

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1930**of 4 November 2016****approving chlorocresol as an existing active substance for use in biocidal products of product-types 1, 2, 3, 6 and 9****(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 chlorocresol.
- (2) Chlorocresol has been evaluated for use in products of product-type 1, human hygiene, of product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, of product-type 3, veterinary hygiene, of product-type 6, preservatives for products during storage, and of product-type 9, fibre, leather, rubber and polymerised materials preservatives, as described in Annex V to Regulation (EU) No 528/2012.
- (3) France was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 8 October 2013, 15 November 2013 and 18 December 2013.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 13 April 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to those opinions, biocidal products of product-types 1, 2, 3, 6 and 9 and containing chlorocresol 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 chlorocresol for use in biocidal products of product-types 1, 2, 3, 6 and 9, 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

Chlorocresol is approved as an active substance for use in biocidal products of product-types 1, 2, 3, 6 and 9, subject to the specifications and conditions set out in the Annex.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.⁽²⁾ 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).

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, 4 November 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
Chlorocresol	IUPAC Name: 4-chloro-3-methyl- phenol EC No: 200-431-6 CAS No: 59-50-7	99,8 % w/w	1 May 2018	30 April 2028	1	The authorisations of biocidal products are subject to the following condition: 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 addressed in the Union-level risk assessment of the active substance.
					2	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 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: a) industrial and professional users; b) children for products used in private and institutional areas.
					3	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 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: a) professional users; b) soil compartment. 3. 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 ⁽²⁾ or Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽³⁾ shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
					6	<p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> 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 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: <ol style="list-style-type: none"> a) professional users during the formulation of product to be preserved and during the application of the preserved product in paper production; b) infants crawling on a surface that has been cleaned with the preserved product.
					9	<p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> 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 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 professional users.

⁽¹⁾ The purity indicated in this column was the minimum degree of purity of the active substance evaluated in accordance with Article 89(1) of Regulation (EU) No 528/2012. 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.

⁽²⁾ 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).

⁽³⁾ 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).