

Date of issue: 11 Apr. 2019

ADVICE
Nr. 2854BIO/01/12.24

Under the Order of the Ministry of Health, Minister of the Environment and Forests and of the President of the National Sanitary, Veterinary and Food Safety Authority no. 10/368/11/2010, regarding the approval of the procedure for the advice of biocidal products placed on the Romanian market, with the subsequent amendments and the Order of the Ministry of Health, Minister of the Environment and Forests and of the President of the National Sanitary, Veterinary and Food Safety Authority no. 637/2492/50/2012 regarding the approval of the members of the National Committee for Biocidal Products and of its organisation and operation regulation, with the subsequent amendments and additions, based on the documents filed for the completion of the technical file, CNPB, in the meetings from 07 Dec. 2017 and 10 Apr. 2019, decided that the biocidal product may be placed on the Romanian market, under the legal provisions in force

I. COMMERCIAL DESIGNATION IN ROMANIA

HYGIENEX GEL ANTIBACTERIAN

Other commercial designations, if required

**TRUSSA GEL ANTIBACTERIAN; HYGIENIUM GEL ANTIBACTERIAN;
DELHAIZE GEL ANTIBACTERIAN; NR. 1 GEL ANTIBACTERIAN
FRESKO GEL ANTIBACTERIAN**

II. MANUFACTURER'S IDENTIFICATION DATA (name, address, country, including the work point for the Romanian producers)

Grande Gloria Production S.R.L., sat Costi, com. Vanatori, str. Tuluc, nr. 1, Hala nr.68, Biroul nr.2, jud. Galati, Romania

Work point: sat Costi, com. Vanatori, str. Tuluc, nr. 1, Hala nr.68, Biroul nr. 2, jud. Galati

III. APPLICANT'S IDENTIFICATION DATA (name, address, country)

Grande Gloria Production S.R.L., sat Costi, com. Vanatori, str. Tuluc, nr. 1, Hala nr.68, Biroul nr. 2, jud. Galati, Romania

IV. BIOCIDAL PRODUCT'S FRAMING (under Annex V to Regulation (EU) nr. 528/2012 of the European Parliament and Council from 22 May 2012 regarding the sale on the market and the use of biocidal products, with the subsequent amendments)

A. Main group	1
B. Product type/types	1

V. DATA REGARDING THE ACTIVE SUBSTANCE/SUBSTANCES

A. Chemical substances

No.	Chemical designation (IUPAC, ISO or others)	CE no.	CAS no.	Concentration in metric units
1	Ethylic alcohol (96%)	200-578-6	64-17-5	70%

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VI. CONDITIONING FORM

Liquid

VII. PACKING MANNER (type, capacity)

PET packing with the capacity of 0.065L; 0.07L; 0.075L; 0.08L; 0.085L; 0.25L; 0.3L; 0.5L; 1L; 3L; 5L
5-liter HDPE packing



VIII. UTILISATION FIELD AND AREA

A. Utilisation field	Human hygiene
B. Application area	Used for hand's hygienic disinfection

IX. EFFICIENCY

Activity	Testing method / Testing protocol	Species / Strand	Concentration	Action times
Bactericidal	PN EN 1500/2002	<i>Escherichia coli</i> K12 NCTC 10538	3ml (undiluted)	30 seconds

X. UTILISATION INDICATIONS

Application method	Working solution's concentration / application dosage	Action time
By direct hand application	3ml undiluted product	30 seconds

XI. BIOCIDAL PRODUCT'S LABELLING

A. Biocidal product with active substances - substances

Pictograms, symbols and hazard indication	GHS02	Hazard
Hazard pictograms (H)	H225 – Highly flammable liquid and vapours	
Precautionary statements (P)	P102 – Keep out of the reach of children P210 – Keep away from heat / sparks / open flame / hot surfaces sources – Smoking is forbidden P305+P351+P338-In the event of eye contact: rinse carefully with water for several minutes. Remove the contact lenses, if required, and provided this could be easily done. Continue rinsing P301+P310-In the event of swallowing: immediately call a Toxicology Information Centre or a physician. P410+P412 – Protect from sunlight. Do not expose to temperatures in excess of 5-25°C	

XII. CATEGORY OF USERS

Population

XIII. RECOMMENDATIONS/RESTRICTIONS REGARDING HEALTH PROTECTION AND ENVIRONMENTAL FACTORS

Not available

The advice is valid through: 31 Dec. 2024

The advice contains 2 pages

PRESIDENT
Dr. Chem. Gabriela Cilinca
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Subsemnatul, Vicol Claudiu Octavian, traducător autorizat de Ministrul Justiției din România cu autorizația nr. 7402/2002, certific exactitatea acestei traduceri cu textul înscrisului fotocopie în limba engleză vizat de mine. Traducătorul nu își asumă răspunderea pentru conținutul și autenticitatea înscrisului în limba engleză.

Traducător Vicol Claudiu Octavian
Autorizația nr. 7402/2002

