Commission Implementing Regulation (EU) 2016/105 of 27 January 2016 approving biphenyl-2-ol as an existing active substance for use in biocidal products for product-types 1, 2, 4, 6 and 13 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/105

of 27 January 2016

approving biphenyl-2-ol as an existing active substance for use in biocidal products for product-types 1, 2, 4, 6 and 13

(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 biphenyl-2-ol.

(2) Biphenyl-2-ol has been evaluated for use in product-type 1, human hygiene, in product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, product-type 4, food and feed area, product-type 6, preservatives for products during storage, and product-type 13, working or cutting fluid preservatives, as defined in Annex V to Regulation (EU) No 528/2012.

(3) Spain was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 2 June 2014.

(4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 5 February 2015 and 15 June 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products used for product-types 1, 2, 4, 6, and 13 and containing biphenyl-2-ol may be expected to satisfy the requirements of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain conditions concerning its use are complied with.

(6) It is therefore appropriate to approve biphenyl-2-ol for use in biocidal products for product-types 1, 2, 4, 6, and 13 subject to compliance with certain specifications and conditions.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/105. (See end of Document for details)*

(7) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing biphenyl-2-ol in materials and articles intended to come into contact directly or indirectly with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council[3]. Such materials may require the establishment of specific limits on the migration into food, as referred to in Article 5(1)(e) of that Regulation. The approval should therefore not cover such use unless the Commission has established such limits or it has been established pursuant to that Regulation that such limits are not necessary.

(8) 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.

(9) 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

Biphenyl-2-ol is approved as an active substance for use in biocidal products for product-types 1, 2, 4, 6 and 13, 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, 27 January 2016.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/105. (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
Biphenyl-2-ol	IUPAC Name: ortho-phenylphenol EC No: 201-993-5 CAS No: 90-43-7	995 g/kg	1 July 2017	30 June 2027	1	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.
					2	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,

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						but not addressed in the Union level risk assessment of the active substance. The authorisations of biocidal products are subject to the following condition: For 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.
					4	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