Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

BTK (*Bacillus thuringiensis* subsp. *Kurstaki,* Serotype 3a3b, Strain ABTS-351)

Product type: 18

ECHA/BPC/089/2016

Adopted

16 February 2016

Opinion of the Biocidal Products Committee

on the application for approval of the active substance *Bacillus thuringiensis* subsp. *Kurstaki,* Serotype 3a3b, Strain ABTS-351 for product type 18

In accordance with Article 90(2) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type PT18 of the following active substance:

Common name:	***Bacillus thuringiensis* subsp. *Kurstaki,* Serotype 3a3b, Strain ABTS-351**
Chemical name(s):	**not applicable**
EC No.:	**not applicable**
CAS No.:	**not applicable**
New active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Sumitomo Chemical Agro Europe SAS (abbreviated to SCAE) on 30 January 2013, the evaluating Competent Authority France submitted an assessment report and the conclusions of its evaluation to the ECHA on 29 May 2015. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the approval of the active substance *Bacillus thuringiensis subsp. Kurstaki*, Serotype 3a3b, Strain ABTS-351 in product type 18 was adopted on 16 February 2016.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the *Bacillus thuringiensis* subsp. *Kurstaki*, Serotype 3a3b, Strain ABTS-351 in product type 18 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of *Bacillus thuringiensis* subsp. *Kurstaki (Btk)*, Serotype 3a3b, Strain ABTS-351 (abbreviated to *Btk* ABTS-351) in product type 18 (insecticide).

Btk ABTS-351 originates from a natural wild strain of the organism and has not been genetically modified nor is it the result of a spontaneous or an induced mutation. The strain *Bacillus thuringiensis* subsp. *Kurstaki* ABTS-351 was registered at American Type Culture Collection under No. ATCC-SD-1275.

The mode of action of *Btk* ABTS-351 results from the production of protoxins by bacteria, i.e. toxic proteins contained in a parasporal crystal. The crystals are taken up by the target insect larvae via ingestion and under the alkali conditions present in the larvae gut, the crystal dissolves releasing the active protein δ-endotoxins that induce disintegration of the gut epithelium and consequent death of the larvae. There are no other active metabolites or degradation products that are known to contribute to the insecticidal toxicity of *Btk* ABTS-351.

Specifications for the reference source are established. The minimum content in the representative product is 5.0 10^8 CFU/g or 1.0 10^4 IU/mg. The maximum content of 1.0 10^{10} CFU/g or 1.4 10^4 IU/mg in the representative product should not be exceeded.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product. However, additional data are required before the approval of the active substance (see chapter 2.5).

Validated analytical methods are available for the microbial active substance but validation data are required (see chapter 2.5). The detection and quantification of microbial contaminants *Staphylococcus, Enterococci, Clostridium, Coliform, Salmonella and Pseudomonas aeruginosa* in the reference product needs further supporting information.

No classification and labelling is necessary with regards to Regulation (EC) No 1272/2008. However, based on the precautionary principle all microorganisms should be considered to have the potential to provoke sensitising reactions.

b) Intended use, target species and effectiveness

Btk ABTS-351 is intended to be used by professionals as an insecticide (PT18) against the larvae *Lepidoptera* insect species and the specific use is for the control of pine and oak processionary caterpillars, *Thaumetopoea pityocampa* and *Thaumetopoea processionea*. The purpose is to protect the human and animal populations from the irritant effects of the hairs from the late instar caterpillars. When hairs are shed and may remain in aerosols and if inhaled they can have a systemic action and can cause tissue necrosis.

Btk ABTS-351 is applied in non agricultural and non silviculture zones including parks and gardens as long as the intended use is not covered by the scope of the Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.

The representative product is a suspension concentrate (SC) formulation typically applied undiluted at the rate of 4 L/ha by aerial spray using ultra-low volume micronisers such as micronair equipment or using ground equipment with tractor/pick-up mounted aerosolizing spray equipment or lances. The product can be used also diluted in water (until 500 L/ha).

The data on *Btk* ABTS-351 and the representative biocidal product have demonstrated sufficient efficacy against the target species for the approval of the active substance.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

The derivation of reference values was not considered needed since the microorganism was not shown to be toxic, pathogenic or infective based on the available data and studies.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Mixing and Loading	Primary exposure, qualitative assessment	Professionals	Acceptable with PPE and RPE
Spraying application	Primary exposure, qualitative assessment of aerial or ground applications. Sprayers are inside the enclosed vehicle or aircraft cab.	Professionals	Acceptable
Aerial spraying	Primary exposure, qualitative assessment of ground markers during aerial spraying	Professionals	Acceptable with PPE and RPE
Cleaning	Primary exposure, qualitative assessment	Professionals	Acceptable with PPE
Bystander	Secondary exposure; qualitative assessment assuming bystanders excluded from treated area	General public	Acceptable
Exposure via food contamination	Secondary exposure; qualitative assessment	General public	Acceptable

No models are currently available to estimate professional exposure from the application of micro-organisms. Therefore, a quantitative estimation of professional exposure is not feasible and the exposure has only been qualitatively estimated.

Primary exposure

Professional users could potentially be exposed during mixing/loading of the spray solution, during application, including when acting as ground markers for aerial spraying and during cleaning the spraying equipment. In case of enclosed vehicle or aircraft cabs, the exposure of the user inside the cab is considered negligible during application. Due to the potential of all micro-organisms to be sensitizers, users are required to wear protective gloves, working

coverall and dust mask) during all phases with potential exposure. Only operators wearing protective equipment are permitted in areas being treated. Therefore, considering the intended use and the recommended PPE, the risk for professionals is considered acceptable. However, as a precautionary measure, *Btk* ABTS-351 based products should not be used by professionals affected by immunodeficiency, primary or secondary, or in treatment with immunosuppressive agents, which can significantly reduce the effectiveness of the immune system response.

Secondary exposure: bystander/resident
Ground spray application could lead to an exposure to the spray drift if a bystander is walking next to an area being treated. Since bystanders are excluded from treated areas to ensure only protected professionals can possibly be exposed to *Btk* ABTS-351 based product, the risk is considered minimal. Adequate risk mitigation measures, such as a drift buffer zone, should be respected in order to avoid exposure of general population to spray drift expected during aerial application.

Secondary exposure via food contamination
Even if the product applied aerially can reach food crops located nearby, risk of oral exposure to residues after application via residues of *Btk* ABTS-351 on food crops is considered to be negligible. However at product authorisation level, adequate risk mitigation measures such as drift buffer zone should be considered in order to ensure that adjacent agricultural and horticultural areas are not exposed.

Environment

The active substance *Btk* ABTS-351 is a microorganism containing toxic proteins. Several expressions of metrics of the ecotoxicity are appropriate to microorganisms containing toxins: the weight of active substance (g or mg), the density of microorganism (number of bacteria as colony forming unit (CFU)) and the biopotency (activity of a microbial substance against a target (IU)). The environmental risk assessment has been carried out with the three different units. The environmental risk assessment has not been carried out considering directly the toxins contained in the microorganisms. There is no direct relation between the applied density of microorganisms and the biopotency and toxins are implied in the observed toxic effects which could support the requirement of a complete risk assessment on toxins. However, the biopotency can be considered as an indirect way to assess the risk of the toxins and the most relevant unit to assess the risk for the environment. Nevertheless, the conclusions of the risk assessment carried out in previous dossier with similar substances are based on density (CFU). Therefore the conclusion of the risk assessment based on density is also reported in the present conclusion.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Aerial application		
Aerial spraying via aircraft (spray using ultra-low volume micronisers) on forest	**1 to 5 applications** Direct release to aquatic compartment (direct application on surface water) Direct release to soil compartment	Acceptable for only one application (assessment based on density) Acceptable for 4 applications (assessment based on weight) Acceptable for 5 applications (assessment based on biopotency)
Ground application		
Tractor/pick-up mounted aerosolizing spray equipment or lances for terrestrial spraying in parks and gardens	**1 to 5 applications** Direct release to aquatic compartment (through drift of the application) Direct release to soil compartment	Acceptable for only one application (assessment based on density) Acceptable for 4 applications (assessment based on weight) Acceptable for 5 applications (assessment based on biopotency)

Regarding the environment, acceptable risks for the aquatic compartment are expected whatever the scenario assessed and whatever the units considered.

When assessment is based on density of microorganisms in soil, unacceptable risk for the terrestrial compartment is identified after 2 up to 5 applications in both scenarios. However, acceptable risk is identified for the terrestrial compartment after one single application, except if the application occurs just before a rain event. However, rain event scenario is considered as a worst case. Moreover, study on soil organisms shows no adverse effects and predicted density of *Btk* ABTS-351 after 5 applications is in the same order of magnitude than density of *Bacillus thuringiensis* that naturally occurs in soil. Moreover, *Bacillus thuringiensis* has been shown to not compete aggressively with other soil micro-organisms.

It was agreed that biopotency is the most relevant unit to use for risk characterisation and to base the overall conclusions on the uses for the environment. When assessment is based on biopotency, acceptable risks for the terrestrial compartment are identified for 5 applications of product. However, application of the biocidal product should be avoided when significant rainfall is imminent or during windy conditions.

No toxicity data on non targeted Lepidoptera have been provided and effects arising from long term and large scale use of *Btk* ABTS-351 on present Lepidoptera should be assessed at product authorization stage.

Overall conclusion

With regard to human health and environmental exposures and effects, safe use of *Btk* ABTS-351 based product is identified if professional operators wear appropriate protective equipment and when the terrestrial compartment via aerial and ground applications is exposed to five applications of product which is the claimed use. Exposure of public should be avoided during aerial and ground applications. The biocidal product should not be applied when significant rainfall is imminent or during windy conditions.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

<table>
<tr><th colspan="3">Property</th><th>Conclusions</th></tr>
<tr><td rowspan="3">CMR properties</td><td>Carcinogenicity (C)</td><td>no classification required</td><td rowspan="3">*Btk* does not fulfil criterion (a), (b) and (c) of Article 5(1)</td></tr>
<tr><td>Mutagenicity (M)</td><td>no classification required</td></tr>
<tr><td>Toxic for reproduction (R)</td><td>no classification required</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td rowspan="3">*Btk* is excluded from the PBT assessment based on Annex XIII of the REACH Regulation 1272/2008.</td><td rowspan="3">*Btk* does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)</td></tr>
<tr><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td></tr>
<tr><td>Toxic (T)</td></tr>
<tr><td>Respiratory sensitisation</td><td colspan="3">No classification required. *Btk* does not fulfil criterion (b) of Article 10(1)</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">Not considered to have endocrine disrupting properties. *Btk* does not fulfil criterion (d) of Article 5(1)</td></tr>
<tr><td>Concerns linked to critical effects</td><td colspan="3">*Btk* does not fulfil criterion (e) of Article 10(1)</td></tr>
<tr><td>Proportion of non-active isomers or impurities</td><td colspan="3">Not relevant. *Btk* does not fulfil criterion (f) of Article 10(1)</td></tr>
</table>

Consequently, the following is concluded:

Bacillus thuringiensis subsp. Kurstaki, Serotype 3a3b, Strain ABTS-351 does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Bacillus thuringiensis subsp. Kurstaki, Serotype 3a3b, Strain ABTS-351 does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[1] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[2] agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation (EU) No

[1] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)
2 See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

The POP criteria are not relevant as *Btk* ABTS-351 is a micro-organism.

2.3. BPC opinion on the application for approval of the active substance *Bacillus thuringiensis* subsp. *Kurstaki*, Serotype 3a3b, Strain ABTS-351 in product type 18

In view of the conclusions of the evaluation, it is proposed that *Bacillus thuringiensis* subsp. *Kurstaki*, Serotype 3a3b, Strain ABTS-351 shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: *Bacillus thuringiensis* subsp. *Kurstaki*, Serotype 3a3b, Strain ABTS-351 and "no relevant impurity".

2. The authorisation of biocidal products are subject to the following conditions:

    a. The product assessment shall pay particular attention to the exposure, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed at the Union level risk assessment of the active substance.

    b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

        i) professional users;
        ii) general population exposed to spray drift;
        iii) soil compartment when the product is applied before a rain event;

As all microorganisms are considered as potential sensitisers, based on the precautionary principle, the active substance may not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) No 528/2012.

2.4. Elements to be taken into account when authorising products

1. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

    a. For professional users, since the active substance is a microorganism which may cause sensitization reactions, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.

    b. Label of products should indicate that the product should not be used by professionals affected by immunodeficiency, primary or secondary, or in treatment with immunosuppressive agents, which can significantly reduce the effectiveness of the immune system response, unless it is demonstrated that such statement is not necessary.

    c. Label of products should indicate that the product application should be avoided when significant rainfall is imminent or during windy conditions.

    d. Adequate risk mitigation measures, such as a drift buffer zone, should be respected in order to avoid exposure of general population to spray drift expected during aerial application and ground application with a vehicle mounted motorized spray equipment.

    e. At product authorisation level adequate risk mitigation measures should be introduced in order to ensure that adjacent agricultural and horticultural areas are not exposed.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of *Bacillus thuringiensis subsp. Kurstaki*, Serotype 3a3b, Strain ABTS-351.

However, further data on the active substance are required and must be provided as soon as possible to the evaluating Competent Authority (FR) but no later than the date of approval of the active substance:

1. Validation data (linearity, repeatability) of the method for the quantification of viable spores of *Btk* ABTS-351 in the product.
2. In order to support the specifications, a new analytical profile of batches analysis or available quality control data of the technical active substance, including microbial active ingredient content (CFU/g) and potency (IU/mg) respecting thresholds for the determination of microbial contaminants of the OECD analytical requirements.
3. No toxicity data on non-target *Lepidoptera* have been provided. Information on effects arising from long term and large scale use of *Btk* on Lepidoptera should be submitted.