

## **Biocidal Products Committee (BPC)**

Opinion on the application for approval of the active substance:

**Prallethrin**

**Product type: 18**

ECHA/BPC/411/2024

Adopted

26 February 2024

**BPC**  
BIOCIDAL PRODUCTS  
COMMITTEE



## Opinion of the Biocidal Products Committee

on the application for approval of the active substance

**Prallethrin 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 approval in product type 18 of the following active substance:

<b>Common name:</b>	<b>Prallethrin</b>
<b>Chemical name:</b>	<b>2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate</b>
<b>EC No.:</b>	<b>245-387-9</b>
<b>CAS No.:</b>	<b>23031-36-9</b>

### 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 an application by Sumitomo Chemical on 25 April 2006 and Endura on 25 April 2006, the evaluating Competent Authority Greece submitted an assessment report and the conclusions of its evaluation to the Commission on 9 April 2012. To review the assessment report and the conclusions of the evaluating Competent Authority, after the vertebrate data sharing negotiations between the interested parties were finalized, the Agency organised consultations via the BPC (BPC-50) and its Working Groups (WG-III-2017, WG-IV-2017, WG-III-2018, WG-IV-2023). 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 available at <https://echa.europa.eu/public-consultation-on-potential-candidates-for-substitution/-/substance-rev/75216/term> on 21 November 2023, in accordance with the requirements of Article 10(3) of BPR. Interested third parties were invited to submit relevant information by 22 January 2024.

## **Adoption of the BPC opinion**

### **Rapporteur: Greece**

The BPC opinion on the application for approval of the active substance prallethrin in product type 18 was adopted on 26 February 2024.

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 consensus. The opinion is 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 prallethrin in product type 18 may 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

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

This evaluation covers the use of prallethrin in product type 18. Prallethrin is a pyrethroid insecticide with eight isomers (1R-trans, S isomer is the predominant isomer). Specifications for the reference sources are established.

The physico-chemical properties of the active substance prallethrin and representative biocidal products have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal products. For further information see also point 2.5.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities.

Validated analytical methods are available for monitoring *prallethrin* in the soil, surface and drinking water and air.

Validated analytical methods for monitoring *metabolites M3 (wt-COOH-S-4068SF)*, *M4 (PGLS)* and *t-COOH-CA* in soil are missing and required by Sumitomo Chemical and Endura.

Validated analytical methods for monitoring *metabolites M3 (wt-COOH-S-4068SF)*, *M4 (PGLS)* and *t-COOH-CA* in drinking water are missing and required by Sumitomo Chemical and Endura.

Validated analytical methods for monitoring *metabolites M3 (wt-COOH-S-4068SF)*, *M4 (PGLS)*, *M8*, *M12*, *t-COOH-CA* in surface water are missing and required by Sumitomo Chemical and Endura.

Validated analytical methods are available for monitoring *prallethrin* in body fluids and tissues by Sumitomo Chemical.

Validated analytical methods for monitoring *prallethrin* in body fluids and tissues are missing and required by Endura.

No analytical methods were submitted for monitoring in food or feedstuffs and therefore will have to be provided at product authorisation level, in case the hydrolysis study shows potential residues via food.

A harmonised classification is available for prallethrin (CLP00<sup>1</sup>). Submission of a CLH dossier to ECHA with the purpose to amend the harmonised classification based on the outcome of the prallethrin assessment and working groups discussions is intended (timelines not set yet).

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<sup>1</sup> <https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/50861>

The harmonised and proposed (in the CAR) classification and labelling for prallethrin according to Regulation (EC) No 1272/2008 (CLP Regulation) is included in the following table:

	<b>Harmonised Classification according to the CLP Regulation (CLP00)</b>	<b>Proposed Classification according to the CLP Regulation</b>
Hazard Class and Category Codes	Acute Tox. 4 (oral) Acute Tox. 3 (inhalation) Aquatic Acute 1 Aquatic Chronic 1	Acute Tox 3 (oral) Acute Tox 3 (inhalation) STOT SE 1 (nervous system) Aquatic Acute 1 Aquatic Chronic 1
<b>Labelling</b>		
Pictogram codes	GHS06, GHS09	GHS06, CHS08, GHS09
Signal Word	Danger	Danger
Hazard Statement Codes	H302 Harmful if swallowed H331 Toxic if inhaled H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects	H301 Toxic if swallowed H331 Toxic if inhaled H370 Causes damage to nervous system H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
<b>Specific Concentration limits, M-Factors</b>	None	ATE <sub>oral</sub> = 190 mg/kg bw ATE <sub>inhalation</sub> = 0.658 mg/L  M = 100 (acute & chronic)

## b) Intended use, target species and effectiveness

### Sumitomo Chemical dossier

(3 representative biocidal products: Etoc LV, Etoc 10mg Mat, and Pesguard EG092 RTU)

#### Etoc LV

Etoc LV is a ready-to-use liquid vaporiser containing 292 mg of prallethrin in 40 ml (0.87% w/w), intended to be used indoors by non-professionals against mosquitoes (*Aedes albopictus* and *Culex quinquefasciatus*). After evaluating the submitted efficacy data, it is concluded that Etoc LV has the following efficacy:

- Effective, in terms of knockdown and killing effect, against mosquitoes (*Culex quinquefasciatus* and *Aedes albopictus*)
- One 40 ml LV bottle is effective for 30 days at a maximum 8 hours use a day for an average sized room (30 m<sup>3</sup>)

#### Innate effect of prallethrin

The efficacy data with Etoc LV support the innate effect of prallethrin, when used in a 40 ml liquid vaporiser containing 292 mg prallethrin, against *Culex quinquefasciatus* and *Aedes albopictus* in a room sized 30 m<sup>3</sup> for 30 days by 8 hours usage per day.

#### Etoc 10mg Mat

Etoc 10mg Mat is a ready-to-use mat vaporiser containing 10 mg prallethrin/mat to be used indoors by non-professionals against mosquitoes (*Aedes albopictus* and *Culex quinquefasciatus*). After evaluating the submitted efficacy data, it is concluded that Etoc 10mg mat has the following efficacy:

- Effective, in terms of knockdown and killing effect, against mosquitoes (*Culex quinquefasciatus* and *Aedes albopictus*)
- One mat is effective for 10 hours and suitable for an average sized room (30m<sup>3</sup>)

#### *Innate effect of prallethrin*

The efficacy data with Etoc 10mg mat support the innate effect of prallethrin, when used in a mat vaporiser at 10 mg/mat against mosquitoes (*Culex quinquefasciatus* and *Aedes albopictus*) in a room sized 30 m<sup>3</sup> for 10 hours.

#### **Pesguard EG092 RTU**

Pesguard EG092 RTU is a ready-to-use trigger spray product containing 0.1/0.2% w/w prallethrin/cyphenothrin to be used indoors by non-professionals as direct spray onto the insect pest at 1g against German cockroaches (*B. germanica*), bedbugs (*C. lectularius*), ants (*L. niger*) and catfleas (*C. felis*), as well as surface spray treatment at 25 g/m<sup>2</sup> against German cockroaches (*B. germanica*), Oriental cockroaches (*B. orientalis*), American cockroaches (*P. americana*), bedbugs (*C. lectularius*), ants (*L. niger*) and catfleas (*C. felis*), and at 9.9 g/m<sup>2</sup> against German cockroaches (*B. germanica*), American cockroaches (*P. americana*), bedbugs (*C. lectularius*), ants (*L. niger*) and catfleas (*C. felis*).

After evaluating the submitted efficacy data, it is concluded that Pesguard EG092 RTU has the following efficacy:

- Effective, in terms of knockdown and killing effect, by direct spray onto the insects at 1 g against German cockroaches, bedbugs, ants, and catfleas.
- Effective, in terms of knockdown and mortality, by surface residual spray at 25 g/m<sup>2</sup> against German cockroaches, Oriental cockroaches, American cockroaches, bedbugs, ants and catfleas, and at 9.9 g/m<sup>2</sup> against German cockroaches, American cockroaches, bedbugs, ants and catfleas.

#### *Innate effect of prallethrin*

The applicant submitted efficacy data with the representative product containing only prallethrin (0.1% w/w) as active substance (without cyphenothrin), with direct spray onto the insects at 1 g and as surface spray treatment at 25 g/m<sup>2</sup> against the target organisms. These data support the innate effect, in terms of knockdown and killing effect, of prallethrin in the representative product as direct spray onto German cockroaches, ants, bedbugs and catfleas at the dose rate of 1 g product, as well as the innate effect, in terms of knockdown and killing effect, of prallethrin in the representative product as surface treatment onto ants, German cockroaches, catfleas and bedbugs at the dose rate of 25 g/m<sup>2</sup>.

However, efficacy of the representative product containing both cyphenothrin (0.2% w/w) and prallethrin (0.1% w/w) as surface treatment against the target organisms (ants, German cockroaches, catfleas, American cockroaches and bedbugs) at 9.9 g/m<sup>2</sup>, does not support the innate effect of prallethrin at this dose rate, i.e., efficacy of the product cannot be attributed to prallethrin alone since the product also contains another PT18 active substance.

#### **Endura dossier**

(1 representative biocidal product: EnduLed)

## EnduLed

EnduLed is a ready-to-use liquid vaporiser containing 331 mg of pure prallethrin (sum of stereoisomers) per 30 ml (1.451% w/w) to be used indoors by non-professionals against mosquitoes (*Aedes* spp. and *Culex* spp.). After evaluating the submitted efficacy data, it is concluded that EnduLed has the following efficacy:

- Effective, in terms of knockdown and killing effect, against mosquitoes (*Aedes* spp. and *Culex* spp.)
- One 30 ml bottle will remain effective against mosquitoes (*Aedes* spp. and *Culex* spp.) for 8 hours usage per day over about 30 days in a room sized 20 m<sup>3</sup>.

### *Innate effect of prallethrin*

The efficacy data with EnduLed support the innate effect of prallethrin, when used in 30 ml bottle containing 1.451% w/w prallethrin against mosquitoes (*Aedes* spp. and *Culex* spp.) for 8 hours usage per day over about 30 days in a room sized 20 m<sup>3</sup>.

## Mode of action

Pallethrin is a synthetic pyrethroid insecticide. Pyrethroid insecticides act on the sodium channel in the nerve membranes of the invertebrate nervous system and are termed sodium channel modulators. They cause 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. This action is demonstrated by the rapid knockdown action caused by pyrethroid compounds against target insects.

## Resistance

Under the intended usage pattern, prallethrin is not considered to have a high selection pressure for the development of resistance. However, it is well known that resistance is a potential problem, especially for synthetic pyrethrins, hence some general strategies, in order to avoid resistance, are recommended as follows:

- Where possible, it is recommended that application treatments should be combined with non-chemical measures.
- Products should always be used in accordance with label recommendations.
- Where an extended period of control is required, treatments should be alternated with products with different modes of action.
- Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and the proximity of untreated refuges can contribute to the risk of re-infestation.

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

### Human health

Pallethrin is rapidly absorbed after single oral administration; it is extensively metabolised and efficiently excreted *via* urine and faeces. There is no potential for accumulation in the body. Pallethrin is toxic by the oral and inhalation routes and classification as Acute Tox. 3 with H301 [Toxic if swallowed] and H331 [Toxic if inhaled] is proposed. It is of low acute



dermal toxicity, and it is not irritating to skin and eye. It does not show potential for skin sensitization.

Prallethrin is not considered to be immunotoxic, carcinogenic, genotoxic (including theoretical photodegradation products) or toxic to reproduction. The most critical effect of prallethrin after single or repeated oral administration is clinical signs of neurotoxicity, such as tremors, twitching and hyperexcitability, typical for Type I pyrethroids. Since there is evidence of acute pyrethroid neurotoxicity after oral, inhalation and dermal exposure to prallethrin at non-lethal doses, classification as STOT SE 1 with H370 [Causes damage to nervous system] is proposed.

Further data need to be generated at renewal to conclude on ED potential of prallethrin as outlined on page 16.

The table below summarises the exposure scenarios assessed for each product supported in the CAR.

### **Etoc® LV**

<b>Summary table: human health scenarios</b>			
<b>Scenario</b>	<b>Primary or secondary exposure and description of scenario</b>	<b>Exposed group</b>	<b>Conclusion</b>
Application	Primary exposure – application of electrical evaporator	Non- professionals (adults), toddlers	Acceptable (adult, toddler– 8 hrs & 24 hrs)
Post-application	Secondary exposure – inhalation to volatilised residues	Toddlers* (bystander)	Acceptable (toddler – 8 hrs & 24 hrs)
Post-application	Secondary exposure – post-application and re-entry	Toddlers* (bystander)	Acceptable (toddler – 8 hrs & 24 hrs)
Application + post-application	Primary exposure during operation of electrical evaporator and Secondary exposure post-application and re-entry	Toddlers* (bystander)	Acceptable (toddler – 8 hrs & 24 hrs)

\*Considered as a worst-case, covering also children and adults

Exposure of adults and toddlers during and after operation of EtocLV is considered acceptable when the product is used as intended (8 hrs) or even when it is used for a prolonged period (24 hrs).

No risk has been identified for combined exposure for toddlers when evaporators are employed for 8 hours or even for a prolonged period of 24 hours.

### **Etoc® 10mg mat vaporiser**

<b>Summary table: human health scenarios</b>			
<b>Scenario</b>	<b>Primary or secondary exposure and description of scenario</b>	<b>Exposed group</b>	<b>Conclusion</b>
Application	Primary exposure – application of mat evaporizer	Non- professionals (adults), toddlers	Acceptable (10 hrs)
Post-application	Secondary exposure – inhalation to volatilised residues	Toddlers* (bystander)	Acceptable (toddler– 10 hrs)

Post-application	Secondary exposure – post-application and re-entry	Toddlers* (bystander)	Acceptable (toddler – 10 hrs)
Application + post-application	Primary exposure during operation of mat evaporizer and Secondary exposure post-application and re-entry	Toddlers* (bystander)	Acceptable (toddler – 10 hrs)

\*Considered as a worst-case, covering also children and adults

Exposure of adults and toddlers during and after operation of Etoc mat is considered acceptable when the product is used as intended (10 hrs).

No risk has been identified for combined exposure for toddlers when the product is used as intended (10 hrs).

### EndurLED

<b>Summary table: human health scenarios</b>			
<b>Scenario</b>	<b>Primary or secondary exposure and description of scenario</b>	<b>Exposed group</b>	<b>Conclusion</b>
Application	Primary exposure – application of electrical evaporator	Non- professionals (adults), toddlers	Acceptable (adult, 8 hrs & 24 hrs)  Acceptable (toddler, 8 hrs & 12 hrs)  Unacceptable (toddler, 24 hrs)
Post-application	Secondary exposure – inhalation to volatilised residues	Toddlers* (bystander)	Acceptable (toddler – 8, 12 hrs & 24 hrs)
Post-application	Secondary exposure – post-application and re-entry	Toddlers* (bystander)	Acceptable (toddler – 8, 12 hrs & 24 hrs)
Application + post-application	Primary exposure during operation of electrical evaporator and Secondary exposure post-application and re-entry	Toddlers* (bystander)	Acceptable (toddler, 8 hrs & 12 hrs)  Unacceptable (toddler, 24 hrs)

\*Considered as a worst-case, covering also children and adults

Exposure of adults and toddlers during operation of EndurLED is considered acceptable when the product is used as intended (8 hrs) or even for longer periods of use i.e. 12 hrs. In case of use for a prolonged period (24 hrs) an acceptable risk is identified only for adults.

Secondary exposure of toddlers is considered acceptable when the product is used as intended or even for a prolonged period of 24 hrs. For application and post-application no risk is identified for toddlers when the product is used as intended (8 hrs) or longer (12 hrs) whereas, for prolonged exposures (24 hrs), an unacceptable risk is identified. At product authorization level, further actions can be taken such as adaptation of the device so that it cannot operate longer than the intended period e.g. by including a timer.

For the product EndurLED the supplemental hazard information EUH066 has been assigned. No risk is identified following the respective local risk assessment and characterization performed.

### **Pesguard® EG092 RTU**

<b>Summary table: human health scenarios</b>			
<b>Scenario</b>	<b>Primary or secondary exposure and description of scenario</b>	<b>Exposed group</b>	<b>Conclusion</b>
Application	Primary exposure: Surface spraying (covering also spot treatment)	Non-professional (adults)	Acceptable (adult)
Post-application	Secondary exposure – inhalation to volatilised residues	Toddlers* (bystander)	Acceptable (toddler)
Post-application	Secondary exposure: re-entering a treated area after spraying on surfaces	Toddlers* (bystander)	Unacceptable (toddler)
Post-application	Combined Secondary exposure – inhalation to volatilised residues and re-entering a treated area after spraying on surfaces	Toddlers* (bystander)	Unacceptable (toddler)

\*Considered as a worst-case, covering also children and adults

Exposure of adults applying Pesguard® EG092 RTU is considered acceptable. For secondary exposure of toddlers re-entering the treated areas after application, an unacceptable risk is identified. It should be noted though, that a conservative dermal absorption value of 70% has been used in the assessment leading possibly to overestimation of the exposure. Therefore, at product authorization level further refinement may be possible with appropriate product specific dermal absorption data.

### **Dietary Exposure**

Dietary risk assessment showed safe use, for all three airspace treatment products, after results were refined, considering deposition of biocidal product on all surfaces in a room (floor, ceiling, walls) and not only on horizontal ones.

For surface treatments, , the acute/chronic consumer exposure via food is estimated at 23.8 – 29.7% for the product Pesguard an application rate 9.9 mL/m<sup>2</sup> and 60 – 75% for the product Pesguard an application rate 25 mL/m<sup>2</sup>.

Finally, for all products more than 10% of the ADI is exceeded, so a hydrolysis study would be required for product authorisation unless further information shows exposure lower than 10%.

In the case of surface treatments (Pesguard RTU) as to ensure that no food or feedstuff will be exposed to prallethrin, the following mitigation measures are proposed to be taken into consideration:

"Remove all food, feed and drinks prior to treatment."

"Do not apply directly to surfaces on which food or feed is stored, prepared or eaten."

## Environment

Prallethrin has been shown to be not readily biodegradable and is not susceptible to hydrolysis in the pH-range from 4 to 7 at 20 °C and 25 °C. At pH 9, prallethrin showed hydrolytic degradation with a half-life of 8.1 days at 20 °C. Prallethrin undergoes photodegradation in aqueous media and is susceptible to photodegradation in air (the half-life is estimated to be 0.079 d). Prallethrin is a very persistent substance regarding the results of degradation studies in water/sediment systems (DT50 = 143.7 days at 12°C) and the soil compartment (DT50>180 days). The active substance indicates a potential for bioaccumulation in the aquatic compartment, but the B(ioaccumulation) criterion is not fulfilled. Based on aquatic studies with fish, daphnia and algae (short-term and long-term) it can be concluded that the substance is very toxic to fish and invertebrates. Prallethrin is classified as very toxic to aquatic life and can cause long lasting effects. Several major metabolites were formed in the environmental compartments and were covered in the risk assessment where relevant.

The active substance prallethrin shows an intrinsic hazard to bees.

The table below summarises the exposure scenarios assessed.

<b>Summary table: environment scenarios</b>		
<b>Scenario</b>	<b>Description of scenario including environmental compartments</b>	<b>Conclusion</b>
Vapourising liquid formulation non-professional use Etoc® LV	The product is applied indoors by non-professional users in private areas against mosquitoes. 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
Vapourising liquid formulation non-professional use EndurLED	The product is applied indoors by non-professional users in private areas against mosquitoes. 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	Acceptable

<b>Summary table: environment scenarios</b>		
<b>Scenario</b>	<b>Description of scenario including environmental compartments</b>	<b>Conclusion</b>
	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.	
Vapourising releasing impregnated mats (diffusor) formulation- non-professional use Etoc® 10 mg mat	The product is applied indoors by non-professional users in private areas against mosquitoes. 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
Manual direct spraying with handheld device - non-professional use Pesguard® EG092 RTU- Ready to use product (RTU product)	The product is applied indoors by non-professional users in private households by spraying directly onto target insects (cockroaches, bedbugs, black ants and fleas). 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
Surface residual treatment by manual	The product is applied indoors by non-professional users by residual	<b>Not acceptable (residual surface spray)</b>

Summary table: environment scenarios		
Scenario	Description of scenario including environmental compartments	Conclusion
spraying with handheld device - non-professional use Pesguard® EG092 RTU- Ready to use product (RTU product)	spraying (barrier treatment) in private households against target insects (cockroaches, bedbugs, black ants and fleas). 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.	Unacceptable risks are identified for the aquatic compartment (surface water and sediment) and terrestrial compartment. In addition, the trigger value of 0.1 µg/L in groundwater is exceeded.

Applied as a diffuser and as vapourising liquid formulation used inside private households (non-professional use), no unacceptable risks were identified for prallethrin for the environment. Acceptable risk is identified for manual direct spraying onto the target insects with a handheld device. However, unacceptable risk is identified for surface residual treatment indoors by manual spraying with handheld sprays (non-professional use) in private households.

No risk management measures (RMM) are considered feasible to reduce the unacceptable risks for the surface residual spray applications.

### Overall conclusion

Regarding human health risk assessment, a safe use has been demonstrated for the vapour releasing impregnated mats and vaporizing liquid formulations when the products are used as intended. However, and based on the outcome of the risk assessment for the supported liquid vaporizing formulation EndurLED, for prolonged periods of use (24 hrs) at product authorization level, further actions should be taken such as adaptation of the device so that it cannot operate longer than the intended period e.g. by including a timer.

With respect to the ready-to-use spray product, no safe use has been demonstrated as a result of the secondary exposure/risk assessment for toddlers. However, at product authorization level, further refinement may be possible with appropriate product specific dermal absorption data.

For the environment, acceptable risks have been identified for the vapor releasing impregnated mats and vapourising liquid formulations (both non-professional use) and for the RTU product when it is sprayed directly onto the target insects. No safe use could be demonstrated for the surface residual treatment indoors by manual spraying with handheld sprays (RTU product).

Overall, it can be concluded that safe uses can be identified when combining the outcomes of

the human health and environmental risk assessment identified for the vapor releasing impregnated mats and vapourising liquid formulations.

## 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 of Article 5 and 10 BPR<sup>2</sup>:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	No classification required	Prallethrin does not fulfil criterion (a), (b) and (c) of Article 5(1) BPR
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	vP	Prallethrin does not fulfil criterion (e) of Article 5(1) BPR but fulfils criterion (d) of Article 10(1) BPR
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	
	Toxic (T)	T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	Further data need to be generated at renewal to conclude on ED potential	No conclusion on ED properties is possible (fulfilling Article 5(1)(e) or on fulfilling Article 10(1)(e) BPR.
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	Further data need to be generated at renewal to conclude on ED potential	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s)	No	
Respiratory sensitisation	Prallethrin does not fulfil criterion (b) of Article 10(1) BPR.		

<sup>2</sup> If the active substance meets substitution due to the properties of metabolite(s) or impurity(ies), explain this below the table by describing for which criteria the evaluation is based on the metabolite(s) or impurity(ies).

Property	Conclusions
properties	No classification required.
Concerns linked to critical effects other than those related to endocrine disrupting properties	No other concerns identified.
Proportion of non-active isomers or impurities	Prallethrin does not fulfil criterion (f) of Article 10(1) BPR.

Consequently, the following is concluded:

Prallethrin does not meet the exclusion criteria laid down in Article 5 BPR.

Prallethrin meets the conditions laid down in Article 10(1)(d) BPR, and is therefore considered as a candidate for substitution since it is vP and T.

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"<sup>3</sup>, "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"<sup>4</sup> and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment"<sup>5</sup> agreed at the 54<sup>th</sup>, 58<sup>th</sup> and 77<sup>th</sup> meeting respectively, of the representatives of Member States Competent Authorities for the implementation of BPR. 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) BPR.

For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, no conclusion can be drawn on the available data. For reports submitted before 1 September 2013, the CA meeting note mentioned above sets out that the evaluating Competent Authority has to conclude based on the already available data and/or the data provided by the applicant and, in case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. It is noted that the evaluation of prallethrin for PT 18 was submitted before 1 September 2013.<sup>5</sup>

### 2.2.2. POP criteria

Prallethrin is not B and has no potential for long-range transport. Therefore, the substance does not meet the the POP criteria (persistent organic pollutant (POP) under Regulation (EC) No 850/2004).

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

Three non-confidential and two confidential contributions were received.

The first confidential contribution was submitted by one of the applicants stating that there

<sup>3</sup> See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available <https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/efada790-f874-4667-b3cf-d15a09060ac8/details>).

<sup>4</sup> 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/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/c6bf2c1b-e281-4955-93f1-56b0422425ab/details>).

<sup>5</sup> See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (available from <https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/c6bf2c1b-e281-4955-93f1-56b0422425ab/details>).



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 with the exception of *Chrysanthemum cinerariaefolium*. In addition, they stated that biocidal products should not be restricted based on PBT criteria, if a restriction has been proven unnecessary in the risk assessment based on the intended use of the biocidal product. 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. This is of relevance in application where rotation of insecticides with different mode of action is not possible (e.g. vaporising products).

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

In the three non-confidential comments it was also noted that there are no alternative active substances authorised under the BPR that are not themselves candidates for substitution, with the exception of *Chrysanthemum cinerariaefolium*. Moreover, limitations of *C. cinerariaefolium* were identified. More specifically, ensuring a consistent supply and compliant specification of *C. cinerariaefolium* ext. could be an issue for this potential alternative. In the event of crop failures there can be limitations of supply. With increased issues relating to climate change the impact on crop production due to drought, floods and other weather-related issues increases globally year on year. Therefore, this supply of specification compliant active cannot be assured unlike prallethrin.

In addition to the above, there was also one comment proposing that prallethrin should not be approved and if approved it should be limited to authorized personnel.

### **Potential alternative active substances:**

For PT 18, 43 active substances have already been approved. However, prallethrin is a photolabile molecule. According to the input received during the public consultation phase all the approved photolabile PT18 active substances are candidates for substitution with the sole exception of *Chrysanthemum cinerariaefolium* extract.

### **2.3. BPC opinion on the application for approval of the active substance Prallethrin in product type 18**

In view of the conclusions of the evaluation, it is proposed that prallethrin be approved and included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated:

92.0% w/w (Sumitomo Chemical)

93% w/w (Endura)

Note: 1R-trans, S isomer, is present at >80% (w/w) in the technical active substance of both applicants.

Relevant impurities:

Toluene: 1.0% w/w (Sumitomo Chemical) (Endura)

Prallethrin chloro derivative 2: 0.3% w/w (Endura)

BHT (Butylated hydroxytoluene): 1.9% w/w (Sumitomo Chemical) 2.0% w/w (Endura)

2. Prallethrin is considered a candidate for substitution in accordance with Article 10(d) of Regulation (EU) No 528/2012.
3. The authorisations of biocidal products are subject to the following conditions:
  - a. The product assessment should pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
  - b. In view of the risks identified for the uses assessed, the product assessment should pay particular attention to:
    - i. Children (toddlers)
    - ii. Surface water, sediment, soil and groundwater for products applied indoors by non-professional users by residual spraying (barrier treatment) in private households.
  - c. For products containing prallethrin that may lead to residues in food or feed, Member States should verify the need to set new or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.
4. The placing on the market of treated articles is subject to the following condition:
  - a. The person responsible for the placing on the market of a treated article treated with or incorporating prallethrin shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) BPR.
  - b. Member state competent authorities or, in the case of a union authorisations the Commission shall specify in the SPC of a product containing prallethrin the relevant instructions for use and precautions to be indicated on the label of the treated articles under article 58(3)(e) BPR.

The active substance does not fulfil the criteria according to Article 28(2) BPR to enable inclusion in Annex I to BPR as it has a harmonized classification as Acute Tox. 3 (inhalation), H331 and Aquatic Acute 1, H400. In addition, it is proposed to be classified as Acute Tox. 3 (oral), H301 and STOT SE 1 (nervous system), H370. Furthermore, it fulfils the criteria for being very persistent and toxic.

#### **2.4. Elements to be taken into account when authorising products**

1. The active substance prallethrin is considered as a candidate for substitution in accordance with Article 10(1)(d), and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for either national or Union authorisation.
2. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

- a. An unacceptable risk for children (toddlers) is identified following exposure to liquid evaporizers for a prolonged period of use (24 hrs) and following secondary exposure when re-entering a treated area after spraying on surfaces. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.
  - b. Potential animal health risks of pyrethroid-sensitive pets (e.g. cats and poikilothermic animals) have to be assessed and mitigated by appropriate label instructions.
  - c. In case a risk is identified for surface treatment the following mitigation measures are proposed to be taken into consideration: "Remove all food, feed and drinks prior to treatment." and "Do not apply directly to surfaces on which food or feed is stored, prepared or eaten."
  - d. For products that may lead to residues in food or feed a dietary risk assessment has to be performed at product authorisation.
  - e. For airspace treatments, it is necessary to have information on deposition of the active substance.
  - f. An unacceptable risk for the aquatic compartment (surface water and sediment), terrestrial compartment and groundwater is identified following surface residual treatment by manual spraying with handheld device (non-professional use). If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.
  - g. This active substance shows an intrinsic hazard to bees. As indicated in document "CA-Dec20-Doc.4.1" agreed at the 90th CA meeting, the warning sentence proposed in this document should only be required for products containing active substances for which scientific evidence exists in regard to their hazard (intrinsic) properties to bees, which is the case for this active substance.
3. Under the intended usage pattern, prallethrin is not considered to have a high selection pressure for the development of resistance. However, it is well known that resistance is a potential problem, especially for synthetic pyrethrins, hence some general strategies, in order to avoid resistance, are recommended as follows:
- a) Where possible, it is recommended that application treatments should be combined with non-chemical measures.
  - b) Products should always be used in accordance with label recommendations.
  - c) Where an extended period of control is required, treatments should be alternated with products with different modes of action.
  - d) Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and the proximity of untreated refuges can contribute to the risk of re-infestation.

## 2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of prallethrin.

Further tests should be provided to fulfil the information requirements regarding the following:

### Endura:

The following data must be provided as soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority (eCA):

- Absorption spectra (UV-VIS, IR, NMR) and mass spectrum (MS) must be determined and provided for all identified relevant impurities.
- Analytical methods for monitoring of the active substance and residues in body fluids and tissues.

### Sumitomo Chemical:

The following data must be provided as soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority (eCA):

- Absorption spectra (UV-VIS, IR, NMR) and mass spectrum (MS) must be determined and provided for relevant impurity BHT.
- Measurements of viscosity of the active substance provided at 20°C and 40°C
- For vapour pressure and water solubility the applicant should provide the isomer ratio of tested material.

### Sumitomo Chemical & Endura:

The following data must be provided as soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority (eCA):

- Analytical methods for monitoring metabolites *M3 (wt-COOH-S-4068SF)*, *M4 (PGLS)* and *t-COOH-CA* in soil.
- Analytical methods for monitoring metabolites *M3 (wt-COOH-S-4068SF)*, *M4 (PGLS)* and *t-COOH-CA* in drinking water.
- Analytical methods for monitoring metabolites *M3 (wt-COOH-S-4068SF)*, *M4 (PGLS)*, *M8*, *M12*, *t-COOH-CA* and *d-trans-CA* in surface water.

The following data must be provided in the product authorisation dossiers:

- A hydrolysis study to address potential residues via food in the case that the estimated dietary exposure is higher than 10% of the ADI.
- An analytical method for the determination of prallethrin residues in food and feed, in case the hydrolysis study shows potential residues via food.