

TECHNICAL DOSSIER

OF

BIOCIDE

CLEAN HANDS SPRAY

The technical dossier has been prepared in accordance with the requirements of Annex № 2 to Art. 3, para. 1 of the Ordinance on the form and content of the documents required for issuing a permit for placing on the market of a biocide or a group of biocides under Art. 18 of the Law for protection against the harmful effects of chemical substances and mixtures CMD № 8 / 22.01.2018.
(SG No. 9 / 26.01.2018).

2020

I. Details of the person placing the biocidal product on the market and the manufacturer of the biocidal product and the active substance.

1. Name, address and telephone number of the person placing the biocidal product on the market.

Diva 691 Ltd
Varshava str. № 35, Plovdiv
Phone: +359 888 99 20 64
dvproduct691@gmail.com

2. Name and address of the manufacturer of the biocidal product and address of the manufacturing plant.

Diva 691 Ltd
Varshava str. № 35, Plovdiv
Phone: +359 888 99 20 64
dvproduct691@gmail.com

3. Name and address of the manufacturer of the active substances and address of the manufacturing plants.

Ethanol

Supplier and manufacturer of the active substance: (1st supplier)

ZAHARNI ZAVODI AD
Gorna Oryahovitza, 5100
Str. “St. Knyaz Boris I“ № 29
Phone: 0618/69-500; fax: 0618/2 17 09
[e-мейл:office@zaharnizavodi.com](mailto:office@zaharnizavodi.com)
ethanol@zaharnizavodi.com

The supplier ZAHARNI ZAVODI AD is included in the list under Art. 95 of Regulation (EC) (528/2012 for the active substance ethanol for product types 1,2, and 4.

Trade name: Ethanol (ethyl alcohol) of agricultural origin (80-100%), denatured by a general method according to PPZADS, with methyl ethyl ketone, isopropyl alcohol and denatonium benzoate (bitrex).

The active substance contains ethanol 96.5%, isopropyl alcohol 1%, methyl ethyl ketone 1% and denatonium benzoate 0.001%. It does not contain methanol (see analytical certificate of Zaharni Zavodi AD – (**Annex № 1**).

Supplier and manufacturer of the active substance: (2nd supplier)

VP BRANDS INTERNATIONAL AD, owner of Essentika alcohol factory, Plovdiv

Dunav boulevard № 5

4003 Plovdiv, North region

Bulgaria

Phone: 359 (0)32 606 916 /+359 (0)32 306 783

e-mail: office@vp-brands.com/office@essentica.eu

The provider VP BRANDS INTERNATIONAL AD is included in the list under Art. 95 of Regulation (EU) No 528/2012 for the active substance ethanol for product types 1,2, and 4.

Trade name: Ethanol denatured with isopropanol, methyl ethyl ketone and denatonium benzoate (bitrex). The active substance contains ethanol 96.54% v / v, isopropyl alcohol 1 l / 100 l, methyl ethyl ketone 1 l / 100 l and denatonium benzoate 1 g / 100 l. Does not contain methanol (attached certificate of analysis - Annex № 1).

Annex № 1:

- Documents of ZAHARNI ZAVODI AD:
 - o ECHA decision on the inclusion in the list of active substances and suppliers referred to in Article 95 (1) of REGULATION (EU) № 528/2012
 - o Declaration by an approved supplier for compliance with Art. 95 (1) of Regulation 528/2012 on the placing on the market and use of biocidal products.
 - o Analysis certificate.
 - Documents of VP BRANDS INTERNATIONAL AD:
 - o ECHA decision to include in the list of active substances and suppliers referred to in Article 95 (1) of REGULATION (EU) № 528/2012
 - o Declaration by an approved supplier for compliance with Art. 95 (1) of Regulation 528/2012 on the placing on the market and use of biocidal products.
- Certificate of analysis.

Annex № 2:

- Safety data sheet of ZAHARNI ZAVODI AD for Ethanol (ethyl alcohol) of agricultural origin (80-100%), denatured by a common method according to PPZADS, with methyl ethyl ketone, isopropyl alcohol and denatonium benzoate (bitrex);
- Safety data sheet of VP BRANDS INTERNATIONAL AD for Ethanol, denatured with Isopropanol, Methyl ethyl ketone and Denatonium benzoate (Bitrex).

II. Identity of the biocide.

1. Trade name of the biocidal product and production code, where appropriate.

CLEAN HANDS SPRAY

2. Detailed quantitative and qualitative data on the composition of the biocidal product:

Chemical name	CAS № EC №	Trade name	Function	Contents g/100 g (w/w)	Classification, Regulation CLP
ethanol	64-17-5 200- 578-6	1. Ethanol (ethyl alcohol) of agricultural origin (80-100%), denatured by the general method according to PPZADS, with methyl ethyl ketone, isopropyl alcohol and denatonium benzoate (bitrex)	Active substance	75,0	According to table 3.1. of Annex VI to Regulation (EC) (1272/2008 Flam. Liq. 2 H225 The manufacturer also classifies ethanol as Eye Irrit. 2 H319; STOT SE 3 H336 (see SDS of Confectioneries and VP Brands International AD and Analytical Certificate of Ethanol, Appendix №2).

Isopropyl alcohol (Annex №2)	67-63-0/200-661-2	Ethanol (ethyl alcohol) of agricultural origin (80-100%), denatured by the general method according to PPZADS, with methyl ethyl ketone, isopropyl alcohol and denatonium benzoate (bitrex)	Denaturing ingredient of the active substance	≤1%	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3 H225; H319; H336;
Methyl ethyl ketone (Annex №2)	76-93-3/201-159-0	Ethanol (ethyl alcohol) of agricultural origin (80-100%), denatured by the general method according to PPZADS, with methyl ethyl ketone, isopropyl alcohol and denatonium benzoate (bitrex)	Denaturing ingredient of the active substance	≤1 %	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3 H225; H319; H336; EUH066
Linden extract (Annex №3)	mixture	Natural herbal extracts	Perfume composition	0,3	Not classified
PK Lavender (Annex №3)	mixture	CARIN. LAVANDA- FRESH F P408155	Perfume composition	0,2	Skin corrosion / irritation, Category 2 H315 Serious eye damage / eye irritation, Category 2 H319 Skin sensitization, Category 1 H317 Aspiration hazard, Category 1 H304 Hazardous to the aquatic environment - chronic hazard, category 2 H411 (see Annex 3 - Certificate of Analysis). The content of the individual allergic ingredients in the perfume composition is less than 0.1%

Deionized water	7732-18-5 231-791-2		Solvent	Up to 100 %	Not classified
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The content of the individual allergic ingredients in the perfume composition is less than 0.1% (see Certificate of Analysis - Annex №3.

2.1. Data on the active substances:

ETHANOL (see the Safety data sheet– Annex № 2)

2.1.2. Identifier of the active substance according to art. 18 (2) of Regulation (EC) № 1272/2008 (CLP)

Table № 1

CAS-No.	64-17-5
EC-No.	200-578-6
Chemical name according to IUPAC	Not available
Index No:	603-002-00-5
REACH registration number	01-2119457610-43-XXXX

Chemical name under Annex II of Regulation (EC)№ 1451/2007: Ethanol

2.1.3. Concentration in metric units in the composition of the biocidal product.

75 g/100 g (75 w/w%)

The active substance is included in Annex II to Commission Delegated Regulation (EU) № 1062/2014 of 4 August 2014 concerning the work program for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) № 528 / 2012 of the European Parliament and of the Council.

MAIN GROUP 1: Disinfectants:

Product type 1: Human hygiene, in accordance with Regulation (EU) № 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.

2.1.4. Efficacy and resistance to the target organisms and field of application:

2.1.4.1. Efficacy (see Annex № 5):

(a) spectrum of action: bactericidal, including tuberculocidal, yeasticidal, fungicidal, virucidal (enveloped viruses)

(b) organisms which are the subject of the proposed use and products, organisms or objects which must be protected:

(c) effects on organisms which are the subject of the proposed use and recommended concentrations for the use of the active substance:

-It has bactericidal (incl. Tuberculocidal), virocidal (viruses with envelopes), yeast and fungicidal action.

- recommended concentrations: 68 - 76%.

(d) mode of action, including exposure time:

- The specific mode of action of alcohols is little known. It is generally believed that based on increased efficiency in the presence of water, alcohols lead to cell membrane destruction and rapid denaturation of proteins, with consequences for cellular metabolism and cell lysis. This is supported by evidence of denaturation of dehydrogenases in Escherichia coli and increased lag phase in Enterobacter aerogenes, which could be due to inhibition of the metabolism required for rapid cell division.

- exposure time: 30 seconds - 60 seconds.

2.1.4.2. Information on identified cases or possibility of developing resistance and appropriate measures to prevent development when data are available:

There are insufficient data on the selective acquisition of resistance to the active substance, regardless of its long-term use.

2.1.4.3. Intended field of application and category of users:

The active substance is included in Annex II to Commission Delegated Regulation (EU) № 1062/2014 of 4 August 2014 concerning the work program for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) № 528 / 2012 of the European Parliament and of the Council.

MAIN GROUP 1: Disinfectants: Product type 1: Human hygiene, in accordance with Regulation (EU) № 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.

For hygienic hand disinfection (in medical and health establishments, in sites for trade and production of food and beverages; in sites for public use - hotels, nurseries, kindergartens, schools, social homes, homes for the elderly, pharmaceutical and cosmetic industry, for hand disinfection in veterinary practice and in everyday life).

Consumer category: professional.

2.1.5. Summary of physico-chemical, toxicological and ecotoxicological data for the active substance related to the classification of the active substance as dangerous; hazard category (s), pictograms, hazard statements:

2.1.5.1. Physico-chemical, toxicological and ecotoxicological data related to the classification of the active substance as dangerous according to Regulation (EC)№ 1272/2008 (CLP).

Physico-chemical data

Source – ECHA

<https://echa.europa.eu/bg/brief-profile/-briefprofile/100.000.526>

Table № 2

Indicators	Source: ECHA
Type	Liquid, very mobile, colorless
Smell	Characteristic of alcohol
Flash point at 101 325 Pa	12.85 °C
Melting / freezing point at 101 325 Pa	-114.15 °C
Partial coefficient Log Kow (Log Pow)	-0.35 (20°C)
Boiling point at 101 325 Pa	78.29°C
Vapor pressure	57.26 hPa (19.65°C)
Dynamic at 20 °C	1.2 mPa.s
Density	0.786 g/cm ³ (25°C)
Solubility in water	789 g/L (20°C)
Flammability	Highly flammable (100%)

Toxicological data

Source – ECHA

<https://echa.europa.eu/bg/brief-profile/-briefprofile/100.000.526>

Acute toxicity

Orally

LD50 1 187 - 15 010 mg/kg bw (rats)

LD50 7 800 - 22 500 mL/kg bw (rats)

LD50 8 300 mg/kg bw (mice)

Inhalatory:

LC50 (6 h) 82.1 - 92.6 mg/L air (rats)

LC50 (4 h) 115.9 - 133.8 mg/L air (rats)

LC50 (60 min) 60 000 ppm (mice)

Irritation / corrosivity

Skin: No harmful effects (non-irritating)

Eyes: Adverse effects (irritation)

Sensitization

Skin sensitization

No adverse effects observed (not a sensitizer)

Respiratory sensitization

No adverse effects (not a sensitizer)

Repeated dose toxicity

Orally

NOAEL (mice): 9 700 mg/kg bw/day

NOAEL (mice): 9 400 mg/kg bw (total dose)

Inhalatory

NOAEC (rats): 6.66 mg/L air

NOAEC (mice): 1.3 mg/L air

NOEC (rats): 130 mg/m³ air

NOEC (mice): 130 mg/m³ air

Neurotoxicity

Inhalation route: Adverse effects have been observed with NOAEC 19,000 mg / m³ (subchronic, rats)

Immunotoxicity

Inhalation route: No adverse effects were observed with NOAEC 40 000 mg / m³ (subchronic, rats)

Genotoxicity: no data available;

Carcinogenesis: no carcinogenic effect

Teratogenesis: no data available

Ecotoxicological data

Source: ECHA

<https://echa.europa.eu/bg/brief-profile/-briefprofile/100.000.526>

Biodegradability in water - easily biodegradable (100%)

Bioaccumulation: The substance has a low potential for bioaccumulation. Bioconcentration factor (BCF): 3.2 and bioaccumulation is not expected.

Ecotoxicity:

Acute (short-term) toxicity to fish

LC50 for freshwater fish - 11.2 g/L

LC50 (96 h) for Pimephales Promelas: 15300 mg/L

LC50 (96 h) for Oncorhynchus mykiss - 13000 mg/L

Chronic aquatic toxicity to fish

EC10 / LC10 or NOEC for freshwater fish - 250 mg/L

Acute (short-term) toxicity to aquatic invertebrates

EC50 / LC50 for freshwater invertebrates - 5.012 g/L

EC50 / LC50 for marine invertebrates - 857 mg/L

Chronic aquatic toxicity to invertebrates

EC10 / LC10 or NOEC for freshwater invertebrates - 9.6 mg/L

EC10 / LC10 or NOEC for marine invertebrates - 79 mg/L

Toxicity to algae

EC50 / LC50 for freshwater algae - 275 mg/L

EC50 / LC50 for seaweed - 1.9 g/L

EC10 / LC10 or NOEC for freshwater algae - 11.5 mg/L

EC10 / LC10 or NOEC for seaweed - 1.58 g/L

2.1.5.2. Physico-chemical, toxicological and ecotoxicological data leading to specific requirements and / or restrictions on use (e.g. in persons at risk, in case of significant skin resorption, etc.)

Chemical stability: Stable under recommended conditions of use, transport and storage (protected from sunlight, in a cool place, separate from incompatible substances - strong oxidizers and strong acids).

Reactivity: no dangerous reactions are known under the recommended conditions of storage and use of the product. If not stored and used as directed, vapors may form explosive mixtures with air at room temperature.

Conditions to avoid – high temperatures (above 30°C), flames, sparks and ignition sources, direct sunlight, freezing.

Materials to avoid – violent reaction is possible with oxidants, alkali metals, alkaline earth metals, strong acids and strong bases, metals, peroxides, metal salts, halogens, flammable materials.

Dangerous reactions: are not known under the recommended storage and use conditions.

Incompatible materials: are not known under recommended storage and use conditions. Reducing substances; aluminum metals, at high temperatures; strong mineral acids; oxidants.

Hazardous decomposition products: does not decompose if stored and used as intended! During a fire or thermal decomposition, carbon dioxide is released (CO₂).

2.1.6. A Classification of the active substance according to Regulation 1272/2008.

The active substance is included in Table 3.1. and 3.2. of Annex № 6 to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548 / EEC and 1999/45 / EC and amending Regulation (EC) № 1907/2006.

The active substance has a harmonized classification.

Flammable liquids, category 2, H225.

The supplier Zaharni Zavodi AD provides additional classification

Serious eye damage / eye irritation, cat.2, H319

Specific target organ toxicity, single exposure, category 3, H336

(see SDS – Annex №2).

Labeling:

Pictograms:



GHS02



GHS07

Signal word: Dangerous

Hazard warnings

H225: Highly flammable liquid and vapors.

H319: Causes serious eye irritation.

H336: May cause drowsiness or dizziness.

Safety recommendations:

P102 Keep out of reach of children

P210 Protect from heat / sparks / open flame / hot surfaces. No smoking.

P233 Keep container tightly closed.

P240 Grounding / equipotential bonding of the vessel and the receiving device.

P241 Use explosion-proof electrical / ventilating / lighting / equipment.

P242 Use only non-sparking tools.

P243 Take precautions against releasing static electricity.

P244 Store only in the original package.

P280 Wear protective gloves / protective clothing / safety goggles / face shield.

P303+P361+P353 IN THE CASE OF SKIN CONTACT (OR HAIR): Take off immediately all contaminated clothing. Rinse skin with water / shower.

P370+P378 IN THE CASE OF FIRE: Use for extinguishing: alcohol-resistant foam dry powder or water jet.

P264 Wash thoroughly after use.

P305+P351+P338 IN THE CASE OF EYE CONTACT: Rinse gently with water for a few minutes. Remove contact lenses, if present and easy to do. Keep rinsing.

P370+P378 In the case of fire: Use ABC powder fire extinguisher for extinguishing.

P337+P313 In case of prolonged eye irritation: seek medical advice or seek medical advice.

P403+P235 Store in a well-ventilated place. Store in a cool place.

P501 Dispose of contents / container in accordance with regulations.

2.2. Data for each of the other chemicals included in the biocidal product:

Chemical name	CAS / EC №	Trade name	Contents g/100 g	Classification
Linden extract	-	Natural Herbal Glycerin Extracts	0,3	Not classified
PK Lavender		CARIN. LAVANDA-FRESH F P408155	0,2	Skin corrosion / irritation, Category 2 H315 Serious eye damage / eye irritation, Category 2 H319 Skin sensitization, Category 1 H317 Aspiration hazard, Category 1 H304 Hazardous to the aquatic environment - chronic hazard, category 2 H411 (see Annex 3 - Certificate of Analysis). The content of the individual allergic ingredients in the perfume composition is less than 0.1%
Deionized water	7732-18-5 231-791-2	Deionized water	Up to 100 %	Not classified

Annex № 3– ingredient safety data sheets

III. Physical and chemical properties of the biocidal product:

Appearance:	A transparent viscous liquid with a slight opalescent by standard
Color:	Transparent, by standard
Smell:	Slight alcoholic odor of the used perfume composition.
pH (undiluted at 20°C):	5,50-7,0

Melting / freezing point (°C):	No data
Boiling point / interval:	No data
Flash point:	12,85 C (ethanol)
Auto-ignition temperature	No data
Decomposition temperature	No data
Evaporation rate:	No data
Flammability (solid, gas):	Flammable liquid
Lower / upper explosion limit	No data
Vapor pressure	No data
Vapor density	No data
Relative density	0,8720 - 0,8740
Solubility	Unlimited in water Dissolves well in acetone, benzene, methyl alcohol
Partition coefficient: n-octanol / water	No data
Viscosity	No data
Oxidizing properties	No data
Explosive properties	Ethanol forms vapors / mixed with air can explode.

1. Storage stability, shelf life. Influence of light, temperature and humidity on the technical characteristics of the biocidal product. Reactivity with respect to the material of which the packaging is made.

Stable under recommended storage and use conditions.

The specified shelf life is 36 months from the date of manufacture. The stability of the product is also guaranteed by the storage conditions. Packages must be stored tightly closed in closed and dry storage rooms at a temperature of 5 to 25 ° C, without direct sunlight and away from heat sources.

According to physico-chemical properties the product is classified as highly flammable, category 2, H 225 Highly flammable liquids and vapors, in accordance with Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548 / EEC and 1999/45 / EC and amending Regulation (EC)№ 1907/2006.

2. Technical characteristics of the biocidal product (e.g. foaming, wettability and dusting).

Non-foaming liquid product.

3. Physical and chemical compatibility with other products including other biocidal products with which it is co-administered.

Reactivity: No dangerous reactions are known under the recommended storage and use conditions. Stable under normal conditions and conditions of use.

Chemical stability: Stable under normal conditions and conditions of use. Shelf life: 3 years.

Conditions to avoid: High temperatures, heat sources, direct sunlight, frost. Store in a dry, well-ventilated place.

Incompatible materials: Not known under recommended storage and use conditions.

Reducing substances; metals-aluminum, at hightemperatures; strong mineral acids; oxidants.

Dangerous reactions: are not known under the recommended storage and use conditions.

Hazardous decomposition products: does not decompose if stored and used as intended! During a fire or thermal decomposition, carbon dioxide is released (CO₂).

Compatibility with regard to packaging material: does not interact with the packaging material.

IV. Analytical methods for determining the concentration of the active substances in the biocidal product (Annex № 4).

Analytical method for determining the concentration of alcohols in the biocidal product:

The alcohol content is determined by capillary gas chromatography with a flame ionization detector. Butan-2-ol is used as an internal standard.

Equipment

Gas chromatograph

Flame ionization detector

Quartz capillary column 30 m long and 0.32 mm internal diameter coated with poly [(cyanopropyl) (phenyl)] [dimethyl] siloxane (film thickness) 1.8 µm).

Gas chromatographic software, computer and printer

Test solutions

(a): Tested preparation

(b) Internal standard test solution: Dilute 1.0 ml of butan-2-ol to 50.0 ml with test solution (a). Dilute 5.0 ml of this solution to 100.0 ml with test solution (a).

(c) Comparison solution: Dilute 0.5 ml of butan-2-ol, 0.5 ml of propan-1-ol and 0.5 ml of propan-2-ol to 50.0 ml with water.

Way of working

The chromatographic procedure can be performed as follows:

- carrier gas helium or nitrogen, flow division 1: 5 and linear velocity 35 cm/s;
- temperature mode: column 40°C - 12 min / 10°C / min up to 240°C / holding 10 min.

injector: 280 °C
detector: 280 °C

Inject 1 µl of reference solution (c). The sensitivity of the system is adjusted so that the height of the alcohol peaks is not less than 50% of the scale of the recorder..

Inject 1 µl of test solution (b). The areas of the ethanol peaks are determined in the chromatogram obtained.

The calculation of the results is performed by the method of the internal standard.

- The relative correction factor for the substance is determined RCF:

$$RCF(i) = \frac{\frac{AREA(i)}{MASS(i)}}{\frac{AREA(in\ cm)}{MASS(in\ cm)}}$$

where:

Area (i) = the area of the peak of the i-th determined component of the analyzed mixture;

Mass (i) = mass of the sample of the test mixture to which has been added the amount of internal standard;

Area (in cm) = the peak area of the internal standard;

Mass (i) = the mass of the added internal standard;

- The amount of the determined substance (i) is calculated by the formula:

$$G(i) = \frac{AREA(i) \times MASS(in\ cm)}{MASS(i) \times RCF(i)}$$

V. Type of the biocide and areas of application:

1. Type of the biocide:

Liquid.

2. Type of biocides / group of biocides, according to Annex V to Regulation (EU)№ 528/2012.

MAIN GROUP 1: Disinfectants: Product type 1: Human hygiene.

3. Spectrum of action

Bactericidal, including tuberculocidal, yeasticidal, fungicidal, virucidal (enveloped viruses).

4. Field of application:

Ready-to-use product for hygienic hand disinfection in medical and healthcare establishments, in food and beverage trade and production sites; in public facilities - hotels, nurseries, kindergartens, schools, social homes, homes for the elderly, the pharmaceutical and cosmetic industries, for hand disinfection in veterinary practice and in everyday life.

Use: A small amount of the biocide is applied to the skin of the hands, rubbed in and allowed to dry. Do not rinse. Used for cleaning and as often as needed. Children under 6 years of age should use the product only with parental control.

Reliable deep cleaner, refreshes and protects hands. Suitable for everyday use. The formula is based on ethyl alcohol, which cleanses the hands, and the added glycerin extract of linden has a refreshing and hydrating effect..

5. Organisms that are the subject of the proposed use:

Bacteria, incl. mycobacteria, yeasts, fungi, viruses (enveloped viruses).

6. Products, organisms or objects that need to be protected, where available:

Food for humans and animals, drinks, pets.

7. Consumer category: *professional and mass.*

VI. Efficacy and resistance to test report data and / or literature data, when applicable.

1. Biological efficacy data, while taking into account the proposed areas of application and uses, including geographical and climatic conditions:

- Bactericidal action:

Protocol № 148 / 02.07.2020 - Laboratory for disinfection, sterilization and bioindicators at NCIPD (Appendix № 5):

Examination method: BDS EN 13727: 2012 + A2: 2015 Chemical disinfectants and antiseptics. Quantitative suspension test to evaluate the bactericidal action in the medical field. Test method and requirements (phase 2 / step 1).

Tested test strains:

Staphylococcus aureus ATCC 6538

Pseudomonas aeruginosa ATCC 15442

Enterococcus hirae ATCC 10541

Escherichia coli K12NTTC10538

Conclusion: According to the requirements of BDS EN 13727: 2012 + A2: 2015 for evaluation of the bactericidal action of a product intended for hygienic disinfection of hands by rubbing (handrub), the tested sample of „Clean hands spray” **achieves bactericidal activity ($\lg R \geq 5$)** in respect of all test strains tested, when administered as **a ready to use product (without dilution)** with a contact time of **15 seconds** at the following conditions: **20°C** and the presence of an additional load for **pure conditions - (0.3 g / l bovine albumin).**

Fungicidal and yeasticidal action

Protocol № 149/02.07.2020г. – Laboratory for Disinfection, Sterilization and Bioindicators at NCIPD (Annex № 5):

Examination method: BDS EN 13624: 2013: Chemical disinfectants and antiseptics. Testing of the amount of suspension for evaluation of yeasticidal and fungicidal action in the field of medicine. Test method and requirements (phase 2 / step 1).

Tested test strains:

Candida albicans ATCC10231

Aspergillus brasiliensis ATCC 16404

Conclusion: According to the requirements of BDS EN 13624: 2013 for evaluation of the yeasticidal / fungicidal action of a product intended for hygienic disinfection of hands by rubbing (handrub), the tested sample from „Clean hands spray” **achieved yeasticidal activity ($\lg R \geq 4$)** with respect to the test strain Candida albicans ATCC10231 when administered as **a ready to use product (without dilution)** with a contact time of **15 seconds** and under the following conditions: **20°C** and the presence of an additional load for **clean conditions - (0.3 g / l bovine albumin).**

Under the same test conditions, the disinfectant „Clean hands spray” **achieves fungicidal activity** in regard to the test strain of Aspergillus brasiliensis, when administered as **a ready - to - use product (without dilution)** at a contact time of

30 seconds and at the following conditions: **20°C** and the presence of an additional load for **clean conditions – (0.3 g/l bovine albumin)**.

- **Virucidal action: Annex № 5 Efficacy data** – see literature data **on the virocidal effect of a biocidal product for enveloped viruses:**

- 1. Efficacy of ethanol against viruses in hand disinfection, G. Kampf (Journal of Hospital Infection 98 (2018) 331-338);**
- 2. Efficacy of various disinfectants against SARS coronavirus, H.F. Rabenau, G. Kampf, J. Cinatl, H.W. Doerr (Journal of Hospital Infection (2005) 61, 107–111);**

3. Hand hygiene and personal protection, AESIC.EU (Association for European Safety & Infection Control in Dentistry, February 2010).

Mode of action and time of impact: The specific mode of action of alcohols is little known. It is generally believed that based on increased efficiency in the presence of water, alcohols lead to cell membrane destruction and rapid denaturation of proteins, with consequences for cellular metabolism and cell lysis. This is supported by evidence of denaturation of dehydrogenases in *Escherichia coli* and increased lag phase in *Enterobacter aerogenes*, which could be due to inhibition of the metabolism required for rapid cell division..

2. Resistance data, if available.

There are no data on established cases of resistance or on the possibility of developing resistance.

VII. How to use. Exposure time

1. A description of the method of use, including a description of the application systems, if any.

The product is applied ready to use.

Hygienic hand disinfection - The biocide is ready for use and is applied undiluted. 3 ml or a sufficient amount of disinfectant is rubbed into the skin on dry and visibly clean hands for 30 seconds. Hands must remain moist until the exposure time has elapsed, ie. it is also possible to apply additional amounts of biocide. For the entire time of exposure, hands should be well moistened. After disinfection, hands should not be rinsed.

2. Concentration of working solution and consumption rate.

The product is ready for use and is applied undiluted.

3. Number and duration of treatments and, if necessary, additional information on specific geographical and climatic requirements:

The product is applied as often as necessary, observing the recommended exposure time and according to the disinfection practice..

4. Final concentration of the biocide and of the active substance in the treated object, if necessary (for example, water in cooling or heating systems, surface water)

Not applicable.

5. The time interval to be observed between:

- a) the individual applications of the biocide - no interval is required.
- b) the application of the biocide and the use of the treated products - no interval is required.
- c) the use of the biocide and the access of humans or animals to the treated areas, indicating the means and measures for disposal, the time for ventilation of these areas, instructions for cleaning the equipment: no interval is required.

6. Precautions for use, transport and storage as means of collective and personal protection, fire-fighting measures, covering of furniture or equipment, disposal of foodstuffs for humans and / or animals, instructions to prevent exposure of animals.

6.1. Handling of the substance / product

For professional use:

Only store quantities necessary for the normal course of the work process at the workplace; do not leave containers / packages / containers open; to be used in well-ventilated / ventilated rooms. Avoid contact with eyes and skin, inhalation of vapors / aerosols. Take off contaminated clothing immediately. Do not eat, drink or smoke while working. Wash hands before breaks and after work. Take off work clothes immediately after work. Wear chemically resistant gloves (EN 374) / protective clothing / safety goggles with side protection (EN 166); / face mask.

Used only with adequate ventilation / ventilation. Store in a tightly closed original container.

Follow safety instructions.

Work in accordance with the rules of industrial hygiene and safety. Do not mix with other products.

Keep away from flames and hot surfaces. Protect from heat and direct sunlight.

In mass use:

There are no special requirements for the recommended conditions of use.

6.2. Storage: Store in the original package. Keep container tightly closed. Keep away from flames and hot surfaces. Protect from heat and direct sunlight, oxidizing substances.

Properly stored, the biocide has a shelf life of 3 years.

Materials to avoid - oxidizing agents.

To comply with the requirements of the Ordinance on the procedure and manner of storage of hazardous chemical substances and mixtures.

6.3. Firefighting measures

Suitable fire extinguishing media

Depending on the burning material. Dry powder. A jet of water aerosol. Extinguish larger fires with water jet or alcohol-resistant foam.

Means unsuitable for fire fighting for security reasons – not recommended: dense water jet, inert gases, halons.

Specific hazards arising from exposure to the substance / product, combustion products, gases

As a result of combustion or thermal decomposition, hazardous products can be released: carbon dioxide, carbon monoxide. Exposure to products resulting from burns or thermal decomposition may be hazardous to health..

Special protective equipment for firefighters: wear self-contained breathing apparatus and suitable protective clothing, incl. gloves and face / eye protection.

6.4. Occupational exposure control

Limit values in the air at the workplace, according to Ordinance № 13 for protection of workers from risks associated with exposure to chemical agents at work:

Chemical agent	CAS №	8 hours	15 minutes
Ethyl alcohol	64-17-5	1000 mg/m ³	-
Isopropyl alcohol	67-63-6	980.0 mg/m ³	1225.0 mg/m ³
Methylethyl	78-93-3	590 mg/m ³	885 mg/m ³

ketone			
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Respiratory protection: There are no special requirements for the recommended conditions of use. Avoid inhalation of vapors / aerosols.

Hand protection: chemically resistant gloves (EN 374)/

Eye protection: safety goggles with side protection (EN 166); / face mask

Skin protection: Suitable protective clothing and footwear.

Environmental exposure control: Do not allow to enter drains, surface or ground water, or soil. In case of an accident and / or accident to notify the relevant authorities - RIEW.

6.5. Measures in case of accidents and incidents

Personal precautions

Avoid contact with the substance. Do not breathe vapor / spray. Take measures to ensure the supply of fresh air indoors. Switch off all sources of ignition and ventilate the entire area.

The work in the affected area is terminated, the affected area is limited and marked; only workers, repair or other activities to eliminate the accident or incident are allowed in the area, and their number is limited to the required minimum. Workers must wear appropriate personal protective equipment - gloves and goggles / mask. Absorbed with liquid binders (sand, diatomaceous earth, universal binders, sawdust). Emergency workers must wear appropriate work clothes, shoes and personal protective equipment - protective gloves / protective clothing / safety goggles / face mask.

6.6. Environmental protection measures and cleaning agents

Do not allow to enter the environment.

Do not allow to enter sewers, surface or ground water or soil.

Dilute with plenty of water. In case of undiluted product entering the sewerage, surface and groundwater or soil, notify the relevant RIEW, dilute with a large amount of water.

- Do not allow pollution of the environment. In case of accident and / or spillage of the product, take measures for its localization and limitation. Limit spillage when using inert absorbent materials (for example, sand, earth, diatomaceous earth, sawdust); to collect and place the spilled quantity in a container for temporary storage, after which it shall be handed over to persons holding a permit by the order of art. 67 of the WMA. In case of discharge into surface and groundwater, soil, wastewater, drainage systems to notify the control body - RIEW.

Expired biocide and residues thereof, as well as its packaging are treated in compliance with the requirements of the Waste Management Act.

7. First aid measures, including antidotes, if known.

Description of first aid measures

General advice: Show the label and / or safety data sheet to the doctor at admission.

In the case of inhalation:

Move the victim immediately to fresh air. If symptoms persist, seek qualified medical attention.

In the case of skin contact:

Wash off immediately with drinking water. Remove contaminated work clothing immediately. If symptoms of skin irritation (for example, redness) occur and persist, seek medical attention.

In the case of eye contact: immediately rinse thoroughly with running drinking water with open eyelids for at least 15 minutes and seek medical advice.

In the case of swallowing: seek medical attention immediately and show this container or label. Rinse mouth with drinking water and spit out water.

Do not induce vomiting. Do not give anything by mouth to an unconscious person.

Treatment: The treatment is specialized.

Protection of first aiders: Use personal protective equipment.

8. Procedures for waste management of biocidal mixtures and their packaging.

The waste from the biocide as residual quantities and packages to be collected temporarily in special tightly closing and marked containers, after which to be handed over to persons, possessing a permit by the order of art. 67 of the Waste Management Act.

Waste code from the mixture (determined by the respective operator):

Wastes from the production, formulation, supply and use of greases, lubricants, soaps, laundry and cleaning mixtures, disinfectants and cosmetics

07 06 01 * - washing waters and mother liquors

Packaging, waste code 15 01 10 *, packaging containing residues of dangerous substances or contaminated with dangerous substances.

9. Data on specific environmental hazards, including adverse or unintended side effects, for example, on beneficial or other non-target organisms.

No data available.

10. Details of any repellents or preservatives contained in the biocidal product intended to prevent adverse effects on non-target organisms (where available).

Not applicable.

11. Transport of a product containing ethanol and quaternary ammonium compound:

Land transport, Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR)

UN number: 1170

The exact name of the shipment: ethanol solution

Hazard class (es):

Class: 3

Label (s): 3

Packing group: II

Dangerous for the environment: No.

Marine pollutant: No.

Special precautions for user: None known.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC

Code: The product is not transported in bulk tankers.

Other important information:

ADR

Classification code: F1

Tunnel restriction code: D / E

Hazard identification number: 33

IMO / IMDG

EmS: F-E, S-D

The product is classified, labeled and packaged in accordance with the requirements of ADR and the provisions of the IMDG Code

Transport includes special provisions for certain classes of dangerous substances packaged in limited quantities

According to physicochemical properties the product is classified as highly flammable, category 2 with H 225 Highly flammable liquids and vapors, in accordance with Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548 / EEC and 1999/45 / EC and amending Regulation (EC) № 1907/2006.

VIII. Toxicological and ecotoxicological data on the biocidal product

1. Toxicological and ecotoxicological data related to the classification of the biocidal product as hazardous.

Toxicological data:

No test data on the mixture.

Data on the active substances in the mixture - see data on the active

substance described above.

Additional toxicological information – none.

According to the presented SDS of the ethyl alcohol of the company producing ethanol, the biocide is classified as: serious eye damage / eye irritation, category 2, H319 and Specific target organ toxicity from single exposure, category 3, H336.

Ecotoxicological data

No test data for the mixture.

Details of the active substances in the mixture - - see details of the active substance above.

In terms of ecotoxicological properties, the biocidal product is not classified as hazardous to the aquatic environment under Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67 / 548 / EEC and 1999/45 / EC and amending Regulation (EC)№ 1907/2006.

2. Toxicological and ecotoxicological data that lead to specific requirements and / or restrictions on use (e.g. in persons at risk, in case of significant skin resorption, etc.)) :

No data.

IX. Product classification

The product is classified as Highly flammable, category 2.

Serious eye damage / eye irritation, cat.2, H319.

Specific target organ toxicity - single exposure, category 3, H336

Labeling:

Pictograms:



GHS02



GHS07

Signal word: Dangerous

Hazard warnings:

H 225 Highly flammable liquids and vapors.

H 319 Causes serious eye irritation.
H 336 May cause drowsiness or dizziness.

Safety recommendations:

P102 - Keep out of the reach of children

P 210 Protect from heat, hot surfaces, sparks, open flames and other sources of ignition. No smoking.

P233 Keep container tightly closed.

P241 Use explosion-proof electrical / ventilating / lighting /.../ equipment.

P242 Use only non-sparking tools.

P243 Take precautions against the release of static electricity.

P244 Store only in the original package.

P403+P235 Store in a well-ventilated place. Keep cool.

P370+P378 In the case of fire: Use ABC powder extinguisher for extinguishing.

P305+P351+P338 – In the case of EYE CONTACT: Rinse cautiously with water for several minutes. Remove contact lenses, if present. Keep rinsing.

P501 Dispose of the contents / container in accordance with the regulations. Product vapors may form explosive mixtures with air.

Contains: ethanol, isopropanol, methyl ethyl ketone.

X. Biocide packaging data

1. Material, type, shape

Type, shape and graphic design of the packaging:

The product is packaged in plastic vials (PET, PP) with different capacities. The vials are closed with nebulizer caps and transport caps (polypropylene plastic). Packaging materials comply with Regulation (EC) 1907/2006 (REACH) and the current requirements of the Packaging Ordinance and Packaging Waste of August 2013.

Packages for mass use:

Polyethylene terephthalate (PET) of 100 ml

Polypropylene (PP) with a capacity of 250 ml

Polyethylene terephthalate (PET) with a capacity of 500 ML

Polyethylene terephthalate (PET) with a capacity of 1000 ML

Packaging for professional use:

Polypropylene (PP) with a capacity of 5 L

Polypropylene (PP) with a capacity of 10 L

Acrylonitrile butadiene styrene (ABS) CUB with a capacity 1 000 L

2. Compatibility of the material with the biocide

Interaction with the packaging material - The biocide does not interact with the packaging material. The tests for compatibility of the commercial packaging with the final product at room temperature, refrigerator, thermostat and light, show no deviations from the standard analytical specification.

Tactile hazard warnings and devices that make the package inaccessible to children:

Packages for general use must be provided with tactile hazard statements.

3. Capacity (mass or volume).

See page 1

XI. Consumer category: Professional and mass

XII. Draft label – Annex № 6

XIII. Product Safety Data Sheet - Annex № 7.