

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

Opinion on the Union authorisation of the biocidal product family:

### **Knieler & Team Propanol Family**

ECHA/BPC/292/2021

Adopted

7 October 2021



## **Opinion of the Biocidal Products Committee**

### **on the Union authorisation of Knieler & Team Propanol 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 family:</b>	<b>Knieler &amp; Team Propanol Family</b>
<b>Authorisation holder:</b>	<b>Knieler &amp; Team GmbH</b>
<b>Active substances common name:</b>	<b>Propan-1-ol, Propan-2-ol</b>
<b>Product types:</b>	<b>PT 1, 2 and 4</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 17.04.2019, recorded in R4BP3 under case number BC-AQ050985-22, 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 29.03.2021. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-40) and its Working Groups (WG II 2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

## **Adoption of the BPC opinion**

### **Rapporteur: Switzerland**

The BPC opinion on the Union authorisation of the biocidal product family was reached on 7 October 2021.

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 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 meets 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 Knieler & Team Propanol 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

###### General

The biocidal products of the *Knieler & Team Propanol Family* are disinfectants for PT1 (*Human Hygiene*), PT 2 (*Disinfectants and algacides not intended for direct applications to humans or animals*) and PT4 (*Food and Feed Area*). The products are ready-to-use leave-on disinfectants for hygienic and surgical handrub in health care facilities and industry without the use of washbasin and water (meta-SPC 1 – 5) and for rapid spray / wipe or pouring / wipe disinfection of small hard surfaces (disinfection in the presence of soil, meta-SPC 6 - 9) in health care facilities, pharmaceutical, cosmetic and food industry. All products are restricted for industrial and professional use only. The active substance Propan-1-ol is used in the concentration range 12.229 – 35 % w/w and Propan-2-ol is used in the concentration range 30 - 63.14 % w/w. The products of the *Knieler & Team Propanol Family* do not contain any substances of concern.

###### Physico-chemical properties

The physicochemical properties of the *Knieler & Team Propanol Family* have been characterised. The storage stability data presented support the claim of a 2-year shelf life of products in the biocidal products family. The products need to be stored at temperatures above 0°C. Furthermore, the following storage conditions have been defined:

- Store in dry, cool, well-ventilated area;
- Keep container tightly closed;
- Keep out of direct sunlight. Recommended storage temperature: 0-30 °C.

With regard to physical hazards, the products of meta SPC 1, 6, 8 are classified as flammable liquids category 3 (H226: Flammable liquid and vapour). The products of meta-SPC 2, 3, 4, 5, 7 and 9 are classified as flammable liquids category 2 (H225: Highly flammable liquid and vapour). The products do not have oxidising properties and they are not explosive, self-heating, corrosive to metals or self-reactive.

###### Efficacy

The target organisms of the *Knieler & Team Propanol Family* are obligatory or facultative

pathogenic bacteria, yeasts, tuberculosis bacilli/mycobacteria and viruses (including enveloped and a limited spectrum virucidal activity according to EN 14476). According to the Assessment Reports of the active substances, no known acquired resistance has been reported against the target species.

Sufficient efficacy is demonstrated for the following claimed uses:

<b>Meta-SPC</b>	<b>Use code</b>	<b>Use</b>	<b>Target organisms and label claims</b>
Meta-SPC 1	#1.1	PT 1: Hygienic handrub, liquid	<ul style="list-style-type: none"> <li>• bacteria, mycobacteria, yeasts, enveloped viruses</li> <li>• for hygienic handrub – 30 s</li> <li>• for surgical handrub – 90 s</li> </ul>
	#1.2	PT 1: Surgical handrub, liquid	
Meta-SPC 2	#2.1	PT 1: Hygienic handrub, liquid	<ul style="list-style-type: none"> <li>• bacteria, tuberculosis bacilli, yeasts, enveloped viruses</li> <li>• for hygienic handrub – 30 s</li> <li>• for surgical handrub – 90 s</li> </ul>
	#2.2	PT 1: Surgical handrub, liquid	
Meta-SPC 3	#3.1	PT 1: Hygienic handrub, liquid	<ul style="list-style-type: none"> <li>• bacteria, tuberculosis bacilli, yeasts, enveloped viruses</li> <li>• for surgical handrub – 90 s</li> </ul>
	#3.2	PT 1: Surgical handrub, liquid	
Meta-SPC 4	#4.1	PT 1: Hygienic handrub, gel	<ul style="list-style-type: none"> <li>• bacteria, mycobacteria, yeasts, enveloped viruses</li> <li>• for hygienic handrub – 30 s</li> <li>• for surgical handrub – 90 s</li> </ul>
	#4.2	PT 1: Surgical handrub, gel	
Meta-SPC 5	#5.1	PT 1: Hygienic handrub, gel	<ul style="list-style-type: none"> <li>• bacteria, tuberculosis bacilli, yeasts, enveloped viruses</li> <li>• for hygienic handrub – 30 s</li> <li>• for surgical handrub – 90 s</li> </ul>
	#5.2	PT 1: Surgical handrub, gel	
Meta-SPC 6	#6.1	PT 2: Hard non-porous small surface disinfection RTU liquid	<ul style="list-style-type: none"> <li>• effective against bacteria (dirty conditions, 20°C) - 60 s</li> <li>• effective against yeasts (dirty conditions, 20°C) - 60 s</li> <li>• effective against enveloped viruses (dirty conditions, 20°C) - 60 s</li> <li>• limited spectrum of virucidal activity (dirty conditions, 20°C) - 5 min</li> </ul>
Meta-SPC 6	#6.2	PT 4: Hard non-porous small surface disinfection RTU liquid	<ul style="list-style-type: none"> <li>• effective against bacteria - 60 s (dirty conditions, 20°C)</li> <li>• effective against yeasts - 60 s (dirty conditions, 20°C)</li> </ul>
Meta-SPC 7	#7.1	PT 2: Hard non-porous small surface disinfection RTU liquid	<ul style="list-style-type: none"> <li>• effective against bacteria (dirty conditions, 20°C) - 60 s</li> <li>• effective against yeasts (dirty conditions, 20°C) - 60 s</li> <li>• virucidal against enveloped viruses (dirty conditions, 20°C) - 60 s</li> </ul>

Meta-SPC	Use code	Use	Target organisms and label claims
	#7.2	PT 4: Hard non-porous small surface disinfection RTU liquid	<ul style="list-style-type: none"> <li>effective against bacteria - 60 s (dirty conditions, 20°C)</li> <li>effective against yeasts - 60 s (dirty conditions, 20°C)</li> </ul>
Meta-SPC 8	#8.1	PT 2: Hard non-porous small surface disinfection RTU wipes	<ul style="list-style-type: none"> <li>effective against bacteria (dirty conditions, 20°C) - 60 s</li> <li>effective against yeasts (dirty conditions, 20°C) - 60 s</li> <li>effective against enveloped viruses (dirty conditions, 20°C) - 60 s</li> <li>limited spectrum of virucidal activity (dirty conditions, 20°C) - 5 min</li> </ul>
	#8.2	PT 4: Hard non-porous small surface disinfection RTU wipes	<ul style="list-style-type: none"> <li>effective against bacteria - 60 s (dirty conditions, 20°C)</li> <li>effective against yeasts - 60 s (dirty conditions, 20°C)</li> </ul>
Meta-SPC 9	#9.1	PT 2: Hard non-porous small surface disinfection RTU wipes	<ul style="list-style-type: none"> <li>effective against bacteria (dirty conditions, 20°C) - 60 s</li> <li>effective against yeasts (dirty conditions, 20°C) - 60 s</li> <li>virucidal against enveloped viruses EN 14476 (dirty conditions, 20°C) - 60 s</li> </ul>
	#9.2	PT 4: Hard non-porous small surface disinfection RTU wipes	<ul style="list-style-type: none"> <li>effective against bacteria - 60 s (dirty conditions, 20°C)</li> <li>effective against yeasts - 60 s (dirty conditions, 20°C)</li> </ul>

## Human health

Based on the active substance content, the *Knieler & Team Propanol Family* is classified as:

- Eye Dam. cat. 1 - H318: Causes serious eye damage;
- STOT SE 3 - H336: May cause drowsiness or dizziness;
- EUH066: Repeated exposure may cause skin dryness or cracking.

A qualitative risk assessment for local effects during skin and eye contact was performed due to the classification as H318 and EUH066.

### Primary exposure:

Exposure of professional user (including industrial user) was evaluated for dermal and inhalation exposure routes and the inhalation route for professional bystanders<sup>1</sup> for the scenarios summarised in the table below:

<sup>1</sup> The exposure of professional bystanders is covered by the scenario of the professional users. Please see the PAR for further details.

Scenario	Primary and secondary exposure and description of scenario	Conclusion of systemic exposure
Hand disinfection (PT 1, meta-SPC 1-5)	<p>Primary exposure of the professional user resulting from application of an alcohol-based disinfectant in form of a ready to use product for hand disinfection in naturally ventilated rooms.</p> <p>Secondary exposure of a professional bystander who is present in the patient room where the hand disinfection is carried out can be expected.</p>	Acceptable
Small surface disinfection in medical, institutional and industrial premises (PT 2, meta-SPC 6-9)	<p>Primary exposure of the professional user resulting from application (wiping) of an alcohol-based disinfectant in form of a ready to use product on small surfaces.</p> <p>Secondary exposure of a professional bystander who is present in the laboratory where the surface disinfection is carried out can be expected.</p>	Acceptable if number of applications is limited to 6 per day
Small surface disinfection in kitchens and canteens (PT 4, meta-SPC 6-9)	<p>Primary exposure of the professional user resulting from application (wiping) of an alcohol-based disinfectant in form of a ready to use product on small surfaces in food contact areas e.g. a work bench in a kitchen.</p> <p>Secondary exposure of a professional bystander who is present in the kitchen or canteen where the surface disinfection is carried out can be expected.</p>	Acceptable
Small surface disinfection in food processing industry (PT 4, meta-SPC 6-9)	<p>Primary exposure of the professional user resulting from application (wiping) of an alcohol-based disinfectant in form of a ready to use product in food processing machinery and its parts in a technically ventilated and cooled production hall of e.g. a meat processing factory.</p> <p>Secondary exposure of a professional bystander who is present in food processing industry where the surface disinfection is carried out can be expected.</p>	Acceptable

No unacceptable risks were identified for primary and secondary systemic exposure of professional bystanders. The risk related to the use of the mixture for meta-SPC 6, 7, 8 and 9 is considered acceptable only when the number of applications is limited to 6 per day during the disinfection of small surface in medical, institutional and industrial premises (PT 2).

The local risk has been considered acceptable for all professional/industrial uses if risk mitigation measures for the protection of eyes are implemented:

- For the biocidal products applied by hand rubbing (PT 1, meta-SPC 1-5):
  - "Avoid contact with eyes."
- For the biocidal products applied by spraying/pouring (PT 2, meta-SPC 6):
  - "The use of eye protection during handling of the product is mandatory."
- For the biocidal products applied by spraying/pouring (PT 4, meta-SPC 6):
  - "The use of eye protection during handling of the product is mandatory."



- For the biocidal products applied by spraying/pouring (PT 2, meta-SPC 7):
  - “The use of eye protection during handling of the product is mandatory.”
- For the biocidal products applied by wiping (PT 2 & 4, meta-SPC 7):
  - “The use of eye protection during handling of the product is mandatory.”
- For the biocidal products applied by wiping (PT 2, meta-SPC 8):
  - “Avoid contact with eyes.”
- For the biocidal products applied by wiping (PT 4, meta-SPC 8):
  - “Avoid contact with eyes.”
- For the product applied by wiping (PT 2 & 4, meta-SPC 9):
  - “Avoid contact with eyes.”

The *Knieler & Team Product Family* is intended for professional use only. In order to prevent use by non-professional users, in the field of use and instruction of use the phrase “For professional use only” is included and the additional risk mitigation measure “Keep out of reach of children” is added.

#### Secondary exposure:

The general public is exposed via the inhalation route when professional workers use the products of the *Knieler & Team Propanol Family* to disinfect their hands or for surface disinfection in patient-near areas. According to the risk assessment, the risk is acceptable for the general public.

#### **Dietary exposure / Consumer risk assessment:**

Due to the high vapour pressure and gravimetric detection of residues below the limit of quantification (0.002%), dietary exposure to humans can be excluded for the intended uses of the biocidal product family and there is no risk to consumers.

#### **Environment**

The environmental risk assessment for the *Knieler & Team Propanol Family* has taken into account the agreements made within both active substances assessments (propan-1-ol and propan-2-ol CARs) and considered a 90% loss to air and 10 % loss to sewer system after application of products for all emission scenarios for professional uses.

For all environmental compartments, acceptable levels of risk have been demonstrated for the proposed uses of the BPF.

In conclusion, there is no unacceptable risk for the environment

**Overall conclusion**

<b>Uses</b>	<b>Target organisms</b>	<b>User categories</b>	<b>Authorised application rates</b>	<b>Use conditions : risk mitigations measures</b>
Use # 1.1 – PT1 Hygienic handrub, RTU liquid	Bacteria Mycobacteria Yeasts Enveloped viruses	Professional / Industrial user	Dosage: At least 3 ml <sup>2</sup> Contact time: 30 s	For professional use only RMM: - Avoid contact with eyes - Keep out of reach of children
Use # 1.2 – PT1 Surgical handrub, RTU liquid		Professional user	Dosage: Rub sufficient amount in portions of 3 ml <sup>2</sup> Contact time: 90 s	For professional use only RMM: - Avoid contact with eyes - Keep out of reach of children
Use # 2.1 – PT1 Hygienic handrub, RTU liquid	Bacteria Tuberculosis bacilli Yeasts Enveloped viruses	Professional / Industrial user	Dosage: At least 3 ml <sup>2</sup> Contact time: 30 s	For professional use only RMM: - Avoid contact with eyes - Keep out of reach of children
Use # 2.2 – PT1 Surgical handrub, RTU liquid		Professional user	Dosage: Rub sufficient amount in portions of 3 ml <sup>2</sup> Contact time: 90 s	For professional use only RMM: - Avoid contact with eyes - Keep out of reach of children
Use # 3.1 – PT1 Hygienic handrub, RTU liquid	Bacteria Tuberculosis bacilli Yeasts Enveloped viruses	Professional / Industrial user	Dosage: At least 3 ml <sup>2</sup> Contact time: 30 s	For professional use only RMM: - Avoid contact with eyes - Keep out of reach of children
Use # 3.2 – PT1 Surgical handrub, RTU liquid		Professional user	Dosage: Rub sufficient amount in portions of 3 ml <sup>2</sup> Contact time: 90 s	For professional use only RMM:

<sup>2</sup> There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.

Uses	Target organisms	User categories	Authorised application rates	Use conditions : risk mitigations measures
				<ul style="list-style-type: none"> <li>- Avoid contact with eyes</li> <li>- Keep out of reach of children</li> </ul>
Use # 4.1 – PT1 Hygienic handrub, gel	Bacteria Mycobacteria Yeasts Enveloped viruses	Professional / Industrial user	Dosage: At least 3 ml <sup>2</sup> Contact time: 30 s	For professional use only RMM: <ul style="list-style-type: none"> <li>- Avoid contact with eyes</li> <li>- Keep out of reach of children</li> </ul>
Use # 4.2 – PT1 Surgical handrub, gel		Professional user	Dosage: Rub sufficient amount in portions of 3 ml <sup>2</sup> Contact time: 90 s	For professional use only RMM: <ul style="list-style-type: none"> <li>- Avoid contact with eyes</li> <li>- Keep out of reach of children</li> </ul>
Use # 5.1 – PT1 Hygienic handrub, gel	Bacteria Tuberculosis bacilli Yeasts Enveloped viruses	Professional / Industrial user	Dosage: At least 3 ml <sup>2</sup> Contact time: 30 s	For professional use only RMM: <ul style="list-style-type: none"> <li>- Avoid contact with eyes</li> <li>- Keep out of reach of children</li> </ul>
Use # 5.2 – PT1 Surgical handrub, gel		Professional user	Dosage: Rub sufficient amount in portions of 3 ml <sup>2</sup> Contact time: 90 s	For professional use only RMM: <ul style="list-style-type: none"> <li>- Avoid contact with eyes</li> <li>- Keep out of reach of children</li> </ul>
Use # 6.1 – PT 2 Hard non-porous small surface disinfection RTU liquid	Bacteria Yeasts Enveloped viruses Limited spectrum of virucidal activity	Professional / Industrial user	20°C, dirty conditions Minimum exposure time <sup>3</sup> : <ul style="list-style-type: none"> <li>• for the control of bacteria, yeasts and enveloped viruses: 60 sec</li> <li>• for the control of viruses (limited spectrum virucidal activity): 5 min</li> </ul>	Maximum number of applications is 6 per day. For professional use only RMM: <ul style="list-style-type: none"> <li>- The use of eye protection during handling of the product is mandatory</li> <li>- Keep out of reach of children</li> </ul>

<sup>3</sup> A reasonable frequency of disinfection is 1-2 per day. No safety intervals need to be considered between the application phases.

Uses	Target organisms	User categories	Authorised application rates	Use conditions : risk mitigations measures
Use # 6.2 – PT 4: Hard non-porous small surface disinfection RTU liquid	Bacteria Yeasts	Professional / Industrial user	20°C, dirty conditions Minimum exposure time is 60 sec <b>Error! Bookmark not defined.</b>	For professional use only RMM: - The use of eye protection during handling of the product is mandatory - Keep out of reach of children
Use # 7.1 – PT2 Hard non-porous small surface disinfection RTU liquid	Bacteria Yeasts Enveloped viruses	Professional / Industrial user	20°C, dirty conditions Minimum exposure time is 60 sec <b>Error! Bookmark not defined.</b>	Maximum number of applications is 6 per day For professional use only RMM: - The use of eye protection during handling of the product is mandatory - Keep out of reach of children
Use # 7.2 – PT4 Hard non-porous small surface disinfection RTU liquid	Bacteria Yeasts	Professional / Industrial user	20°C, dirty conditions Minimum exposure time is 60 sec <b>Error! Bookmark not defined.</b>	For professional use only RMM: - The use of eye protection during handling of the product is mandatory - Keep out of reach of children
Use # 8.1 – PT2 Hard non-porous small surface disinfection RTU wipes	Bacteria Yeasts Enveloped viruses limited spectrum of virucidal activity	Professional / Industrial user	20°C, dirty conditions Minimum exposure time <b>Error! Bookmark not defined.</b> <ul style="list-style-type: none"> <li>• for the control of bacteria, yeasts and enveloped viruses: 60 sec</li> <li>• for the control of viruses (limited spectrum virucidal activity): 5 min</li> </ul> Make the surface completely wet.	Maximum number of applications is 6 per day For professional use only RMM: - Avoid contact with eyes - Keep out of reach of children

Uses	Target organisms	User categories	Authorised application rates	Use conditions : risk mitigations measures
Use # 8.2 – PT 4 Hard non-porous small surface disinfection RTU wipes	bacteria yeasts	Professional / Industrial user	20°C, dirty conditions Minimum exposure time is 60 sec <sup>Error! Bookmark not defined.</sup> Make the surface completely wet	For professional use only RMM: - Avoid contact with eyes. - Keep out of reach of children
Use # 9.1 – PT2 Hard non-porous small surface disinfection RTU wipes	bacteria, yeasts, enveloped viruses	Professional / Industrial user	20°C, dirty conditions Minimum exposure time is 60 sec <sup>Error! Bookmark not defined.</sup> Make the surface completely wet.	Maximum number of applications is 6 per day For professional use only RMM: - Avoid contact with eyes. - Keep out of reach of children
Use # 9.2 – PT4 Hard non-porous small surface disinfection RTU wipes	bacteria, yeasts	Professional / Industrial user	20°C, dirty conditions Minimum exposure time is 60 sec <sup>Error! Bookmark not defined.</sup> Make the surface completely wet.	For professional use only RMM: - Avoid contact with eyes. - Keep out of reach of children

It is concluded that the evaluation has shown that sufficient data have been provided to permit the authorisation of the *Knieler & Team Propanol Family* for hygienic and surgical handrub and disinfection of small hard surfaces.

When using the products of the *Knieler & Team Propanol 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 or to the environment.

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

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

**d) Comparative assessment**

The active substances Propan-1-ol and Propan-2-ol contained in the biocidal product family do not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered candidates for substitution. Therefore, a comparative assessment of the biocidal product family 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 substances in the biocidal product family are met.

The physico-chemical properties of the biocidal product family 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 family is sufficiently effective;
2. the biocidal product family has no unacceptable effects on the target organisms;
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 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 family**

As the conditions of Article 19(1) are met it is proposed that the biocidal product family shall be authorised<sup>4</sup>, for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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<sup>4</sup> 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.