo Gregorio Quejido C/F Oeste Nave 68 50016 Zaragoza Spain Tel: +34 976 588 585	El Buste, Aragon, Spain Post Code 50548 Latitude 41° 52' 01" N, Longitude 01° 36' 23" W Mediterranean zone	EPPO PP 1/152(3), PP 1/181(3), PP 1/242(1), CEB Method no. 143 9 x 8.4m, 3 reps	As above	As above	A – 79-83 B – 81-85 C – 81-85 D – 83-85 E – 83-85	Application volumes A – 700 l/ha B – 698 l/ha C to E – 700 l/ha Variety – Garnacha (red wine production for taint testing). Treatments applied at 4 timings (A-D or B-E)
AF/12267/ED/6 (2007)	GAB Biotechnologie GmbH 75223 Niefern-öschelbronn Eutingen Straße 24	Malsch, Baden-Württemberg, Germany Post code 69254	EPPO PP 1/152(3), PP 1/181(3),	As above	Solo Mistblower sprayer	A – 81 B – 83 C – 85	Application volumes A to E – all 600 l/ha Variety – Müller-Thurgau

Test report (year of trial)	Testing Unit	Trial location EPPO climatic zone	Test Methods Plot size Sample size	Application details			Remarks
				Method	Equipment	Crop GS (BBCH)	
	21684 Stade Carl-Goerdeler-Weg 3	Latitude 49° 25' 47" N, Longitude 08° 69' 27" W Maritime zone	PP 1/242(1), CEB Method no. 143 4 x 24m, 3 reps			D – 87 E – 85	(white wine production for taint testing). Treatments applied at 4 timings (A-D or B-E)
AF/12267/ED/7 (2007)	As above	Weistadt, Baden- Württemberg, Germany Post code 71384 Latitude 49° 79' 81" N, Longitude 09° 37' 45" W Maritime zone	EPPO PP 1/152(3), PP 1/181(3), PP 1/242(1), CEB Method no. 143 2 x 18m, 3 reps	As above	Stihl Mistblower sprayer	A – 85 B – 85-89 C – 85-89 D – 85-89 E – 89	Application volumes A to E – all 800 l/ha Variety – Dornfelder (red wine production for taint testing). Treatments applied at 4 timings (A-D or B-E)

Sites

Trials were conducted in Greece, Spain, Portugal, France and Germany. All trials were conducted in representative vine growing regions of each country. All trials included in this Biological Assessment Dossier were located within the Mediterranean and Maritime zones as defined by EPPO Standard PP 1/241(2).

Standard methodologies

The design, analysis of results and reporting of taint testing studies were carried out in accordance with EPPO guidelines PP 1/152(2 or 3) Design & analysis of efficacy evaluation trials and PP 1/181(2 or 3) Conduct and reporting of efficacy evaluation trials. The conduct of the fieldwork, transformation processes and taint tests was commensurate with local 'Good Agricultural Practice' and in accordance with EPPO guidelines PP 1/242(1) Taint tests and/or CEB Method no. 143 Méthode d'étude des effets non intentionnels des produits phytopharmaceutiques sur l'élaboration et la qualité des vins et eaux de vie.' (Study method to evaluate the non-intended effects of agrochemical products on processing and quality of wine and brandies).

There were no significant deviations from the EPPO guidelines.

Taint testing was carried out in accordance with AFNOR, Sensory analysis. Methodology. Triangle test, Standard NF V 09-013, Agence française de normalisation, 1976 or ISO 4120:2004 equivalent.

Experimental design

All trials were conducted with either unreplicated plots split into 3 sub-plots or in a randomised complete block design with three replicates and plot size ranged from 2 to 3m wide by 60 to 84m long (range 132m² - 244m²) in the unreplicated trials and from 2 to 9m wide by 8.4 to 24m long (range 30m² - 96m²) in the replicated trials.

Treatments: Formulations applied and application rates

A list of products applied in all trials carried out to generate samples for taint testing is shown in Table 3.4-2.

Treatments involving the application of 3AEY with a wetting agent were included in some trials studies but data from these treatments is not included in this dossier as there are no claims for the application of 3AEY with a wetting agent on the proposed label.

Table 3.4-2 Formulations included in trials to generate samples for taint testing and transformation processes

Product	Authorisation Number(s)	Active substance	Active substance content	Formulation type
3AEY	-	Eugenol + geraniol + thymol	33.0 g as/l + 66.0 g as/l + 66.0 g as/l	CS

Details of application rates and timings applied in all trials to generate samples for taint testing and transformation processes are shown in

Table 3.4-3.

Table 3.4-3 Rates and timings of applications of 3AEY in trials to generate samples for taint testing and transformation processes

Trial reference numbers	Product	Application timings – growth stage (BBCH) / intervals	Application rate	
			g as/hl or g as/ha	Product/hl or product/ha
Study no. AF/10726/ED Trials 1-3	Co-operator treatments#	Commercial	-	-
	3AEY-L (eugenol + geraniol + thymol)	A = 73-77 B = A + 7-10 days C = B + 7-10 days D = C + 7-10 days E = D + 7-10 days F = E + 7-10 days G = F + 7-10 days H = G + 7-10 days I = H + 7-10 days J = I + 7-10 days	25.6 + 51.2 + 51.2/hl	800 ml/hl
Study no. AF/12265/ED Trial 1	Co-operator treatments#	Commercial	-	-
	3AEY (eugenol + geraniol + thymol)	B = 24 days pre-harvest C = B + 7 days D = C + 7 days E = D + 7 days	12.8 + 25.6 + 25.6/hl	400 ml/hl
	3AEY (eugenol + geraniol + thymol)	A = 31 days pre-harvest B = A + 7 days C = B + 7 days D = C + 7 days	12.8 + 25.6 + 25.6/hl	400 ml/hl
Study no. AF/12267/ED Trials 1-4	Co-operator treatments#	Commercial	-	-
	3AEY (eugenol + geraniol + thymol)	B = 28 days pre-harvest C = B + 7 days D = C + 7 days E = D + 7-8 days	128 + 256 + 256/ha	4.0 l/ha
	3AEY (eugenol + geraniol + thymol)	A = 35 days pre-harvest B = A + 7 days C = B + 7 days D = C + 7 days	128 + 256 + 256/ha	4.0 l/ha
Study no. AF/12267/ED Trial 5-7	Co-operator treatments#	Commercial	-	-
	3AEY (eugenol + geraniol + thymol)	B = 28 days pre-harvest C = B + 7 days D = C + 7 days E = D + 7 days	12.8 + 25.6 + 25.6/hl	400 ml/hl
	3AEY (eugenol + geraniol + thymol)	A = 35 days pre-harvest B = A + 7 days C = B + 7 days D = C + 7 days	12.8 + 25.6 + 25.6/hl	400 ml/hl

- The treatment used to generate samples for taint tests and transformation processes, as a comparison to that treated with 3AEY, was sprayed with a programme of commercial fungicide products as applied by the grower to the rest of the vineyard. These products were applied as per the label recommendations

Climate during trials

The climate during all trials was within the normal range for the area in which they were conducted.

Application methods

Applications to all trials were made using hydraulic knapsack or airblast sprayers with a single nozzle to represent or simulate commercial application.

On trials carried out in Greece, Spain, Portugal and Germany, applications were made in a spray volume of between 600 and 1000 l/ha, to achieve good coverage, based on the size of the vines. On trials carried out in France, applications were made in a spray volume of 120 l/ha, with the spray specific-

ly targeted at the bunches. Full details, together with information on crop growth stage, weather and temperature at application for all trials are shown in Appendix 5.

Sampling methods

Details of sampling dates and crop growth stages for all trials to generate samples for taint and transformation processes are provided in Table 3.4-4. Additional information is shown in the following text.

On trials to generate samples of fresh table grape and grapes for transformation to juice and raisins, a minimum of 7kg of grapes were sampled from each of the 3 sub-plots or replicate plots, kept cool and despatched to the processing/taint testing facility within 48 hours.

On trials to generate samples of grape for vinification and subsequent wine taint testing, a minimum of 20 kg, 25 kg or 30 kg of grapes were sampled from each of the 3 sub-plots or replicate plots, kept cool and despatched to the processing facility for vinification within 48 hours of sampling. From trials AF/12267/ED/1, 2, 3, 4 and 5 only, an additional minimum 1.0 kg sample of grapes was taken for freezing and maturity control.

Table 3.4-4 Details of sampling timings on trials carried out to generate samples of grapes for taint testing and transformation processes following the application of 3AEY

Trial number	Sample timing	Sampling date	Timing ^a	Crop growth stage (BBCH)	Taint tests
AF/10726/ED/1	S4	25 Sep 06	14 DALA	89-90	White wine
AF/10726/ED/3	S2	07 Sep 06	3 DALA	87-89	Table grape Juice Raisin
	S4	18 Sep 06	14 DALA	87-89	Table grape Juice Raisin
AF/12265/ED/1	S1	19 Sep 07	2 DALA	89	Table grape Juice Raisin
	S2	24 Sep 07	7 DALA	89	Table grape Juice Raisin
			14 DALA	89	Table grape Juice Raisin
AF/12267/ED/1	S1	04 Sep 07	7 DALA	89	White wine
			14 DALA	89	White wine
AF/12267/ED/2	S1	04 Oct 07	7 DALA	89	Red wine
			14 DALA	89	Red wine
AF/12267/ED/3	S1	08 Oct 07	7 DALA	89	White wine
			14 DALA	89	White wine
AF/12267/ED/4	S1	16 Oct 07	7 DALA	89	Red wine
			15 DALA	89	Red wine
AF/12267/ED/5	S1	15 Oct 07	7 DALA	89	Red wine
			14 DALA	89	Red wine
AF/12267/ED/6	S1	03 Sep 07	7 DALA	89	White wine
			14 DALA	89	White wine
AF/12267/ED/7	S1	17 Sep 07	7 DALA	89	Red wine
			14 DALA	89	Red wine

^a DALA – Days after last application

Processing methods

Juice

Samples of grapes were taken at harvest from Trial AF/10726/ED/3 (2006) and Trial AF/12265/ED/1 (2007) to produce juice for taint testing. Juice was produced by placing the samples of grape in heavy duty bags and applying mechanical pressure until a set amount of juice has been extracted, dependent on the amount of grapes. The amount of juice is then measured and then transferred into glass bottles.

Raisins

Samples of grapes were taken at harvest from Trial AF/10726/ED/3 (2006) and Trial AF/12265/ED/1 (2007) to produce raisins for taint testing. Artificial drying methods were used to produce the raisins, whereby the grapes were oven dried at 40°C. Samples of berries were weighed prior to placing in the oven, then checked and mixed regularly to ensure homogeneous drying. Once the berries have the typical appearance of raisins, they are weighed to check the process is complete, which is when they have lost two thirds of their original weight.

Wine

Details of the transformation methods used for the production of wine from grapes sampled from the trials are given in Section "3.4.4 Effects on transformation processes".

Taint testing methods

For all taint tests on fresh table grapes, juice, raisins and wine the three cornered, triangle test (ISO 4120:2004) was used. Under controlled conditions, each assessor is presented with three coded samples, two the same and one different (either treated with commercial standard products or with 3AEY) and asked to identify the different sample and the two samples that are the same, based on flavour (including odour).

For wines produced from grapes sampled from trials, two taint testing were carried out, the first a few weeks after bottling and the second approximately a year later.

In tests on fresh grapes, juice and raisins, a team of 16 assessors was used for all taint tests on samples from Trial AF/10726/ED/3 and a team 12 assessors was used for all taint tests on samples from Trial AF/12265/ED/1. In tests on wine, a team of 16 assessors was used for all taint tests on samples of wine produced from Trial AF/10726/ED/1 and teams of 5-13 assessors were used for all taint tests on samples of wine produced from the 7 trials of series AF/12267.

Statistical analysis

Taint test data was analysed according to statistical methods in AFNOR V-09 013 / ISO 4120:2004 to determine whether or not any two samples were significantly different at the 95% probability level.

Summary and evaluation of individual trials results – taint tests on table grapes, juice, raisins and wine following the application of 3AEY in grapevine

Fresh table grapes

Trial AF/10726/ED/3

On one trial carried out in the 2006 season in Greece, 10 applications of 3AEY” applied at 800 ml/hl (in 800 l/ha = 6.4 l/ha) were made at 7-10 day intervals. 3AEY” caused no perceivable significant difference in the taste of fresh table grapes sampled 3 or 14 days after the last application, compared to those sampled from crop sprayed with a programme of standard commercial products.

Therefore, when applied as per proposed label recommendations, with up to 4 applications at a rate up to 4 l/ha and with a 7 day minimum pre-harvest interval following the last application, 3AEY should not taint the taste of fresh table grapes.

Trial AF/12265/ED/1

On one trial carried out in the 2007 season in Greece, 4 applications of 3AEY, applied at 400 ml/hl (in 1000 l/ha = 4 l/ha), were made at 7 day intervals. 3AEY gave perceivable differences in the taste of fresh table grapes sampled 2 days after the last application in all 3 replicate tests, compared to those sampled from crop sprayed with a programme of standard commercial products. On grapes sampled 7 and 14 days after the last application, no significant differences were perceived in the taste of grapes treated with 3AEY compared to those sampled from crop sprayed with a programme of standard commercial products.

Therefore, when applied as per proposed label recommendations, with up to 4 applications at a rate up to 4 l/ha and with a 7 day minimum pre-harvest interval following the last application, 3AEY did not taint the taste of fresh table grapes.

Juice

Trial AF/10726/ED/3

Following ten applications of 3AEY, applied at 800 ml/hl (in 800 l/ha = 6.4 l/ha), there were no perceivable significant differences in the taste of juice produced from grapes sampled 3 and 14 days after the last application, compared to that produced from grapes sampled from crop sprayed with a programme of standard commercial products.

Therefore, when applied as per proposed label recommendations, with up to 4 applications at a rate up to 4 l/ha and with a 7 day minimum pre-harvest interval following the last application, 3AEY should not taint the taste of grape juice.

Trial AF/12265/ED/1

Following 4 applications of 3AEY, applied at the rate of 400 ml/hl (in 1000 l/ha = 4 l/ha), there were no perceivable significant differences in the taste of juice produced from grapes sampled 3 and 14 days after the last application, compared to that produced from grapes sampled from crop sprayed with a programme of standard commercial products.

Therefore, when applied as per proposed label recommendations, with up to 4 applications at a rate up to 4 l/ha and with a 7 day minimum pre-harvest interval following the last application, 3AEY did not taint the taste of grape juice.

Raisins

Trial AF/10726/ED/3

Following ten applications of 3AEY applied at 800 ml/hl (in 800 l/ha = 6.4 l/ha), differences in the taste of raisins produced from grapes sampled 3 days after the last application were perceived in all 3 replicate tests, compared to those sampled from crop sprayed with a programme of standard commercial products. The nature of the differences was identified but were not necessarily adverse taint. On grapes sampled 14 days after the last application, no significant differences were perceived in the taste of raisins produced from grapes treated with 3AEY.

From the results of this trial, 3AEY applied as per proposed label recommendations, with up to 4 applications at a rate up to 4 l/ha and with a 7 day minimum pre-harvest interval following the last application, should not taint the taste of raisins.

Trial AF/12265/ED/1

Following 4 applications of 3AEY, applied at the rate of 400 ml/hl (in 1000 l/ha = 4 l/ha), differences in the taste were perceived in all 3 replicate tests on raisins produced from grapes sampled 2 and 7 days after the last application and in 2 of the 3 replicate tests on raisins produced from grapes sampled 14 days after the last application, compared to those produced from grapes sampled from crop sprayed

with a programme of standard commercial products. The nature of the differences were not recorded but were not necessarily adverse taint.

On this trial 3AEY applied as per proposed label recommendations, with up to 4 applications at a rate up to 4 l/ha and with a 7 day minimum pre-harvest interval following the last application, affect the taste of raisin.

Due to differences in taste detected, the following label warning relating to the use of 3AEY on grapes for raisin production is proposed;

“Use on crops for raisin production; when applied close to harvest 3AEY may affect the taste of raisins produced from treated crops”.

Wine

Trial AF/10726/ED/1

On one trial carried out in Portugal in the 2006 season, 10 applications of 3AEY, at a rate of 800 ml/hl (in 1000 l/ha = 8 l/ha), which is twice the maximal proposed label rate, were made at 7-10 day intervals. 3AEY caused no perceivable significant difference in the taste of wine produced from grapes sampled 14 days after the last application, compared to that produced from grapes where the crop was sprayed with a programme of standard commercial products, either 3-4 months or 13 months after bottling.

Therefore, when applied as per proposed label recommendations, with up to 4 applications at a rate up to 4 l/ha and with a 7 day minimum pre-harvest interval following the last application, 3AEY should not cause taints of wine.

Trials AF/12267/ED/1 and AF/12267/ED/2

On trials 12267/ED/1 and 12267/ED/2 carried out in Northern France in the 2007 season, 4 applications of 3AEY, at a rate of 4 l/ha in a water volume of 120 l/ha, were made at 7 day intervals. The applications were made according to two different programmes, one with a 7 day and the other a 14 day interval between the last application and harvest. Before applications with the test product, a usual farmer fungicide protection programme was applied throughout the season.

In trial 12267/ED/1 (white wine), significant differences were detected between the taste of the reference and samples treated with 3AEY. At the tasting conducted 3 months after bottling, 10 out of 10 assessors correctly distinguished the samples with the 7 day PHI from the control, having a preference for the 3 AEY treatment in 6 out of 10 cases. No significant difference was detected between the reference and samples treated with 3AEY with a 14 day PHI, when only 6 out of 10 assessors correctly identified the samples.

The differences in taste were correlated with differences in must analyses (see section "3.4.4 Effects on transformation processes"). The cause of these differences was not explained but all wine samples were noted as being of poor quality because of the lack of maturity of the harvest. The applications of 3AEY in this trial were also made in a much lower water volume, only 120 l/ha compared to the proposed 400-1000 l/ha, so that the product was much more concentrated. No differences in taste were found at the tasting conducted 12 months after bottling with only 5 out of 13 assessors correctly identifying the samples for both 7 and 14 days PHI.

In trial 12267/ED/2, 3AEY caused no perceivable differences in the taste of red wine produced from grapes sampled 7 or 14 days after the last application, compared to the untreated control, either 3 months or 12 months after bottling.

Trials AF/12267/ED/3 and AF/12267/ED/4

On two trials carried out in Southern France in the 2007 season, 4 applications of 3AEY, at a rate of 4 l/ha in a water volume of 120 l/ha, were made at 7 day intervals. The applications were made ac-

cording to two different programmes, one with a 7 day and the other a 14 day interval between the last application and harvest. Before applications with the test product, a usual farmer fungicide protection programme was applied throughout the season.

In trial 12267/ED/3 significant differences were detected in the taste of the control and samples treated with 3AEY. At the tasting conducted 12 months after bottling, 5 out of 6 assessors correctly distinguished the samples with the 7 day PHI from the control. With the 14 day PHI, all six assessors correctly distinguished the samples. All the wine samples were rated as 'flawless' and none were considered tainted.

The differences in taste were almost certainly a result of differences in the quality of the grapes harvested. The control sample had a high incidence (30%) of damaged berries compared to the two treated samples (5%). This resulted in differences in initial sugar content and pH, which led to differences in the must quality. The differences in taste are not therefore a result of tainting but of enhanced grape quality resulting from protection of the berries. These results of the grape, must and wine analyses are presented in section "3.4.4 Effects on transformation processes".

In trial 12267/ED/4 a significant difference was detected at the tasting conducted 3 months after bottling, between the taste of the control and samples treated with 3AEY with a 7 day PHI, with 4 out of 5 assessors correctly identifying the samples. No difference was detected between the control and samples treated with 3AEY with a 14 day PHI, when only 3 out of 5 assessors correctly identified the samples. The differences in taste were correlated with differences in berry and must analyses (see section "3.4.4 Effects on transformation processes"). The cause of these differences was not explained but all wine samples were noted as being of good quality and the report from the assessment stated that the test products did not produce a blemish or affect the quality of the wine. The applications of 3AEY in this trial were also made in a much lower water volume, only 120 l/ha compared to the proposed 400-1000 l/ha, so that the product was much more concentrated. No differences in taste were found at the tasting conducted 12 months after bottling with only 4 out of 7 assessors correctly identifying the samples.

In these trials the 4.0 l/ha application rate, combined with the low application volume and targeting of the spray at the bunches represents a case where the amount of 3AEY applied to the actual grapes is higher than when applied as proposed on the label. Therefore, when applied as per proposed label recommendations, with up to 4 applications at a rate of 400 ml/hl and with a 14 day minimum pre-harvest interval following the last application, 3AEY should not cause taints of wine.

Trial AF/12267/ED/5

On one trial carried out in Spain in the 2006 season, 4 applications of 3AEY, at a rate of 400 ml/hl (in 700 l/ha = 2.8 l/ha), were made at 7 day intervals. The applications were made according to two different programmes, one with a 7 day and the other a 14 day interval between the last application and harvest.

3AEY caused no perceivable differences in the taste of white wine produced from grapes sampled 7 or 14 days after the last application, compared to that produced from grapes where the crop was sprayed with a programme of standard commercial products, either 3 months or 12 months after bottling.

Therefore, when applied with up to 4 applications at a rate of 2.8 l/ha and with a 7 day minimum pre-harvest interval following the last application, 3AEY did not cause taints of wine.

Trials AF/12267/ED/6 and AF/12267/ED/7

On trials 12267/ED/6 and 12267/ED/7 carried out in Germany in the 2007 season, 4 applications of 3AEY at a rate of 400 ml/hl in a water volume of respectively 600 and 800 l/ha corresponding to respectively 2.4 and 3.2 l/ha, were made at 7 day intervals. The applications were made according to two different programmes, one with a 7 day and the other a 14 day interval between the last application and harvest.

In trials 12267/ED/6 and 12267/ED/7, 3AEY caused no perceivable differences in the taste of white wine and red wine produced from grapes sampled 7 or 14 days after the last application, compared to that produced from grapes where the crop was sprayed with a programme of standard commercial products, either 1 month or 12 months after bottling.

Therefore, when applied with up to 4 applications at a rate of 2.4 or 3.2 l/ha and with a 7 day minimum pre-harvest interval following the last application, 3AEY did not cause taints of wine.

Conclusions on taint test

In the two trials carried out in the 2006 and 2007 seasons in Greece, 3AEY applied at, or above, the maximum number of timings and application rate as proposed on the label did not cause perceivable differences in the taste of fresh table grapes or juice produced from grapes, when sampled 14 days after the last application.

In the two trials carried out in the 2006 and 2007 seasons in Greece, 3AEY caused taints of raisins, including those produced from grapes sampled 14 days after the last application on one trial. Therefore the statement “when applied close to harvest 3AEY may affect the taste of raisins produced from treated crops” is included on the label.

In the eight trials carried out in the 2006 and 2007 seasons in France, Portugal, Spain and Germany, 3AEY applied at, or above, the maximum number of times and application rate as proposed on the label differences in tastes of wines were detected between the control samples and those treated with 3AEY in three of the trials. However, these were not considered as adverse taints. In the one trial in which taste differences were noted at the final tasting these differences were a result of far lower numbers of damaged berries being present in the 3AEY treated samples than the control and can therefore be attributed to the enhanced disease control of 3AEY. In the other two trials in which taste differences were recorded these were also related to grape quality.

Therefore, 3AEY applied as recommended in the GAPs, with up to 4 applications at 4 l/ha, in water volumes of 400-1000 l/ha and between crop growth stages BBCH 60-89 does not cause taints of fresh table grapes, juice or wine. No undesirable taint was noted for fresh table grapes, but at 2 days after application there was a perceivable difference in taste (not taint). At 7 days after application there was no perceivable difference in taste. For this reason the PHI in table grapes is set at 7 days.

Comments of zRMS on: Effect on the quality of plants or plant products (3.4.3)

~~Due to the data submitted by the applicant it can be concluded that no negative effect of Mevalone on the quality of plants and plant products is expected.~~

Based on the submitted trial results and possible adverse effect of Mevalone on taste of raisins produced from treated crops, additional remark is recommended to be included in the product label: “when applied close to harvest, 3AEY may affect the taste of raisins produced from treated crops”

3.4.4 Effects on transformation processes (KCP 6.4.4)

~~The apples used for transformation processes are not concerned by storage disease.~~

~~On grape,~~ As a product based on natural terpene compounds, Mevalone has no established MRL (Maximal Residue Limit) so no additional transformation process trials were carried out. As it was stated in part 3.4.3 previous results of several vine processing trials showed that Mevalone has no impact on the vine process after treatment on grapes against *Botrytis cinerea*. Results from these trials are presented below.

Introduction

Nine trials in total were conducted during the 2006 and 2007 seasons to generate samples of grapes treated with 3AEY for taint testing and transformation processes.

Two trials (1 in Portugal and 1 in Spain) were conducted in 2006 to generate samples of grapes for vinification and subsequent taint testing of the wine produced. Of these trials, the one in Spain (AF/10726/ED/2) was harvested by the grower before samples were taken and therefore produced no samples for vinification processes or taint data.

Seven trials (2 in Northern France, 2 in Southern France, 1 in Spain and 2 in Germany) were conducted in 2007 to generate samples of grapes for vinification and subsequent taint testing of the wine produced.

Materials and Methods

Full details of these trials are reported in Section "3.4.3 Effects on the quality of plants or plant products" including a summary of sites and applications (Table 3.4-1), product formulations used (Table 3.4-2) and treatments and application rates (

Table 3.4-3).

Vinification methods

All trials followed a similar vinification process

Upon receipt of the three samples of 20 kg grapes per treatment, one from each of the 3 sub-plots, in the trial, the percentage of damaged berries was estimated and a sample of 200 berries was taken for determining the refractometric index. Following the bulking of 3 batches per treatment, grapes were pressed and a 50ml sample taken to measure the assimilated nitrogen. Pectolytic enzymes were added (KZYM PLUS of Institut Coopératif du Vin) to the juice (2 g/hl) to facilitate decantation and the juice was sulphited at 5 g/hl or higher, dependent on the health status of the grapes. After a minimum of 12 hours the must was decanted to allow the clear juice to ferment. The must turbidity was measured and made equal for the two different treatment batches by thin must deposit addition. Following decantation, alcoholic fermentation was induced by adding yeast (*Saccharomyces cerevisiae*) at a rate of 10 g/hl (Trial AF/10726/ED/1) or 20 g/hl (AF/12267/ED/1, 2, 3, 4, 5, 6 and 7). The process of alcoholic fermentation was followed by regular measurement of density and temperature, the latter being maintained at 18-20°C. A diammonic phosphate addition was made if the assimilating nitrogen amount was below 150 mg/l. At the end of alcoholic fermentation, the wine was sulphited at a rate of 25-50 mg/l. A number of days after the addition of the SO₂, the wine was decanted, fined with isinglass at a rate of 0.1ml/l, clarified by cold storage (minimum 1 month at +5°C), filtered and bottled. At bottling, the SO₂ level was readjusted in order to obtain a free SO₂ level between 25 and 30 mg/l. Bottles were stored at 12°C for up to one year.

Summary and evaluation of individual trials results – Transformation to wine following the application of 3AEY in grapevine

Wine

Trial AF/10726/ED/1

On one trial carried out in Portugal in the 2006 season, 10 applications of 3AEY at a rate of 800 ml/hl (in 1000 l/ha = 8 l/ha), which is twice the maximal proposed label rate, were made at 7-10 day intervals. Grapes for production of wine were sampled 14 days after the last application timing. A summary of the various quantified parameters of the fermentation process and the wine produced are given in Table 3.4-5.

Wine produced from grapes treated with 10 applications of 3AEY at a rate of 8 l/ha, which is twice the maximal proposed label rate, had slightly reduced sulphite levels. This had no effect on fermentation, final wine quality or taste (see "3.4.3 Effects on the quality of plants or plant products") did not affect the kinetics of the fermentation processes, compared to wine produced from grapes where the crop was sprayed with a programme of standard commercial products.

Therefore, when applied with up to 4 applications at a rate of 8 l/ha and with a 14 day minimum pre-harvest interval following the last application, 3AEY does not affect the kinetics of the fermentation processes or the quality of wine.

Trials AF/12267/ED/1, 2, 3 and 4

On four trials carried out in France in the 2007 season, 4 applications of 3AEY at a rate of 4 l/ha in a water volume of 120 l/ha were made at 7 day intervals. A summary of the various quantified parameters of the fermentation process and the wine produced are given in Table 3.4-5.

In these trials the 4.0 l/ha application rate, combined with the low application volume and targeting of the spray at the bunches represents a case where the amount of 3AEY applied to the actual grapes is higher than when applied as proposed on the label.

In trial 12267/ED/1, the berries and must analysis showed that the alcoholic contents were comparable within the treatments but were less than the 9% threshold requested by the CEB method 143. The sug-

ar content was low and the acidity too high, showing a lack of maturity at harvest. The assimilating nitrogen content was low, especially for the reference. A taste difference was also noted between the reference and 3AEY treated samples with a 7 day PHI, but not a 14 day PHI (see "3.4.3 Effects on the quality of plants or plant products"). The cause of these differences was not explained but all wine samples were noted as being of poor quality because of the lack of maturity of the harvest.

In trial AF/12267/ED/3 samples of grapes treated with 3AEY had a significantly lower proportion of damaged berries than did the samples treated with the standard commercial products. Although the nature of the damage was not recorded this is likely to be as a result of effective disease control provided by 3AEY. Irrespective of the reason, the berry damage in the reference sample has clearly had a major impact on berry and wine quality parameters and are clearly not an adverse effect related to the treatment. Although the effects resulted in differences in the taste of the wine, all three samples produced wine of good character see "3.4.3 Effects on the quality of plants or plant products".

In trial AF/12267/ED/3 there were also small differences detected in the must parameters, that resulted in slightly lower alcohol content in the 3AEY treated samples compared to the reference. A taste difference was also noted between the reference and 3AEY treated samples with a 7 day PHI, but not a 14 day PHI (see "3.4.3 Effects on the quality of plants or plant products").

Without disease assessments taken before harvest the cause of these differences was not explained. However, all three samples produced wine of good character. In addition although 3AEY treated samples produced wine of slightly lower alcohol content in this trial, the reverse was true in trial AF/12267/ED/5, where the 3AEY treated samples produced wine with a higher alcohol content than the reference treated samples. This is therefore unlikely to be a direct treatment related effect and the differences cannot therefore be considered to be taint.

No clear difference was observed regarding the berries, must analysis and fermentation process in the other two trials AF/12267/ED/2 and AF/12267/ED/4.

Trial AF/12267/ED/5

On one trial carried out in Spain in the 2006 season, 4 applications of 3AEY, at the proposed label rate of 400 ml/hl (in 700 l/ha = 2.8 l/ha) were made at 7 day intervals. A summary of the various quantified parameters of the fermentation process and the wine produced are given in Table 3.4-5.

Four applications of 3AEY applied at the rate of 400 ml/hl (in 700 l/ha = 2.8 l/ha) with a PHI of 7 or 14 days did not affect the kinetics of the fermentation processes, compared to wine produced from grapes where the crop was sprayed with a programme of standard commercial products. Wine produced from "samples treated with 3AEY produced wine with a slightly higher alcohol content than those treated with the normal commercial programme. Given that other trials, *e.g.* AF/12267/ED/above, showed an opposite effect on alcohol content, this difference is unlikely to be a direct treatment related effect. There was no difference in final wine taste (see "3.4.3 Effects on the quality of plants or plant products"). Similarly, the differences in potassium levels between 3AEY and reference treated samples were smaller with a 7 day pre-harvest interval (PHI) than with a 14 day PHI. This also indicates that these are unlikely to be a direct result of the treatment with 3AEY. Therefore, when applied with up to 4 applications at a rate of 2.8 l/ha and with a 14 day minimum pre-harvest interval following the last application, 3AEY does not affect the kinetics of the fermentation processes.

Trial AF/12267/ED/6 and Trial AF/12267/ED/7

On trials 12267/ED/6 and 12267/ED/7 carried out in Germany in the 2007 season, 4 applications of 3AEY, at a rate of 400 ml/hl in a water volume of respectively 600 and 800 l/ha corresponding to respectively 2.4 and 3.2 l/ha, were made at 7 day intervals. The applications were made according to two different programmes, one with a 7 day and the other a 14 day interval between the last application and harvest.

No difference was observed regarding the fermentation kinetics. In one trial the total acidity in the must was slightly higher with 3AEY compared to the reference, and in both trials the sugar content in the wine was lower with 3AEY, but there was no difference in final wine taste (see "3.4.3 Effects on the quality of plants or plant products").

Conclusions

In one trial in Portugal in 2006, 10 applications of 3AEY at the rate of 800 ml/hl (in 1000 l/ha = 8 l/ha), which is twice the proposed label rate, were made at 7-10 day intervals and had no effect on transformation of grapes into wine.

In one trial in Spain in 2006, 4 applications of 3AEY at the rate of 400 mL/hL (in 700 l/ha = 2.8 l/ha) made at 7 day intervals resulted in wine with a slightly higher alcohol content but no difference in taste.

In four trials in France in 2007, 4 applications of 3AEY at the rate of 4 l/ha in a water volume of 120 l/ha were made at 7 day intervals. Two trials showed differences in the must and at the 3 months tasting, one trial also showed a difference in final wine taste. However, this was not considered to be an adverse change and in the trial in which differences were seen at the final tasting almost certainly due to the higher level of disease control achieved by the 3AEY treatment programme that resulted in a much lower proportion of damage berries.

In two trials carried out in Germany in the 2007 season, 4 applications of 3AEY, at a rate of 400 ml/hl in a water volume of respectively 600 and 800 l/ha corresponding to respectively 2.4 and 3.2 l/ha, were made at 7 day intervals resulted in wine with a slightly lower sugar content but no difference in taste.

Table 3.4-5 Measured parameters of the vinification processes

TRIAL		AF/10726/ED/1		AF/12267/ED3			AF/12267/ED4			AF/12267/ED5		
Parameter	Treat-ment	Ref	P1	Ref	7 day PHI	14 day PHI	Ref	7 day PHI	14 day PHI	Ref	7 day PHI	14 day PHI
Variety		Alvarinho (white)		Len de lel			Cabernet			Garnacha		
Harvest date		25/09/2006		08/10/2007			16/10/2007			16/10/2007		
Start of vinification		26/09/2006		09/10/2007			17/10/2007			17/10/2007		
End of vinification		16/10/2006	13/10/2006	26/10/2007	26/10/2007	26/10/2007	03/11/2007	02/11/2007	02/11/2007	08/11/2007	08/11/2007	08/11/2007
Bottling		08/12/2006		08/12/2007			16/04/2008			16/04/2008		
Grape analysis												
Probable alcohol content		12.80	12.70	13.1	9.9	11.2	13.57	12.27	12.87	12.43	12.60	13.33
Total acidity				2.64	2.77	2.76	3.89	4.71	4.64	4.88	4.63	4.79
pH				3.41	3.23	3.28	3.29	3.24	3.20	3.11	3.12	3.14
% P.G				30%	5%	5%	2%	2%	2%			
Must Parameters												
Sugars	g/L	217.2	217.2	237	193	192	225	215	201	202	202	200
Alcoholic content		12.4	12.4									
Total Acidity		5.1	5.1	2.34	2.98	2.53	3.75	4.73	4.89			
Turbidity (initial)		94	108									
Turbidity (final)		107	106									
Assimilating Nitrogen	mg/L	297.5	325.5	122	71	77	43	48	37	137	167	119
pH		3.2	3.19	3.64	6.44	3.48	3.36	3.25	3.16	3.11	3.19	3.16
Potassium		1500	1630	1400	770	840	1340	940	1320	1420	1230	1320
Wine Parameters												
Alcoholic content	% vol	12.62	12.4	14.53	11.68	11.58	13.84	13.08	12.8	12.52	12.8	13.47
Total Acidity	g/L H ₂ SO ₄	5.5		3.1	3.26	3.25	3.41	3.28	3.29	3.91	3.83	3.74
after de-acidifying		3.5	3.35									
Volatile acidity	g/L H ₂ SO ₄	<0.1	<0.1	0.41	0.35	0.29	0.32	0.21	0.25	0.3	0.26	0.21
SO ₂ Total	mg/L	177	155	132	143	139	75	86	78	55	61	46
Free SO ₂	mg/L	75	64	21	22	22	24	22	22	26	29	24
pH		3.64	3.66	3.66	3.44	3.42				3.18	3.19	3.26
Sugars	g/L	1	0.9	0.81	1.08	0.84	0.86	0.68	0.25	0.55	0.62	0.65
DO 420		0.07	0.06	1.07	0.64	0.69	0.481	0.371	0.403	0.204	0.21	0.248
DO 520							0.775	0.574	0.636	0.387	0.399	0.479
DO 620							0.187	0.137	0.155	0.065	0.065	0.078

	TRIAL	AF/12267/ED1			AF/12267/ED2			AF/12267/ED6			AF/12267/ED7		
Parameter	Treat-ment	Ref	7 day PHI	14 day PHI	Ref	7 day PHI	14 day PHI	Ref	7 day PHI	14 day PHI	Ref	7 day PHI	14 day PHI
Variety		Sylvaner			Cabernet-franc			Müller-Thurgau			Dornfelder		
Harvest date		04/09/2007			04/10/2007			Not reported			Not reported		
Start of vinification		05/09/2007			04/10/2007			06/09/2007			21/09/2007		
End of vinification		27/09/2007	27/09/2007	27/09/2007	16/10/2007	16/10/2007	16/10/2007	18/09/2007	18/09/2007	18/09/2007	08/10/2007	08/10/2007	08/10/2007
Bottling		18/02/2008			27/02/2008			Not reported			Not reported		
Grape analysis													
Probable alcohol content		8.44	9.03	8.70	11.10	11.15	11.15	-	-	-	-	-	-
Total acidity		-	-	-	-	-	-	-	-	-	-	-	-
pH		-	-	-	-	-	-	-	-	-	-	-	-
% damaged berries		<5%	<5%	<5%	<1%	<1%	<1%	-	-	-	-	-	-
Must Parameters													
Sugars	g/L	136	140	137	185	187	190	182.6	184.2	182.7	157.6	154.3	165.1
Alcoholic content		8.1	8.3	8.1	-	-	-	3.7	2.9	3.2	Not measurable	1.1	Not measurable

Total Acidity		7.20	7.26	7.06	5.04	5.10	4.86	7.5	9.3	9.3	8.8	8.6	8.7
Assimilating Nitrogen	mg/L	78	93	89	68	60	60	-	-	-	-	-	-
pH		2.99	3.01	3.00	3.02	2.97	2.99	3.2	3.3	3.4	3.4	3.3	3.1
Potassium		-	-	-	-	-	-	-	-	-	-	-	-
Wine Parameters													
Alcoholic content	% vol or g/L	11.4 %vol	11.4 %vol	11.5 %vol	12.1 %vol	12.2 %vol	12.4 %vol	83.9 g/L	83.9 g/L	84.6 g/L	70.1 g/L	69.2 g/L	72.8 g/L
Total Acidity	g/L H ₂ SO ₄	5.4	5.4	5.2	4.61	4.55	4.34	6.7	7.1	6.4	7.5	7.4	7.5
after de-acidifying													
Volatile acidity	g/L H ₂ SO ₄	0.18	0.19	0.15	0.21	0.22	0.20	0.3	0.3	0.3	0.5	0.5	0.6
SO ₂ Total	mg/L	119	121	123	46	51	49	-	-	-	-	-	-
Free SO ₂	mg/L	35	34	34	22	25	24	-	-	-	-	-	-
pH		3.09	3.14	3.22	3.11	3.09	3.10	3.3	3.2	3.3	3.8	3.5	3.5
Sugars	g/L	<2	<2	<2	<2	<2	<2	2.7	1.7	1.6	2.5	2.0	1.0
DO 420		0.047	0.043	0.039	0.308	0.312	0.321	-	-	-	-	-	-
DO 520		-	-	-	0.598	0.595	0.606	-	-	-	-	-	-
DO 620		-	-	-	0.142	0.152	0.150	-	-	-	-	-	-

Comments of zRMS on:

Effects on transformation processes (3.4.4)

Due to the data submitted by the applicant, no relevant negative effect of Mevalone on transformation-vinification processes is expected.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Mevalone is recommended for foliar application to apple trees and grapevine. Under these circumstances, there is a potential risk to cuttings that may be taken for propagation purposes.

Mevalone is a fungicide and therefore no inherent risk to plant cuttings would be predicted. Indeed, no adverse effects of any kind were seen in any trial, either at the proposed label rate or doses up to twice this rate (2N). Following the criteria laid out in PP 1/135 (3) – ‘Phytotoxicity assessment’, no further data are required. Therefore overall no specific studies were undertaken and the risk to cuttings is considered to be negligible.

Comments of zRMS on:

Impact on treated plants or plant products to be used for propagation (3.4.5)

Acceptable. No negative effect of Mevalone on treated plants or plant products to be used for propagation is expected.

Summary and conclusion of point 3.4 Adverse effect on treated crop

- Results from 26 efficacy trials on grapevine and 19 practical value trials on apple trees showed that Mevalone applied according to the recommendations up to 4 L/ha and max. 4 times per season is safe on grapevine and apple trees.
- Yield results from 6 trials on apple showed that Mevalone applied in a fungicide program according to the recommendations up to 4 L/ha and max. 4 times per season has no negative impact on yield.
- Mevalone applied according to recommendations for the control of *Botrytis cinerea* in grapevine and storage diseases in apple is not expected to have any impact on the quality of plants and plant products.

- No impact on treated plants or plant products used for propagation is expected.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

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.

3.5.1 Impact on succeeding crops (KCP 6.5.1)

No specific studies were undertaken to evaluate effects on succeeding crops in the event of grapevine and apple trees treated with Mevalone being grubbed up and replaced. However, in the absence of any phytotoxic effects in any of the efficacy trials and given the ready biodegradability of the active substances it is considered unlikely that Mevalone would adversely affect the growth and development of any crops planted following the grubbing up of a vineyard or an orchard.

Comments of zRMS on: Impact on succeeding crops (3.5.1)

Acceptable. No negative effect of Mevalone on succeeding crops is expected.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

No specific studies were undertaken to evaluate for any effects on other plants. No adverse effects were observed on any crops adjacent to those on which any of the efficacy or taint trials were located. The efficacy of Mevalone against diseases on other crop types has been investigated in a range of glasshouse and field trial studies and these have not reported any observed phytotoxic effects at rates equivalent or higher than that proposed for Mevalone on grapes and apple trees. In addition, Mevalone has been tested on 14 different crops. This includes potatoes, oilseed rape, strawberries, turf, winter wheat courgettes and cucumbers, all of which were tested in GEP trials. In no trial were any phytotoxic effects recorded. Mevalone is currently approved on 40 different crops and no adverse effects were ever reported.

Due to the relative crop safety of Mevalone it is considered unlikely that Mevalone applied as per the proposed label recommendations, would have any impact on other plants including adjacent crops.

Comments of zRMS on: Impact on other plants including adjacent crops (3.5.2)

Due to data submitted by the applicant, no negative effect of Mevalone on other crops including adjacent crops is expected.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

No adverse effects were reported from efficacy trials and it is unlikely that Mevalone will pose a significant risk to beneficial organisms when used as per proposed label recommendations. Data presented in a previous Zonal BAD indicate that no adverse effect is likely to occur on *Aphidius* sp. or *Typhlodromus pyri*.

Comments of zRMS on:

Effects on beneficial and other non-target organisms (3.5.3)

Adverse effects on non-target organisms have not been observed in a part of efficacy trials. In other trials no observations on beneficial or non-target organisms have been reported. Due to observations from efficacy trials and data submitted by the applicant, no negative effect of Mevalone on beneficial and other non-target organisms is to be expected.

3.6 Other/special studies

None.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Testing facility	Full address	GEP certified
Agrisearch UK / Eurofins Agroscience Services	Slade Lane, Wilson, Melbourne, Derbyshire DE73 8AG, UK	Yes
BioChem Agrar GmbH*	D-04827 Machern OT Gerichshain, Kupferstr. 6, GERMANY	Yes
Eurofins Agroscience Services GmbH	Carl Goerdeler Weg 5, 21684 Stade, GERMANY	Yes
Eurofins Agroscience Services Kft.	H-8000 Székesfehérvár, Új Váralja sor 16, HUNGARY	Yes
Eurofins Agroscience Services SAS	Z.I. des Sabotiers, F-49350 Gennes-Val de Loire, FRANCE	Yes
GAB Biotechnologie GmbH*	75223 Niefern-öschelbronn Eutingen Strasse 24, GERMANY	Yes
InTec Agro Trials, spol. S.r.o.	Blatnická 179, 687 24 Uherský Ostroh, CZECH REP.	Yes
Raison'Alpes	190 route de Gap, 04200 Sisteron, FRANCE	Yes
Stähler International GmbH	Stader Elbstrasse DE-21683 Stade Postfach 2047 DE-21660 Stade, GERMANY	Yes
Staphyt sp. Z.o.o.	ul. Ziebicka 2, 61-164 Poznan, POLAND	Yes
VŠÚO Holovousy s.r.o.	Holovousy 129 508 01 Hořice, CZECH REP.	Yes

*Field part on the behalf of Agrisearch UK / Eurofins Agroscience Services GmbH

GEP certificates are provided hereafter.

Appendix C - Copy of the Certificate of Official Recognition of Efficacy Testing Facilities or Organisations



Official Recognition of Efficacy Testing Facilities or Organisations in the United Kingdom

Department of
**Agriculture and
Rural Development**

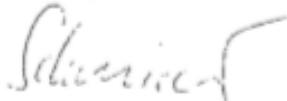
GEP certificate of BioChem Agrar GmbH

Anerkennungsbescheinigung

Die Versuchseinrichtung BioChem agrar GmbH
mit Hauptsitz in D-04827 Machern OT Gerichshain, Kupferstr. 6
und organisatorisch zugehörigen Arbeitseinheiten in Güstrow, Neustadt/Dosse, Cadolzburg,
Neugattersleben, Motterwitz
ist auf Antrag vom 07.01.2004
und durchgeführter Besichtigung vom 24.03.2004
durch Herrn Dr. Schmiedeknecht, Herrn Dittrich
von der Sächsischen Landesanstalt für Landwirtschaft am 07.05.2004 befristet
amtlich anerkannt worden im Sinne des § 1c Abs. 5 der Pflanzenschutzmittelverordnung.
Die Anerkennungsfrist beginnt am 24.03.2004 und endet mit Ablauf des 23.03.2009.

Recognition Certificate

The testing facility BioChem agrar GmbH
with headquarters in D-04827 Machern OT Gerichshain, Kupferstr. 6
and subsidiary testing units in Güstrow, Neustadt/Dosse, Cadolzburg, Neugattersleben, Motterwitz
has been restricted officially recognized under paragraph (5) of Article 1c of the Plant Protection
Products Ordinance following its application dated 2004-01-07
and pre-inspection of 2004-03-24
by Herrn Dr. Schmiedeknecht, Herrn Dittrich
from the Sächsische Landesanstalt für Landwirtschaft on 2004-05-07.
This recognition starts on 2004-03-24 and it runs out on 2009-03-23.



Dr. Schmiedeknecht
Sächsische Landesanstalt für Landwirtschaft
Stübelfallee 2
D-01307 Dresden



(Dichstiegel)

GEP certificate of Eurofins Agrosience Services GmbH

Anerkennungsbescheinigung

Die Versuchseinrichtung
mit Hauptsitz in

und organisatorisch
zugehörigen Arbeitseinheiten in

**Eurofins Agrosience
Service GmbH
Carl-Goerdeler-Weg 5
21684 Stade**

siehe Seite 2

ist auf Antrag vom

und nach durchgeführter
Besichtigung
durch

23.09.2015

15.12.2015

Frau Warnecke-Busch

vom

LWK-Niedersachsen

am

15.01.2016

in den Versuchskategorien

**Ackerbau, Gemüsebau,
Obstbau, Zierpflanzen,
Forst, Sonderkulturen**

als Einrichtung für die Prüfung
der Wirksamkeit von
Pflanzenschutzmitteln im Sinne
des § 8 Abs. 6 der
Pflanzenschutzmittelverordnung
und gemäß Verordnung (EU)
Nr. 284/2013 für 5 Jahre
amtlich anerkannt worden.

Recognition Certificate

The testing facility
with headquarters in

and subsidiary testing units
in

on application from

and after inspection

by

dated

on

in the trial cate

has been officially
recognised as an
organisation for efficacy
testing facility of plant
protection products
according to § 8 par. 6 of
the Plant Protection
Products Ordinance and
the Commission
Regulation (EU) No
284/2013 for 5 years.

7.2.18 *[Signature]*

Datum

Unterschrift

Date

Sign

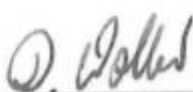

**Wunstorfer
Landstraße 9
30453 Hannover**

Adresse der
Anerkennungsbehörde
address of the
recognising authority



Organisatorisch zugehörigen Arbeitseinheiten/ subsidiary testing units

Eurofins Agrosience Service Markgröningen	Eurofins Agrosience Services GmbH Lettenbödle 2 71706 Markgröningen
Eurofins Agrosience Service Bernau	Eurofins Agrosience Services GmbH Karl-Liebknecht-Str. 29a 16321 Bernau
Eurofins Agrosience Service Heidelberg	Eurofins Agrosience Services GmbH Lempenseite 50/1 69168 Wiesloch
Eurofins Agrosience Service Osnabrück	Eurofins Agrosience Services GmbH Pastor-Reins-Str. 14 49586 Merzen
Eurofins Agrosience Service Detmold	Eurofins Agrosience Services GmbH Bad Meinberger Str. 168 32760 Detmold
Eurofins Agrosience Service Zwickau	Eurofins Agrosience Services GmbH Culten 30 08459 Neuenkirchen
Eurofins Agrosience Service Groß Schenkenberg	Eurofins Agrosience Services GmbH Dieksredder 3 23860 Groß Schenkenberg
Eurofins Agrosience Service Haselbach	Eurofins Agrosience Services GmbH Buchhof 1 94354 Hasselbach
Eurofins Agrosience Service Hundisburg	Eurofins Agrosience Service Wallstraße 7 39343 Hundisburg

7.2.18		Wunstorfer Landstraße 9 30453 Hannover	
Datum	Unterschrift	Adresse der Anerkennungsbehörde address of the recognising authority	
Date	Sign		

GEP certificate of Eurofins Agrosience Services Kft.



n é b i h
Termőföldtől az asztalig

National Food Chain Safety Office
President



H-1024 Budapest, Keleti Károly u. 24.
Hungary
Tel: 36/1/336-9100 Fax: 36/1/336-9099
E-mail: efoghirt@karsag@nebih.gov.hu

Your ref.: -

Our ref.: 04.2/10083-6/2014

13th October 2014

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by the **Eurofins Agrosience Services Kft. (H-8000 Székesfehérvár, Új Váralja sor 16, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (hereinafter: GEP), I, acting as the food chain control body, has made the following

D E C I S I O N :

I authorise that the Eurofins Agrosience Services Kft. (H-8000 Székesfehérvár, Új Váralja sor 16, Hungary) continues to operate the premises as a GEP testing facility for 5 years, i.e. until 22 October 2019, from the entry into force of this Decision.

The client may carry out efficacy trials for authorisation purposes for the following categories of products and cultivation:

- product categories:** herbicides, fungicides, bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- cultivation categories:** field crops, vegetables, fruits, grapevines, ornamental plants, forest, public place, others.

The present certificate is valid for 5 years from the entry into force of this Decision.

The administrative fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) which was paid by the client.

No legal remedy against this Decision can be placed in an administrative way. With reference to infringement of law, revision of this Decision may be asked at the Capital Administrative and Employment Court by lodging a claim note against the decision-making National Food Chain Safety Office. The claim shall be submitted (in three copies) to the National Food Chain Safety Office within thirty days of the communication of this Decision or mailed as registered.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted.

J U S T I F I C A T I O N

The client submitted an application on 22 July 2014 to renew the GEP certification obtained on 15 May 2012. Conditions for carrying out efficacy trials according to GEP are regulated in Article 22 of the *Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004)*. As a follow-up to the application, the competent authority made a local inspection at the client's facility at Székesfehérvár, Új Váralja sor 16, on 29 July 2014. Statements made during the local inspection are reported in the protocol Nr. 04.2/10083-3/2014.

Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Decree 89/2004 and in the Decision Nr. 04.2/10083-4/2014 it calls the client to fill the data gap.

Article 22 of Decree 89/23004 – “(5) Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.”

Client filled the missing data gap and reported on it in the letter of 22 September 2014, therefore I made the Decision as specified in the first part.

The fee of the present procedure was established in accordance with point 8.19.2 of Annex 1 to the *Decree 63/2012. (VII. 2.) VM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees.*

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

Respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority.

If during the official inspection it is stated that the testing facility does not respect the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of *Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office*, Article 3, Article 22 paragraph (1) of Decree 89/2004. I made this Decision in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of *Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).*

I provided the possibility of judicial review in compliance with Article 100 paragraph (1) point e) and paragraph (2), Article 109 paragraph (1) point a) of Act CXL of 2004, and Article 330 paragraph (2) of *Act III of 1952 on Civil Procedure.*


dr. Márton Oravecz
president


Decision is made in two copies:

- Client (with acknowledgement of receipt)
- Archives

GEP certificate of Eurofins Agrosience Sevices SAS



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

DÉCISION D'AGRÈMENT POUR RÉALISER DES ESSAIS OFFICIELLEMENT RECONNUS

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 2949,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 27/11/2018,

L'agrément pour réaliser des essais officiellement reconnus est renouvelé et étendu, à l'organisme :

Eurofins Agrosience Service France
3 rue d'Italie
67230 BENFELD

sous le numéro : **BPE - 038**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
EAS France Alsace 3 rue d'Italie 67230 BENFELD (<i>unité centrale</i>)	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 01 – EAS France Sud Roussillon 17 boulevard Archimède 66200 ELNE	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles - <i>Traitement de semences : grandes cultures et cultures légumières</i>
UE 02 – EAS France Bretagne Zone artisanale de tréhuinec 6 rue Ampère 56890 PLESCOP	<ul style="list-style-type: none"> - Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 03 – EAS France Sud Est Vallée du Rhône 79 chemin des costières 84100 ORANGE	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 04 – EAS France Sud-Ouest Zone artisanale du rival 82130 LAFRANÇAISE	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles - Traitement des produits récoltés : cultures fruitières (<i>trempage, gaz</i>)
UE 05 – EAS France Centre Beauce 8 rue de la collerette 45300 ROUVRES SAINT JEAN	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 06 – EAS France Val de Loire ZI des sabotiers 49350 GENNES VAL DE LOIRE	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 07 – EAS France Bourgogne ZA de l'aubépin 71700 UCHIZY	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Zones non agricoles

Cet agrément est délivré pour une durée de cinq ans à compter du 24/02/2019 jusqu'au 23/02/2024. En application de l'article 5 de l'arrêté susmentionné, une nouvelle évaluation aura lieu dans un délai compris entre vingt-quatre et trente-six mois à compter du 24/02/2019.

Date : 04 FEV. 2019

La sous directrice de la qualité,
 de la santé et de la protection
 des végétaux


 Anne-Cécile COTILLON

GEP certificate of GAB Biotechnologie GmbH

Anerkennungsbescheinigung

Die Versuchseinrichtung	GAB Biotechnologie GmbH
mit Hauptsitz in	75223 Niefern-Öschelbronn
und organisatorisch zugehörigen	Eutinger Straße 24
Arbeitseinheiten in	21684 Stade
	Carl-Goerdeler-Weg 3
ist auf Antrag vom	03. November 2004
und durchgeführter Besichtigung vom	13. Dezember 2004
durch	Herrn Dr. Bischof, Herrn Dr. Maier
	Regierungspräsidium Karlsruhe
vom	Regierungspräsidium Karlsruhe
	- Pflanzenschutzdienst -
am	17. März 2005
amtlich anerkannt worden im Sinne des § 1c Abs. 5 der Pflanzenschutz-	
mittelverordnung.	
Diese Bescheinigung ist gültig bis 31.März 2010.	

Recognition Certificate

The testing facility	GAB Biotechnologie GmbH
with headquarters in	75223 Niefern-Öschelbronn
and subsidiary testing units in	Eutinger Straße 24
	21684 Stade
	Carl-Goerdeler-Weg 3
has been officially recognized under paragraph (5) of Article 1c of the Plant	
Protection Products Ordinance	
following its application dated	November 3 rd 2004
and pre-inspection of	December 13 th 2004
by	Mr. Dr. Bischof, Mr. Dr. Maier
	Regierungspräsidium Karlsruhe
from the	Regierungspräsidium Karlsruhe
	- Pflanzenschutzdienst -
on	March 17 th 2005.
This certificate is valid until March 31 st 2010.	

Karlsruhe, 17.03.2005

F. Bischof
Dr. F. Bischof



GEP certificate of InTec Agro Trials, spol. S.r.o.



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Hroznová 2
656 06 Brno

www.ukzuz.cz
ID DS: ugbaig7

IČO: 00020338
DIČ: CZ00020338

InTec Agro Trials, spol. s r.o.
Blatnická 179
687 24 Uherský Ostroh
IČO: 06774512

Útvar:	OPOR	Spisová zn.:	SZ UKZUZ 010368/2018/01399
Vyřizuje:	Ing. Ivana Minářová	Č. j.:	UKZUZ 013294/2018
E-mail:	ivana.minarova@ukzuz.cz		
Telefon:	+420 545 110 444		
Adresa:	Zemědělská 1a, 613 00 Brno	Datum:	7. 2. 2018

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“), v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **InTec Agro Trials, s.r.o.**, a to:

žádosti o uznání osoby za způsobilou k provedení zkoušek podle § 45 odst. 1 zákona ze dne 24. 1. 2018, doručené ÚKZÚZ dne 26. 1. 2018, č.j. UKZUZ 010368/2018

rozhodl takto:

Společnost InTec Agro Trials, s.r.o. je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právníká osoba: **InTec Agro Trials, s.r.o.**

sídlo právnické osoby: Blatnická 179, Ostrožské Předměstí, 687 24 Uherský Ostroh

IČ právnické osoby: 06774512

GEP kód: GEP/ITU/2018

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory

dobu platnosti rozhodnutí: 5 let ode dne nabytí účinnosti tohoto rozhodnutí

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 24. 1. 2018, doručené ÚKZÚZ dne 26. 1. 2018.

Do firmy InTec Agro Trials, s.r.o. přechází původní personální obsazení a zařízení firmy ATC – Agro Trial Center GmbH, organizační složky, původního držitele povolení č.j. UKZUZ 073735/2016 ze dne 1. 7. 2016. Nedošlo ke změnám v oblasti personálního obsazení, v prostorách, v nichž je činnost realizována, na pozemcích, na nichž je činnost prováděna a změnám v základní dokumentaci.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě předložené dokumentace, Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo ÚKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené ÚKZÚZ dne 26. 1. 2018, č.j. UKZUZ 010368/2018, byl uhrazen dne 26. 1. 2018 formou kolkové známky.

Poučení o odvolání:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Ing. Pavel Minář, Ph.D.
ředitel OPOR

GEP certificate of Raison'Alpes



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

DÉCISION D'AGRÈMENT POUR RÉALISER DES ESSAIS OFFICIELLEMENT RECONNUS

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 2842,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 06/10/2017,

L'agrément pour réaliser des essais officiellement reconnus est renouvelé, à l'organisme :

RAISON'ALPES
190 route de Gap
04200 SISTERON

sous le numéro : **BPE - 052**

ET POUR LE PERIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
Raison'Alpes 190 route de Gap 04200 Sisteron (unité centrale)	- Grandes cultures - Cultures fruitières et arboriculture

Cet agrément est délivré pour une durée de cinq ans à compter du 30/01/2018 jusqu'au 29/01/2023. En application de l'article 5 de l'arrêté susmentionné, une nouvelle évaluation aura lieu dans un délai compris entre vingt-quatre et trente-six mois à compter du 30/01/2018.

Date : 08 JAN. 2018

Le Chef du Service des Actions Sanitaires
en Production Primaire

Aïain TRIDON

GEP certificate of Stähler International GmbH

Anerkennungsbescheinigung

Die Versuchseinrichtung Stähler Deutschland GmbH & Co. KG
Biologische Entwicklung/Versuchswesen
Stader Elbstraße, 21683 Stade

ist auf Antrag vom 10. Dezember 2002

und durchgeführter Besichtigung vom 26. Februar 2003

durch Herrn Dr. H. Bötger, Pflanzenschutzamt Hannover

vom Pflanzenschutzamt der Landwirtschaftskammer Hannover **am** 12. März 2003

amtlich anerkannt worden im Sinne des § 1c Abs. 5 der Pflanzenschutzmittelverordnung vom 17. August 1998 (BGBl. I S. 2161) gemäß den Richtlinien 91/414/EWG und 93/71/EWG (GEP-Anerkennung).

Diese Bescheinigung ist gültig bis März 2008.

Recognition Certificate

The testing facility Stähler Deutschland GmbH & Co. KG
Biological development/research institute
Stader Elbstraße, 21683 Stade

is officially recognized under paragraph (5) of Article 1c of the Plant Protection Products Ordinance according to the guidelines 91/414/EEC and 93/71/EEC (GEP-recognition) following its application dated 10th of December 2002

and pre-inspection of 26th of February 2003

by Mr. Dr. H. Bötger, Pflanzenschutzamt Hannover

from the Pflanzenschutzamt der Landwirtschaftskammer Hannover **on** 12th of March 2003.

This certificate has a validity until March 2008.

Hannover, 07.01.2004



Certified translation from Polish

Main Inspector
of Plant Health and Seed Inspection
Tadeusz Kłos

WO-505-14/2012

Warsaw, 25th of September 2012

DECISION no. 7/2012

In accordance with section 155 of the Act - Code of Administrative Proceedings of 14th of June 1960 (Dz.U. [Journal of Laws] of 2000, no 98, item 1071 as amended) and section 40, item 1 of the Act on plant protection of 18th December 2003 (Dz.U. [Journal of Laws] from 2008, no. 133, item 849 as amended), having analyzed the application from 6th of September 2012, I change the decision no. 9/2005 from the 1st of May 2005, amended by the decisions: no. 3/2006 from 5th of May 2006, no. 8/2006 from 11 December 2006, no. 2/2009 from 18th of February 2009, no. 12/2011 from 31st of March 2011 and no. 4/2012 from 4th of April 2012.

The final decision shall have the following wording:

I authorize

STAPHYT sp. z o.o.
ul. Ziebiga 2, 61-164 Poznań

to run the research into the effectiveness of plant protection products

from the group of fungicides, herbicides, insecticides, molluscicides, acaricides, growth regulators, seed treatment and to apply jointly plant protection products in the field crops of: cereals, corn, rapeseed, sugar beets, sunflowers, potatoes, vegetables, in orchards (apple trees, pear trees, currants, strawberries, stone fruit) in the warehouses and storages, and in the lawns, and in the cultivation of ornamental plants in the field and under covers.

Grounds

On 6th of September 2012, Staphyt sp. z o.o., (ul. Ziębicka 2, 61-164 Poznań) submitted an application to broaden the scope of the decision of the Main Inspector of Plant Health and Seed Inspection giving powers to run the research into the effectiveness of plant protection products no. 9/2005 from the 1st of May 2005, amended by the decisions: no. 3/2006 from 5th of May 2006, no. 8/2006 from 11 December 2006, no. 2/2009 from 18th of February

Obtaining Results



GEP certificate of VŠÚO Holovousy s.r.o.



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Výzkumný a šlechtitelský ústav ovocnářský
Holovousy s.r.o.
Holovousy 129
508 01 Holovousy

Útvar: Odbor přípravků na ochranu rostlin
Adresa: Zemědělská 1a, 613 00 Brno

Sp.zn: SZ UKZUZ 059896/2016/17780 Č.j.: UKZUZ 081296/2016 Datum: 22. 7. 2016
Vyřizuje: ing. Minářová Tel.: 545 110 444 E-mail: ivana.minarova@ukzuz.cz

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona, v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **VÝZKUMNÝ A ŠLECHTITELSKÝ ÚSTAV OVOCNÁŘSKÝ HOLOVOUSY s.r.o.**, Holovousy 129, 508 01 Holovousy, IČ 25271121 dále jen „společnost Výzkumný a šlechtitelský ústav ovocnářský Holovousy s.r.o.“ a to:

žádosti o prodloužení platnosti rozhodnutí o způsobilosti k provádění zkoušek podle § 45 odst. 1 zákona ze dne 20. 5. 2016, doručené ÚKZÚZ dne 24. 5. 2016, č.j. UKZUZ 059896/2016

rozhodl takto:

Výzkumný a šlechtitelský ústav ovocnářský Holovousy s.r.o., je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právnícká osoba: **VÝZKUMNÝ A ŠLECHTITELSKÝ ÚSTAV OVOCNÁŘSKÝ HOLOVOUSY s.r.o.**

sídlo právnické osoby: Holovousy 129, 508 01 Holovousy

IČ právnické osoby: 25271121

GEP kód: GEP/HOL/2016

1

ÚKZÚZ
Hroznová 2
656 06 BRNO

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Fax: +420 543 211 148
E-mail: podatelna@ukzuz.cz

IČ: 00020338
DIČ: CZ00020338

www.ukzuz.cz
ID DS: ugbaiq7

oblasti zkoušení: **trvalé kultury**
skleníky a jiné kryté prostory

rozhodnutí se vydává s účinností od 1. 9. 2016

dobu účinnosti rozhodnutí: 5 let

Tímto rozhodnutím se k datu nabytí jeho účinnosti zrušuje rozhodnutí č.j. SRS 031051/2009 ze dne 9. 10. 2009.

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 20. 5. 2016, doručené UKZÚZ dne 24. 5. 2016.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě kontroly předložené dokumentace pracoviště Výzkumný a šlechtitelský ústav ovocnářský Holovousy s.r.o., Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo UKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené UKZÚZ dne 24. 5. 2016, č.j. UKZUZ 059896/2016, byl uhrazen dne 24. 5. 2016 formou kolkové známky.

Poučení:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Otisk úředního razítka

Ing. Pavel Minář, Ph.D.
ředitel odboru

2

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Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2	Staphyt Regulatory	2021	BAD of Mevalone - Central zone – Core assessment (authorization for Mevalone product) Staphyt Regulatory Report n°: N/A GLP/GEP: N/A Unpublished	N	Eden Research plc
KCP 6.2 /01 Also cited in KCP 6.4	Sutherland J. Sipos P.	2019 2018	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine, 1 site South-east zone, 2018 Eurofins Agroscience Services Report n°: S18-05195-01 GEP Unpublished	N	Eden Research plc
KCP 6.2 /02 Also cited in KCP 6.4	Sutherland J. Sipos P.	2019 2018	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine, 1 site South-east zone, 2018 Eurofins Agroscience Services Report n°: S18-05195-02 GEP Unpublished	N	Eden Research plc
KCP 6.2 /03 Also cited in KCP 6.4	Sutherland J. Sipos P.	2019 2018	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine, 1 site South-east zone, 2018 Eurofins Agroscience Services Report n°: S18-05195-03 GEP Unpublished	N	Eden Research plc
KCP 6.2 /04 Also cited in KCP 6.4	Sutherland J. Leitner A.	2019 2018	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine, 1 site Maritime zone, 2018 Eurofins Agroscience Services Report n°: S18-05195-04 GEP Unpublished	N	Eden Research plc

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2 /05 Also cited in KCP 6.4	Sutherland J. Karrasch H.	2019 2018	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine, 1 site Maritime zone, 2018 Eurofins Agroscience Services Report n°: S18-05195-05 GEP Unpublished	N	Eden Research plc
KCP 6.2 /06 Also cited in KCP 6.4	Sutherland J. Hubner H.	2019 2018	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine, 1 site Maritime zone, 2018 Eurofins Agroscience Services Report n°: S18-05195-06 GEP Unpublished	N	Eden Research plc
KCP 6.2 /07 Also cited in KCP 6.4	Sutherland J. Sipos P.	2020 2019	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine OUTDOOR 2019 Eurofins Agroscience Services Report n°: S19-20334-01 GEP Unpublished	N	Eden Research plc
KCP 6.2 /08 Also cited in KCP 6.4	Sutherland J. Sipos P.	2020 2019	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine OUTDOOR 2019 Eurofins Agroscience Services Report n°: S19-20334-02 GEP Unpublished	N	Eden Research plc
KCP 6.2 /09 Also cited in KCP 6.4	Sutherland J. Alexandru A.	2020 2019	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine OUTDOOR 2019 Eurofins Agroscience Services Report n°: S19-20334-03 GEP Unpublished	N	Eden Research plc
KCP 6.2 /10 Also cited in	Sutherland J. Beber M.	2020 2019	Determination of Efficacy / Crop Safety of 3AEY against <i>Botryotinia fuckeliana</i> in Grapevine OUTDOOR 2019 Eurofins Agroscience Services	N	Eden Research plc

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.4			Report n°: S19-20334-04 GEP Unpublished		
KCP 6.2 /11 Also cited in KCP 6.4	Sutherland J. Beber M.	2020 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	Eden Research plc
KCP 6.2 /12 Also cited in KCP 6.4	Sutherland J. Beber M.	2020 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	Eden Research plc
KCP 6.2 /13 Also cited in KCP 6.4	Sutherland J. Hubner H.	2020 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	Eden Research plc
KCP 6.2 /14 Also cited in KCP 6.4	Sutherland J. Karrasch H.	2020 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	Eden Research plc
KCP 6.2 /15 Also cited in KCP 6.4	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	Eden Research plc

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2 /16 Also cited in KCP 6.4	Hilweg M.	2006	Fungicides based on terpenes 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	Eden Research plc
KCP 6.2 /17 Also cited in KCP 6.4	Matkin M. Harrison C.	2009 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	Eden Research plc
KCP 6.2 /18 Also cited in KCP 6.4	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	Eden Research plc
KCP 6.2 /19 Also cited in KCP 6.4	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	Eden Research plc
KCP 6.2 /20 Also cited in KCP 6.4	Pesteil L. Curti M.	2018	Study of the effectiveness of several fungicides applied before harvest against storage diseases on apple Raison'Alpes Report n°: 18-Fa-Pm-11 GEP Unpublished	N	Eden Research plc
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	N	Eden Research plc

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2 /22 Also cited in KCP 6.4	Mota is F.	2020 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	Eden Research plc
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	Eden Research plc
KCP 6.2 /24 Also cited in KCP 6.4	Mota is F.	2020 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	Eden Research plc
KCP 6.2 /25 Also cited in KCP 6.4	Kloutvorová J.	2018 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	Eden Research plc
KCP 6.2 /26 Also cited in KCP 6.4	Kolník M.	2019 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	Eden Research plc
KCP 6.2 /27	Kolník M.	2020	Comparison of the efficacy of different fungicide combinations applied preharvest in apple against storage	N	Eden Research

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
Also cited in KCP 6.4		2019	diseases Intec Agro Trials Report n°: F-20-O-501-01 GEP Unpublished		plc
KCP 6.2 /28 Also cited in KCP 6.4	Kussinszky T.	2019 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	Eden Research plc
KCP 6.2 /29 Also cited in KCP 6.4	Kussinszky T.	2019 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	Eden Research plc
KCP 6.2 /30 Also cited in KCP 6.4	Mota- is F.	2020 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	Eden Research plc
KCP 6.2 /31 Also cited in KCP 6.4	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	Eden Research plc
KCP 6.2 /32 Also cited in KCP 6.4	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	N	Eden Research plc

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2 /33 Also cited in KCP 6.4	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	Eden Research plc
KCP 6.2 /34 Also cited in KCP 6.4	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	Eden Research plc
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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 6.4/01	XXXXXX	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	Y	Eden Research plc
KCP 6.4/02	XXXXXX	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	Y	Eden Research plc
KCP 6.4/03	XXXXXXX	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	Y	Eden Research plc

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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List of data submitted by the applicant and not relied on

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

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

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