

## COMMISSION IMPLEMENTING REGULATION (EU) No 637/2012

of 13 July 2012

## amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch

(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)(c) thereof,

Whereas:

(1) The active substances iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch were included in Annex I to Council Directive 91/414/EEC <sup>(2)</sup> by Commission Directive 2008/127/EC <sup>(3)</sup> 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 <sup>(4)</sup>. 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 <sup>(5)</sup>.

(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 iron sulphate <sup>(6)</sup>, repellents by smell of animal or plant origin/tall oil crude <sup>(7)</sup> and repellents by smell of animal or plant

origin/tall oil pitch <sup>(8)</sup> 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 iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch.

(3) The Authority communicated its views on iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch to the notifiers, and the Commission invited them to submit comments on the review reports.

(4) It is confirmed that the active substances iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch 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 iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch. It is, in particular, appropriate to require further confirmatory information as regards those active substances.

(6) The Annex to Regulation (EU) No 540/2011 should therefore be amended accordingly.

(7) 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.

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

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

<sup>(2)</sup> OJ L 230, 19.8.1991, p. 1.

<sup>(3)</sup> OJ L 344, 20.12.2008, p. 89.

<sup>(4)</sup> OJ L 379, 24.12.2004, p.13.

<sup>(5)</sup> OJ L 153, 11.6.2011, p. 1.

<sup>(6)</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance iron sulfate. EFSA Journal 2012;10(1):2521. Available online: [www.efsa.europa.eu/efsajournal.htm](http://www.efsa.europa.eu/efsajournal.htm)

<sup>(7)</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance tall oil crude. EFSA Journal 2012;10(2):2543. Available online: [www.efsa.europa.eu/efsajournal.htm](http://www.efsa.europa.eu/efsajournal.htm)

<sup>(8)</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance tall oil pitch. EFSA Journal 2012;10(2):2544. Available online: [www.efsa.europa.eu/efsajournal.htm](http://www.efsa.europa.eu/efsajournal.htm)

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.

*Article 2*

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing repellents by

smell of animal or plant origin/tall oil crude as active substances in order to comply with the Annex to this Regulation by 1 May 2013.

*Article 3*

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, 13 July 2012.

*For the Commission*

*The President*

José Manuel BARROSO

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## ANNEX

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

(1) Row 235 on the active substance iron sulphate is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'235	<p><i>Iron sulphate:</i></p> <p>Iron(II)sulfate anhydrous: CAS No 7720-78-7</p> <p>Iron(II)sulfate monohydrate: CAS No 17375-41-6</p> <p>Iron(II)sulfate heptahydrate: CAS No 7782-63-0</p> <p>CIPAC No 837</p>	Iron(II)sulphate or iron(2+) sulfate	<p>Iron(II)sulfate anhydrous: ≥ 350 g/kg total iron.</p> <p>Relevant impurities:</p> <p>arsenic, 18 mg/kg</p> <p>cadmium, 1,8 mg/kg</p> <p>chromium, 90 mg/kg</p> <p>lead, 36 mg/kg</p> <p>mercury, 1,8 mg/kg</p> <p>expressed on the basis of the anhydrous variant</p>	1 September 2009	31 August 2019	<p>PART A</p> <p>Only uses as herbicide may be authorised.</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 iron sulphate (SANCO/2616/2008) 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>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the risk for operator;</li> <li>— the risk to children/residents playing on treated turf;</li> <li>— the risk to surface waters and to aquatic organisms.</li> </ul> <p>Conditions of use shall include, where appropriate, risk mitigation measures and the application of adequate personal protective equipment. The notifier shall submit to the Member States, the Commission and the Authority, confirmatory information as regards the equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicity dossiers.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission such information by 1 May 2013.'</p>

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

(2) Row 250 on the active substance Repellents by smell of animal or plant origin/tall oil crude is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'250	<p><i>Repellents by smell of animal or plant origin/tall oil crude:</i></p> <p>CAS No 8002-26-4</p> <p>CIPAC No 911</p>	Not available	<p>The qualitative parameters below comprise the specification of repellents by smell of animal or plant origin/tall oil crude:</p> <p>acid number: min. 125 mgKOH/g</p> <p>water content: max. 2 %</p> <p>rosin acid content: min. 35 % (proposed)</p> <p>ash content: max. 0,2 %</p> <p>pH: approx. min. 5,5</p> <p>unsaponifiables: max. 12 %</p> <p>free mineral acids: max. 0,02 %</p>	1 September 2009	31 August 2019	<p>PART A</p> <p>Only uses as repellent applied by glove or brush may be authorised.</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 repellents by smell of animal or plant origin/tall oil crude (SANCO/2631/2008) 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>In assessing applications to authorise plant protection products containing Repellents by smell of animal or plant origin/tall oil crude for uses other than as a repellent 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 information is provided before such an authorisation is granted.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operator, worker and bystander;</li> <li>— the risk to non target species.</li> </ul> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ol style="list-style-type: none"> <li>(a) the equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicity dossiers;</li> <li>(b) the toxicological profile of repellents by smell of animal or plant origin/tall oil crude.</li> </ol> <p>The Member States concerned shall ensure that the notifier submits to the Commission the information set out in point (a) by 1 May 2013 and the information set out in point (b) by 31 May 2014.'</p>

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

(3) Row 251 on the active substance Repellents by smell of animal or plant origin/tall oil pitch is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'251	<p><i>Repellents by smell of animal or plant origin/tall oil pitch:</i></p> <p>CAS No 8016-81-7</p> <p>CIPAC No 912</p>	Not available	Complex mixture of esters of fatty acids, rosin and small amounts of dimers and trimers of resin acids and fatty acids.	1 September 2009	31 August 2019	<p>PART A</p> <p>Only uses as repellent may be authorised.</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 repellents by smell of animal or plant origin/tall oil pitch (SANCO/2632/2008) 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>In assessing applications to authorise plant protection products containing repellents by smell of animal or plant origin/tall oil pitch for uses other than as a repellent in forestry applied by glove or brush, 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 information is provided before such an authorization is granted.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operator, worker and bystander;</li> <li>— the risk to non target species.</li> </ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ul style="list-style-type: none"> <li>(a) the equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicity dossiers;</li> <li>(b) the toxicological profile of repellents by smell of animal or plant origin/tall oil pitch.</li> </ul> <p>The Member States concerned shall ensure that the notifier submits to the Commission the information set out in point (a) by 1 May 2013 and the information set out in point (b) by 31 May 2014.'</p>

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