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COMMISSION

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[...](2017) **XXX** draft

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

**of **XXX****

**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)

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(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:

- (1) 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 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

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<sup>1</sup> OJ L 167, 27.6.2012, p. 1.

<sup>2</sup> 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 L 294, 10.10.2014, p. 1).

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,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*