Commission Implementing Regulation (EU) 2017/2005 of 8 November 2017 approving margosa extract, cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical carbon dioxide as an existing active substance for use in biocidal products of product-type 19 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2005

of 8 November 2017

approving margosa extract, cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide as an existing active substance for use in biocidal products of product-type 19

(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[(1)], and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014[(2)] establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes margosa extract, cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide.

(2) Margosa extract, cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide has been evaluated for use in products of product-type 19, repellents and attractants, as described in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as evaluating competent authority and submitted the assessment report together with its recommendations on 3 December 2015.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 3 March 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products of product-type 19 containing margosa extract, cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide may be expected to satisfy the criteria of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.

(6) It is therefore appropriate to approve margosa extract, cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide for use in

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/2005. (See end of Document for details)*

biocidal products of product-type 19, 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

Margosa extract, cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide is approved as an active substance for use in biocidal products of product-type 19, 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, 8 November 2017.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/2005. (See end of Document for details)*

ANNEX

Common Name	**IUPAC NameIdentification Numbers**	**Minimum degree of purity of the active substance**[a]	**Date of approval**	**Expiry date of approval**	**Product type**	**Specific conditions**
Margosa extract, cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide	IUPAC Name: Not applicable EC No: 283-644-7 CAS No: 84696-25-3	1 000 g/kg	1 April 2019	31 March 2029	19	The authorisations of biocidal products are subject to the following conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not

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 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 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).

c 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).

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							addressed in the Union-level risk assessment of the active substance. 2. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to surface water, sediment and soil. 3. For products that may lead to residues in food

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 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 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).

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