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Information obtained during the consultation on potential candidates for substitution from 21/11/2023 until 22/01/2024.

Substance name:	2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin)
Product type:	18
Intended use:	Used as a spray application for direct and surface residual treatment, used in mat vaporisers and in liquid vaporisers, innate knockdown and killing effects against various insect species.
EC number:	245-387-9
CAS number:	23031-36-9
eCA:	Greece

Comment 1	**2024/01/17 13:30**
Country	Italy
Name of organization/institution	Endura S.p.A.
General information	
Product Type	18
Alternative Identity and Properties	
Technical Feasibility	
Economic Feasibility	
Hazards and Risks of the Alternative	
Availability	
Conclusion on suitability and availability of the alternative	There are currently no authorised alternatives on the market, i.e. no biocidal products (authorised according to the BPR) containing photolabile active substances that are not themselves candidates for substitution.
Other comments	Comments are provided in the atachment.

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References	
Attachments (non-confidential information)	Prallethrin_CfS_public_consultation_CONFIDENTIAL_Endura_2024-01-17.pdf
Attachments (confidential information)	

Comment 2	**2024/01/19 12:07**
Country	United Kingdom
Name of organization/institution	SC Johnson
General information	
Product Type	18
Alternative Identity and Properties	
Technical Feasibility	
Economic Feasibility	
Hazards and Risks of the Alternative	
Availability	
Conclusion on suitability and availability of the alternative	Please see comments in the attached pdf file.
Other comments	
References	
Attachments (non-confidential information)	Prallethrin public consultation v2.pdf
Attachments (confidential information)	

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Comment 3	**2024/01/22 11:06**
Country	Italy
Name of organization/institution	Zobele Holding S.p.A
General information	The comments below come from a prominent manufacturer of PT 18 insecticide products with more than 70 years in this industry compartment. The products are supplied all over Europe. Products containing prallethrin account for a significant part of the product portfolio. Zobele have been formulating and supplying products containing prallethrin for over 30 years and to date have not had any reported instances of adverse effects for human health or environment. The company are well versed in the efficacy and safety aspects of the active and the formulated products. It is noted that unlike consultations for harmonised classification and labelling (CLH), the public have no access to the data leading to the vP classification. There is no study summary available and therefore, industry cannot comment on its accuracy or scientific relevance. The lack of transparency in this situation leads to an inability to fully assess whether this decision, in risk assessment terms, poses any realistic threat to the environment. It is not possible therefore to compare half-lives of the actives in the relevant compartment without sight of the data.
Product Type	18
Alternative Identity and Properties	Prallethrin is used as an active substance in products such as coils, liquid electric diffusers and plug in mats. Prallethrin is an ideal active substance for these types of products due to its ability to volatilise on heating to provide a distributed air concentration for sufficient time to kill mosquitoes. In many countries of the EU mosquitoes are a significant problem during the summer months. Consumers use the products in the evenings outdoors and in the day and overnight indoors to protect them from the bites of mosquitoes. These types of products protect people from bites and consequently, irritation and some diseases whilst sleeping. There are limited insecticide substances that can be formulated in these types of products as their physical chemical properties do not allow the active to volatilise and achieve a concentration high enough to kill mosquitoes in a reasonable timeframe – i.e., before they locate a host. Zobele have over the years experimented with the majority of PT 18 active substances on the market for this purpose

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	and determined the only other alternatives to be metofluthrin, transfluthrin or Chrysanthemum cinerariaefolium extract (generated from either production method), (C. cinerariaefolium ext.). However, as discussed below these actives have either more serious health hazard classifications and critical toxicity endpoints, environmental toxicity values, formulation issues or potential supply issues. Diffuser formulation types (such as coils and plug in electrics) generally have much lower emission to water (and hence resulting compartments of sediment and soil) than other formulation types (see OECD PT18 Emission Scenario Document). Therefore, it is not appropriate to look at active substances used in aerosols for comparison.
Technical Feasibility	One of the alternatives for prallethrin would be C. cinerariaefolium ext. In our experience, this alternative has significant drawbacks. Firstly, it is not as effective as prallethrin and hence, would need to be incorporated into insecticide products in much higher amounts, leading to the use of a greater amount of active substance. Also, C. cinerariaefolium ext. cannot be used in liquid electric devices as it leads to clogging due to its natural origins and physical chemical properties. In addition, the specification of prallethrin is guaranteed due to its synthetic production whereas the identity of C. cinerariaefolium ext. varies year on year and crop by crop leading to potential issues with formulation, effectiveness and impurities.
Economic Feasibility	Prallethrin has a sure and constant supply/availability unlike the alternative C. cinerariaefolium ext. This is because the supply of C. cinerariaefolium ext. is reliant on successful and consistent crop harvests. This is likely to become an increasing issue in the future due to climate change. A limitation in supply or quality would have a significant detrimental economic affect. The use of alternative C. cinerariaefolium ext. is also more expensive for the consumer because a greater amount is required to reach the same efficacy. This will lead to increased costs and potentially a reduction in feasibility for consumers, leading to issues with bites from mosquitoes and pressure on the healthcare systems. As climate change increases this will become a more significant issue. The risks from disease from mosquitoes in European countries cannot be discounted.
Hazards and Risks of the Alternative	The safety for human health and the environment should be based on risk assessment and not hazard classification. If the risk assessment for a product containing prallethrin

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	passes, then the product should be authorised. Many PT 18 substances have significantly worse hazard classifications such as metofluthrin (classified: STOT SE 1 H370 - Nervous system and STOT RE 2 H373), cypermethrin (STOT SE 3, H335 and STOT RE 2, H373) and transfluthrin (Carc. 2, H351), but are not deemed CFS. Indeed, these actives also have significantly worse profiles in terms of AEL and PNECs. However, despite greater toxicity, they have 10-year approvals compared to CFS substances which may only receive 5 years. The potential for effects on human health in particular is evident and is characterised by the difficulty in passing a risk assessment for a product using these substances. The environmental emission scenarios for PT 18 products are highly conservative and extremely protective and therefore, if a safe use can be determined in this way, then a hazard classification should not be used as a justification for expedited re-evaluation. In addition, prallethrin is not used as a crop protection product, therefore, the overall exposure to the environment from its use is negligible in comparison to other substances – such as deltamethrin. Deltamethrin also has a worse environmental toxicity but is not currently a candidate for substitution. Current indications (as we do not have sight of agreed endpoints for prallethrin) that the alternative metofluthin has a PNEC in freshwater that is 3 times worse than prallethrin and that the PNEC in soil is an order of magnitude worse for metofluthrin. Part of the issue here with analysis of alternatives is that we do not have the draft assessment report for prallethrin for comparison. When considering the other alternatives – transfluthrin is not appropriate as most diffuser products would contain a level of active that would lead the whole product to be classified as a carcinogen. Although, C. cinerariaefolium ext. has a better toxicity profile, it would be used in higher amounts and often requires an additional active to increase effectiveness. This also drives a higher overall toxicity and more challenging risk assessment.
Availability	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. Although, there would not be supply issues with

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	metofluthrin or transfluthrin the classification and toxicity leads to other issues.
Conclusion on suitability and availability of the alternative	To conclude, as a well-established manufacturer of insecticide products for the EU market, we strongly assert that prallethrin is a very suitable active substance in terms of availability, cost, ease of formulation, efficacy and risk profile. We do not believe that there are any alternatives that can easily replace prallethrin in our products. The effect of a CFS categorisation will have a detrimental effect on our continued use of it due to the additional regulatory burden every five years and will inevitably increase the cost of manufacture which will impact the consumer and economy in the ways we have outlined. Any product authorised under the BPR will have undergone rigorous safety assessment for human health and the environment and it should be that risk assessment which determines how long a product should be authorised rather than a hazard classification on the active ingredient. The need for such products in terms of managing disease which, has the potential to worsen in the coming years should be weighed against the negligible impact on the environment that is likely to occur from household use of prallethrin products. In addition, it is noted that there are substantial number of substances which are potentially more toxic or of a worse environmental fate profile than prallethrin, of which, are still on the market and will not be evaluated under BPR before prallethrin undergoes a second evaluation at renewal. We urge the BPC to carefully consider our comments.
Other comments	It is very difficult for industry – especially formulators of biocidal products - to manage issues such as a widely used active substance being classed as CFS. In this instance, as is the case for most BPR active substances, the product manufacturer or supplier gets very little notice in which to provide robust and evidenced contributions to this public consultation. In addition, the short period of time between learning that the active will be classified in this way and the approval date is extremely short. It takes many years to develop alternative products. In the case of a product authorisation submission, business decisions on conducting expensive efficacy and storage stability studies must be made years in advance. This is not only due to forecasting if the BPR submission will be financially viable but also these studies take a long time to conduct. Therefore, data gap analysis and commissioning of studies happens long before the vote at the BPC. A decision such as this not only changes the anticipated profit or loss profile but also adds a

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	continued risk of the substance receiving a non-approval every 5 years. Resistance is also a factor to be considered. The lack of availability of different active substances for insecticidal products could also lead to a greater chance of resistance development. This can be seen with highly used actives in crop protection e.g. cypermethrin. The loss of prallethrin via BPR non-approval or resistance development due to overuse could lead to outbreaks of disease such as Chickungunya, Dengue and west Nile Virus which do have documented outbreaks in Europe.
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Comment 4	**2024/01/22 14:18**
Country	Finland
Name of organization/institution	
General information	
Product Type	18
Alternative Identity and Properties	
Technical Feasibility	
Economic Feasibility	
Hazards and Risks of the Alternative	
Availability	
Conclusion on suitability and availability of the alternative	As a conclusion the active substance phrallethrin does not require any substituting substance but can be completely eliminated among the approved biocides. It is potentially extremely harmful for the life supporting polluting insects, its use is mostly for convenience reasons, and it is

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	commonly misused by consumers to which it is currently available.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	[redacted]
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Comment 5	**2024/01/22 23:10**
Country	United Kingdom
Name of organization/institution	Sumitomo Chemical (UK) Plc
General information	
Product Type	18
Alternative Identity and Properties	

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Technical Feasibility	
Economic Feasibility	
Hazards and Risks of the Alternative	
Availability	
Conclusion on suitability and availability of the alternative	Please see attached document.
Other comments	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	[redacted]
Justification for confidential attachment	