Commission Implementing Regulation (EU) No 1038/2013 of 24 October 2013 approving tebuconazole as an existing active substance for use in biocidal products for product-types 7 and 10 (Text with EEA relevance)

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approving tebuconazole as an existing active substance for use in biocidal products for product-types 7 and 10

(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 Regulation (EC) No 1451/2007[(2)] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council[(3)]. That list includes tebuconazole.

(2) Tebuconazole has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 7, film preservatives, and product-type 10, masonry preservatives, as defined in Annex V to that Directive, which correspond respectively to product-types 7 and 10 as defined in Annex V to Regulation (EU) No 528/2012.

(3) Denmark was designated as rapporteur Member State and submitted the competent authority reports, together with recommendations, to the Commission on 16 April 2012 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority reports were reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 27 September 2013, in two assessment reports.

(5) It appears from those reports that biocidal products used for product-types 7 and 10 and containing tebuconazole may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC.

(6) It also appears from the reports that the characteristics of tebuconazole 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[(4)]. The period of approval should be 10 years in consistency with the current practice

under Directive 98/8/EC, since the conditions of Article 90(2) of Regulation (EU) No 528/2012 are not met. However, for the purpose of authorising products in accordance with Article 23 of Regulation (EU) No 528/2012, tebuconazole shall be considered as a candidate for substitution pursuant to Article 10(1)(d) of that Regulation.

(7) It is therefore appropriate to approve tebuconazole for use in biocidal products for product-types 7 and 10.

(8) Since the evaluations did not address nanomaterials, the approvals should not cover such materials pursuant to Article 4(4) of Regulation (EU) No 528/2012.

(9) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit Member States, interested parties, and the Commission where appropriate, to prepare themselves to meet the new requirements entailed.

(10) 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

Tebuconazole shall be approved as an active substance for use in biocidal products for product-types 7 and 10, 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 October 2013.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1038/2013. (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[b]
Tebuconazole	IUPAC Name: 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol EC No: 403-640-2 CAS No: 107534-96-3	950 g/kg	1 July 2015	30 June 2025	7	Tebuconazole 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.

a 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 8 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 technically equivalent with the evaluated active substance.

b For the implementation of the common principles of Annex VI to Regulation (EU) No 528/2012, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1038/2013. (See end of Document for details)*

						Authorisations are subject to the following condition: For industrial users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
					10	Tebuconazole is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012. The product

a 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 8 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 technically equivalent with the evaluated active substance.

b For the implementation of the common principles of Annex VI to Regulation (EU) No 528/2012, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm