

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the single biocidal product:

DEC-SPORE 200 Plus

ECHA/BPC/374/2023

Adopted

2 March 2023

Opinion of the Biocidal Products Committee

on the Union authorisation of the single biocidal product DEC-SPORE 200 Plus

In accordance with Article 44(3) 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, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

Name of the biocidal product:	DEC-SPORE 200 Plus¹
Authorisation holder:	Veltek Associates Inc. Europe
Active substance:	Peracetic acid (CAS number 79-21-0)
Product type:	2

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 28 September 2017, recorded in R4BP3 under case number BC-WV034235-09, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 30 August 2022. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-46) and its Working Groups (WG-IV-2022). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

¹ tradename: DEC-SPORE 300 Plus

Adoption of the BPC opinion

Rapporteur: The Netherlands

The BPC opinion on the Union authorisation of the biocidal product was reached on 2 March 2023.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the biocidal product is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012.

The biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of DEC-SPORE 200 Plus referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

General

The biocidal product DEC-SPORE 200 Plus is used to disinfect hard surfaces in clean rooms of pharmaceutical, biopharmaceutical, medical device, healthcare and diagnostic product manufacturing facilities (PT 2).

The applicant applied for two uses where the first use contains a surface disinfectant for indoor use and the second use a surface disinfectant for indoor use (sporicidal use). The product is used by industrial users only.

DEC-SPORE 200 Plus contains Peracetic acid (PAA, 5.13% w/w) as active substance. Hydrogen peroxide (21.7% w/w) and Glacial Acetic Acid (10.4% w/w) are equilibrium partners of PAA and part of the active substance. An overview of the authorised uses is given in the following table:

AS content (%)	Equilibrium partners	User category	Use #	Use assessed	Use authorised
5.13% w/w PAA	Hydrogen peroxide 21.7%w/w Acetic acid 10.4%w/w	industrial	#1	PT2: Surface disinfectant; use indoors	Yes
5.13% w/w PAA	Hydrogen peroxide 21.7%w/w Acetic acid 10.4%w/w	industrial	#2	PT2: Surface disinfectant; use indoors; sporicidal use	Yes

Identity, physical and chemical properties and analytical methods

The formulation was determined to be a clear, colourless, non viscous, homogeneous liquid with an intense, pungent, vinegar type odour. The product is not surface active and when

diluted with water, remains a homogeneous solution and does not produce any foam. The pH is 0.81 (neat), 3.22 (1% w/v) and the acidity was measured to be 6.908% calculated as %w/w H₂SO₄.

The formulation was proven to be chemically and physically stable in commercial high density polyethylene (HDPE) containers in the accelerated storage test (35°C for 12 weeks), ambient storage (20 °C for two years) and low temperature (0°C for 1 week). The shelf life of the biocidal product is 2 years in HDPE packaging.

The formulation is classified as an Organic Peroxide Type F and Corrosive to Metals 1. The formulation does not meet the criteria for classification in any other physical hazard class.

Adequate analytical titration methods for the determination of the active substance peracetic acid and the equilibrium partners acetic acid and hydrogen peroxide are available.

Efficacy

The target organisms for this biocidal product family include bacteria, yeasts, fungi and bacterial spores. All the effective concentrations have been based on the complete efficacy data package provided for the product. Efficacy tests performed according to suspension and surface standards have been submitted: Phase 2/Step 1 and Step 2 efficacy tests as mandatory tests for products intended to be used for surface disinfection by soaking or trigger spraying. The application methods are without mechanical action, but mop, cloth or wipe can be used to distribute the product. Detailed function, field of use, application rates and contact times of the products are described in the Efficacy part of the PAR and described in the section # 2.1.4." Authorized use(s)".

It can be concluded that DEC-SPORE 200 Plus is efficacious, when used in accordance with the use instructions as proposed in the SPC.

Human health

The product 'DEC-SPORE 200 Plus' is classified as H314 - Causes severe skin burns and eye damage. Hence appropriate PPE should be worn by the industrial user during handling the concentrated product. For this purpose the following RMM was assigned: Wear protective chemical resistant gloves (EN 374) and a protective coverall (at least Type 6 EN13034) which is impermeable for the biocidal product during product handling. The use of eye or face protection during handling of the product is mandatory. In addition, 'DEC-SPORE 200 Plus' is classified as H302 - Harmful if swallowed, H332 – Harmful if inhaled, H312 – Harmful in contact with skin, H318 – Causes serious eye damage, H335 – May cause respiratory irritation and EUH071 – Corrosive to the respiratory tract.

Based on the human health risk assessment it is concluded that inhalation exposure to hydrogen peroxide and peracetic acid for a industrial user disinfecting articles when using an immersion bath is acceptable without the use of respiratory protective equipment (RPE). For all other intended uses (mixing and loading and surface disinfection with trigger spray, cloth or mopping), the use of respiratory protective equipment (RPE) with an Assigned Protection Factor (APF) 4 or 10 reducing the exposure by 75% and 90% respectively is required to demonstrate a safe use when using a 6.7% dilution. When applying the 0.5% dilution, RPE is not required for any of the uses.

The product 'DEC SPORE 200 Plus' may be applied as either a 6.7 % w/w (sporicidal) or 0.5% w/w (bactericidal/yeasticidal) dilution. Based on the local risk assessment, no adverse health effects are expected for the industrial user wearing appropriate protective gloves, eye protection and coveralls during wiping, spraying and/or using the diluted product in an

immersion bath is deemed acceptable. The proposed 6.7% w/w and 0.5% w/w product dilution would not be classified according to Regulation 1272/2008/EC.

Furthermore, as the product is applied indoors by industrial users only in strictly controlled, occupational settings. The general public will be excluded from areas where these products will be used. Moreover, 'DEC-SPORE 200 Plus' is not used in the food or farming industry therefore there is no potential for transfer of the biocidal active substance into food as a result of industrial applications. Therefore, no adverse health effects are expected for the general public when DEC-SPORE 200 Plus is used according to the SPC.

Exposure of livestock to the product 'DEC-SPORE 200 Plus' will not occur; there are no proposed uses that would result in livestock exposure.

Environment

DEC-SPORE 200 Plus is a sporicide/disinfectant product for PT 2; it contains the active substance PAA. Next to the active substance, the environmental risk assessment was needed and is performed also for hydrogen peroxide (equilibrium partner), as it is seen for the aspect environment also as a substance of concern due to the fact it is an active substance in other PTs and in concentration >0.1%. The product contains no other substance of concern. Following product use, it is assumed that exposure of the sewage treatment plant (STP) via wastewater will occur due to rinsing and wet cleaning of the treated area, followed by subsequent indirect exposure of freshwater sediment and surface water and agricultural land due to spreading of sewage sludge. Releases to waste water may also occur due to rinsing or flushing of empty product containers with tap water. No marine or air exposure is anticipated based on the intended use of this product. Acceptable risk was demonstrated for both substances (PAA and HP) and for all relevant environmental compartments following product use under realistic worst-case assumptions.

b) Presentation of the biocidal product including classification and labelling

The description of the biocidal product is available in the SPC.

The hazard and precautionary statements of the biocidal product according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance Peracetic acid contained in the biocidal product does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, no comparative assessment of the biocidal product was performed.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product are met.

The physico-chemical properties of the biocidal product are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised uses, according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product is sufficiently effective;
2. the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product on non-target organisms,
 - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product

As the conditions of Article 19(1) are met it is proposed that the biocidal product shall be authorised², for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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² This is without prejudice of any specific conditions that might apply in the territory of Member State(s) in accordance with Article 44(5) of the BPR.