

## **Biocidal Products Committee (BPC)**

Opinion on the Union authorisation of:

**DEC-AHOL® Product Family**

ECHA/BPC/261/2020

Adopted

17 June 2020



## Opinion of the Biocidal Products Committee

### on the Union authorisation of the DEC-AHOL® Product Family

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:

<b>Name of the biocidal product:</b>	<b>DEC-AHOL® Product Family</b>
<b>Authorisation holder:</b>	<b>Veltek Associates, Inc. Europe</b>
<b>Active substance common name:</b>	<b>Propan-2-ol</b>
<b>Product type:</b>	<b>2</b>

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 29 June 2016, recorded in R4BP3 under case number BC-XF025530-45, the evaluating Competent Authority (The Netherlands) submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Family Characteristics (SPFC) to ECHA on 9 December 2020. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-35) and its Working Groups (WG I 2020). Revisions agreed upon were presented and the draft PAR and the draft SPFC were finalised accordingly.

## **Adoption of the BPC opinion**

### **Rapporteur: The Netherlands**

The BPC opinion on the Union authorisation of the biocidal product family was adopted on 17 June 2020.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA website.

## Detailed BPC opinion and background

### 1. Overall conclusion

The biocidal product family is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(s).

The biocidal product family does meet the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of the DEC-AHOL® Product Family 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

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

##### General

The biocidal product family DEC-AHOL® Product Family contains the active substance propan-2-ol (65.4% w/w, 70.0% v/v) for hard non-porous surface disinfection gloves disinfection by professional users in cleanrooms. As the product contains the active substance and water only (apart from the propellant in meta-SPC 2), no substances of concern or alerts for endocrine disruptors are identified.

The following uses have been assessed:

- Meta-SPC 1, use #1.1: Disinfection of hard non-porous surfaces by professionals: wipes (individual impregnated wipes and multi-pack wipes);
- Meta-SPC 2, use #2.1: Disinfection of hard non-porous surfaces by professionals: aerosols (propellant);
- Meta-SPC 3, use #3.1: Disinfection of hard non-porous surfaces by professionals: trigger spray (liquid);
- Meta-SPC 3, use #3.2: Disinfection of hard non-porous surfaces (including. floors) by professionals: wiping;
- Meta-SPC 3, use #3.3: Disinfection of cleanroom gloves by professionals;
- Meta-SPC 4, use #4.1: Disinfection of hard non-porous surfaces by professionals: aerosols.

##### Physico-chemical properties

The DEC-AHOL® Product Family consists of four meta SPCs, comprising of ready to use products, either as wipes, pressurized containers, trigger sprayers or ready to use liquids.

All products within the family have virtually the same composition with a propan-2-ol concentration of 70% v/v, not taking into account propellants included in the aerosols. The differentiation in meta SPCs is therefore primarily based on use and packaging resulting in differences in classification and labelling.

The products are transparent liquids and proved to be stable during the storage stability studies. The relevant technical properties were determined before and after storage for the wipes, trigger sprayer, container and aerosols. The content of the active substance was measured using GC-FID. The GC-FID method was validated.

The amount of product per wipe is 13.8 g, the amount of liquid dispensed onto the surface is 7 mL and evaporation of the product during simulated use of the wipes showed no significant weight loss.

The MMAD, spray characteristics and valve clogging were determined for the trigger sprayer and the aerosols and were acceptable.

The flash point of the product is <23°C (which is the classification limit). Since the boiling point is >35°C, the products (except the aerosols) are classified as Flammable Liquid category 2 under EU CLP. The aerosols (both the normal aerosol can and the bag-on-valve aerosol can) are classified as Aerosol Category 1. No classification under any other physchem endpoint is required.

### **Efficacy**

The assessed uses all include disinfection in non-healthcare area's; in manufacturing facilities including cleanrooms of pharmaceutical, biopharmaceutical, medical device and diagnostic product industries and are distinguished by the application methods: wiping with ready to use wipes (use #1.1), aerosol spraying (use #2.1 and use #4.1), trigger spraying (use #3.1) and wiping with a wetted sterile wipe/cloth (use #3.2) and dispensing of liquid droplets (use #3.3).

Efficacy against bacteria and yeasts has been tested in phase 2 step 1 and phase 2 step 2 tests according to the international guidelines EN1276, EN1650, EN16615 and EN13697. The tests provided demonstrated efficacy according to the requirements for PT2 non-porous surfaces indicated in the Guidance on the BPR volume II Part B+C for all uses.

### **Human health**

Based on the active substance content, the BPF is classified for:

- Eye irritation cat. 2 - H319: Causes serious eye irritation;
- STOT SE 3 - H336: May cause drowsiness or dizziness;
- EUH066: Repeated exposure may cause skin dryness or cracking.

Professional users are exposed through pouring RTU liquid from a container for refilling trigger sprayer or when wetting a cloth/wipe prior to application and through disinfection of:

- small surfaces, using wiping tissues/cloth;
- small surfaces, using aerosol spray;
- small surfaces, using trigger spray;
- disinfecting gloved hands using a liquid dispenser.

Exposure may be primary and secondary (bystander inhalation exposure).

### **Industrial user risk assessment**

The active substance assessment for propan-2-ol informs that the AEC for professional users of 52.6 ppm for 8 hours/day (converted to a systemic AEL of 17.9 mg/kg bw/d) also sufficiently covers local irritant effects in the eyes/airways.

Professional users are exposed through hard surface disinfection by wiping, aerosol spraying or by trigger spraying, or through glove disinfection. Exposure may be primary and secondary (bystander inhalation exposure).

Secondary exposure (bystander inhalation exposure) for members of the general public is excluded considering the product is used in controlled environments only.

Due to the high volatility of propan-2-ol, inhalation of vapour is the major route for exposure for the industrial users. The calculation of exposure to vapour depends on many different parameters such as room size, ventilation rate of the room, application rate, product amount applied in a room, and disinfection frequency. The exposure assessment was performed by using the parameters agreed in the HEAd hoc recommendation no.15 for cleanrooms. As agreed in HEAd hoc recommendation no.15, 8 and 20 ACH is used as ventilation rate for Tier 1 and Tier 2 calculations, respectively.

For each of the proposed uses, the exposure was calculated to be below the AEL of propan-2-ol for unprotected professional users at Tier 1 ( $\leq 32\% \text{AEL}$ ). Therefore no adverse effects are expected from the use of DEC-AHOL® Product Family in cleanrooms. Based on local effects of the product (H319 and EUH066), gloves and eye protection are prescribed for the professional users.

Regarding secondary exposure of the bystanders (professionals present in the same room) from inhalation of volatilised residues the following conclusions can be drawn:

On the basis that acceptable exposure has been identified for all professional user scenarios without RPE (respiratory protective equipment), no additional RMMs are required.

### **General public risk assessment**

Biocidal products in the DEC-AHOL® Product Family are intended to be used by professional workers only in industrial/manufacturing settings (e.g. cleanrooms). These are strictly controlled environments and members of the general public will be excluded from entering these premises. Exposure of the general public is not therefore relevant.

### **Environment**

The products in the DEC-AHOL® Product Family containing propan-2-ol are intended for use indoors only, therefore there will be no direct exposure of the environment. However, according to the ESD for PT 2 there could be exposure of the STP via waste water after wet washing of the treated area and subsequent exposure of surface water and agricultural land after spreading of sewage sludge. In addition, there may be emissions to air both from the STP and during product application, followed by subsequent deposition to soil and leaching to groundwater.

The use of propan-2-ol as a disinfectant for PT2 is acceptable for the environment. The assessment demonstrated an acceptable risk for all compartments. No risk mitigation measures are necessary.

### **Overall conclusion**

To summarise, taking all information into consideration and noting that:

- physical, chemical and technical properties of the BPF are considered to be acceptable;
- the BPF is efficacious against bacteria and yeast;
- no unacceptable risks are identified for professional users, the general public or the environment;

the BPC considers that using the products belonging to this biocidal product family according to the conditions as stated in the SPC, the products will be efficacious and will not present an unacceptable risk to human and animal health nor the environment.

### **b) Presentation of the biocidal product family including classification and labelling**

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

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

### **c) Description of uses proposed to be authorised**

The description of the uses proposed to be authorised are available in the SPC.

### **d) Comparative assessment**

The active substance propan-2-ol 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, a comparative assessment of the biocidal product family in accordance with Article 23 of the BPR is not required.

### **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 family have been evaluated.

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

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



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

1. the biocidal product family is sufficiently effective;
2. the biocidal product family 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 family 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 family 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 products 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 products on non-target organisms;
  - the impact of the biocidal products on biodiversity and the ecosystem.

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

## **2.2 BPC opinion on the Union authorisation of the biocidal product family**

As the conditions of Article 19(1) are met it is proposed that biocidal product family DEC-AHOL® Product Family shall be authorised, for the use(s) described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

oOo