

COMMISSION IMPLEMENTING REGULATION (EU) 2021/427**of 10 March 2021****approving the active substance 24-epibrassinolide as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, 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 13(2) in conjunction with Article 22(1) thereof,

Whereas:

- (1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 Sunttion GmbH submitted to Austria on 28 April 2017 an application for the approval of the active substance 24-epibrassinolide.
- (2) In accordance with Article 9(3) of that Regulation, Austria, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') of the admissibility of the application on 30 May 2017.
- (3) On 6 June 2018 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supplies additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report on 22 October 2019.
- (5) On 4 May 2020 the Authority communicated to the applicant, the Member States and the Commission its conclusion ⁽²⁾ on whether the active substance 24-epibrassinolide can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.
- (6) On 17 July 2020, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for 24-epibrassinolide and on 4 December 2020, a draft Regulation providing that 24-epibrassinolide is approved.
- (7) The applicant was given the possibility to submit comments on the review report.
- (8) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

⁽¹⁾ 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 (OJ L 309, 24.11.2009, p. 1).

⁽²⁾ EFSA (European Food Safety Authority), Conclusion on the peer review of the pesticide risk assessment of the active substance 24-epibrassinolide; EFSA Journal 2020;6123 <https://doi.org/10.2903/j.efsa.2020.6132>. Available online: www.efsa.europa.eu.

- (9) The Commission further considers that 24-epibrassinolide is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. 24-epibrassinolide is not a substance of concern and it fulfils the conditions set out in point 5.1 of Annex II to Regulation (EC) No 1107/2009.
- (10) It is therefore appropriate to approve 24-epibrassinolide as a low-risk substance.
- (11) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾ should be amended accordingly.
- (12) 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

Approval of the active substance

The active substance 24-epibrassinolide, as specified in Annex I, is approved as 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

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

⁽³⁾ 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).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
24-epibrassinolide CAS No: 78821-43-9 CIPAC No: Not applicable	(3aS,5R,6S,7aR,7bS,9aS,10- R,12aS,12bS)-10((2S,3R,4R,5R)-3,4- dihydroxy-5,6-dimethylheptan-2-yl) 5,6-dihydroxy-7a,9a- dimethylhexadecahydro-3Hbenzo[c] indeno[5,4-e]oxepin-3-one	≥ 900 g/kg	31 March 2021	31 March 2036	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 4 December 2020, and in particular Appendices I and II thereto, shall be taken into account.

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

ANNEX II

In Part D of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'27	24-epibrassinolide CAS No: 78821-43-9 CIPAC No: Not applicable	(3aS,5R,6S,7aR,7bS,9aS,10- R,12aS,12bS)-10 ((2S,3R,4R,5R)-3,4- dihydroxy-5,6-dimethylheptan- 2-yl)5,6-dihydroxy-7a,9a- dimethylhexadecahydro- 3Hbenzo[c]indeno[5,4-e] oxepin-3-one	≥ 900 g/kg	31 March 2021	31 March 2036	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 4 December 2020, and in particular Appendices I and II thereto, shall be taken into account.'

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