Commission Implementing Regulation (EU) 2015/985 of 24 June 2015 approving clothianidin as an existing active substance for use in biocidal products for product-type 18 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/985

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approving clothianidin as an existing active substance for use in biocidal products for product-type 18

(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 or inclusion into Annex I to Regulation (EU) No 528/2012.

(2) That list includes clothianidin.

(3) Clothianidin has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council[(3)] for use in product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to that Directive, which corresponds to product-type 18 as defined in Annex V to Regulation (EU) No 528/2012.

(4) Germany was designated as evaluating competent authority and submitted the assessment report, together with its recommendations, to the Commission on 27 May 2009 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007[(4)].

(5) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 2 October 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(6) According to that opinion, biocidal products used for product-type 18 and containing clothianidin may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC provided that certain conditions concerning its use are complied with.

(7) It is therefore appropriate to approve clothianidin for use in biocidal products for product-type 18 subject to compliance with the specific conditions in the Annex.

(8) The opinion concludes that the characteristics of clothianidin render it very persistent (vP) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[5].

(9) Since pursuant to Article 90(2) of Regulation (EU) No 528/2012, substances for which the Member States' evaluation has been completed by 1 September 2013 should be approved in accordance with Directive 98/8/EC, the period of approval should be 10 years in accordance with the practice established under that Directive.

(10) For the purposes of Article 23 of Regulation (EU) No 528/2012 however, clothianidin meets the conditions of Article 10(1)(d) of that Regulation and should therefore be considered a candidate for substitution.

(11) 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.

(12) 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

Clothianidin is approved as an active substance for use in biocidal products for product-type 18, 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, 24 June 2015.

For the Commission

The President

Jean-Claude JUNCKER

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**
Clothianidin	IUPAC Name: (E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-Nitroguanidine EC No: 433-460-1 CAS No: 210880-92-5	93 % w/w	1 October 2016	30 September 2026	18	Clothianidin is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012. 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. The authorisations of biocidal products are subject

						to the following conditions: (1) For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means. (2) Products shall not be authorised for uses in animal housings where emission to a

						sewage treatment plant or direct emission to surface water cannot be prevented, unless it can be demonstrated that risks to the environment can be reduced to an acceptable level by other means.
					(3)	Due to the risks identified for the soil compartment, products shall not be authorised for uses in animal housings others than