

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1086
of 23 July 2020
approving icaridin as an existing active substance for use in biocidal products of product-type 19
(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 icaridin.
- (2) Icaridin has been evaluated for use in biocidal products of product-type 19, repellents and attractants as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ⁽³⁾, which corresponds to product-type 19 as described in Annex V to Regulation (EU) No 528/2012.
- (3) Denmark was designated as a rapporteur Member State and its evaluating competent authority submitted the assessment report together with its recommendations to the Commission on 14 January 2011.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency ⁽⁴⁾ was adopted on 10 December 2019 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) It can be derived from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be evaluated in accordance with the provisions of Directive 98/8/EC. Following the opinion of the Agency, biocidal products of product-type 19 containing icaridin may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.
- (6) It is therefore appropriate to approve icaridin for use in biocidal products of product-type 19, subject to compliance with certain specifications and conditions.
- (7) Since it can be derived from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be approved under the terms of Directive 98/8/EC, the period of approval should be 10 years, in accordance with the practice established under that Directive.
- (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.

⁽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⁾ Biocidal Products Committee Opinion on the application for approval of the active substance Icaridin, Product type: 19, ECHA/BPC/229/2019, adopted on 10 December 2019.

- (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

Icaridin is approved as an active substance for use in biocidal products of product-type 19, 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, 23 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

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
Icaridin	IUPAC name: (RS)-sec-butyl (RS)-2-(2-hydroxyethyl)piperidine-1-carboxylate EC No: 423-210-8 CAS No: 119515-38-7	97 % w/w	1 February 2022	31 January 2032	19	The authorisations of biocidal products are subject to the following conditions: (a) 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; (b) for products that may lead to residues in food and 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; (c) in view of the risks identified for the uses assessed, the product assessment shall pay particular attention to children younger than two years following dermal and secondary exposure.

⁽¹⁾ The purity indicated in this column was the minimum degree of purity of the active substance evaluated. 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).