

Brussels, XXX PLAN/2024/1105 ANNEX (POOL/E4/2024/1105/1105-EN ANNEX.docx) [...](2024) XXX draft

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to the

COMMISSION IMPLEMENTING REGULATION (EU) .../...

approving 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (prallethrin) as an existing active substance for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

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Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ¹	Date of approval	Expiry date of approval	Product type	Specific conditions
prallethrin	IUPAC name: 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecar boxylate EC No: 245-387-9 CAS No: 23031-36-9	92,0 % weight per weight (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)	1 March 2026	29 February 2036	18	Prallethrin is considered a candidate for substitution in accordance with Article 10(1), point (d), of Regulation (EU) No 528/2012. The authorisation of biocidal products containing prallethrin as an active substance is subject to the following conditions: (1) the product assessment shall 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; (2) the product assessment shall pay particular attention to: (a) children (toddlers); (b) surface water, sediment, soil and groundwater for products applied indoors by non-professional users by residual spraying (barrier treatment) in private households; (3) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels ('MRLs') need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council ² or Regulation (EC)

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The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European

		No 396/2005 of the European Parliament and of the Council ³ , and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded.
		The placing on the market of treated articles is subject to the following conditions:
		(1) 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 Article 58(3), second subparagraph, of Regulation (EU) No 528/2012;
		(2) Member States' competent authorities or, in the case of a Union authorisation the Commission, shall specify in the summary of the biocidal product characteristics of a biocidal product containing prallethrin the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), second subparagraph, point (e), of Regulation (EU) No 528/2012.

Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11, ELI: http://data.europa.eu/eli/reg/2009/470/oj).

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³ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1, ELI: http://data.europa.eu/eli/reg/2005/396/oj).