Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

D-Allethrin

Product type: 18

ECHA/BPC/293/2021

Adopted

12 October 2021

Opinion of the Biocidal Products Committee

on the application for approval of the active substance d-allethrin for product type 18

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the non-approval in product type 18 of the following active substance:

Common name:	**d-allethrin**
Chemical name:	**(RS)-3-allyl-2-methyl-4-oxocyclopent-2-enyl-(1R,3RS)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate**
EC No.:	**not allocated**
CAS No.:	**231937-89-6**

Existing active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of the BPC opinion

Following the submission of two applications, one by Sumitomo Chemical (UK) Plc, United Kingdom and one by Endura S.p.A, Italy, both received on 26 April 2006, the evaluating Competent Authority Germany submitted an assessment report and the conclusions of its evaluation to the Agency on 11 January 2017. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-40) and its Working Groups (WG III 2017, WG V 2018). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at https://echa.europa.eu/de/potential-candidates-for-substitution-previous-consultations/-/substance-rev/15709/term on 10 February 2017, in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 10 April 2017.

Adoption of the BPC opinion

Rapporteur: Germany

The BPC opinion on the non-approval of the active substance d-allethrin in product type 18 was adopted on 12 October 2021.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position including their grounds are published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that d-allethrin in product type 18 may not be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

Due to the different manufacturing processes of the two applicants, the impurity profiles differ from each other. Only the analytical data submitted by Endura was sufficiently specific and had the required analytical closure to derive a reference specification. However, the toxicological assessment given below is mainly based on the studies submitted by the applicant Sumitomo. Endura submitted a letter of access to these studies. The proposed specification includes three impurities that are potentially genotoxic. These impurities were not determined in the batches used by Sumitomo for the toxicological assessment. Therefore, the proposed specification, set on the Endura source, is not covered by the toxicological studies and subsequently no reference specification can be set for the active substance. Even in cases where the assessment does not show any unacceptable risks for human health, it cannot be concluded that d-allethrin with the proposed specification would show acceptable risks as well.

Even under the assumption that the toxicological studies would cover the proposed specification, no safe use can be demonstrated with the data submitted. The human health risk assessment, based mainly on toxicological studies of Sumitomo, demonstrates only a safe use for the professional use with risk mitigation measures necessary to protect the user and the general public, but not for the non-professional use due to unacceptable risk for the general public. In contrast, the environmental risk assessment only results in a safe use for the non-professional use of a vaporiser, but not for the professional use as a spray application. Consequently, no safe use could be demonstrated when combining the outcomes of the human health and environmental risk assessment.

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of d-allethrin in product type 18. D-allethrin is a synthetic pyrethroid. Of the possible eight stereoisomers of the molecule four are minor stereoisomers with contents of <10%. The four main stereoisomers that represent the active substance d-Allethrin are the [1R,trans;1S]-isomer, the [1R, trans;1R]-isomer, the [1R, cis;1S]-isomer and the [1R cis;1R]-isomer at a ratio of 4:4:1:1. All four isomers have a biocidal activity. However, the [1R, trans;1S]-isomer is the one with the most potent biological activity. The minimum purity based on the four main isomers is 900 g/kg.

There were two separate applications for approval submitted. For both applicants, the initially submitted 5-Batch analyses were not acceptable based on the facts that the used method was not highly specific (not all stereoisomers determined), the analytical closure was < 98% and that, in addition, the analyses were older than 10 years. In the further process however, the applicant Sumitomo Chemical (UK) Plc refused to submit a valid 5-batch analysis as well as the other requested information. Therefore, specifications for the reference source are established only based on the data (5-batch analysis and quality control (QC) data) submitted by Endura S.p.A. Italy meeting the requested requirements. As the information for the two manufacturing processes are different in the precision, in the

number of synthesis steps and in the starting material purity, it cannot be concluded without a specific analysis of the two substance sources that the respective composition that the impurity profile is the same or comparable.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Sufficiently validated primary and confirmatory methods for determination of d-allethrin residues (sum of the isomers) in drinking water, surface water and soil are missing although they are required. Relevant exposure of plants, plant products or animal products is unlikely for the intended uses. Therefore, analytical methods are not needed for these matrices. If the Committee for Risk Assessment (RAC) confirms the proposed classification of d-Allethrin as Acute Tox. 3 (H301), a confirmatory method in blood and a validated method (including confirmatory method) in tissues would be required before biocidal products could be authorised.

A harmonised classification is not available. A CLH dossier was submitted to ECHA on 16 January 2017. The revised CLH dossier will be submitted to ECHA in December 2021.

The proposed classification and labelling for d-allethrin according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 3, H301 Acute Tox. 4, H332 STOT-SE 1, H370 STOT-RE 2 dermal, H373 Repr. 2, H361d Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Labelling	
Pictogram codes	GHS06 GHS08 GHS09
Signal Word	Danger
Hazard Statement Codes	H301 Toxic if swallowed. H332 Harmful if inhaled. H370 Causes damage to the nervous system after oral and inhalation exposure. H373 May cause damage to the skin through prolonged or repeated exposure. H361d Suspected of damaging the unborn child. H410 (Very toxic to aquatic organisms with long lasting effects.)
Specific Concentration limits, M-Factors	M = 100 (acute and chronic)

b) Intended use, target species and effectiveness

As representative products, vapor releasing impregnated mats used in conjunction with an electric heating unit intended to be used indoors (domestic households excluding kitchens) by non-professional users as well as a spray application have been evaluated. The spray application is intended to be used by professional users in commercial and industrial buildings whereas a ready-to-use formulation of this product is intended to be used by non-professionals in domestic households excluding kitchens. The products are intended for the control of mosquitoes (e.g. *Anopheles spp, Aedes spp, Culex spp*) and flies (*Musca domestica*).

D-allethrin is a pyrethroid insecticide. It acts on the sodium channel in the nerve membranes of the invertebrate nervous system causing pronounced repetitive activity and a prolongation of the transient increase in sodium permeability of the nerve membranes. This results in continual nerve impulse transmission leading to tremors and death.

The data on d-allethrin and the representative biocidal product have demonstrated sufficient efficacy against the target species.

Resistance against pyrethroids can occur in relevant pest species. In Europe, the main resistance problems have occurred with pests of agricultural significance - among them some species of flies and cockroach populations. Cross-resistance of pest species to other pyrethroids is to be anticipated due to a common mode of action. Furthermore, instances of cross-resistance (or multiple resistance) between pyrethroids and organochlorine insecticides have been reported.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

It should be noted that the assessment of the risk for human health is based on the submitted toxicological data. However, it could not be demonstrated that the proposed specification is covered by these data. During the evaluation of the toxicological relevance of impurities and whether the toxicological batches cover the proposed specification, 8 impurities in the proposed specification were considered relevant. Since some of the toxicological studies were conducted with Sumitomo's material which does not contain all of these impurities, an assessment was performed to determine whether the toxicological batches cover the proposed specification (which is based on Endura's 5-batch analysis).

Following the evaluation of QSAR alerts and a positive Ames test with Endura's material showing a positive result, it was concluded that the proposed specification of d-allethrin is not covered by the batches of the toxicological studies. In this Ames test, an approximately two-fold increase in revertant colonies in comparison to the negative control was observed in bacterial strains TA100 and TA102 (including metabolic activation). That means that impurities of the proposed specification that are not present in the toxicological batches have potentially genotoxic properties. Therefore, these toxicological studies cannot be used for the assessment of d-allethrin with the proposed specification from Endura.

Based on the available data and information used for the assessment of human health in the context of Regulation (EU) 528/2012 and Regulation (EC) 1272/2008, d-allethrin is considered to be toxic if swallowed (Acute Tox. 3, H301) and harmful if inhaled (Acute Tox. 4, H332). Furthermore, it is considered to cause damage to the skin through prolonged or repeated exposure (STOT-RE 2, H373) and to the nervous system after oral and inhalation exposure (STOT-SE 1, H370). D-allethrin is suspected of damaging the unborn child (Repr. 2, H361d).

Based on the available information the majority of the BPC WG was not convinced of the mutagenic properties of the active substance. The basis for this conclusion are the toxicological studies performed with the testing material from Sumitomo. The Ames test performed with the testing material from Endura indicated a mutagenic potential. Assuming that the active substance is not mutagenic, this finding could be attributed to (one or more) impurities present in the active substance source from Endura. Furthermore, pyrethroids have the potential to provoke paresthesia.

Mutagenicity of photometabolites:

Mutagenicity in bacteria was observed following light exposure to substances of the allethrin series. This mutagenic finding is attributed to the formation of reactive photometabolites. Based on this finding the photometabolites epoxide on the cyclopropyl alcohol moiety and allethronyl glyoxylate monohydrate are considered mutagenic. Based on the mutagenicity of the photometabolites, the TTC (Threshold of Toxicological Concern) approach applying a value of 2.5×10^{-6} mg/kg bw/day was applied for the risk assessment of the photometabolites.

Furthermore, it is concluded that d-allethrin is converted in real-life exposure conditions by sunlight to these genotoxic photodegradation products at a yield of approximately 0.5 % (50 % exposure and 1 % formation rate). It is considered that the available data do not show that glass shields inhibit the photodegradation, and that no further refinement is applicable.

Systemic effects:

The risk assessment for systemic effects of d-allethrin is performed with the AEL approach. The AEL is based upon the oral NOAEL of 6 mg/kg bw/day (liver toxicity) from a 123-wk rat study, and the knowledge of 60 % oral absorption rate. By using a (default) assessment factor of 100 and assuming 60% oral absorption, an $AEL_{long\text{-}term}$ of 0.04 mg/kg bw/day is derived for long-term exposure towards d-allethrin

Local effects:

Acute irritation studies revealed that d-allethrin is not irritating to the skin or the eyes of rabbits. Nevertheless, severe inflammatory response in rabbits is observed after repeated dose 21-day dermal application of d-allethrin.

Therefore, a semi-quantitative risk characterisation for local dermal effects of d-allethrin is performed taking into account the $NOAEC_{local,\ dermal\ effects}$ as well as the in-use concentration of d-allethrin in %. The dermal NOAEC of 0.15 % (a no adverse effect concentration) is derived from a 21-d dermal rabbit study.

Human health scenarios

The table below summarises the exposure scenarios assessed. The risk assessment described hereafter was done under the assumption that the available toxicological studies would cover the proposed specification which is not the case.

Summary table: human health scenarios[a]			
Scenario	**Primary or secondary exposure[1] and description of scenario**	**Exposed group**	**Conclusion**
Pynamin® Forte 40 mg Mat (vapor releasing impregnated mats)			
Application	Primary systemic exposure (dermal) of non-professional users to d-allethrin in Pynamin® Forte 40 mg Mat	Non-professional user	Acceptable
Post application	Secondary (medium-term) systemic exposure (inhalative and dermal for adult, inhalative, dermal and oral for toddler) of the general public to d-allethrin in Pynamin® Forte 40 mg Mat	General public	Acceptable
Post application	Secondary systemic exposure of the general public to the photometabolites from Pynamin® Forte 40 mg Mat	General public (adult and toddler)	**Not acceptable**
Duracide A - FIK aerosol (RTU spray)			
Application	Primary systemic exposure (inhalative, dermal, oral) of non-professional users to d-allethrin in Duracide A - FIK aerosol	Non-professional user	Acceptable
Application	Secondary (acute) systemic exposure (inhalative, dermal, oral) of the general public to d-allethrin in Duracide A - FIK aerosol: by-stander during application RMM: reducing contact to the biocidal product (e.g. by prohibiting the presence of children/ toddlers during application.)	General public	Acceptable with RMM
Post application	Secondary (medium-term) systemic exposure (dermal, oral for toddler) of the general public to d-allethrin in Duracide A - FIK aerosol: contact to parent's clothing	General public	Acceptable
Post application	Secondary (medium-term) systemic exposure (dermal, oral for toddler) of the general public to d-allethrin in Duracide A - FIK aerosol: contact to residues on the floor and other surfaces	General public	Acceptable
Post application	Secondary systemic exposure (dermal and oral for toddler) of the general public to the photometabolites from Duracide A – FIK aerosol	General public	**Not acceptable**

[1] See document: Terminology primary and secondary exposure (available from https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/80f71044-fce2-43b3-a73c-e156effc9fcb/Terminology%20primary%20and%20secondary%20exposure.pdf)

Summary table: human health scenarios[a]			
Duracide A (concentrate, spray application)			
Application	Primary exposure (dermal): Mixing and loading PPE: protective coverall and protective gloves	Professional user	Acceptable with PPE
Application	Primary exposure (dermal, inhalative): spraying of water based Duracide A-EC PPE: protective coverall and protective gloves	Professional user	Acceptable with PPE
Application	Primary exposure (dermal, inhalative): spraying of solvent based Duracide A PPE: protective coverall and protective gloves	Professional user	Acceptable with PPE
Application	Primary exposure (dermal, inhalative): ULV (ultra low volume) application of solvent based Duracide A PPE: protective coverall and protective gloves	Professional user	Acceptable with PPE
Application	Primary exposure (dermal, inhalative): ULV application of water based Duracide A-EC PPE: protective coverall and protective gloves	Professional user	Acceptable with PPE
Application	Primary exposure (dermal, inhalative): cold and thermal fogging of solvent based Duracide A PPE: protective coverall and protective gloves	Professional user	Acceptable with PPE
Application	Primary exposure (dermal, inhalative): cold and thermal fogging of water based Duracide A-EC PPE: protective coverall and protective gloves	Professional user	Acceptable with PPE
Post-Application	Secondary exposure (dermal) to d-allethrin PPE: protective gloves	Professional user	Acceptable with PPE
Post-Application	Secondary exposure (dermal) to photometabolites PPE: protective gloves	Professional user	Acceptable with PPE
Post application	Secondary systemic exposure of the general public to d-allethrin in Duracide A (concentrate):	General public	Acceptable
Post application	Secondary systemic exposure of the general public to the photometabolites of Duracide A (concentrate) RMM: The use of the biocidal product is restricted to areas that are not accessible to the general public	General public (children and toddler)	Acceptable with RMM.

[a] Note that the assessment was done under the assumption that the proposed specification would be covered by the available toxicological data. However, the batches used in the toxicological studies submitted by Sumitomo do not cover the proposed specification that is based on the data submitted by Endura.

Professional User

For all considered exposure scenarios regarding Duracide A, the risk assessment does not indicate a concern taking into account the described protection measures (either only wearing of protective gloves or wearing of protective coverall as well as protective gloves). It is essential to indicate that the conclusion only applies to d-allethrin in the biocidal product and the generated photometabolites (and not to other ingredients).

For secondary exposure to the generated photometabolites dermal exposure reduction to hands (e.g. gloves) is needed.

If risk mitigation measures (wearing of protective coverall and protective gloves) are taken into account for the preparation phase or mixing and loading phase as well as for the application and post-application phase, the use of d-allethrin containing products is considered to be acceptable.

Non-professional user / general public

Systemic effects:

Primary exposure of non-professionals as well as secondary exposure of the general public to d-allethrin from Pynamin forte 40 mg mat or from Duracide A or Duracide - FIK aerosol is acceptable regarding human health. The risk identified for combined secondary acute and medium-term exposure to Duracide – FIK aerosol for children/toddlers can be managed by appropriate risk mitigation measures, reducing contact to the biocidal product (e.g. by prohibiting the presence of children/toddlers during application). Exposure to d-allethrin for the general public after professional use of Duracide A (concentrate) is considered acceptable.

Regarding the exposure to genotoxic photodegradation products, a non-acceptable human health risk is identified for the general public after non-professional use. Further potential refinement options (e.g. UV reduction factor for glass, use in the absence of sunlight) are considered not acceptable. Thus, no overall safe non-professional use is identified in relation to the human health risk assessment.

Based on the risk assessment for the general public performed for non-professional use products, a human health risk is also be expected after exposure of the general public to the photometabolites generated after professional use. Therefore, the professional use should be restricted to areas inaccessible for the general public.

Dietary risk assessment:

For non-professional uses, the dietary risk assessment has shown that the exposure to residues of d-allethrin leads to unacceptable health risks for adults and children. Therefore, non-professional use of d-allethrin containing products in food preparation or storage areas, e.g. kitchens, has to be excluded.

For professional uses, no dietary risk assessment has been performed for active substance approval, as currently no guidance document is publicly available.

Consumer exposure to potential residues in drinking water has not been evaluated.

Environment

D-allethrin has been shown to be not readily biodegradable and is not susceptible to hydrolysis in the pH-range from 4 to 7. At pH 9, d-allethrin showed hydrolytic degradation with a half-life of 12.2 days. D-allethrin undergoes photodegradation in aqueous media and is susceptible to photodegradation in air (the half-life is estimated to be 1.733 h). D-allethrin is a persistent substance regarding the results of degradation studies in

water/sediment systems (DT_{50} = 143.7 days at 12°C) and the soil compartment (DT_{50} > 120 days). Several major metabolites were formed in the environmental compartments. The active substance indicates a potential for bioaccumulation in the aquatic compartment, but the B criterion is not fulfilled. Based on aquatic studies with fish, daphnia and algae (short-term and one long-term) it can be concluded that the substance is very toxic to fish and invertebrates. D-allethrin is classified as very toxic to aquatic life and can cause long lasting effects.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Vapour releasing impregnated mats (diffusor) - non-professional use Pynamin® Forte 40 mg Mat	The product is applied indoors by non-professional users in private areas. Releases to the wet cleaning zone of a house enter the sewer system via wet cleaning. Simultaneous emissions from several households within the catchment of one sewage treatment plant (STP) are cumulated in the STP. Surface water and sediment are exposed through STP discharge into the receiving water course, whereas soil and groundwater are exposed via sludge application to agricultural land or grassland. Finally, the bioconcentration and bioaccumulation in the aquatic and terrestrial food chain has been assessed.	Acceptable
Air-space treatment by spraying pump, ULV, hot or cold fogging - professional use Duracide A Emulsifiable concentrate Duracide A – As it is	The product is applied indoors by professional users in commercial or industrial buildings. Releases to the wet cleaning zone of the buildings enter the sewer system via wet cleaning. Simultaneous emissions from several buildings within the catchment of one sewage treatment plant (STP) are cumulated in the STP. Surface water and sediment are exposed through STP discharge into the receiving water course, whereas soil and groundwater are exposed via sludge application to agricultural land or grassland. Finally, the bioconcentration and bioaccumulation in the aquatic and terrestrial food chain has been assessed.	**Not acceptable** Unacceptable risks are identified for the aquatic compartment (surface water and sediment) and for soil. In addition, the trigger value of 0.1 µg/L in groundwater is exceeded.
Air-space treatment by manual spraying with handheld spray - non-professional use Duracide A – Ready to use product (RTU product)	The product is applied indoors by non-professional users in private households. Releases to the wet cleaning zone of a house enter the sewer system via wet cleaning. Simultaneous emissions from several households within the catchment of one sewage treatment plant (STP) are cumulated in the STP. Surface water and sediment are exposed through STP discharge into the receiving water course, whereas soil and groundwater are exposed via sludge application to agricultural land or grassland. Finally, the bioconcentration and bioaccumulation in the aquatic and terrestrial food chain has been assessed.	**Not acceptable** Unacceptable risks are identified for the aquatic compartment (surface water and sediment). In addition, the trigger value of 0.1 µg/L in groundwater is exceeded.

Applied as a diffusor used inside private households (non-professional use), no unacceptable risks were identified for d-allethrin for the environment. The intended use for air-space treatment indoors both by manual spraying with handheld sprays (non-professional use) in private households and by spraying pump, ULV, hot or cold fogging (professional use) in commercial/industrial buildings leads to unacceptable risks for the environment.

No RMM are considered feasible to reduce the unacceptable risks for the spray applications. Further information could lead to a refinement of the risks identified. However, this has not been considered as the evaluation of the toxicological data already leads to the situation that the non-approval of the active substance is proposed.

Overall conclusion

The assessment of the risk for human health is based on the submitted toxicological data. However, it could not be demonstrated that the proposed specification is covered by these data. During the evaluation of the toxicological relevance of impurities, several impurities have been considered as relevant in the proposed specification. Some of the toxicological studies were conducted with Sumitomo's material, which does not contain all of these impurities. An assessment of these impurities was performed, and it was concluded that the toxicological studies cannot be used for the assessment of d-allethrin with the proposed specification, which is based on Endura's 5-batch analysis. This fact leads to the situation that, finally, it is not possible to conclude whether one of the representative products fulfil Article 19(1) of Regulation (EU) No 528/2012.

From the uses assessed (under the assumption that the proposed specification would be covered by the available toxicological data), no unacceptable risks have been identified for the professional user and professional bystander wearing personal protective equipment (coverall and gloves). An unacceptable risk has been identified for the general public due to secondary exposure to genotoxic photometabolites formed after the application of the products. As these risks cannot be reduced by any risk mitigation measure, overall, this indicates that no safe non-professional use could be identified. Secondary exposure of the general public after professional use has not been assessed and would have to be considered at product authorisation stage. If an unacceptable risk for the general public after professional use could not be excluded, the use of corresponding biocidal products would have to be restricted to areas that are inaccessible to the general public.

For the environment, acceptable risks have only been identified for the vapor releasing impregnated mats whereas for the spray applications (concentrate and RTU product), no safe use could be demonstrated.

Overall, it can be concluded that no safe uses can be identified when combining the outcomes of the human health and environmental risk assessment. However, further risk refinement options for the environmental risk assessment (e.g. a degradation study for the metabolites in the terrestrial compartment and/or a sewage treatment plant simulation study) would be possible, but have not be considered as the evaluation of the toxicological data already leads to the situation that the non-approval of the active substance is proposed.

2.2. Exclusion, substitution and POP criteria

2.2.1 Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	no classification required	D-allethrin does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	Repr. 2	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	d-allethrin: vP Relevant metabolites of the a.s.: t-COOH-CA: vP d-c-CRA: P ωt-COOH-d-t-allethrin: potentially P	D-allethrin does not fulfil criterion (e) of Article 5(1) but fulfils criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	d-allethrin: not B or vB d-c-CRA, t-COOH-CA and ωt-COOH-d-t-allethrin: not B	
	Toxic (T)	d-allethrin: T d-c-CRA, t-COOH-CA and ωt-COOH-d-t-allethrin: not T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	An assessment of the endocrine disrupting properties according to Regulation (EU) 2017/2100 was not conducted as non-approval is proposed. Consequently, no conclusion can be drawn whether d-allethrin fulfils criterion (d) of Article 5(1) with respect to humans or criterion (e) of Article 10(1) with respect to non-target organisms.	
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms		
	Article 57(f) and 59(1) of REACH		
	Intended mode of action that consists of controlling target organisms via their endocrine system(s)		
Respiratory sensitisation properties	No classification required (no data available). D-allethrin does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related	D-allethrin does not fulfil criterion (e) of Article 10(1).		

Property	Conclusions
to endocrine disrupting properties	
Proportion of non-active isomers or impurities	D-allethrin does not fulfil criterion (f) of Article 10(1)

Consequently, the following is concluded:

D-allethrin does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

D-allethrin does meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012 and is therefore considered as a candidate for substitution. D-allethrin fulfils criterion (d) of Article 10(1) being very persistent and toxic.

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[2], "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[3] and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment"[4] agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

The endocrine disruptor properties have not been assessed as defined in Regulation (EU) No 2017/2100 and it is therefore not possible to finally conclude on the exclusion criteria related to Article 5(1)(d) and 10(1)(a), and on whether d-allethrin shall be considered a candidate for substitution related to Article 10(1)(e). This is in line with paragraph 16 of the "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment" [4].

2.2.2 POP criteria

D-allethrin is not B and has no potential for long-range transport. Therefore, the substance does not meet the POP criteria.

D-allethrin is not B and has no potential for long range transport. Therefore, the substance does not meet the POP criteria.

[2] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc

[3] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

[4] See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).

2.2.3 Identification of potential alternatives substances or technologies, including the results of the public consultation for potential candidates for substitution

Results of the public consultation:

One non-confidential and one confidential contribution was received. The non-confidential contribution was submitted by one of the applicants stating that there are no alternatives available on the market. They justified this statement claiming that there were no biocidal products authorised under the BPR containing photolabile active substances that are not themselves candidates for substitution. Furthermore, the company argued that, in the interest of minimising the occurrence of pesticide resistance, exclusion and substitution of active substances should be avoided. According to their opinion, this applies to the number of chemical groups of active substances and to the number of active substances within a chemical group. According to the company, this is of particular relevance in applications where rotation of insecticides with different modes is required. In addition, the company referred to the World Health Organization (WHO) saying that "one sixth of the illness and disability suffered worldwide is due to vector-borne diseases, with more than half the world's population currently estimated to be at risk of these diseases." The company concluded that substitution of biocides without adequate replacement may profoundly harm children and adults in addition to causing substantial financial and physical stress to the public health care system.

The confidential comment did not contain any statement with regard to the availability of alternatives.

Potential alternative active substances:

For PT 18, 45 active substances have already been approved.

Conclusion:

Based on the available information and especially considering the high number of active substances already approved or still under evaluation for PT 18, it is concluded that there are alternative active substances on the market which can be used as substitute for d-allethrin.

2.3. BPC opinion on the application for approval of the active substance d-allethrin in product type 18

In view of the conclusions of the evaluation, it is proposed that d-allethrin shall not be approved and included in the Union list of approved active substances in product type 18.

The proposed specification for d-allethrin is based on the only data (5 batch and QC of Endura) that are sufficiently specific and whose analytical closure has been submitted in sufficient quality. However, it could not be demonstrated that this proposed specification is covered by the submitted toxicological data. On the contrary, studies submitted give rise to the assumption that d-allethrin, which complies with the proposed specification, has different properties than the d-allethrin test material used in the toxicological studies submitted. Therefore, the toxicological data package cannot be used for the evaluation of d-allethrin with the proposed specification. As there is not enough data of sufficient quality to define a different specification, it is not possible to conclude whether d-allethrin fulfils the conditions for approval set out in Article 4(1) of Regulation (EU) No 528/2012, in particular with regard to the criteria referred to in Article 19(1)(b)(iii). As compliance with the conditions for approval cannot be confirmed, it is proposed that d-allethrin shall not be approved.

It should be noted that even under the assumption that the toxicological studies would cover the proposed specification, no safe use could be demonstrated with the data

submitted. The human health risk assessment, based mainly on toxicological studies of Sumitomo, demonstrates only a safe use for the professional use with risk mitigation measures necessary to protect the user and the general public, but not for the non-professional use. In contrast, the environmental risk assessment only results in a safe use for the non-professional use of a vaporiser, but not for the professional use due to unacceptable risks for the general public. Consequently, no safe use could be demonstrated when combining the outcomes of the human health and environmental risk assessment.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012. D-allethrin is proposed to be classified as Acute Tox. 3 (H301), Repr. 2 (H361d), STOT SE 1 (H370), STOT RE 2 (H373) and Aquatic Acute 1 (H400). Furthermore, it fulfils the criteria for being very persistent and toxic.

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