Commission Implementing Regulation (EU) 2015/1757 of 28 September 2015 approving folpet as an active substance for use in biocidal products for product-type 6 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1757

of 28 September 2015

approving folpet as an active substance for use in biocidal products for product-type 6

(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 Article 90(2) thereof,

Whereas:

(1) Italy received on 13 July 2009 an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council[(2)], for the inclusion of the active substance folpet in its Annex I for use in product-type 6, in-can preservatives, as defined in Annex V to that Directive, which correspond to product-type 6 as defined in Annex V to Regulation (EU) No 528/2012.

(2) Italy submitted an assessment report, together with its recommendations, to the Commission on June 2011 in accordance with Article 11(2) of Directive 98/8/EC.

(3) The opinion of the European Chemicals Agency was formulated on 17 June 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(4) According to that opinion, biocidal products used for product-type 6 and containing folpet 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 satisfied.

(5) It is therefore appropriate to approve folpet for use in biocidal products for product-type 6 subject to compliance with the specific conditions in the Annex.

(6) Since folpet meets the criteria for classification as skin sensitiser category 1 as defined in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(3)], treated articles treated with or incorporating folpet should be appropriately labelled when placed on the market.

(7) 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

Folpet is approved as an active substance for use in biocidal products for product-type 6, 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, 28 September 2015.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1757. (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**
Folpet	IUPAC Name: N-(trichloromethylthio) phthalimide EC No: 205-088-6 CAS No: 133-07-3	940 g/kg	1 January 2016	31 December 2025	6	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 users, safe operational procedures and

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 11 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1757. (See end of Document for details)*

							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)	In view of the risks to the soil compartment, labels and, where provided, safety data sheets of products shall indicate that measures shall

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 11 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.