Commission Implementing Regulation (EU) 2020/1771 of 26 November 2020 approving reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) as an existing active substance for use in biocidal products of product-types 2, 3 and 4 (Text with EEA relevance)

# COMMISSION IMPLEMENTING REGULATION (EU) 2020/1771

# of 26 November 2020

approving reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) as an existing active substance for use in biocidal products of product-types 2, 3 and 4

# (Text with EEA relevance)

# THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products<sup>(1)</sup>, and in particular the third subparagraph of Article 89(1) thereof,

### Whereas:

- Commission Delegated Regulation (EU) No 1062/2014<sup>(2)</sup> establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes peroxyoctanoic acid, to be renamed reaction mass of peracetic acid and peroxyoctanoic acid, as the result of its evaluation.
- (2) Reaction mass of peracetic acid and peroxyoctanoic acid has been evaluated for use in biocidal products of product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, product-type 3, veterinary hygiene, and product-type 4, food and feed area, as described in Annex V to Regulation (EU) No 528/2012.
- (3) France was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('the Agency') on 2 January 2019.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the Agency<sup>(3)</sup> on 4 March 2020, having regard to the conclusions of the evaluating competent authority.
- (5) According to those opinions, biocidal products of product-types 2, 3 and 4 containing reaction mass of peracetic acid and peroxyoctanoic acid may be expected to meet the criteria laid down in point (b) of Article 19(1) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.

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- (6) Taking into account the opinions of the Agency, it is appropriate to approve reaction mass of peracetic acid and peroxyoctanoic acid for use in biocidal products of product-types 2, 3 and 4, subject to compliance with certain specifications and conditions.
- (7) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

# Article 1

Reaction mass of peracetic acid and peroxyoctanoic acid is approved as an active substance for use in biocidal products of product-types 2, 3 and 4 subject to the specifications and conditions set out in the Annex.

# Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 26 November 2020.

For the Commission The President Ursula VON DER LEYEN Status: Point in time view as at 31/12/2020. Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1771. (See end of Document for details)

#### ANNEX

	entifikatie			Date of approva	Expiry date of l approva	type	Specific conditions	
mass of peracetic acid a(PolicA) and	the active not releva substance equilibriu peroxide, octanoic a materials. auvie spon concentra	substance nt as the a is a doubl m using hy acetic acid acid as star The speci d to a rang tion.	is ctive e vdrogen l and ting fications ge of	1 April 2022	31 March 2032	2	The authorisations of biocidal products are subject to the following conditions: (a) The	
EC No: 201-186-8 and 450-280-7 CAS A No: 79-21-0 and 33734-57- <sup>SU</sup> R	3 7		range content (%w/w)	ions	ions			product assessment shall pay
			1,8–13,9				particular attention to	
	Active Peroxyoctable					the exposures,		
	Relevant impurity						the risks and the efficacy linked to any uses covered by an application for authorisation but not addressed in the Union	
	Nameld Number IUPAC name: Reaction mass of peracetic acid a(INAA) and peroxyoct acid (POOA) EC No: 201-186-8 and 450-280-7 CAS No: 79-21-0	NameIdNumbersIUPACThe mininname:the activeReactionnot relevamass ofsubstanceperaceticequilibriuacidperoxide,andmaterials.peroxyoctconcentra(POOA)ComponeEC No:201-186-8and450-280-7CASActiveNo:substance79-21-0andandsubstanceRelevantRelevant	NameIdentificative substanceNumbersIUPACIUPACThe minimum purityname:the active substanceReactionnot relevant as the amass ofsubstance is a doublperaceticequilibrium using hyacidperoxide, acetic acidacidoctanoic acid as starandmaterials. The speciperoxyoctatorie spond to a rangacidconcentration.(POOA)ComponentsEC No:201-186-8and450-280-7CASActiveNo:substanceacidacid79-21-0Activeand33734-57RelevantHydrogn	NameIdent/fibrative substance*NumbersIUPACThe minimum purity ofname:the active substance isReactionnot relevant as the activemass ofsubstance is a doubleperaceticequilibrium using hydrogenacidperoxide, acetic acid andacidoctanoic acid as startingandmaterials. The specificationsperoxyoctconcentration.(POOA)ComponentsSpecificat201-186-8content(%w/w)and450-280-7(%w/w)CASActivePeracetic1,8–13,9No:substanceacid2,42RelevantHydrogn1,1–	NameIdent/finative substanceof approvaIUPACThe minimum purity of the active substance is not relevant as the active substance is a double peracetic acid afterial1 April 2022Reaction mass of peracetic acid afterial1 april 2022Reaction mass of peracetic acid afterial1 april 2022Reaction mass of peracetic acid afterial1 april 2022Reaction peroxide, acetic acid and octanoic acid as starting materials. The specifications peroxyoctamorespond to a range of concentration.1 april 2022RecevantComponentsSpecifications range content (%w/w)CAS and 33734-57Active substance acidPeracetic acid 2,42RelevantHydrogn 1,1-	NameIdent/fibation/setureof approvaldate of approvalIUPAC name:The minimum purity of the active substance is not relevant as the active substance is a double peracetic equilibrium using hydrogen acid and materials. The specifications peroxyoct anorespond to a range of concentration.1 April 202231 March 2032IUPAC name:The minimum purity of the active substance is substance is a double equilibrium using hydrogen acid and materials. The specifications peroxyoct anorespond to a range of concentration.1 April 20222032IUPAC (POOA) EC No: 201-186-8 and 450-280-7Components Peracetic acidSpecifications range content (%w/w)1 April 202231 March 2032CAS nd 33734-57Active substance acidPeracetic 2,421,8–13,9 substance1,1–	NameIdent/finative substanceof approvaldate of approvaltypeIUPAC name:The minimum purity of the active substance is not relevant as the active substance is a double equilibrium using hydrogen acid and materials. The specifications peroxyoct aurie spond to a range of acid COMPONENT1 April 2022312(POOA) EC No: 201-186-8Components substanceSpecifications range content (%w/w)Specifications range content (%w/w)1CAS 79-21-0 and 33734-57Active substancePeracetic acid 2,421,8-13,9 2,421No: 33734-57Active substancePeroxyoct anofec- acid 2,422,42RelevantHydrogn 1,1-1,1-	

**a** 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.

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						(b)	assessment of the active substance. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.
	Relevant impurity	Acetic acid	5,74–51		3	The authorisa	ations
- purity indicated	Relevant impurity	acid	1,63– 9,03	ty of the active substa	nnce evaluated. The	of biocidal products are subject to the followin condition (a)	g

**a** 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.

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				(b)	and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level assessment of the active substance. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional
				-	users.
			4	The authorisat	
substance in the prod	in this column was the minimum degree of p luct placed on the market can be of equal or luated active substance.	purity of the active substance different purity if it has been	evaluated. The proven to be te	e active echnically	
	1935/2004 of the European Parliament and come into contact with food and repealing Di				
13.11.2004, p. 4).	1 0		<b>`</b>		

articles intended t 13.11.2004, p. 4).

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	of	
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		the
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	(b)	Products
		containing
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1		reaction
		reaction
		mass
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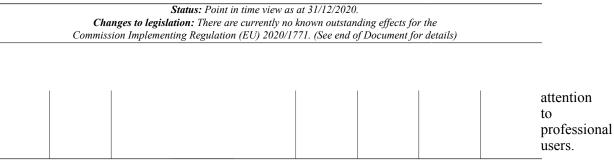
**a** The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

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- **a** 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.
- **b** Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

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- (1) OJ L 167, 27.6.2012, p. 1.
- Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ (2) L 294, 10.10.2014, p. 1).
- Biocidal Products Committee Opinions on the application for approval of the active substance reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA); Product type: 2, 3 and 4; ECHA/BPC/242, 243 and 244, adopted on 4 March 2020. (3)

# **Status:**

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#### Changes to legislation:

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