

**COMMISSION IMPLEMENTING REGULATION (EU) 2016/1929****of 4 November 2016****approving *Bacillus thuringiensis* subsp. *kurstaki*, serotype 3a3b, strain ABTS-351, as an active substance for use in biocidal products of product-type 18****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products <sup>(1)</sup>, and in particular Article 90(2) thereof,

Whereas:

- (1) France received on 30 January 2013 an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council <sup>(2)</sup>, for the inclusion of the active substance *Bacillus thuringiensis* subsp. *kurstaki*, serotype 3a3b, strain ABTS-351, in Annex I of that Directive for use in products of product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to that Directive, which corresponds to product-type 18 as defined in Annex V to Regulation (EU) No 528/2012.
- (2) France submitted the assessment report together with its recommendations on 29 May 2015 in accordance with Article 90(2) of Regulation (EU) No 528/2012.
- (3) The opinion of the European Chemicals Agency was formulated on 16 February 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (4) According to that opinion, biocidal products of product-type 18 and containing *Bacillus thuringiensis* subsp. *kurstaki*, serotype 3a3b, strain ABTS-351, may be expected to satisfy the criteria of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.
- (5) It is therefore appropriate to approve *Bacillus thuringiensis* subsp. *kurstaki*, serotype 3a3b, strain ABTS-351, for use in biocidal products of product-type 18, subject to compliance with certain specifications and conditions.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

*Article 1*

*Bacillus thuringiensis* subsp. *kurstaki*, serotype 3a3b, strain ABTS-351, is approved as an active substance for use in biocidal products of product-type 18, subject to the specifications and conditions set out in the Annex.

*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*.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

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

Done at Brussels, 4 November 2016.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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## ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance <sup>(1)</sup>	Date of approval	Expiry date of approval	Product type	Specific conditions
<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> , serotype 3a3b, strain ABTS-351	Not applicable	No relevant impurities	1 March 2017	28 February 2027	18	<p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> <li>1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.</li> <li>2. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: <ol style="list-style-type: none"> <li>(a) professional users;</li> <li>(b) general population exposed to spray drift;</li> <li>(c) soil compartment when the product is applied before a rain event.</li> </ol> </li> </ol>

<sup>(1)</sup> The purity indicated in this column was the minimum degree of purity of the active substance evaluated in accordance with Article 90(2) of Regulation (EU) No 528/2012. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.