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COMMISSION IMPLEMENTING REGULATION (EU) No 22/2013

of 15 January 2013

approving the active substance cyflumetofen, 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 the Annex to Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

(OJ L 11, 16.1.2013, p. 8)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) 2019/716 of 30 April 2019	L 122	39	10.5.2019

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(Text with EEA relevance)

Article 1

Approval of active substance

The active substance cyflumetofen, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing cyflumetofen as an active substance by 30 November 2013.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing cyflumetofen as either the only active substance or as one of several active substances, all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 31 May 2013 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

(a) in the case of a product containing cyflumetofen as the only active substance, where necessary, amend or withdraw the authorisation by 30 November 2014 at the latest; or

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(b) in the case of a product containing cyflumetofen as one of several active substances, where necessary, amend or withdraw the authorisation by 30 November 2014 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or those substances, whichever is the latest.

Article 3

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 4

Entry into force and date of 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 June 2013.

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

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ANNEX I

Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Cyflumetofen CAS No 400882-07-7 CIPAC No 721	2-methoxyethyl (*RS*)-2-(4-*tert*-butylphenyl)-2-cyano-3-oxo-3-(*α,α,α*-trifluoro-o-tolyl)propionate	≥ 975 g/kg (racemic)	1 June 2013	31 May 2023	►**M1** Plant protection products containing cyflumetofen shall only be authorised for uses where the level of metabolite B3 in groundwater is expected to be below 0,1 µg/L. 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 cyflumetofen, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012 shall be taken into account. In this overall assessment, Member States shall pay particular attention to: — the protection of operators and workers; — the protection of groundwater, in particular for metabolite B3, when the substance is applied in regions with vulnerable soils and/or climatic conditions; — the protection of drinking water; — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. ◄

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

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ANNEX II

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

Number	Common name, identification numbers	IUPAC name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
‘31	Cyflumetofen CAS No 400882-07-7 CIPAC No 721	2-methoxyethyl (*RS*)-2-(4-*tert*-butylphenyl)-2-cyano-3-oxo-3-(*α,α,α*-trifluoro-o-tolyl)propionate	≥ 975 g/kg (racemic)	1 June 2013	31 May 2023	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 cyflumetofen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers; — the protection of groundwater, when the substance is applied in regions with vulnerable soils and/or climatic conditions; — the protection of drinking water; — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, like the use of personal protection equipment, where appropriate. The applicant shall submit confirmatory information as regards: (a) the possible mutagenic potential of the metabolite B3 (2-(trifluoromethyl) benzamide), by excluding an *in vivo* relevance of observed *in vitro* effects by an appropriate test protocol (*in vivo* Comet assay); (b) additional information to establish an ARfD for metabolite B3; (c) further ecotoxicological studies and assessments for aquatic vertebrates that cover their full life-cycle. The applicant shall submit to the Commission, the Member States and the Authority that information by 31 May 2015.’

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