

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1758**of 28 September 2015****approving folpet as an existing active substance for use in biocidal products for product-types 7 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.
- (2) That list includes folpet.
- (3) Folpet has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council ⁽³⁾ for use in product-type 7, film preservatives, and product-type 9, fibre, leather, rubber and polymerised materials preservatives, as defined in Annex V to that Directive, which correspond respectively to product-type 7 and 9, as defined in Annex V to Regulation (EU) No 528/2012.
- (4) Italy was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, to the Commission in June 2011 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 ⁽⁴⁾.
- (5) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 17 June 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating Competent Authority.
- (6) According to those opinions, biocidal products used for product-types 7 and 9 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 complied with.
- (7) It is therefore appropriate to approve folpet for use in biocidal products for product-types 7 and 9 subject to compliance with the specific conditions in the Annex.
- (8) 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 ⁽⁵⁾, treated articles treated with or incorporating folpet should be appropriately labelled when placed on the market.

⁽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).

⁽³⁾ 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).

⁽⁴⁾ 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).

⁽⁵⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

- (9) 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.
- (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

Folpet is approved as an active substance for use in biocidal products for product-types 7 and 9, 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

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
Folpet	IUPAC Name: N-(trichloromethylthio) phthalimide EC n°: 205-088-6 CAS n°: 133-07-3	940 g/kg	1 October 2016	30 September 2026	7	<p>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.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) For industrial 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.</p> <p>(2) In view of the risks to the soil compartment, labels and, where provided, safety data sheets of products shall indicate that measures shall be taken to protect the soil during the outdoor application by brushing of the preserved mixtures to prevent losses and minimise emissions to the environment, unless it can be demonstrated that risks can be reduced to an acceptable level by other means.</p> <p>(3) In view of the risks to the soil compartment, products shall not be authorised for preservation of mixtures to be applied outdoor by spraying, unless it can be demonstrated that risks can be reduced to an acceptable level.</p> <p>The placing on the market of treated articles is subject to the following condition:</p> <p>The person responsible for the placing on the market of a treated article treated with or incorporating folpet shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.</p>
					9	<p>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.</p> <p>The authorisations of biocidal products are subject to the following condition:</p> <p>For industrial 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.</p>

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
						<p>The placing on the market of treated articles is subject to the following condition:</p> <p>The person responsible for the placing on the market of a treated article treated with or incorporating folpet shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.</p>

⁽¹⁾ 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.