

**COMMISSION DELEGATED REGULATION (EU) 2021/807****of 10 March 2021****amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include potassium sorbate as an active substance in Annex I thereto****(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 <sup>(1)</sup>, and in particular Article 28(1) thereof,

Whereas:

- (1) Potassium (E,E)-hexa-2,4-dienoate (potassium sorbate) has been assessed as an existing active substance included in the work programme for the systematic examination of all existing active substances, referred to in Article 89(1) of Regulation (EU) No 528/2012 and carried out in accordance with Commission Delegated Regulation (EU) No 1062/2014 <sup>(2)</sup>.
- (2) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency ('the Agency') was adopted on 4 December 2014 by the Biocidal Products Committee <sup>(3)</sup>, having regard to the conclusions of the evaluating competent authority. As the evaluation of the competent authority was completed on 20 October 2010, the application for approval of potassium sorbate was examined in accordance with Directive 98/8/EC of the European Parliament and of the Council <sup>(4)</sup>, as provided for in Article 90(2) of Regulation (EU) No 528/2012, and the Agency concluded in its opinion that biocidal products of product-type 8 containing potassium sorbate may be expected to fulfil the requirements of Article 5 of Directive 98/8/EC.
- (3) Potassium sorbate was therefore approved as an active substance for use in biocidal products of product-type 8 by Commission Implementing Regulation (EU) 2015/1729 <sup>(5)</sup>.
- (4) Potassium sorbate is still included in the work programme for the systematic examination of all existing active substances for its use in biocidal products of product-type 6.
- (5) In the opinion of 4 December 2014, the Agency also concluded that potassium sorbate fulfils the criteria for inclusion in Annex I to Regulation (EU) No 528/2012.
- (6) Taking into account the opinion of the Agency, it is appropriate to include potassium sorbate in Annex I to Regulation (EU) No 528/2012. As potassium sorbate has been assessed on the basis of an active substance dossier that has been accepted in accordance with Article 11(1) of Directive 98/8/EC, potassium sorbate should be included in category 6 of Annex I to Regulation (EU) No 528/2012.
- (7) Article 89(3) of Regulation (EU) No 528/2012 contains transitional measures where an existing active substance included in the work programme for the systematic examination of existing active substances is approved in accordance with that Regulation. With respect to potassium sorbate for product-type 6, the date of approval for the purposes of Article 89(3) of that Regulation should be set at 1 February 2023, in order to allow sufficient time for applications for authorisation to be submitted in accordance with the second subparagraph of Article 89(3) of that Regulation,

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> Biocidal Products Committee Opinion on the application for approval of the active substance: Potassium sorbate, Product type: 8, ECHA/BPC/37/2014, adopted on 4 December 2014.

<sup>(4)</sup> 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).

<sup>(5)</sup> Commission Implementing Regulation (EU) 2015/1729 of 28 September 2015 approving potassium sorbate as an existing active substance for use in biocidal products of product-type 8 (OJ L 252, 29.9.2015, p. 24).

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex I to Regulation (EU) No 528/2012 is amended in accordance with the Annex to this Regulation.

*Article 2*

For the purposes of Article 89(3) of Regulation (EU) No 528/2012, the date of approval of potassium sorbate for product-type 6 is 1 February 2023.

*Article 3*

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, 10 March 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

In Annex I to Regulation (EU) No 528/2012, in Category 6 of the List of active substances referred to in Article 25(a), the following entry is added:

EC number	Name/group	Restriction	Comment
246-376-1	Potassium (E,E)-hexa-2,4-dienoate (potassium sorbate) (*)	Minimum degree of purity of the active substance (**): 990 g/kg	CAS No 24634-61-5

(\*) The date of approval of potassium sorbate for product-type 6 for the purposes of Article 89(3) is 1 February 2023.

(\*\*) 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.'