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)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/2029

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[(1)], and in particular the first subparagraph of Article 44(5) thereof,

Whereas:

(1) On 29 June 2016, SCC GmbH (on behalf of CVAS Development GmbH), submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a single biocidal product named 'CVAS Disinfectant product based on Propan-2-ol' of product-types 2 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Germany had agreed to evaluate the application. The application was recorded under case number BC-DH025620-60 in the Register for Biocidal Products.

(2) 'CVAS Disinfectant product based on Propan-2-ol' contains propan-2-ol, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.

(3) On 17 August 2018, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').

(4) On 25 March 2019, the Agency submitted to the Commission an opinion[(2)], the draft summary of the biocidal product characteristics ('SPC') of 'CVAS Disinfectant product based on Propan-2-ol' and the final assessment report on the single biocidal product in accordance with Article 44(3) of Regulation (EU) No 528/2012. The opinion concludes that 'CVAS Disinfectant product based on Propan-2-ol' is a 'single biocidal product' within the meaning of Article 3(1)(r) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) of that Regulation.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/2029. (See end of Document for details)*

(5) On 3 June 2019, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'CVAS Disinfectant product based on Propan-2-ol'.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

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.

Done at Brussels, 29 November 2019.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/2029. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product

CVAS Disinfectant product based on Propan-2-ol

Product type 2 — Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Product type 4 — Food and feed area (Disinfectants)

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 SCHNELLDESINFEKTION IPADES 70 Alpha Septin Blu-Sept Disinfect home Schnell Des Disinfect Rapid Bakt-Ex Pur Bakt-Ex Rapid ROTIE-DES quick Bactazol I 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	Dr Albert Reimann Str. 16a, 68526, Ladenburg, Germany
Authorisation number	EU-0020461-0000	
R4BP asset number	EU-0020461-0000	
Date of the authorisation	24 December 2019	
Expiry date of the authorisation	30 November 2029	

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/2029. (See end of Document for details)*

1.3. Manufacturer(s) of the product

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

Name of manufacturer	Calvatis GmbH
Address of manufacturer	Dr Albert Reimann Str. 16a, 68526 Ladenburg Germany
Location of manufacturing sites	Dr Albert Reimann Str. 16a, 68526 Ladenburg Germany

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

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
Location of manufacturing sites	Vondelingenweg 601, 3196 KK, Vodelingenenplaat Rotterdam Netherlands

Active substance	Propan-2-ol
Name of manufacturer	ExxonMobil
Address of manufacturer	4999 Scenic Highway, LA 70897 Baton Rouge, Louisana United States
Location of manufacturing sites	4999 Scenic Highway, LA 70897 Baton Rouge, Louisana United States

Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvents Germany GmbH
Address of manufacturer	Römerstraße 733, 47443 Moers Germany
Location of manufacturing sites	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

2.2. **Type of formulation**

Any other liquid (ready-to-use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER if you feel unwell. If eye irritation persists: Get medical advice. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents/container in accordance with local regulations. Wash hands thoroughly after handling. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF INHALED: Remove person to fresh air and keep comfortable for breathing. In case of fire: Use alcohol-resistant foam to extinguish.

4. AUTHORISED USE(S)