

Ministry of health

License

to put a Biocidal product on the market

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No 2928-1/30.09.2020

On the basis of article 14a and article 18c, paragraph 5, regarding article 15, paragraph 4, p. 16 from the Law on protection against the harmful effects of chemical substances and mixtures, submitted an application with an entry number No 13-BP-440/03.08.2020 and Order No RD 01-287/08.08.2017 by the Minister of Health,

I authorize the distribution to the market of:

I. Trade name of the Biocide

CLEAN HANDS GEL

II. Name and address of the distributor of the Biocide on the market

Diva 691 LTD
Varshava str. 35
Plovdiv
tel. +359 888 992 064; +359 888 148 221
e-mail: dvproduct691@gmail.com

III. Name and address of the manufacturer of the Biocide

DIVA 691 LTD
Varshava str. 35
Plovdiv
tel. +359 888 992 064; +359 888 148 221
e-mail: dvproduct691@gmail.com

IV. Manufacturer of the active substance

Zaharni zavodi AD
Sv. Knyaz Boris I str. 29
Gorna Oryahovitsa 5100
tel. 0618/69-500; fax: 0618/2 17 09
e-mail: office@zaharnizavodi.com; ethanol@zaharnizavodi.com

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VP Brands International AD
(distillery ESENTIKA, Plovdiv)
Dunav bld. 5, region "Severen",
4003 Plovdiv

tel.: 359 (0)32 606 916/ +359 (0)32 306 783
e-mail: office@vp-brands.com; office@essentica.eu

V. Type of the Biocide in accordance with Annex 5 of Regulation (EU) No 528/2012 of the European Parliament and of the Council from the 22nd of May 2012 regarding the distribution on the market and the use of Biocides.

Main group 1 – Disinfectants

Product type 1 – Human hygiene

VI. Type of the Biocide (granulate, liquid, powder and etc.)

Liquid (gel)

VII. Data for the active substance/s in the composition of the Biocide

A. Chemical substance

Number by order	Name	CAS No and EU No, when such were specified	Concentration of the active substance in metric units
1.	Ethanol	CAS No 64-17-5 EU No 200-578-6	75g/100g

VIII. Area/s of application

The Biocide is a bactericidal, fungicidal (incl. yeasticidal) and limited virocidal (enveloped viruses) effect, as the area of application is hygienic hand disinfection.

IX. Usage

The Biocide is ready for use – a minimum of 3ml are rubbed in the skin on dry and visibly clean hands in the span of 60 seconds. The hands must stay wet until the expiration of the time of impact, so it is also possible to apply extra amounts of the Biocide. The hands are rubbed in accordance with the standard technique for hand disinfection.

After the expiration of the time of impact, the hands are not to be rinsed!

X. Classification and labeling data of the Biocide in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Community from the 16th of December 2008, regarding classification, labeling and packaging of substance and mixtures for amendment and repealing of directives 67/548/EEC and 1999/45/EC and for amendment of Regulation (EC) No 1907/2006

A. Biocide with active substance/s – chemical substance/s

Classes and categories with hazard:

Flammable liquids, category 2, H225

Serious eye damage/irritation, category 2, H319.

Specific toxicity to certain organs – single exposure, category 3, H336

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Labeling

Pictograms:



GHS02

GHS07

Signal word: Hazardous

Hazard warnings:

H225 Highly flammable liquid and vapors

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

Safety recommendations:

P102 Keep away from children.

P210 Keep away from heat, hot surfaces, sparks , open flame and other sources of ignition. Smoking is forbidden.

P233 Keep the container tightly closed.

P241 Use electric/ventilating/lighting equipment secured against explosion.

P242 Use instruments, which do not make sparks.

P243 Take action to prevent the release of static electricity.

P244 To be stored only in the original package.

P305+P351+P338 **IN THE CASE OF EYE CONTACT:** Rinse carefully with water for a few minutes. Take off contact lenses if there are any and as much as possible. Continue rinsing.

P370+P378 In the case of fire: Use alcohol-resistant foam, dry powder or water stream to put it out.

P403+P235 To be stored in a well-ventilated place. To be kept cool.

P501 The content/container to be disposed of in accordance with the Regulations.

XI. Packaging data(type of package, capacity / volume)

Packages for mass use:

Bottles of polyethylene terephthalate(PET) of 80ml, 500ml, 1000ml.

Bottles of polypropylene(PP) with a capacity of 100ml and 250ml.

The packages for mass use are equipped with tactile hazard warnings.

Packages for professional use:

Polypropylene(PP) tubes with a capacity of 5L and 10L

XII. User category

Professional and mass

XIII. Specific requirements or restrictions

1. The safety data sheet and the label to be made in accordance with the issued permit as well as in compliance with the requirements in the Law on protection against the harmful effects of chemical substances and mixtures, chapter IV and Annex II of Regulation(EC) No 1907/2006, regarding registration, evaluation, authorization and restriction of chemicals(REACH).
2. To comply with the requirements of Article 5, paragraph 1 of the Ordinance for packages and waste from packages (promulgated SG, No 85 of 2012), by placing the required markings.
3. To fill in the declarations for compliance in accordance with Article 4, paragraph 3 and Article 6, paragraph 2 of the Ordinance for packages and waste from packages.

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Chief state health inspector:

Associate Professor Dr. Angel Kunchev, doctor of medical sciences