

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1192**of 20 July 2015****approving the active substance terpenoid blend QRD 460, 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)**

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) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, the Netherlands received on 14 September 2011 an application from AgraQuest Inc. (now Bayer CropScience AG) for the approval of the active substance terpenoid blend QRD 460. In accordance with Article 9(3) of that Regulation, the Netherlands, as rapporteur Member State, notified the Commission on 4 October 2011 of the admissibility of the application.
- (2) On 30 July 2013 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the European Food Safety Authority (hereinafter '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.
- (3) 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 in May 2014.
- (4) On 26 August 2014 the Authority communicated to the applicant, the Member States and the Commission its conclusion on whether the active substance terpenoid blend QRD 460 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 ⁽²⁾. The Authority made its conclusion available to the public.
- (5) The applicant was given the possibility to submit comments on the review report.
- (6) On 29 May 2015 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for terpenoid blend QRD 460 and a draft Regulation providing that terpenoid blend QRD 460 is approved.
- (7) 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 Commission review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. Those approval criteria are therefore deemed to be satisfied. It is therefore appropriate to approve terpenoid blend QRD 460.
- (8) 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 and restrictions. It is, in particular, appropriate to require further confirmatory information.
- (9) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾ should be amended accordingly.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA Journal 2014;12(10):3816. Available online: www.efsa.europa.eu

⁽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).

- (10) 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 active substance

The active substance terpenoid blend QRD 460, 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 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*.

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

Done at Brussels, 20 July 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Terpenoid blend QRD 460 CIPAC No: 982	Terpenoid blend QRD 460 is a blend of three components: — α -terpinene: 1-isopropyl-4-methylcyclohexa-1,3-diene; — <i>p</i> -cymene: 1-isopropyl-4-methylbenzene; — <i>d</i> -limonene: (<i>R</i>)-4-isopropenyl-1-methylcyclohexene.	The nominal concentration of each component in the active substance as manufactured should be as follows: — α -terpinene: 59,7 %; — <i>p</i> -cymene: 22,4 %; — <i>d</i> -limonene: 17,9 %. Each component should have a minimum purity as follows: — α -terpinene: 89 %; — <i>p</i> -cymene: 97 %; — <i>d</i> -limonene: 93 %.	10 August 2015	10 August 2025	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 terpenoid blend QRD-460, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the stability of formulations on storage; (b) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; (c) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; (d) the protection of surface water and aquatic organisms; (e) the protection of bees and non-target arthropods. 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 (5 batch analysis for the blend should be provided), supported by acceptable and validated methods of analysis. It should be confirmed that there are no relevant impurities present in the technical material; (2) the equivalence of the material used in the toxicological and ecotoxicological studies with the confirmed technical specification. The applicant shall submit that information to the Commission, the Member States and the Authority by 10 February 2016.

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

ANNEX II

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

	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'84	Terpenoid blend QRD 460 CIPAC No: 982	Terpenoid blend QRD 460 is a blend of three components: — α -terpinene: 1-isopropyl-4-methylcyclohexa-1,3-diene; — <i>p</i> -cymene: 1-isopropyl-4-methylbenzene; — <i>d</i> -limonene: (<i>R</i>)-4-isopropenyl-1-methylcyclohexene.	The nominal concentration of each component in the active substance as manufactured should be as follows: — α -terpinene: 59,7 %; — <i>p</i> -cymene: 22,4 %; — <i>d</i> -limonene: 17,9 %. Each component should have a minimum purity as follows: — α -terpinene: 89 %; — <i>p</i> -cymene: 97 %; — <i>d</i> -limonene: 93 %.	10 August 2015	10 August 2025	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 terpenoid blend QRD-460, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the stability of formulations on storage; (b) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; (c) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; (d) the protection of surface water and aquatic organisms; (e) the protection of bees and non-target arthropods. 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 (5 batch analysis for the blend should be provided), supported by acceptable and validated methods of analysis. It should be confirmed that there are no relevant impurities present in the technical material; (2) the equivalence of the material used in the toxicological and ecotoxicological studies with the confirmed technical specification. The applicant shall submit that information to the Commission, the Member States and the Authority by 10 February 2016.'

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