# COMMISSION IMPLEMENTING REGULATION (EU) No 94/2014

## of 31 January 2014

## approving iodine, including polyvinylpyrrolidone iodine, as an existing active substance for use in biocidal products for product-types 1, 3, 4 and 22

**(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 Regulation (EC) No 1451/2007 [2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council [3]. That list includes iodine.

(2) Iodine has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 1, human hygiene biocidal products, product-type 3, veterinary hygiene biocidal products, product-type 4, food and feed area disinfectants, and product-type 22, embalming and taxidermist fluids, as defined in Annex V to that Directive, which correspond respectively to product-types 1, 3, 4 and 22 as defined in Annex V to Regulation (EU) No 528/2012.

(3) The data submitted for the purpose of the evaluation allowed conclusions to be also drawn on polyvinylpyrrolidone iodine.

(4) Sweden was designated as Rapporteur Member State and submitted the competent authority report, together with recommendations, to the Commission on 20 April 2011 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(5) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 13 December 2013, in an assessment report.

(6) It appears from that report that biocidal products used for product-types 1, 3, 4 and 22 and containing iodine may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that the conditions specified in the Annex to this Regulation are satisfied.

(7) It is therefore appropriate to approve iodine, including polyvinylpyrrolidone iodine, for use in biocidal products for product-type 1, 3, 4 and 22.

(8) Since the evaluations did not address nanomaterials, the approvals should not cover such materials pursuant to Article 4(4) of Regulation (EU) No 528/2012.

(9) The evaluation did not address the incorporation of biocidal products containing iodine 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 [4]. Such materials may require the establishment of specific limits on the migration into food, as referred to in Article 5(1)(e) of Regulation (EC) No 1935/2004. 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.

(10) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit Member States, interested parties, and the Commission where appropriate, to prepare themselves to meet the new requirements entailed.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

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

[2] 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).

[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] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

HAS ADOPTED THIS REGULATION:

*Article 1*

Iodine, including polyvinylpyrrolidone iodine, shall be approved as an active substance for use in biocidal products for product-types 1, 3, 4 and 22, 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, 31 January 2014.

*For the Commission*
*The President*
José Manuel BARROSO

*ANNEX*

| Common Name | IUPAC Name<br>Identification Numbers | Minimum degree of purity of the active substance [1] | Date of approval | Expiry date of approval | Product type | Specific conditions [2] |
|---|---|---|---|---|---|---|
| Iodine (including polyvinylpyrrolidone iodine) | IUPAC Name:<br><br>Iodine<br><br>EC No: 231-442-4<br><br>CAS No: 7553-56-2<br><br>IUPAC Name:<br><br>Polyvinylpyrrolidone iodine<br><br>EC No: n.a.,<br><br>CAS No: 25655-41-8 | 995 g/kg of iodine<br><br>For polyvinylpyrrolidone iodine: the iodine content shall have a purity of 995 g/kg | 1 September 2015 | 31 August 2025 | 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. |
| | | | | | 3 | 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.<br><br>Authorisations are subject to the following conditions:<br><br>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 [3] or Regulation (EC) No 396/2005 of the European Parliament and of the Council [4] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. |
| | | | | | 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.<br><br>Authorisations are subject to the following conditions:<br><br>(1) 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 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.<br><br>(2) Products containing iodine shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of iodine into food or it has been established pursuant to that Regulation that such limits are not necessary. |

| 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 (2) |
|---|---|---|---|---|---|---|
| | | | | | 22 | 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 adressed in the Union level risk assessment of the active substance.<br><br>Authorisations are subject to the following condition:<br><br>For professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. |

(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 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) For the implementation of the common principles of Annex VI to Regulation (EU) No 528/2012, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm

(3) 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).

(4) 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).