

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1488

of 6 July 2023

renewing the approval of the low-risk active substance quartz sand in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009, of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 20(1) in conjunction with Article 22(1) thereof,

Whereas:

- (1) Commission Directive 2008/127/EC ⁽²⁾ included quartz sand as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) According to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance quartz sand, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 August 2023 ⁽⁵⁾.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁽⁵⁾ Commission Implementing Regulation (EU) 2022/708 of 5 May 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aclonifen, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, beflubutamid, benthiavalicarb, boscalid, calcium carbide, captan, cymoxanil, dimethomorph, dodemorph, ethephon, ethylene, extract from tea tree, fat distillation residues, fatty acids C7 to C20, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, hydrolysed proteins, iron sulphate, magnesium phosphide, metam, metamitron, metazachlor, metribuzin, milbemectin, phenmedipham, pirimiphos-methyl, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, propamocarb, proquinazid, prothioconazole, pyrethrins, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, sulcotrione, tebuconazole and urea (OJ L 133, 10.5.2022, p. 1).

- (4) An application for the renewal of the approval of the active substance quartz sand was submitted to Latvia, the rapporteur Member State, and Romania, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁶⁾ and within the time period provided for in that Article.
- (5) The applicants also submitted the supplementary dossiers required by Article 6 of Implementing Regulation (EU) No 844/2012 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). The application was found to be admissible by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 2 March 2021. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of quartz sand.
- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicants and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (8) On 16 August 2022, the Authority communicated to the Commission its conclusion ⁽⁷⁾ which indicated that quartz sand can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report regarding quartz sand and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 8 December 2022 and on 25 May 2023 respectively.
- (10) The Commission invited the applicants to submit their comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicants submitted their comments, which have been carefully examined and taken into consideration.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance quartz sand that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) The Commission further considers that quartz sand is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Quartz sand is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009.
- (13) It is therefore appropriate to renew the approval of quartz sand as a low-risk active substance.
- (14) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge and the outcome of the risk assessment, it is, however, necessary to set a minimum purity of quartz sand and a maximum amount of the impurity respirable crystalline silica (SiO₂) with a diameter ≤ 10 µm as manufactured in order to underpin the safety of the active substance to be used in plant protection products.
- (15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

⁽⁶⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

⁽⁷⁾ EFSA (European Food Safety Authority), 2022. Conclusion on the peer review of the pesticide risk assessment of the active substance quartz sand. *EFSA Journal* 2022;20(9):7552, 37 pp. doi:10.2903/j.efsa.2022.7552.

- (16) This Regulation should apply from the day after the date of expiry of the approval of quartz sand.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance quartz sand, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 September 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 July 2023.

For the Commission
The President
Ursula VON DER LEYEN

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ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Quartz sand (there is no ISO common name) (1) 7631-86-9 (CAS) (2) 14808-60-7 (CAS) 855 (CIPAC) [So far they have been indicated as: CAS No: 14808-60-7 CIPAC No: not allocated]	1) Silicon dioxide 2) Quartz	915 g/kg The impurity crystalline silica with a particle diameter $\leq 10 \mu\text{m}$ is of toxicological concern and shall not exceed a level of 0,1 % of particles in the technical material.	1 September 2023	31 August 2038	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on quartz sand, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate.

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, entry 247 on quartz sand is deleted;
 (2) in Part D, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'44	Quartz sand (there is no ISO common name) (1) 7631-86-9 (CAS) (2) 14808-60-7 (CAS) 855 (CIPAC) [So far they have been indicated as: CAS No: 14808-60-7 CIPAC No: not allocated]	(1) Silicon dioxide (2) Quartz	915 g/kg The impurity crystalline silica with a particle diameter $\leq 10 \mu\text{m}$ is of toxicological concern and shall not exceed a level of 0,1 % of particles in the technical material.	1 September 2023	31 August 2038	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on quartz sand, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate.'

(1) Further details on the identity and the specification of the active substance are provided in the renewal report.