

COMMISSION IMPLEMENTING REGULATION (EU) No 608/2012

of 6 July 2012

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances denathonium benzoate, methyl nonyl ketone and plant oils/spearmint oil

(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)(c) thereof,

Whereas:

(1) The active substances denathonium benzoate, methyl nonyl ketone and plant oils/spearmint oil were included in Annex I to Council Directive 91/414/EEC ⁽²⁾ by Commission Directive 2008/127/EC ⁽³⁾ in accordance with the procedure provided for in Article 24b of Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC ⁽⁴⁾. Since the replacement of Directive 91/414/EEC by Regulation (EC) No 1107/2009, these substances are deemed to have been approved under that Regulation and are listed in Part A of the Annex to 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 ⁽⁵⁾.

(2) In accordance with Article 25a of Regulation (EC) No 2229/2004, the European Food Safety Authority, hereinafter 'the Authority', presented to the Commission its views on the draft review reports for denathonium benzoate ⁽⁶⁾, methyl nonyl ketone ⁽⁷⁾ on

2 December 2011 and for plant oils/spearmint oil ⁽⁸⁾ on 16 December 2011. The draft review reports and the views of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 1 June 2012 in the format of the Commission review reports for denathonium benzoate, methyl nonyl ketone and plant oils/spearmint oil.

(3) The Authority communicated its views on denathonium benzoate, methyl nonyl ketone and plant oils/spearmint oil to the notifiers, and the Commission invited them to submit comments on the review reports.

(4) It is confirmed that the active substances denathonium benzoate, methyl nonyl ketone and plant oils/spearmint oil are to be deemed to have been approved under Regulation (EC) No 1107/2009.

(5) 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 amend the conditions of approval of denathonium benzoate, methyl nonyl ketone and plant oils/spearmint oil. It is, in particular, appropriate to require further confirmatory information as regards methyl nonyl ketone. The use of plant oils/spearmint oil should be restricted to postharvest treatment of potatoes.

(6) A reasonable period of time should be allowed before the application of this Regulation in order to allow Member States, notifiers and holders of authorisations for plant protection products to meet the requirements resulting from amendment to the conditions of the approval.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ OJ L 230, 19.8.1991, p. 1.

⁽³⁾ OJ L 344, 20.12.2008, p. 89.

⁽⁴⁾ OJ L 379, 24.12.2004, p. 13.

⁽⁵⁾ OJ L 153, 11.6.2011, p. 1.

⁽⁶⁾ Conclusion on the peer review of the pesticide risk assessment of the active substance denatonium benzoate, EFSA Journal 2012;10(1):2483. Available online: www.efsa.europa.eu/efsajournal.htm

⁽⁷⁾ Conclusion on the peer review of the pesticide risk assessment of the active substance methyl nonyl ketone, EFSA Journal 2012;10(1):2495. Available online: www.efsa.europa.eu/efsajournal.htm

⁽⁸⁾ Conclusion on the peer review of the pesticide risk assessment of the active substance plant oils/spearmint oil, EFSA Journal 2012;10(1):2541. Available online: www.efsa.europa.eu/efsajournal.htm

Article 2

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 November 2012.

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

Done at Brussels, 6 July 2012.

For the Commission

The President

José Manuel BARROSO

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) Row 226 on the active substance denathonium benzoate is replaced by the following

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'226	Denathonium benzoate CAS No 3734-33-6 CIPAC No 845	Benzyl-diethyl-[[2,6- xylyl-carbamoyl] methyl]-ammonium benzoate	≥ 975g/kg	1 September 2009	31 August 2019	PART A Only uses as repellent may be authorised. PART B In assessing applications to authorise plant protection products containing denathonium benzoate for uses other than brushing with automatic rolling equipment in forestry, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. 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 denathonium benzoate (SANCO/2607/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of the operators. Authorised conditions of use must prescribe the application of adequate personal protective equipment. Conditions of use shall include, where appropriate, risk mitigation measures.'

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

(2) Row 238 on the active substance methyl nonyl ketone is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'238	Methyl nonyl ketone CAS No 112-12-9 CIPAC No 846	Undecan-2-one	≥ 975g/kg	1 September 2009	31 August 2019	PART A Only uses as repellent may be authorised. PART B 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 methyl nonyl ketone (SANCO/2619/2008) and in particular Appendices I and II thereof,

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
						<p>as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures. Contact with food and feedcrops shall be avoided.</p> <p>The notifier shall submit confirmatory information as regards:</p> <p>(a) the specification of the material tested in the mammalian toxicology and ecotoxicology studies;</p> <p>(b) the specification with supporting batch data and validated methods of analysis;</p> <p>(c) an appropriate assessment of the fate and behaviour of methyl nonyl ketone and potential transformation products in the environment;</p> <p>(d) the risk to aquatic and to soil living organisms.</p> <p>The notifier shall submit to the Commission, the Member States and the Authority the information set out in points (a) and (b) by 30 April 2013 and the information set out in points (c) and (d) by 31 December 2015.'</p>

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

(3) Row 243 on the active substance plant oils/spearmint oil is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'243	Plant oils/spear mint oil CAS No 8008-79-5 CIPAC No 908	Spearmint oil	≥ 550 g/kg as (R)-Carvone	1 September 2009	31 August 2019	<p>PART A</p> <p>Only uses as plant growth regulator for postharvest treatment of potatoes may be authorised.</p> <p>Member States shall ensure that authorisations provide that hot fogging is performed exclusively in professional storage facilities and that the best available techniques are applied to exclude the release into the environment of the product (fogging mist) during storage, transport, waste disposal and application.</p> <p>PART B</p> <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 amended review report on plant oils/spearmint oil (SANCO/2624/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.'</p>

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