Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

***Bacillus sphaericus* 2362,**

Serotype H5a5b - Strain ABTS1743

Product type: PT18

ECHA/BPC/017/2014

Adopted

19 June 2014

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance *Bacillus sphaericus* 2362, Serotype H5a5b - Strain ABTS1743 for product type 18

In accordance with Article 89(1) 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 18 of the following active substance:

Common name:	***Bacillus sphaericus* 2362 - Serotype H5a5b**
	Strain ABTS1743
Chemical name(s):	**not applicable**
EC No.:	**not applicable**
CAS No.:	**not applicable**

Existing 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 (for Valent BioSciences Corporation) on 30 April 2006, the evaluating Competent Authority Italy submitted an assessment report and the conclusions of its evaluation to the Commission on 9 January 2009. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and the Commission via the Biocides Technical Meetings. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: BPC member of Italy

The BPC opinion on the approval of the active substance *Bacillus sphaericus* 2362 - Serotype H5a5b - Strain ABTS1743 in product type 18 was adopted on 19 June 2014.

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 sphaericus* 2362 - Serotype H5a5b-Strain ABTS1743 (hereafter Bs 2362) in product type 18 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. Opinion

2.1. 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 Bs 2362 in product type 18. Bs 2362 is a typical rod-shaped bacterium that produces a crystalline protein inclusion which is toxic to larvae of certain dipteran insects upon ingestion. Bs 2362 originates from a natural wild strain of the bacteria and has not been genetically modified nor is it the result of an induced mutation. *Bacillus sphaericus* is a common naturally occurring micro-organism with worldwide distribution. The species has been detected both in soil and aquatic environments and will be indigenous to intended areas of application. Specifications for the reference strain are established.

The toxicity of *Bacillus sphaericus*strains, including strain Bs 2362, is primarily due to the production of the crystalline binary toxin Bin during sporulation. After ingestion by targets, BinA and BinB the crystalline inclusions are solubilised under the alkaline conditions in the larval gut. This is followed by activation by gut proteases, producing the 39 and 43-kDa active forms of BinA and BinB, respectively. Target specificity is determined by the specific binding of the binary toxin to the midgut epithelial cells. Quality control of the fermentation slury ensures that no toxins relevant for human health are present. Specifications for the reference strain are established.

The biological, 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. Genetic stability is ensured through manufacturing directions for the fermentation process.

Adequate methods for the identification at strain level are available for the active substance.

The classification and labelling for Bs 2362 according to Regulation (EC) No 1272/2008 (CLP Regulation) is not required as the active substance is a living microorganism not covered under the Regulation. It is not biohazardous according to Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work.[1] . 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

Bs 2362 is a biological insecticide in product type 18 intended for both professional and non-professional uses. The use of Bs 2362 for the control of mosquito larvae (principally

[1] OJ L 262, 17.10.2000 p.21

Culex and Anopheles species while it is not sufficiently effective on Aedes subgenus Stegomyia species) in a range of aquatic breeding habitats, such as stagnant and standing ponds, flood and irrigation water, ditches, storm water retention areas, tidal water and salt marshes, sewerage settling ponds and water with moderate to high organic content. The product is not for use in rice fields during the last month before harvest.

Bs 2362 is a biological larvicide specific to the larvae of mosquito larvae (like Culex spp. and Anopheles spp.) and so the timing of application will depend on the level of larvae infestation and growth stage. Bs 2362 should be applied during the 1st to the early 4th larval instar. During the later part of the 4th instar stage the larvae are no longer feeding and the product is not effective. Treatment is restricted to a maximum of 5 treatments per season.

The occurrence of resistance has been reported in a field study. Resistance to *Bacillus sphericus* (Bs) in target species can be managed using mixtures of *Bacillus thuringiensis isrealiensis* (Bti) and Bs or rotating Microbial Pest Control Products containing either Bti or Bs.

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

Human health

Bs 2362 indicates no evidence of infectivity or pathogenicity in relation to human health, no adverse effects in humans is expected. There are no adverse effects following actual exposure of humans or in the available data and therefore derivation of an AEL for the active substance is not considered necessary. Safety considerations are limited to the sensitizing potential relevant to all microorganisms.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**
Mixing and loading	qualitative assessment and simulations	Professionals and non-professionals
Spraying	Primary, qualitative assessment and simulations	Professionals
Home garden sraying	Primary, qualitative assessment and simulations	Non-professionals
Bystanders	Secondary, qualitative assessment	General public

A qualitative risk assessment was undertaken as due to the lack of adverse effect derivation of AEL was not required. A quantitative exposure assessment based on simulations showed that the exposures are negligible for both professionals and non-professional users without the use of PPE. Regarding systemic effects no unacceptable risks were identified for professionals for all scenarios. However, as microorganisms may cause sensitization reactions, the use of personel protective equipment (PPE) is needed. Professionals are recommended to wear a dust mask to reduce inhalation exposure

during mixing/loading and during application, except if enclosed tractor cabs are used. Only users wearing PPE are permitted in areas being treated.
No unacceptable risks were identified for non-professional users for systemic effects. As 2362 is a micro-organisms it may have the potential to provoke sensitization reactions therefore risk mitigation measures e.g. using water soluble packaging must be considered to reduce contact.

For the general public, no concern is anticipated through indirect exposure.

Environment

Bs 2362 exhibits specific toxicity to some dipteran insect larvae upon ingestion and due to the specific alkaline conditions of the insect gut and specific binding sites of the mosquito larvae, has a very limited impact on non-target organisms and is non-toxic to mammalian species. No other active metabolites and degradation products are known to contribute to the toxicity of *Bacillus sphaericus*. Due to its specific mode of action, *Bacillus sphaericus* will have no other effects on the intended area of use.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Direct application to water and soil	Application rates both on soil and in water of 1.5 kg/ha 'VectoLex' WG and a maximum of 5 repetitions at a minimum interval of 7 days. As a worst case, no adsorption, interception and degradation are assumed for spores and toxins between applications.

Bs 2362 is a microbial product with a specific mode of action and a simple comparison of EED (Expected Environmental Density and PNED (Probable No Effect Environmental Density) is considered appropriate.

No unacceptable risks were identified for surface water and for the terrestrial compartment. Adverse effects on the microbial activity occurring in sewage treatment plants as a result of use of Bs 2362 is not expected.

2.2. Exclusion, substitution and POP criteria

For microorganisms the assessment of exclusion criteria is not relevant. The assessment of substitution criteria is relevant for micro-organisms. It has been agreed that substitution criteria are assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR" agreed at the 54th meeting of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products (CA-March14-Doc.4.1 - Final - Principles for the approval of AS.doc). This implies that the assessment of the substitution criteria is based on Article 10(1)(a, b and d). Of these Article 10(1)(b) may be relevant although micro-organisms are not covered by CLP. All microorganisms are considered as potential sensitizers. In the absence of data indicating respiratory sensitization Bs 2362 does not meet Article 10 (1b). The other criteria (Article 10(1)(a and b) are not applicable for microorganisms.

Therefore, Bs 2362 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.

For microorganisms the assessment of POP criteria is not relevant.

2.3. BPC opinion on the application for approval of the active substance Bs 2362 in product type 18

In view of the conclusions of the evaluation, it is proposed that Bs 2362 shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: *Bacillus sphaericus* 2362 – serotype H5a5b – strain ABTS1743 and "no relevant impurities".
2. 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..
3. For professional users, safe operational procedures and appropriate organisational 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.
4. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009[2] or Regulation (EC) No 396/2005[3] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

As all microorganisms are considered as potential sensitizers, 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) 528/2012.

2.4. Elements to be taken into account when authorising products

1. Considering that all microbials should be regarded as potential sensitisers, the agreed warning phrase on the product label is "Microorganisms may have the potential to provoke sensitising reactions".
2. The possibility of sensitisation from products containing Bs 2362 should be addressed by a qualitative risk assessment covering all potential exposure routes at product authorisation since the active substance is a microorganism which may cause sensitization reactions. Products for non-professionals shall normally not be authorised if the wearing of PPE/RPE is the only mitigation measure to reduce exposure to an acceptable level. Other elements leading to a reduction of exposure like pack size and design should be considerd.
3. Whilst the efficacy data provided is sufficient to recommend approval of the substance, data demonstrating the efficacy of the product at the minimum application rate against the range of proposed target organisms using the recommended application equipment must be provided at the product authorisation stage.

[2] Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11)
[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1

4. The potential resistance of target insects to Bs 2362 could be of concern and, as such, resistance management measures should be included in the authorisation of products. These could include but may not be restricted to the following:

   - application in combination with for example Bacillus thuringiensis;
   - appropriate rotation of application with other microbial pest control agents.

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 Bs 2362.

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