

**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)**

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 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 <sup>(3)</sup> 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 <sup>(4)</sup>.
- (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 <sup>(5)</sup>.
- (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.

<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).

<sup>(3)</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

<sup>(4)</sup> Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

<sup>(5)</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

- (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

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## ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance <sup>(1)</sup>	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 for beef cattle, unless it can be demonstrated that risks to the environment can be reduced to an acceptable level.  (4) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council <sup>(2)</sup> or Regulation (EC) No 396/2005 of the European Parliament and of the Council <sup>(3)</sup> shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

<sup>(1)</sup> The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 16(2) of Directive 98/8/EC. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).