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Peer review of the pesticide risk assessment of the active substance lavandulyl senecioate

European Food Safety Authority (EFSA)

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Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Italy for the pesticide active substance lavandulyl senecioate are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative uses evaluated as a pheromone comprising manual applications to control Planococcus ficus (vine mealybug) populations by mating disruption in table grape, wine grape, raisins and any other crops where *P. ficus* may be a pest in Southern Europe. The reliable endpoints, appropriate for use in regulatory risk assessment are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

Keywords: Lavandulyl senecioate, peer review, risk assessment, pesticide, semiochemical

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Summary

Lavandulyl senecioate is a new active substance for which, in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council, the rapporteur Member State (RMS), Italy received an application from Suterra Europe Biocontrol S.L for approval. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 29 December 2016.

An initial evaluation of the dossier on lavandulyl senecioate was provided by the RMS in the draft assessment report (DAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 12 of Regulation (EC) No 1107/2009. The following conclusions are derived.

Data were submitted to conclude that the uses of lavandulyl senecioate according to the representative uses proposed at EU level result in a sufficient efficacy as a mating disruptor against vine mealybug.

A data gap was identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of lavandulyl senecioate or the representative formulation. In the section identity, physical and chemical properties and analytical methods a data gap was identified for the analytical method used to determine the active substance concentration in the test media for toxicity studies on aquatic organisms.

R-lavandulyl senecioate has not been shown to occur naturally in significant amounts and no toxicological information has been provided to allow read-across from other similar compounds potentially occurring in the environment. Toxicological studies allowing to characterise the toxicity profile and to derive toxicological reference values would be needed to perform a standard non-dietary exposure risk assessment.

In the residues section, in absence of any data supporting a conclusion regarding the dietary exposure potential for consumers from the representative use of lavandulyl senecioate and the identified issues in the section mammalian toxicology, the consumer risk assessment cannot be finalised.

The information on environmental fate and behaviour was considered sufficient to conclude that for the representative use being assessed, *S*-lavandulyl senecioate emitted from the product dispensers to air would be comparable to that produced in a crop with a pest outbreak of vine mealybugs. So *S*-lavandulyl senecioate levels would be comparable to levels of exposure that might occur without the use of the product. However satisfactory information was not available regarding the *R*-lavandulyl senecioate that will be emitted from the product dispensers. This leads to the exposure and risk assessment being not finalised.

In the area of ecotoxicology, pending on the data gap and issue that could not be finalised identified for the isomer *R*-lavandulyl senecioate, further information may be needed to address the risk to birds and mammals. A data gap and issue that could not be finalised were also identified for further information to address the potential effects and risk to bees and other non-target arthropods for lavandulyl senecioate.

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Background

Regulation (EC) No 1107/2009 of the European Parliament and of the Council[1] (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure and conditions for approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant(s) for comments on the initial evaluation in the draft assessment report (DAR), provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 12 of the Regulation, EFSA is required to adopt a conclusion on whether an active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation (also taking into consideration recital (10) of the Regulation) within 120 days from the end of the period provided for the submission of written comments, subject to an extension of 30 days where an expert consultation is necessary, and a further extension of up to 150 days where additional information is required to be submitted by the applicant(s) in accordance with Article 12(3).

Lavandulyl senecioate is a new active substance for which, in accordance with Article 7 of the Regulation, the RMS, Italy (hereinafter referred to as the 'RMS'), received an application from Suterra Europe Biocontrol S.L. approval of the active substance lavandulyl senecioate. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 29 December 2016.

The RMS provided its initial evaluation of the dossier on lavandulyl senecioate in the DAR, which was received by EFSA on 22 August 2017 (Italy, 2017). The peer review was initiated on 15 November 2017 by dispatching the DAR for consultation of the Member States and the applicant, Suterra Europe Biocontrol S.L., for consultation and comments. EFSA also provided comments. In addition, EFSA conducted a public consultation on the DAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 12(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 1 March 2018. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that there was no need to conduct an expert consultation.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, were reported in the final column of the evaluation table.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether lavandulyl senecioate can be expected to meet the approval criteria provided for in Article 4 of the Regulation, taking into consideration recital (10) of the Regulation. A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in December 2018

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative use of lavandulyl senecioate as a semiochemical on grapevines (field use) as proposed by the applicant. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005, provided the active substance will be approved under Regulation (EC) No 1107/2009 without restrictions affecting the residue assessment. In the event of a non-approval of

[1] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

the active substance or an approval with restrictions that have an impact on the residue assessment, a new assessment under Article 12 of Regulation (EC) No 396/2005 will be required. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2018), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the comments received on the DAR;
- the reporting table (27 February 2018);
- the evaluation table (30 November 2018);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its revisions (Italy, 2018) and the peer review report, both documents are considered as background documents to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Lavandulyl senecioate is a common name for (*RS*)-5-methyl-2-(prop-1-en-2-yl)hex-4-en-1-yl 3-methylbut-2-enoate (IUPAC). There is no ISO common name for this substance. The natural pheromone is the enantiomer *S*-Lavandulyl senecioate, i.e. (*S*)-5-methyl-2-(prop-1-en-2-yl)hex-4-en-1-yl 3-methylbut-2-enoate. Whereas lavandulyl senecioate is a racemic mixture.

The representative formulated product for the evaluation was 'CheckMate VMB XL', a vapour releasing product (VP), containing 150 mg/unit (11.79 % w/w) lavandulyl senecioate.

The representative uses evaluated as a pheromone comprise manual applications to control *Planococcus ficus* (vine mealybug) populations by mating disruption in table grape, wine grape, raisins and any other crops where *P. ficus* may be a pest in Southern Europe. Full details of the GAP can be found in the list of end points in Appendix A.

Data were submitted to conclude that the uses of lavandulyl senecioate according to the representative uses proposed at EU level result in a sufficient efficacy as a mating disruptor against vine mealybug following the guidance document SANCO/10054/2013-rev. 3 (European Commission, 2013a).

A data gap has been identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

Conclusions of the evaluation

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3029/99-rev. 4 (European Commission, 2000a), SANCO/3030/99-rev. 4 (European Commission, 2000b), SANCO/825/00-rev. 8.1 (European Commission, 2010a) and ENV/JM/MONO (2001)12, ENV/JM/MONO(2017)33, SANCO/5272/2009 rev. 4.1 (European Commission, 2010b)

Lavandulyl senecioate is the synthetic replicate of the natural sex pheromone of vine mealybug (*Planococcus ficus*). It should be noted that lavandulyl senecioate is synthesised as a racemate, while the sex pheromone of *Planococcus ficus* is the *S*-enantiomer of lavandulyl senecioate: (*S*)-5-methyl-2-(prop-1-en-2-yl)hex-4-en-1-yl 3-methylbut-2-enoate.

The specification is based on batches of industrial scale production. The minimum purity of the technical material is 894 g/kg. An FAO specification is not available currently.

The main data regarding the identity of lavandulyl senecioate and its physical and chemical properties are given in appendix A.

Adequate analytical methods are available for the determination of lavandulyl senecioate in the technical material and the representative formulation.

Methods of analysis for monitoring lavandulyl senecioate in food of plant and animal origin are not required as MRLs are not proposed, but might be needed, so this is an open issue. It was concluded that methods of analysis for monitoring lavandulyl senecioate in soil and water are not essential due to the use pattern of the compound, but might be required for other type of applications. A data gap was identified for a monitoring method in air. Pending on the residue definition in body fluids and tissues a monitoring method might be required.

2. Mammalian toxicity

The studies provided to characterise the toxicological profile to lavandulyl senecioate are limited to acute toxicity and genotoxicity studies. On this basis, the active substance presented low toxicity when administered by the oral, dermal and inhalation routes. Lavandulyl senecioate was not irritant to the eye or skin and did not present skin sensitisation potential. Based on negative in vitro studies for gene

mutation in bacteria and mammalian cells as well as chromosome aberration, although the proof of bone marrow exposure was not fully convincing to substantiate the negative in vivo micronucleus test, it is considered that lavandulyl senecioate is unlikely to be genotoxic. Information on the batches used in these toxicity studies has not been provided and the toxicological relevance of the impurities present in the technical specification has not been addressed (data gap, see as well section 1). The waiving of other toxicological studies was based on the assumption that the levels of human exposure (dietary and non-dietary) to the active substance do not exceed natural background levels. The R isomer might occur naturally but in low amounts (see data gap in section 2, 3, 4 and 5), but information on natural back ground levels was not available to waive the toxicological assessment of this isomer. Toxicological data have not been provided to allow read-across from other similar compounds potentially present in the environment.

Toxicological reference values cannot be concluded and the risk assessment for dietary and non-dietary exposure cannot be performed (see data gap in section 3 and issue not finalised). It is noted that an analysis of the endocrine disruption potential of lavandulyl senecioate according to the Guidance for the identification of endocrine disruptors (ECHA, EFSA, 2018) was not performed and is pending further assessment of the toxicological profile of lavandulyl senecioate since the overall toxicity profile of the substance is open and no conclusion could be reached. The non-dietary exposure assessment could not be performed in the absence of the above information.

3. Residues

The absence of toxicological concerns for *R*-lavandulyl senecioate was however not confirmed in the section on mammalian toxicology (see section 2). Therefore, a data gap is identified for information on the identity and magnitude of residues in plants or at least for evidence to support the claim that detectable residues on the consumable commodities are unlikely to occur or that residue levels of *R*-lavandulyl senecioate are comparable to natural background levels, to enable a conclusion regarding the dietary exposure potential for consumers from the representative uses of lavandulyl senecioate. For the time being a conclusion regarding the dietary exposure potential for consumers from the representative uses of lavandulyl senecioate is not possible and the consumer risk assessment cannot be finalised. The proposal that lavandulyl senecioate satisfies the criteria outlined in SANCO 'Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) N° 396/2005' (European Commission 2013b) cannot be supported based on the lack of data.

According to the RMS the data requirements for metabolism, distribution and expression of residues have been waived based on no significant toxicological concern.

4. Environmental fate and behaviour

A sterile aqueous hydrolysis study was not available for lavandulyl senecioate. A data gap has been identified for the provision of these data. In a satisfactory ready biodegradability test lavandulyl senecioate was not readily biodegradable. With a vapour pressure of $1.7x10^3$ Pa at 20°C lavandulyl senecioate will stay in air after leaving the dispensers and will disperse in air. When it reaches the upper atmosphere it will degrade via photochemical oxidative processes reacting with radicals (e.g. hydroxyl and nitrate). The atmospheric half life of lavandulyl senecioate has been calculated to be 0.732 hours, so lavandulyl senecioate will not be subject to long range atmospheric transport to remote areas.

Following an approach outlined in the guidance document on semiochemical active substances and plant protection products (European Commission, 2016), the natural emission rate of *S*-lavandulyl senecioate from *Planococcus ficus* (vine mealybug) from pest outbreaks in vineyards was calculated as being 11.2 mg/ha.h. Though the basis for this calculation was transparently presented in the DAR, some of the scientific literature that was used as the basis for the inputs in the calculation though included in the applicants dossier and discussed in the DAR, were not transparently evaluated in the DAR. This has resulted in a data gap for a transparent assessment by the RMS (see section 7). The use of Checkmate VMB-XL results in a release rate of *S*-lavandulyl senecioate of 13 mg/ha.h and of *R*-lavandulyl senecioate of 13 mg/ha.h. As the release rate of *S*-lavandulyl senecioate from the dispensers is comparable to the *S*-lavandulyl senecioate from an infestation of vine mealy bug, it can be concluded that the exposure and consequent risk to non target organisms from *S*-lavandulyl senecioate resulting from the use of the product is not higher than if the product was not used. However this does not address the exposure to *R*-lavandulyl senecioate.

To address the exposure and risk from *R*-lavandulyl senecioate release, the applicant provided information on the structurally related compounds *R*-lavandulyl 3-methyl-3-butenoate (a double-bond positional isomer, see appendix B) and *R*-lavandulyl acetate. These two compounds are naturally emitted by the tropical plant pest *Thrips palmi* Karny (melon thrips) and *Lavanandula spp.* (French lavender) respectively. Reference was also made to *R*-lavandulyl acetate and some other (less structurally similar, longer chain) *R*-lavandulyl esters being emitted by other mealybug pests. The applicant provided a comparable calculation for emission from melon thrips to that they had provided regarding emission from vine mealybug. The melon thrip based calculation and the scientific literature that was used as the basis for the inputs in the calculation, though present in the applicant's dossier and discussed in the DAR, were not transparently evaluated in the DAR. The applicant did not provide any assessment of the chemical reactivity or biological effects of the chemical groups present in *R*-lavandulyl 3-methyl-3-butenoate or *R*-lavandulyl acetate to robustly justify the 'read across' to *R*-lavandulyl senecioate other than presenting their chemical structures. Consequently addressing the exposure from *R*-lavandulyl senecioate release is identified as a data gap and results in an assessment not finalised (see sections 7 and 9.1).

5. Ecotoxicology

Toxicity studies on non-target organisms performed with lavandulyl senecioate were not available for most of the non-target organisms. Various studies on non-target organisms were indeed waived on the basis of the fact that the exposure caused by the use of the plant protection product is similar to the natural levels of the semiochemical. It is, however, noted that the natural sex pheromone of *Planococcus ficus* (vine mealybug) is the enantiomer *S*-Lavandulyl senecioate, while the active substance is the racemate. Any information addressing potential differences in toxicity between the isomers is not available and the provided information on structurally similar compounds was not considered sufficient to address this point (data gap, see also Section 4).

Since valid studies performed with lavandulyl senecioate were not available, an assessment of the compliance of the batches used in the ecotoxicity studies with the technical specification was not needed.

Pending on the above data gap, further information may be needed to address the risk to birds and mammals for lavandulyl senecioate. Studies addressing the acute toxicity of lavandulyl senecioate were available in the DAR for mammals but not for birds. It is noted that considering the representative use under assessment (passive dispenser) and the environmental fate and behaviour of the active substance, the main route of exposure to lavandulyl senecioate for **birds and mammals** may be via inhalation (see Section 4).

Specific studies addressing the effects of lavandulyl senecioate on **bees and other non-target arthropods** were not available. It is reported in the DAR that the efficacy data package included a study demonstrating the lack of adverse effects of lavandulyl senecioate on non-target arthropods, however, the latter was not summarised nor evaluated by the RMS. Therefore, a data gap for further information to address the potential effects and risk to bees and other non-target arthropods for lavandulyl senecioate was identified.

The available studies on **aquatic organisms** were not considered sufficiently reliable due to shortcomings (i.e. test concentrations not fully maintained). However, exposure of aquatic organisms to lavandulyl senecioate is not expected for the representative use assessed (see also Section 4), therefore, a low risk could be concluded. The same conclusion could be reached for **earthworms and other soil organisms, soil microorganisms, organisms involved in biological methods for sewage treatment** and **non-target terrestrial plants.**

An assessment according to the guidance document for the identification of endocrine disruptors (ECHA and EFSA, 2018) for the identification of potential endocrine properties of lavandulyl senecioate was not available. The mammalian toxicology dataset was lacking (see Section 2). Exposure to aquatic vertebrates is not anticipated, therefore, no further data and assessments are considered necessary.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

Table 1: Soil

Compound (name and/or code)	Persistence	Ecotoxicology
None		-

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[(a)]	Pesticidal activity	Toxicological relevance
None				

(a): At least one FOCUS scenario or relevant lysimeter

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
None	-

Table 4: Air

Compound (name and/or code)	Toxicology
lavandulyl senecioate	Rat LC_{50} inhalation > 5.21 mg/L air per 4h (no classification proposed)

7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of the Regulation concerning information on potentially harmful effects).

- A search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011; relevant for all representative uses evaluated; submission date proposed by the applicant unknown).

- Analytical method for monitoring the active substance in air (relevant for all representative uses evaluated; see Section 1).

- Assessment of the toxicological relevance of the individual impurities present in the technical specification in comparison with the toxicity profile of the *R*-lavandulyl senecioate (relevant for all representative uses evaluated; submission date proposed by the applicant unknown; see Section 1 and 2).

- Toxicological information allowing to derive toxicological reference values or reliable data regarding the natural background levels to *R*-lavandulyl senecioate, i.e. allowing to read-across from other similar compounds potentially present in the environment (relevant for all representative uses evaluated; submission date proposed by the applicant unknown; see Section 2).

- Information on the identity and magnitude of residues in plants or at least for evidence to support the claim that detectable residues on the consumable commodities are unlikely to occur or that residue levels of *R*-lavandulyl senecioate are comparable to natural background levels, to enable a conclusion regarding the dietary exposure potential for consumers from the representative uses of lavandulyl senecioate. (relevant for all representative uses evaluated; submission date proposed by the applicant unknown; see Section 3).

- A sterile aqueous hydrolysis study for lavandulyl senecioate [(*RS*)-5-methyl-2-(prop-1-en-2-yl)hex-4-en-1-yl 3-methylbut-2-enoate] was not available. The data are needed to fulfil the data requirements and understand the stability of the active substance in water and other media where water is present that support the exposure assessment or hazard characterisation (submission date proposed by the applicant unknown; see Section 4).

- The RMS evaluation of the two studies Levi-Zada et al, 2014 and Lentini et al, 2014 (Italy 2018)) in the amended DAR was inadequate to provide the necessary transparency in the experimental designs and results from these peer reviewed scientific literature articles (relevant for all representative uses evaluated; necessary information from the applicant was available; see Section 4).

- The issue that the synthetic pheromone released from dispensers is a racemate but that emitted from females is the single isomer *S*-lavandulyl senecioate, was not adequately addressed. When considering the information presented by the RMS in the amended DAR (Italy 2018), the references cited of de Alfonso, (2018b), Kirk (2017), Bhosale and Waghmode, (2017) and Gliszczyńska et al., (2011) that have been claimed to demonstrate there would be *R* isomers of related but different compounds emitted by other insects or plants have not been transparently evaluated by the RMS (available in the dossier), nor have the studies Araujo (2007), Canko (2014) Dublon (2009) and SEAL (2013) that were cited in the report Alfonso, (2018b) (also available in the dossier). The structures of the related compounds and justification for any 'read across' was not presented in the amended DAR. There was no estimation of any natural emission rates of *R*-isomer compounds presented in the DAR, though these were provided by the applicant in Alfonso, (2018b) for *R*-lavandulyl 3-methyl-3-butenoate. Considering the functional groups / chemical reactivity of the

related compounds cited, further information from the applicant is needed to address the exposure and risk from *R*-lavandulyl senecioate (relevant for all representative uses evaluated; submission date proposed by the applicant unknown; see Sections 2, 3, 4 and 5).

- Further information to address the potential effects and risk to birds and mammals, bees and other non-target arthropods (relevant for all representative uses; submission date proposed by the applicant unknown; see Section 5).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

No particular conditions are proposed for the representative uses evaluated.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the uniform principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011[2] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation.

1. Exposure estimates for the *R*-lavandulyl senecioate component of lavandulyl senecioate from natural sources were not available. Therefore the exposure and risk assessment to *R*-lavandulyl senecioate resulting from the representative use could not be completed when considering the limited hazard characterisation of the racemate lavandulyl senecioate. This concerns the dietary and non-dietary risk assessment for humans and the risk assessment for other non-target organisms such as birds and mammals, bees and other non-target arthropods (see Sections 2, 3, 4 and 5).

9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of the Regulation.

- None identified.

[2] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

Table 5: Overview of concerns

Representative use		Grape vine (field use) and any other crop where *P. ficus* may be a pest
Operator risk	Risk identified	
	Assessment not finalised	X[1]
Worker risk	Risk identified	
	Assessment not finalised	X[1]
Resident/bystander risk	Risk identified	
	Assessment not finalised	X[1]
Consumer risk	Risk identified	
	Assessment not finalised	X[1]
Risk to wild non-target terrestrial vertebrates	Risk identified	
	Assessment not finalised	X[1]
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	X[1]
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	
Groundwater exposure to active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure to metabolites	Legal parametric value breached	
	Parametric value of 10 µg/L breached	
	Assessment not finalised	

The superscript numbers relate to the numbered points indicated in Sections 9.1.

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Abbreviations

1/*n*	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AAOEL	acute acceptable operator exposure level
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AUC	area under the blood concentration/time curve
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony-forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
Cmax	concentration achieved at peak blood level
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DDD	daily dietary dose
DM	dry matter
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemicals Agency

EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
ETR	exposure toxicity ratio
ETR_{acute}	exposure toxicity ratio for acute exposure
$ETR_{chronic}$	exposure toxicity ratio for chronic exposure
ETR_{larvae}	exposure toxicity ratio for larvae
ETR_{HPG}	exposure toxicity ratio for effects on honeybee hypopharygeal glands
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time-weighted average factor
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FIR	food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as International Group of National Associations of Manufacturers of Agrochemical Products; GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathione
Hb	haemoglobin
Hct	haematocrit
HPG	hypopharygeal glands
HPLC	high-pressure liquid chromatography or high-performance liquid chromatography
HPLC-MS	high-pressure liquid chromatography–mass spectrometry
HQ	hazard quotient
$HQ_{contact}$	hazard quotient for contact exposure
HR	hazard rate
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organization for Standardization

IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
K_{Foc}	Freundlich organic carbon adsorption coefficient
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography–mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDD_{50}	lethal dietary dose; median
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mm	millimetre (also used for mean measured concentrations)
mN	milli-newton
MRL	maximum residue level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water-holding capacity
NESTI	national estimated short-term intake
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen–phosphorus detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types

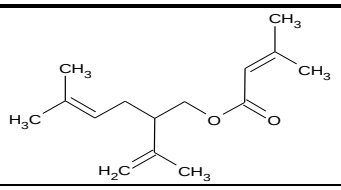
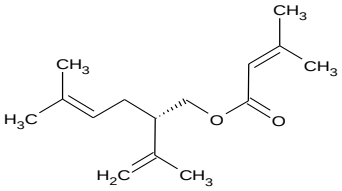
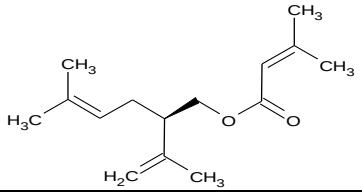
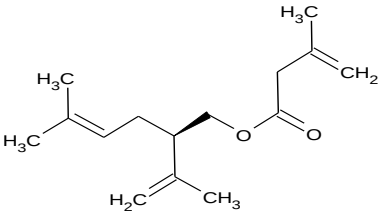
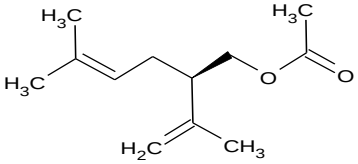
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure–activity relationship
r^2	coefficient of determination
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SPG	specific protection goal
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
Tmax	time until peak blood levels achieved
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid-stimulating hormone (thyrotropin)

TWA	time-weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor
UV	ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organization

Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): http://dx.doi.org/10.2903/j.efsa.20YY.NNNN

Appendix B – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
lavandulyl senecioate	(*RS*)-5-methyl-2-(prop-1-en-2-yl)hex-4-en-1-yl 3-methylbut-2-enoate O=C(\C=C(/C)C)OCC(C\C=C(\C)C)C(=C)C STLUIDJQVVNOAV-UHFFFAOYSA-N	
***S*-lavandulyl senecioate**	(*S*)-5-methyl-2-(prop-1-en-2-yl)hex-4-en-1-yl 3-methylbut-2-enoate O=C(\C=C(/C)C)OC[C@@H](C\C=C(\C)C)C(=C)C STLUIDJQVVNOAV-CQSZACIVSA-N	
***R*-lavandulyl senecioate**	(*R*)-5-methyl-2-(prop-1-en-2-yl)hex-4-en-1-yl 3-methylbut-2-enoate O=C(\C=C(/C)C)OC[C@H](C\C=C(\C)C)C(=C)C STLUIDJQVVNOAV-AWEZNQCLSA-N	
***R*-lavandulyl 3-methyl-3-butenoate**	(*R*)-5-methyl-2-(prop-1-en-2-yl)hex-4-en-1-yl 3-methylbut-3-enoate O=C(CC(=C)C)OC[C@H](C\C=C(\C)C)C(=C)C WYWNGFBLJJWITG-AWEZNQCLSA-N	
***R*-lavandulyl acetate**	(*R*)-5-methyl-2-(prop-1-en-2-yl)hex-4-en-1-yl acetate O=C(C)OC[C@H](C\C=C(\C)C)C(=C)C HYNGAVZPWWXQIU-UHFFFAOYSA-N	

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 06 Sep 2017)
(c): ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 Feb 2018)