

# **Technical dossier OF A BIOCIDES “CLEAN HANDS GEL”**

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 necessary for issuing a permit for placing on the market of a biocide or a group of biocides under Art. 18 of the Law on Protection from the Harmful Impact of Chemical Substances and Mixtures PMS № 8 / 22.01.2018.

(SG No. 9 / 26.01.2018).’

## **2020**

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

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

Diva 691 Ltd

35 Warsaw Street, Plovdiv

phone: +359 888 99 20 64

[dvproduct691@gmail.com](mailto:dvproduct691@gmail.com)

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

Diva 691 Ltd

35 Varshava Street, Plovdiv

phone: +359 888 99 20 64

[dvproduct691@gmail.com](mailto:dvproduct691@gmail.com)

### 3. Active substance: ethanol

Suppliers and manufacturers of the active substance:

1st supplier

ZAHARNI ZAVODI AD

town of Gorna Oryahovitsa, 5100

Str. "St. Knyaz Boris I "№ 29

Tel. 0618 / 69-500; fax: 0618/2 17 09

e-mail: 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%, ethyl methyl ketone 1% and denatonium benzoate 0.001%. It does not contain methanol (see analytical certificate of Zaharni Zavodi AD - Annex № 1).

2nd supplier

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

Dunav Blvd. „5

4003 Plovdiv, district "North"

Bulgaria

Tel.: 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).

**Annex No. 1:**

- Documents of ZAHARNI ZAVODI 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 Delivery declaration for the company Diva 691 EOOD from ZAHARNI ZAVODI AD.
  - o Analysis certificate.
- Documents of VP BRANDS INTERNATIONAL AD:
  - o ECHA decision on inclusion in the list of active substances and suppliers referred to in Article 95 (1) of REGULATION (EU) № 528/2012
  - o Delivery declaration for Diva 691 EOOD from VP Brands International OD,
  - o Analysis certificate.

**Annex No. 2:**

- Safety data sheet of ZAHARNI ZAVODI AD for 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);
- 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 it is appropriate.**

**“CLEAN HANDS GEL”**

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

**Table No. 1**

Chemical name	CAS /EC №	SDS with a trade name	Percentage of each substance in the composition of the biocidal	Classification

			product	
Ethanol (Annex №2)	64-17-5/200-578-6	1.ETHANOL (ETHANOL) OF AGRICULTURAL ORIGIN (80-100%) denatured by the GENERAL METHOD ACCORDING TO PPZADS, with methyl ethyl ketone, isopropyl alcohol and denatonium benzoate (Bitrex)  2.Ethanol, denatured with Isopropanol, Methyl ethyl ketone and Denatonium benzoate (Bitrex)	75 w/w %	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 Zaharni zavodi and VP Brands International AD - Annex №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)	1.0%	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3  H225;  H319;  H336;
Ethylmethyl 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,	1.0%	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3  H225;  H319;  H336;  EUH066

		ISOPROPYL ALCOHOLATHOL OCHLATE		
Carbopol@Ultrez 20- ULTREZ 20 contains  Alcohols, C11-14-iso-, C13-rich, ethoxylated  Cyclohexane Excipient	polymer	Carbopol@Улт pez 20- ULTREZ 20	0.3	Eye dam/eye irrit. Cat.2 H319
Hydrogen peroxide (Annex №3)  Excipient (Annex №3)	7722- 84-1	Hydrogen Peroxide 50% Oxypure	0.125	Skin Corr. 1A H314 Ox. Liq. 1 H271 Acute Tox. 4 H302 Acute Tox. 4 H332
Triethanol amine Excipient (Annex №3)	102-71- 6	Triethanolamine pure	0.1	Not classified
Linden extract  Contains 65% glycerin 0.1% citric acid (Annex №3)	56-81- 5/200- 289-5 – tlycerin  77-92- 9/5949- 29-1 - citric acid	Natural Herbal Glycerin Extracts	0.3	Not classified
PK Lavender  CARIN. LAVANDA-FRESH F P408155 (Annex №3)			0.09	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 The content of the individual allergic ingredients in the perfume composition is less than 0.1%
Deionized water	7732- 18-5  /231- 791-2		Up to 100 %	Not classified

The content of the individual allergic ingredients in the composition of the biocide from the perfume composition is less than 0.01% (see the content of the individual allergic ingredients in the CARIN SDS. LAVANDA-FRESH F P408155 - Annex № 3)

### 3. Active substance – ethanol

#### 3.1. One of the chemical names; CAS № and EU №, when available:

Table No. 2:

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 in Annex II to Regulation (EC) No 1451/2007: **Ethanol**

#### 3.2. 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 (EC) № 1062/2014 of 4 August 2014 on a work program for the systematic investigation 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.

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

##### 3.3.1. Efficiency (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), virucidal (enveloped viruses), 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 on the basis of increased efficiency in the presence of water, alcohols lead to destruction of the cell membrane and rapid denaturation of proteins, with consequences for cellular metabolism and cell lysis. This is supported by evidence of dehydrogenase denaturation 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: 15 seconds - 1 minute

**3.4. Information on identified cases or possibility of developing resistance and appropriate measures to prevent development, where data is available:**

- there is insufficient data on the selective acquisition of resistance to the active substance ethanol, regardless of its long-term use.

**3.5. Intended field of application and category of users:**

The active substance is included in Annex II to Commission Regulation (EU) Д 1062/2014 OF THE COMMISSION of 4 August 2014 on a work program for the systematic investigation 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.

**3.6. 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:**

**Physico-chemical data**

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

**Table No. 3:**

<b>Indicators</b>	
<b>Aggregate condition</b>	Liquid
<b>Colour</b>	Colorless, clear
<b>Smell</b>	Characteristic of alcohol
<b>Flash point at 101 325 Pa</b>	12.85 °C
<b>Melting / freezing point at 101 325 Pa</b>	-114.15 °C
<b>Partial coefficient Log Kow (Log Pow)</b>	-0.35 at 20 °C
<b>Boiling point at 101 325 Pa</b>	78.29 °C
<b>Vapor pressure</b>	57.26 hPa at 19.65 °C
<b>Dynamic at 20 °C</b>	1.2 mPa.s
<b>Density</b>	0.786 g/cm <sup>3</sup> at 25 °C
<b>Solubility in water</b>	789 g/L @ 20 °C
<b>Flammability</b>	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 (not irritating)

Eyes: Adverse effects (irritation)

## **Sensitization**

Skin sensitization

No adverse effects observed (not sensitizer)

Respiratory sensitization

No adverse effects observed (not 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/m<sup>3</sup> air

NOEC (mice): 130 mg/m<sup>3</sup> air

## **Neurotoxicity**

Inhalation route: Adverse effects have been observed with NOAEC 19,000 mg / m<sup>3</sup> (subchronic, rats)

### **Immunotoxicity**

Inhalation route: No adverse effects were observed with NOAEC 40 000 mg / m<sup>3</sup> (subchronic, rats)

**Genotoxicity:** no data available;

**Carcinogenesis:** no data available

**Teratogenesis:** no data available

**Ecotoxicological data** - source ECHA - <https://echa.europa.eu/en/brief-profile/-/briefprofile/100.000.526>

**Biodegradability in water** - easily biodegradable (100%)

**Bioaccumulation:** Bioaccumulation is not expected.

### **Ecotoxicity:**

#### **Acute (short-term) toxicity to fish**

LC50 for freshwater fish - 11.2 g / 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

**Physico-chemical, toxicological and ecotoxicological data that lead to specific requirements and / or restrictions on use (eg in persons at risk, with significant skin resorption, etc.).**

No specific requirements are necessary.

### 3.7. Classification of the active substance in accordance with Regulation 1272/2008

The active substance Ethanol is included in Table 3.1. of Annex № VI 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.**

Classification: Flammable liquids, category 2, H225.

**The supplier Zaharni Zavodi AD has proposed an additional classification**

- Serious eye damage / eye irritation, cat.2, H319
- Specific target organ toxicity, single exposure, category 3, H336

(see SDS - Annex № 2).

**Labeling:**

**Icons:**



GHS02

GHS07

**Signal word:** Dangerous

#### **Hazard warnings**

H225: Highly flammable liquid and vapor.

H319: Causes serious eye irritation.

H 336 May cause drowsiness or dizziness.

#### **Safety recommendations:**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

P243 Take precautionary measures against static discharges.

P280 Wear protective gloves / protective clothing / eye protection / face protection.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing.

Rinse skin with water / shower.

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present. Keep rinsing.

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

P501 Dispose of contents / container in accordance with regulations.

**4. Data for each of the other chemical substances included in the composition of the biocidal product - ingredient safety data sheets Annex № 3:**

**Table No. 4**

Chemical name	CAS /EC №	SDS with trade name	Percentage of each substance in the composition of the biocidal product	Classification
Isopropyl alcohol Accompanying substance (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)	0.70%	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3  H225;  H319;  H336;
Ethylmethyl ketone Accompanying substance (Annex №2)	76-93-3/201-159-0	ETHANOL (ETHYL ALCOHOL) OF AGRICULTURAL ORIGIN (80-100%), DENATURED BY A GENERAL METHOD ACCORDING TO PPZADS, WITH METHYL ETHYL KETONE, ISOPROPYL ALCOHOLATHOL OCHLATE	0.70%	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3  H225;  H319;  H336;  EUH066
Carbopol@Ultrez 20- ULTREZ 20 contains  Alcohols,	polymer	Carbopol@Ultrez 20- ULTREZ 20	0.3	Eye dam/eye irrit. Cat.2 H319

C11-14-iso-, C13-rich, ethoxylated Cyclohexane Excipient				
Hydrogen peroxide  Excipient  (Annex №3)	7722-84-1	Hydrogen Peroxide 50% Oxypure	0.125	Skin Corr. 1A H314 Ox. Liq. 1 H271 Acute Tox. 4 H302 Acute Tox. 4 H332
Triethanol amine  Excipient  (Annex №3)	102-71-6	Triethanolamin e pure	0.1	Not classified
Linden extract  Contains 65% glycerin 0.1% citric acid  (Annex №3)	56-81- 5/200- 289-5 – lycerin  77-92- 9/5949- 29-1 - citric acid	Natural Herbal Glycerin Extracts	0.3	Not classified
PK Lavender  CARIN. LAVANDA- P408155  (Annex №3)			0.09	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 <b>The content of the individual allergic ingredients in the perfume composition is less than 0.1%</b>
Deionized water	7732-18-5  /231-791- 2		Up to 100 %	Not classified

**The content of the individual allergic ingredients in the perfume composition is less than 0.1% (see the content of the individual allergic ingredients in the SDS - Annex №3)**

The inclusion of Hydrogen Peroxide in the composition of the biocidal product does not lead

to a change in the classification of the product due to its low concentration of 0.12% and the specified specific concentration limits.

**Specific concentration limits for Hydrogen Peroxide (Regulation (EC) No 1272/2008 (CLP)):**

Skin Corr. 1A; H314:  $C \geq 70 \%$

Skin Corr. 1B; H314:  $50 \% \leq C < 70 \%$

Skin Irrit. 2; H315:  $35 \% \leq C < 50 \%$

Ox. Liq. 1; H271:  $C \geq 70 \%$

Ox. Liq. 2; H272:  $50 \% \leq C < 70 \%$

STOT SE 3; H335;  $C \geq 35 \%$

Eye Dam. 1; H318:  $8 \% \leq C < 50 \%$

Eye Irrit. 2; H319:  $5 \% \leq C < 8 \%$

**III. Physical and chemical properties of the biocidal product:**

**Table No. 5**

<b>Appearance:</b>	Transparent viscous table, with light opalescent according to the standard
<b>Colour:</b>	Transparent, according to the standard
<b>Smell:</b>	Slight alcoholic odor of the used perfume composition.
<b>pH (undiluted at 20°C):</b>	5,50-7,0
<b>Melting / freezing point (°C):</b>	No data
<b>Boiling point / interval:</b>	No data
<b>Flash point:</b>	19.0 C
<b>Auto-ignition temperature</b>	No data
<b>Decomposition temperature</b>	No data
<b>Evaporation rate:</b>	No data
<b>Flammability (solid, gas):</b>	Flammable liquid
<b>Lower / upper explosion limit</b>	No data
<b>Vapor pressure</b>	No data
<b>Vapor density</b>	No data
<b>Relative density</b>	0,8720 - 0,8740
<b>Solubility</b>	Unlimited in water Dissolves well in acetone, benzene, methyl alcohol

<b>Partition coefficient: n-octanol / water</b>	No data
<b>Viscosity</b>	No data
<b>Oxidizing properties</b>	No data
<b>Explosive properties</b>	Ethanol forms vapors / mixed with air can explode.

**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 normal conditions.

Properly stored, the product has a shelf life of 36 months.

Avoid freezing. Store in a cool place.

Avoid high temperatures, heat sources, direct sunlight.

**According to physico-chemical 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 classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548 / EEC and 1999/45 / EC and amending of Regulation (EC) No 1907/2006.

**Technical characteristics of the biocidal product (eg foaming, wettability and dusting).**

Non-foaming gel product.

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

**Reactivity:** no dangerous reactions known during normal storage and use.

**Conditions to avoid** - high temperatures (above 30.0 C), heat sources, direct sunlight, freezing.

**Materials to avoid** - highly oxidizing substances and acids. Store in a well-ventilated place.

**Hazardous reactions:** not known under normal storage and use.

**Incompatible materials:** not known under normal storage and use.

**Hazardous decomposition substances:** not known under normal storage and use.

**Compatibility with regard to packaging material:** does not interact with 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 (1.8 µm film thickness).

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). Then dilute 5.0 ml of this solution to 100.0 ml with test solution (a).

(c) Solution for comparison: 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 carried out as follows:

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

- Determine the relative correction coefficient for the substance RCF:

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

where:

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

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

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 biocidal product and areas of application:**

### **1. Type of the biocide:**

Gel

### **2. Type of the biocide/ group of biocidal products as defined in Annex V to Regulation (EU) № 528/2012.**

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### **3. Spectrum of action**

Bactericidal, yeasticidal, fungicidal, virucidal (enveloped viruses) action.

### **4. Area of use:**

**Main group 1:** Disinfectants. **Product type 1:** Human hygiene;

For hygienic hand disinfection in medical and health establishments, in sites for trade and production of food and beverages; 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.

### **5. Organisms which are the subject of the proposed use:**

Bacteria, yeast, fungi, enveloped viruses.

### **6. Products, organisms or objects to be protected, where available:**

Food for humans and animals, drinks, pets.

### **7. Category of consumers: professional and mass.**

## **VI. Efficacy and resistance to test report data and / or literature data, where applicable.**

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

### **Performance data:**

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

### **Examination method:**

#### **Bactericidal action:**

#### **Protocol № 150 / 02.07.2020 - Laboratory for disinfection, sterilization and bioindicators at NCIPD (Annex № 5):**

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).

Test strains tested:

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 GEL**" **achieves bactericidal activity (lgR≥5)** on all tested test strains when applied as a **ready-to-use product (without dilution)** at a contact time of **15 seconds** and under the following conditions: **20°C** and the presence of additional load for **clean conditions - (0.3 g / l bovine albumin)**

### **Yeasticidal and fungicidal activity**

**Protocol № 151 / 09.06.2020 - Laboratory for disinfection, sterilization and bioindicators at NCIPD (Annex № 5):**

Test strains tested:

Candida albicans ATCC10231

Aspergillus brasiliensis ATCC 16404 (prickly conidiospores ≥ 75%)

### **Conclusion:**

According to the requirements of BDS EN 13624: 2013 for evaluation of the yeast / fungicidal action of a product intended for hygienic disinfection of hands by rubbing (handrub), the tested sample from "**CLEAN HANDS GEL**" **achieves yeast activity (lgR≥4)** in relation to the test - strain of Candida albicans ATCC10231, when applied as a **ready-to-use product (without dilution)** at a contact time of **15 seconds** and under the following conditions: **20°C** and the presence of additional load for **clean conditions - (0.3 g / l bovine albumin)**.

Test strain Aspergillus brasiliensis reaches the required reduction at a contact time of **60 seconds** and according to the requirements of BDS EN 13624: 2013 **achieves fungicidal activity against Aspergillus brasiliensis from the disinfectant "CLEAN HANDS GEL"** when used as a **ready-to-use product (without dilution)** in contact time **60 seconds** and under the following

conditions: 20°C and the presence of additional load for clean conditions - (0.3 g / l bovine albumin).

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

**1. Efficacy of ethanol against viruses in hand disinfection, G. Kampf \*  
Journal of Hospital Infection 98 (2018) 331-338.**

Ethanol has been shown to be effective against various enveloped viruses. Starting at a concentration of 42.6% (w / w), ethanol is effective within 30 s against coronavirus SARS, Coronavirus MERS, ebolavirus, influenza A virus, including human type H3N2, avian type H3N8 and human type H1N1, influenza B virus, HIV, HBV, vaccinia virus, hepatitis B virus, togavirus, pseudorabies virus, Newcastle disease virus, bovine viral diarrhoea virus, zika virus, herpes simplex virus types 1 and 2 and RSV [5,14e35]. Ethanol was effective at 73.6% (w / w) against HCV for 15 s and 30 s, but not at 40%.

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

**3. Efficacy of various disinfectants against SARS Coronavirus,  
H.F. Rabenau\*, G. Kampf, c, J. Cinatla, H.W. Doerr, Journal of Hospital Infection (2005) 61, 107–111.**

**Course of action and duration of action:** The specific course of action of alcohols is little known. It is generally believed that based on the increased efficiency in the presence of water, alcohols lead to the destruction of the cell membrane and rapid denaturation of proteins, with consequences for cellular metabolism and cell lysis. This is supported by evidence of dehydrogenase denaturation in *Escherichia coli* and increased lag phase in *Enterobacter aerogenes*, which could be due to inhibition of the metabolism required for rapid cell division<sup>1</sup>.

**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 manner of use, including a description of the application systems, where provided for.**

**The product is applied ready to use**

**Hygienic 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 60 seconds. Hands must remain moist until the exposure time has elapsed, i.e. it is also possible to apply additional amounts of biocide, paying special attention to the skin under the nails, on the nail bed, between the fingers and on the folds of the palm. For the entire time of exposure, hands should be well moistened. After disinfection, hands should not be rinsed. Children under 6 years of age should use the product only with parental control.

**2. Concentration of working solution and consumption rate.**

**The biocide 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 biocidal product and of the active substance in the treated article, if necessary (e.g. water in cooling or heating systems, surface water)**

- Not applicable, given the field of application.

**5. The time interval to be observed between:**

- a) the individual applications of the biocidal product - no interval is required
- b) the application of the biocidal product and the use of the treated products - no interval is required.
- c) the use of the biocidal product and the access of humans or animals to the treated areas, indicating the means and measures for disposal, the time for aeration of these areas, instructions for cleaning the equipment: Use and store only in cool, ventilated areas; and keep away from sources of ignition, high temperatures, direct sunlight, away from oxidizing substances.

**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 for prevention of exposure of animals.**

**6.1. Handling of the substance / product** - keep at the workplace only the quantities necessary for the normal course of the work process; 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. Store in tightly closed original container. Follow the instructions for safe work.

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.

**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 36 months.

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 extinguishing media:** depending on the burning material. Carbon dioxide. Dry powder. A jet of water aerosol. Extinguish larger fires with water jet or alcohol-resistant foam.

**Means unsuitable for firefighting for security reasons - not recommended:** dense water jet, inert gases, halons.

**Specific hazards associated with exposure to the substance / mixture, combustion products, exhaust gases:** as a result of combustion or thermal decomposition, hazardous products may be released: carbon dioxide, carbon monoxide. Exposure to products resulting from burns or thermal decomposition can be dangerous to health.

**Special protective equipment for fire-fighters:** In case of fire or thermal decomposition, carbon dioxide (CO<sub>2</sub>) is released. 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:

Table No. 6

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

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. Follow the instructions for safe work.

Used only with adequate ventilation. Store in a tightly closed original container. Follow the instructions for safe work.

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

Keep away from flames and hot surfaces, direct sunlight, oxidizing agents. Keep away from heat.

**Respiratory protection:** Avoid inhalation of vapors / aerosols.

**Hand protection:** chemically resistant gloves (EN 374) /

**Eye protection:** safety glasses with side-shields (EN 166); / face mask

**Skin protection:** Suitable protective clothing and footwear.

**Environmental exposure controls:** 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 delimited 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). Workers in case of accidents should wear appropriate work clothes, shoes and personal protective equipment - protective gloves / protective clothing / safety goggles / protective face mask.

## **7. Environmental protection measures and cleaning agents**

Do not allow to enter the environment.

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

Dilute with plenty of water. In case of undiluted product entering sewage, surface and groundwater or soil, inform the relevant RIEW to 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 (e.g. 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 competent authority - RIEW.

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

## **8. First aid measures, including antidotes, if known.**

### **Description of first aid measures**

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

#### **If inhaled:**

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



**In case of skin contact:**

Wash off immediately with drinking water. Remove contaminated work clothing immediately. In case of symptoms of skin irritation (e.g., redness) and if they persist, seek medical attention.

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

**If swallowed:** seek medical advice 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.

**9. Procedures for waste management of biocidal mixtures and their packaging.**

Waste code from the mixture:

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 lyes

PE packaging, waste code 15 01 10 \* packaging containing residues of dangerous substances or

contaminated with hazardous substances.

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, holding a permit by the order of art. 67 of the Waste Management Act.

**10. Data on specific environmental hazards, including undesirable or unintended side effects, for example on beneficial or other organisms not subject to the proposed use.**

No data available.

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

Not applicable.

**12. Transport of a product containing ethanol and a 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 by 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

**In 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

## **VIII. Toxicological and ecotoxicological data on the biocidal product**

### **1. Toxicological and ecotoxicological data related to the classification of the biocidal product as dangerous.**

#### **Toxicological data:**

**No test data for 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 ethanol supplier of the ethanol supplier "Zaharni Zavodi AD" the biocide is classified as: serious eye damage / eye irritation, category 2, H319 and Specific toxicity to certain organs as a result of a 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 ecotoxicological properties the biocidal product is not classified as hazardous for water** in accordance with 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 Directives Regulation (EC) No 1907/2006.

**2. Toxicological and ecotoxicological data which 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 from single exposure, category 3, H366

**Labeling:**

**Pictograms:**



**GHS02**



**GHS07**

Signal word:

Dangerous

**Danger warnings:**

**H 225** Highly flammable liquids and vapors.

**H 319** Causes serious eye irritation.

**H 366** May cause drowsiness or dizziness.

**Safety recommendations:**

**P102** Keep out of the reach of children

**P 210** Protect from heat, hot surfaces, sparks, open flame 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 precautionary measures against static discharges.

**P244** Store only in the original package.

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

**P501** Dispose of contents / container in accordance with regulations.

**Product vapors may form explosive mixtures with air. Do not use for disinfection of large surfaces (not larger than 2 m<sup>2</sup>) due to the flammability of the biocidal product.**

**Contains:** ethanol, isopropanol, methyl ethyl ketone.

#### **X. Biocidal product packaging data**

Interaction with the packaging material - The biocide does not interact with the packaging material.

Compatibility of the material with the biocidal product: compatible

Type, shape and graphic design of the packaging:

##### **Packages for mass use:**

80 ml polyethylene terephthalate (PET) flasks

Polypropylene (PP) vials with a capacity of 100 ml

Polypropylene (PP) vials with a capacity of 250 ml

Polypropylene terephthalate (PET) vials with a capacity of 500 ml

Polypropylene terephthalate (PET) vials with a capacity of 1000 ml

##### **Packages for professional use:**

Polypropylene (PP) tubes with a capacity of 5 L

Polypropylene (PP) tubes with a capacity of 10 L

#### **Tactile hazard statements and devices that make the package inaccessible to children:**

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

#### **XI. Consumer category: Professional and mass.**

#### **XII. Draft label - Annex № 6**

#### **XIII. Product Safety Data Sheet - Annex № 7.**