COMMISSION IMPLEMENTING REGULATION (EU) 2015/1731

of 28 September 2015

approving medetomidine as an active substance for use in biocidal products for product-type 21

(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) The United Kingdom received on 27 April 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 medetomidine in its Annex I for use in product-type 21, antifouling products, as defined in Annex V to that Directive, which corresponds to product-type 21 as defined in Annex V to Regulation (EU) No 528/2012.

(2) Medetomidine was not on the market on 14 May 2000 as an active substance of a biocidal product.

(3) The United Kingdom submitted an assessment report, together with its recommendations, to the European Chemicals Agency on 12 March 2014 in accordance with Article 8(1) of Regulation (EU) No 528/2012.

(4) The opinion of the European Chemicals Agency was formulated on 3 February 2015 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products used for product-type 21 and containing medetomidine may be expected to satisfy the requirements laid down in 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 medetomidine for use in biocidal products for product-type 21 subject to compliance with certain specifications and conditions.

(7) The opinion concludes that the characteristics of medetomidine 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 ([3]). In addition, the opinion concludes that the active substance contains a significant proportion of non-active isomers or impurities.

(8) Medetomidine meets the conditions set out in points (d) and (f) of Article 10(1) of Regulation (EU) No 528/2012 and should therefore be considered a candidate for substitution.

(9) Pursuant to Article 10(4) of Regulation (EU) No 528/2012, the approval of an active substance that is considered as a candidate for substitution should be for a period not exceeding seven years.

(10) Since medetomidine meets the criteria for being very persistent (vP) according to Annex XIII to Regulation (EC) No 1907/2006, treated articles treated with or incorporating medetomidine should be appropriately labelled when placed on the market.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) 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).

([3]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(11) 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

Medetomidine is approved as an active substance for use in biocidal products for product-type 21, 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
Medetomidine	IUPAC name: (RS)-4-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole EC No: not available CAS No: 86347-14-0	99,5 % w/w. Medetomidine is manufactured as a racemic mixture of R and S enantiomers: dexmedetomidine and levomedetomidine.	1 January 2016	31 December 2022	21	Medetomidine is considered a candidate for substitution in accordance with Article 10(1)(d) and (f) 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. 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 cannot be reduced to an acceptable level by other means. (2) Persons making products containing medetomidine available on the market for non-professional users shall make sure that the products are supplied with appropriate gloves. Labels and, where provided, instructions for use shall indicate whether other personal protective equipment shall be used. (3) Labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry. (4) Labels and, where provided, safety data sheets of products authorised shall indicate that application, maintenance and repair activities shall be conducted within a contained area, on an impermeable hard standing with bunding or on soil covered with an impermeable material to prevent direct losses and minimise emissions to the environment, and that any losses or waste containing medetomidine shall be collected for reuse or disposal. (5) For products that may lead to residues in food or 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.

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
						The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating medetomidine 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.

(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 8(1) 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.

(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).