

**COMMISSION IMPLEMENTING REGULATION (EU) 2022/4**  
**of 4 January 2022**

**approving the active substance *Purpureocillium lilacinum* strain PL11 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 <sup>(1)</sup> 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 LAM International Corp submitted to the United Kingdom on 16 December 2014 an application for the approval of the active substance *Purpureocillium lilacinum* strain PL11.
- (2) In accordance with Article 9(3) of that Regulation, the United Kingdom as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 17 March 2015 of the admissibility of the application.
- (3) On 27 March 2019, UK as 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. Denmark replaced the United Kingdom as rapporteur Member State on the 1 January 2020 due to the withdrawal of the United Kingdom from the Union.
- (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 supply 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 27 November 2020.
- (5) On 20 December 2020 the Authority communicated to the applicant, the Member States and the Commission its conclusion <sup>(2)</sup> on whether the active substance *Purpureocillium lilacinum* strain PL11 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) The Commission presented a review report and a draft Regulation regarding *Purpureocillium lilacinum* strain PL11 to the Standing Committee on Plants, Animals, Food and Feed on 23 March 2021 and on 5 July 2021, respectively.
- (7) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 13(1) of Regulation (EC) No 1107/2009, on the review report. The applicant submitted its comments, which have been carefully examined.
- (8) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> EFSA Journal 2021;19(1):6393, 17 pp. doi:10.2903/j.efsa.2021.6393.

- (9) The Commission further considers that *Purpureocillium lilacinum* strain PL11 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009 as it fulfils the conditions set in Annex II point 5.2 to Regulation (EC) No 1107/2009.
- (10) It is therefore appropriate to approve *Purpureocillium lilacinum* strain PL11 as a low-risk substance.
- (11) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions.
- (12) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, Commission Implementing Regulation (EU) No 540/2011 <sup>(3)</sup> should be amended accordingly.
- (13) 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 *Purpureocillium lilacinum* strain PL11 is approved as set out in Annex I.

*Article 2*

**Amendments to Implementing Regulation (EU) No 540/2011**

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, 4 January 2022.

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

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<sup>(3)</sup> 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 <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
<i>Purpureocillium lilacinum</i> strain PL11	Not applicable	No relevant impurities	25 January 2022	24 January 2037	<p>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 <i>Purpureocillium lilacinum</i> strain PL11 and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ol style="list-style-type: none"> <li>the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>;</li> <li>the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.</li> </ol> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

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

<sup>(2)</sup> [https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\_ppp\\_app-proc\\_guide\\_phys-chem-ana\\_microbial-contaminant-limits.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf).

## ANNEX II

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

'34	<i>Purpureocillium lilacinum</i> strain PL11	Not applicable	No relevant impurities	25 January 2022	24 January 2037	<p>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 <i>Purpureocillium lilacinum</i> strain PL11 and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to:</p> <p>a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (*);</p> <p>b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate.</p>
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(\*) [https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\_ppp\\_app-proc\\_guide\\_phys-chem-ana\\_microbial-contaminant-limits.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf).