COMMISSION IMPLEMENTING REGULATION (EU) 2022/1993

of 20 October 2022

approving *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide as an active substance for use in biocidal products of product-type 19 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 89(1), third subparagraph, 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 *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide.

(2) *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide 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 correspond to product-type 19 as described in Annex V to Regulation (EU) No 528/2012.

(3) Spain was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 1 September 2010. After the submission of the assessment report, discussions took place in technical meetings organised by the Commission and, after 1 September 2013, by the European Chemicals Agency ('the Agency').

(4) It follows 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 assessed in accordance with the provisions of Directive 98/8/EC.

(5) In accordance with Article 75(1) of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinion of the Agency ([4]) on 3 December 2021, having regard to the conclusions of the evaluating competent authority.

(6) According to that opinion, biocidal products of product-type 19 containing *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide may be expected to satisfy the requirements laid down in Article 5(1), points (b), (c) and (d) of Directive 98/8/EC, provided that certain requirements concerning their use are complied with.

([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 *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide; Product-type 19; ECHA/BPC/313/2021, adopted on 3 December 2021.

(7) Taking into account the opinion of the Agency, it is appropriate to approve *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide as an active substance for use in biocidal products of product-type 19 subject to compliance with certain conditions.

(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.

(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

Chrysanthemum cinerariaefolium extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide is approved as an active substance for use in biocidal products of product-type 19 subject to the 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, 20 October 2022.

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
Chrysanthemum cinerariaefolium extract from supercritical carbon dioxide	*Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide EC No: 289-699-3 CAS No: 89997-63-7	100 % w/w of *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide	1 February 2024	31 January 2034	19	The authorisation of biocidal products is subject to the following conditions: (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; (2) The product assessment shall pay particular attention to the exposure of and potential risks for non-professional users and the general public; (3) 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 such MRLs are not exceeded.

[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).