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COMMISSION IMPLEMENTING REGULATION (EU) 2026/747

of 31 March 2026

approving the active substance bixlozone 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 13(2) thereof,

Whereas:

(1) On 2 July 2018, the Netherlands received an application from FMC International Switzerland Sarl ('the applicant') pursuant to Article 7(1) of Regulation (EC) No 1107/2009 for the approval of the active substance bixlozone.

(2) On 28 August 2018, the Netherlands, 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 in accordance with Article 9(3) of Regulation (EC) No 1107/2009.

(3) On 31 August 2021, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether bixlozone can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. In its draft assessment report, the rapporteur Member State proposed that bixlozone can be approved as an active substance.

(4) The Authority circulated the draft assessment report to the applicant and the other Member States. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, the Authority 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 form of an updated draft assessment report on 31 October 2023.

(5) On 2 October 2024, the Authority communicated to the applicant, the Member States and the Commission its conclusion ([2]) on whether the active substance bixlozone 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 of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 2 October 2025 and 10 December 2025, 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 were taken into due consideration.

(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]) OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj.
([2]) 'Conclusion on pesticides peer review of the pesticide risk assessment of the active substance bixlozone', *EFSA Journal* 2024;22:e9054, available online: https://doi.org/10.2903/j.efsa.2024.9054.

(9) It is therefore appropriate to approve bixlozone.

(10) 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 necessary to include certain conditions. It is, in particular appropriate to set a maximum level for one impurity (TBAB) in the active substance as manufactured. In addition, in order to confirm the acceptability of the proposed reference specification, confirmatory information is required on the technical specification of the active substance as commercially manufactured, on the relevance of one of the impurities and on the compliance of the toxicity batches with the confirmed technical specification. Furthermore, in order to confirm the conclusion that there are no concerns expected from exposure through the diet, it is appropriate to require further confirmatory information on the natural occurrence, toxicity and relevance of several metabolites of bixlozone and the effect of water treatment processes on the nature of residues present in surface water and groundwater, when abstracted for drinking water.

(11) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, 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 bixlozone, as specified in Annex I, is approved, 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

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, 31 March 2026.

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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Bixlozone CAS No: 81777-95-9 CIPAC No: Not allocated	2-(2,4-dichlorobenzyl)-4,4-dimethylisoxazolidin-3-one	≥ 960 g/kg The impurity TBAB shall not exceed 2 g/kg in the technical material.	21 April 2026	21 April 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 bixlozone and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the co-formulants present in bixlozone-containing plant protection products, taking into account in particular the criteria for identification of unacceptable co-formulants as set out in Commission Implementing Regulation (EU) 2023/574 (2), — the consumer risk assessment, in particular for residues present in succeeding crops, including the setting of appropriate plant-back intervals, — the protection of aquatic organisms and non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: 1. the technical specification of the active substance as manufactured (based on commercial scale production), the relevance of one of the impurities and the compliance of the toxicity batches with the confirmed technical specification; 2. the natural occurrence of 2,2-dimethyl-3-OH-propionic acid and dimethylmalonic acid; 3. the genotoxic and general toxicity potential of dimethylmalonic acid (free and conjugated), 2,2-dimethyl-3-OH-propionic acid (free and conjugated), F9600-dimethyl-malonamide, F9600-hydroxy-isobutyramide and F9600-3-OH-propanamide; 4. the relevance of the livestock metabolites dimethylmalonic acid, F9600-dimethyl-malonamide and F9600-3-OH-propanamide;

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
					5. the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1 to 5 of the fourth subparagraph by 21 April 2028.

(1) Further details on identity and specification of active substance are provided in the review report.
(2) Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ L 75, 14.3.2023, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2023/574/oj).

ANNEX II

In Part B 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
‘178	Bixlozone CAS No: 81777-95-9 CIPAC No: Not allocated	2-(2,4-dichlorobenzyl)-4,4-dimethylisoxazolidin-3-one	≥ 960 g/kg The impurity TBAB shall not exceed 2 g/kg in the technical material.	21 April 2026	21 April 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 bixlozone and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the co-formulants present in bixlozone-containing plant protection products, taking into account in particular the criteria for identification of unacceptable co-formulants as set out in Implementing Regulation (EU) 2023/574, — the consumer risk assessment, in particular for residues present in succeeding crops, including the setting of appropriate plant-back intervals, — the protection of aquatic organisms and non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: 1. the technical specification of the active substance as manufactured (based on commercial scale production), the relevance of one of the impurities and the compliance of the toxicity batches with the confirmed technical specification; 2. the natural occurrence of 2,2-dimethyl-3-OH-propionic acid and dimethylmalonic acid; 3. the genotoxic and general toxicity potential of dimethylmalonic acid (free and conjugated), 2,2-dimethyl-3-OH-propionic acid (free and conjugated), F9600-dimethyl-malonamide, F9600-hydroxy-isobutyramide and F9600-3-OH-propanamide; 4. the relevance of the livestock metabolites dimethylmalonic acid, F9600-dimethyl-malonamide and F9600-3-OH-propanamide;

No	Common Name, Identification Numbers	IUPAC Name	Purity ([1])	Date of approval	Expiration of approval	Specific provisions
						5. the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1 to 5 of the fourth subparagraph by 21 April 2028.'

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