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►B COMMISSION IMPLEMENTING REGULATION (EU) 2019/2029



of 29 November 2019

granting a Union authorisation for the single biocidal product ‘CVAS Disinfectant product based on Propan-2-ol’

(Text with EEA relevance)

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▼B ●

COMMISSION IMPLEMENTING REGULATION (EU) 2019/2029

of 29 November 2019

granting a Union authorisation for the single biocidal product ‘CVAS Disinfectant product based on Propan-2-ol’

(Text with EEA relevance)

Article 1

A Union authorisation with authorisation number EU-0020461-0000 is granted to CVAS Development GmbH for the making available on the market and use of the single biocidal product ‘CVAS Disinfectant product based on Propan-2-ol’, in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 24 December 2019 until 30 November 2029.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

▼M1 ●

ANNEX

Summary of product characteristics for a biocidal product

CVAS Disinfectant product based on Propan-2-ol

Product type(s)

PT02: Disinfectants and algaecides not intended for direct application to humans or animals

PT04: Food and feed area

Authorisation number: EU-0020461-0000

R4BP asset number: EU-0020461-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	CVAS Disinfectant product based on Propan-2-ol calgonit DS 622 R 3000 SCHNELLEDSEINFEXTION IPADES 70 Alpha Septin Blu-Sept Disinfect home Schnell Des Disinfect Rapid Bakt-Ex Pur Bakt-Ex Rapid ROTIE-DES quick Bactazol I
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Dezynfektator
 EOSSAN-Desinfektionsspray-Fluid
 FS-7-Spray
 Gartengeräte Hygiene Spray
 NeudoClean Hygiene Spray

1.2. Authorisation holder

Name and address of the authorisation holder	Name	CVAS Development GmbH
	Address	Am Hafen 16 68526 Ladenburg Germany
Authorisation number		EU-0020461-0000
<i>R4BP asset number</i>		EU-0020461-0000
Date of the authorisation		24 December 2019
Expiry date of the authorisation		30 November 2029

1.3. Manufacturer(s) of the product

Name of manufacturer	Brenntag GmbH
Address of manufacturer	Messeallee 11 45131 Essen Germany
Location of manufacturing sites	Brenntag GmbH Am Nordseekai 22 73207 Plochingen Germany

Name of manufacturer	ACT GmbH
Address of manufacturer	Weidenweg 12 73087 Bad Boll Germany
Location of manufacturing sites	ACT GmbH Weidenweg 12 73087 Bad Boll Germany

Name of manufacturer	Meyer Chemie GmbH & Co. KG
Address of manufacturer	Werkstr 25 32130 Enger Germany
Location of manufacturing sites	Meyer Chemie GmbH & Co. KG Werkstr 25 32130 Enger Germany

Name of manufacturer	Calvatis GmbH
Address of manufacturer	Am Hafen 16 68526 Ladenburg Germany
Location of manufacturing sites	Calvatis GmbH Am Hafen 16 68526 Ladenburg Germany

Name of manufacturer	Arthur Schopf Hygiene GmbH & Co. KG
Address of manufacturer	Pfaffensteinstr. 1 83115 Neubeuern Germany

Location of manufacturing sites	Arthur Schopf Hygiene GmbH & Co. KG Pfaffensteinstr. 1 83115 Neubeuern Germany
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1.4. Manufacturer(s) of the active substance(s)

Active substance	Propan-2-ol
Name of manufacturer	Shell Nederland Raffinaderij B.V.
Address of manufacturer	Vondelingenweg 601 3196 KK, Vodelingenenplaat Rotterdam Netherlands (the)
Location of manufacturing sites	Shell Nederland Raffinaderij B.V. site 1 Vondelingenweg 601 3196 KK, Vodelingenenplaat Rotterdam Netherlands (the)

Active substance	Propan-2-ol
Name of manufacturer	ExxonMobil
Address of manufacturer	4999 Scenic Highway LA 70897 Baton Rouge, Louisiana United States (the)
Location of manufacturing sites	ExxonMobil site 1 4999 Scenic Highway

sites	LA 70897 Baton Rouge, Louisiana United States (the)
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Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvents Germany GmbH
Address of manufacturer	Römerstraße 733 47443 Moers Germany
Location of manufacturing sites	INEOS Solvents Germany GmbH site 1 Römerstraße 733 47443 Moers Germany

2. **PRODUCT COMPOSITION AND FORMULATION**

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	61,25 % (w/w)

2.2. Type(s) of formulation

Any other liquid (ready-to-use)

3. **HAZARD AND PRECAUTIONARY STATEMENTS**

Hazard statements	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.
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Precautionary statements	<p>P101: If medical advice is needed, have product container or label at hand.</p> <p>P102: Keep out of reach of children.</p> <p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. N</p> <p>P233: Keep container tightly closed.</p> <p>P261: Avoid breathing vapours.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P280: Wear eye protection.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove. Continue rinsing.</p> <p>P312: Call a POISON CENTER if you feel unwell.</p> <p>P337+P313: If eye irritation persists: Get medical advice.</p> <p>P403+P235: Store in a well-ventilated place. Keep cool.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents /container in accordance with local regulations.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing.</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing</p> <p>P370+P378: In case of fire: Use alcohol-resistant foam to extinguish.</p>
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4. ***AUTHORISED USE(S)***

4.1. Use description

Table 1

Use 1 – Disinfection of small surfaces in product type 2 by non-professional users

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including	<p>Scientific name: Bacteria</p> <p>Common name: Bacteria</p>

development stage)	Development stage: All Scientific name: Yeasts Common name: Yeasts Development stage: All
Field(s) of use	indoor use Disinfection of non-porous surfaces in domestic areas.
Application method(s)	Method: Spraying Detailed description: Spraying (with trigger sprayer or pump spray) Method: Spraying and wiping Detailed description: Spraying (with trigger sprayer or pump spray) and wiping Method: Pouring and wiping Detailed description: -
Application rate(s) and frequency	Application Rate: 40-50 mL/m ² - Number and timing of application: -
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	1. Bottle: High-density polyethylene (HDPE, 250 - 1000 mL 2. Bottle with fine mist spray pump or trigger spray head: HDPE, 250 - 1000 mL

4.1.1. *Use-specific instructions for use*

The authorisation holder has to specify the typical application rate in a simple, easily understandable form on the label:

- Trigger spray: Apply 20 spray strokes per 0,5 m².
- Pump spray: Apply 3 jets per 100 cm².
- Bottle: Apply one measuring cup per m²

4.1.2. *Use-specific risk mitigation measures*

See section 5.2.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See section 5.3.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See section 5.4.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See section 5.5.

4.2. Use description

Table 2

Use 2 – Disinfection of small surfaces in product type 2 by professional users

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: Bacteria</p> <p>Common name: Bacteria</p> <p>Development stage: All</p> <p>Scientific name: Yeasts</p> <p>Common name: Yeasts</p> <p>Development stage: All</p>
Field(s) of use	<p>indoor use</p> <p>Disinfection of non-porous surfaces in industry, small enterprises, institutions and domestic areas.</p>
Application method(s)	<p>Method: Spraying</p> <p>Detailed description:</p> <p>Spraying (with trigger sprayer or pump spray)</p> <p>Method: Spraying and wiping</p>

	<p>Detailed description:</p> <p>Spraying (with trigger sprayer or pump spray) and wiping</p> <p>Method: Pouring and wiping</p> <p>Detailed description:</p> <p>-</p>
Application rate(s) and frequency	<p>Application Rate:</p> <p>40-50 mL/m²</p> <p>-</p> <p>Number and timing of application:</p> <p>-</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>1. Bottle: HDPE, 250 - 1000 mL</p> <p>2. Bottle with fine mist spray pump or trigger spray head: HDPE, 250 - 1000 mL</p> <p>3. Intermediate bulk containers (IBC): HDPE, 720 L</p> <p>4. Drum: Steel, zinc coated and painted, 200 - 220 L</p> <p>5. Canister: HDPE, 5 - 50 L</p>

4.2.1. *Use-specific instructions for use*

See section 5.1.

4.2.2. *Use-specific risk mitigation measures*

1. The following personal risk mitigation measure can be considered for disinfection of food processing machinery and refilling procedure unless it can be replaced by technical and / or organisational measures: The use of eye protection during handling of the product is recommended.
2. The product must only be applied for disinfection of small surfaces.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See section 5.3.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See section 5.4.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See section 5.5.

4.3. Use description

Table 3

Use 3 – Disinfection of small surfaces in product type 4 by non-professional users

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: Bacteria</p> <p>Common name: Bacteria</p> <p>Development stage: All</p> <p>Scientific name: Yeasts</p> <p>Common name: Yeasts</p> <p>Development stage: All</p>
Field(s) of use	<p>indoor use</p> <p>Disinfection of non-porous surfaces in kitchens.</p> <p>Disinfection of gardening equipment for human hygiene purpose only.</p>
Application method(s)	<p>Method: Spraying</p> <p>Detailed description: Spraying (with trigger sprayer or pump spray)</p> <p>Method: Spraying and wiping</p>

	<p>Detailed description:</p> <p>Spraying (with trigger sprayer or pump spray) and wiping</p> <p>Method: Pouring and wiping</p> <p>Detailed description:</p> <p>-</p>
Application rate(s) and frequency	<p>Application Rate:</p> <p>40-50 mL/m²</p> <p>-</p> <p>Number and timing of application:</p> <p>-</p>
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<p>1. Bottle: HDPE, 250 - 1000 mL</p> <p>2. Bottle with fine mist spray pump or trigger spray head: HDPE, 250 - 1000 mL</p>

4.3.1. *Use-specific instructions for use*

1. For use at room temperature (20±2°C).
2. The authorisation holder has to specify the typical application rate in a simple, easily understandable form on the label:
 - Trigger spray: Apply 20 spray strokes per 0,5 m².
 - Pump spray: Apply 3 jets per 100 cm².
 - Bottle: Apply one measuring cup per m²
3. Disinfection of gardening equipment for human hygiene purpose only.
4. Disinfect gardening equipment only indoors.

4.3.2. *Use-specific risk mitigation measures*

See section 5.2.

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See section 5.3.

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See section 5.4.

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See section 5.5.

4.4. Use description

Table 4

Use 4 – Disinfection of small surfaces in product type 4 by professional users

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: Bacteria</p> <p>Common name: Bacteria</p> <p>Development stage: All</p> <p>Scientific name: Yeasts</p> <p>Common name: Yeasts</p> <p>Development stage: All</p>
Field(s) of use	<p>indoor use</p> <p>Disinfection of non-porous surfaces in canteens or kitchens, food processing industry (including breweries).</p> <p>Disinfection of gardening equipment for human hygiene purpose only.</p>
Application method(s)	<p>Method: Spraying</p> <p>Detailed description:</p> <p>Spraying (with trigger sprayer or pump spray)</p> <p>Method: Spraying and wiping</p> <p>Detailed description:</p> <p>Spraying (with trigger sprayer or pump spray) and wiping</p>

	Method: Pouring and wiping Detailed description: -
Application rate(s) and frequency	Application Rate: 40-50 mL/m ² - Number and timing of application: -
Category(ies) of users	professional
Pack sizes and packaging material	1. Bottle: HDPE, 250 - 1000 mL 2. Bottle with fine mist spray pump or trigger spray head: HDPE, 250 - 1000 mL 3. IBC: HDPE, 720 L 4. Drum: Steel, zinc coated and painted, 200 - 220 L 5. Canister: HDPE, 5 - 50 L

4.4.1. *Use-specific instructions for use*

1. For use at room temperature (20±2°C).
2. Disinfection of gardening equipment for human hygiene purpose only.
3. Disinfect gardening equipment only indoors.

4.4.2. *Use-specific risk mitigation measures*

1. Provide adequate ventilation (industrial ventilation or keeping windows and doors open).
2. The product must only be applied for disinfection of small surfaces.
3. The following personal risk mitigation measure can be considered for disinfection of food processing machinery and refilling procedure unless it can be replaced by technical and / or organisational measures: The use of eye protection during handling of the product is recommended.

4.4.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See section 5.3.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See section 5.4.

4.4.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See section 5.5.

5. GENERAL DIRECTIONS FOR USE (¹)

5.1. Instructions for use

1. Clean surfaces before use.
2. Apply the product to the surface undiluted by spraying. Make sure to wet surfaces completely. Allow to take effect for at least 15 minutes.
3. Apply the product to the surface undiluted by spraying / pouring the product and wiping of the surface afterwards. Make sure to wet surfaces completely. Allow to take effect for at least 5 minutes.
4. Do not apply more than 50 mL/m².
5. Used wipes must be disposed in a closed container.
6. For non-professional users only: Do not use more than 4 applications per day.

5.2. Risk mitigation measures

1. Keep out of reach of children and pets.
2. Avoid contact with eyes.
3. Do not apply in the presence of small children.
4. Keep children and pets away from rooms, where disinfection is taking place. Provide adequate ventilation before children enter treated rooms.
5. For refilling a funnel must be applied.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid:

1. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
2. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
3. Call a POISON CENTER or doctor/physician if you feel unwell.
4. If eye irritation persists, get medical advice/attention.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store cool (not above 30°C) and protect from frost.

Shelf-life: 24 month.

6. *OTHER INFORMATION*

1. Please be aware of the European reference value of 129,28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for the product.
2. Information on hazard and precautionary statements:

In fact H319 would trigger P280 (Wear eye protection/face protection.). However, for non-professional use correct use of personal protective equipment cannot be assumed. Based on a qualitative risk assessment an additional advice (labelling) with 'Avoid contact with eyes' and the other precautionary statements P305 + P351 + P338 and P337 + P313 are considered sufficient to protect the non-professional user from the corresponding risk.

H319 also triggers P264 (Wash ... thoroughly after handling.). This precautionary statement is also not required since propan-2-ol and the formulated biocidal product is very volatile and will evaporate from contaminated skin rapidly. Thus, washing of hands or other body parts is not necessary.

H336 would trigger P304 + P340 (IF INHALED: Remove person to fresh air and keep comfortable for breathing.). According to the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (2016) this precautionary statement is considered as optional. Based on the low hazard from acute inhalation of the biocidal product this precautionary statement is not required.

(¹) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.