



SAFETY DATA SHEET

SDS according to Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Annex II-EU

Date issued: 10.05.2020 Revision Date: 01.07.2020 Revision Number 1.1

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : MEDEKO OPTIMA hand sanitizer gel

Product type: BIOCIDES

Type of biocidal product according to Annex V of Regulation (EC) 528/2012

Main group 1 – Disinfectants

Product-type 1 – Human hygiene

1.2 Relevant identified uses of the substance or mixture and uses advised against: No further relevant information available.

Use of the substance / mixture:

Disinfectant with bactericidal, fungicidal and partly virucidal (enveloped viruses) action for hygienic disinfection of hands on an alcohol basis. For professional and non-professional use.

The field of application is hygienic hand disinfection in medical and health establishments, schools and kindergartens, food production and trade sites, public facilities, cosmetic and pharmaceutical industry, gyms, sports halls, etc.

1.3 Details of the supplier of the safety data sheet

Authorisation holder:

Medeko Commerce LTD
Bulgaria, 1000 Sofia, 30 Tzar Samuil str.
tel. +359 29588825
www.medeko.biz
e-mail: medeko@medeko.biz

Manufacturer:

RELINA LTD BG-2200 Slivnitsa, 4A P. Hilendarski Str. Tel. +359 727 42081 e-mail: relina@relina.com	CONVOY-WORLD S.A. Kytinsko shose - Zavod Convoy BG - 1280 Sofia - Novi Iskar Tel. +359 2 400 50 23 e-mail: convoy@convoybg.com	BODI BEAUTY LTD BG-4002 Plovdiv 9 Zahari Stoyanov Str. Tel. +359 32 649575 e-mail: office@bodid.net	BULGARIAN ROSE PLC BG-4300 Karlovo, 1 Industrial zone Str. Tel. +359 335 95328 e-mail: contact@bulgarianrose.bg
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1.4 Emergency telephone number

National Toxicology Information Center

Multi-profile hospital for active treatment and emergency medicine "NI Pirogov"

Emergency telephone number: +359 2 9154 233

E-mail: poison_centre@mail.orbitel.bg <http://www.pirogov.bg>

For emergencies: 02 9154 409 (standard working hours without Saturday and Sunday) or 02 9154 346 (uninterrupted service)

SECTION 2: Hazards identification

2.1 Classification of substance or mixture

2.1.1 Classification according to Regulation (EC) No. 1272/2008 (CLP):

H226

2.1.2 Additional information: For the full text of the hazard statements: see SECTION 16

2.2 Label elements

Labeling according to Regulation (EC) No. 1272/2008 (CLP)

Hazard Pictograms: GHS02; GHS07



Signal word: **Danger**

Hazard statements:

H225: Highly flammable liquid and vapour.

H319: Causes serious eye irritation.

Precautionary statements:

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

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



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P233 Keep container tightly closed.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P501 Dispose of contents/container to according to national regulations.

2.3 Other hazards PBT / vPvB The chemical contains no PBT or vPvB substances.

SECTION 3: Composition/information on ingredients

3.1 Chemical characteristics:

3.1.1 Substances Not applicable

3.2. Mixtures

A multi-component mixture that contains the following ingredients:

Substance	CAS №	EC №	Concentration % (w/w)	Hazard classification
Ethanol (ethyl alcohol) (80-100%), denatured	64-17-5	200-578-6	70	H225, H319, H336
Parfum			0-0.1	H315 H319 H317 H411

Additional information: For the full text of the hazard statements: see SECTION 16

SECTION 4: First aid measures

4.1. Description of first aid measures

General:

Emergency telephone number: see section 1.4.

Remove contaminated clothing immediately

Take the affected person out of the danger area and put him to bed.

Remove affected to fresh air.

Laying down to rest and turning.

Inhalation:



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Fresh air and rest. Get medical attention if any discomfort continues.

In case of unconsciousness, place and transport in a stable lateral lying position.

Skin contact:

Cleaning with soap and water, if possible with polyethylene glycol 400.

Get medical attention if skin irritation continues.

Eye contact:

Flush immediately with plenty of water for at least 5 minutes. Hold the eyelids apart. Remove any contact lenses. Contact physician if irritation persists.

Ingestion:

Immediately rinse mouth and drink plenty of water (200-300 ml). Do not induce vomiting. Contact physician if larger quantity has been consumed.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

The preparation is flammable. Larger fires are extinguished with alcohol-resistant foam. Small fires - with carbon dioxide or fire extinguishing powder.

Improper extinguishing media: Do not use water jet. It can be used to cool containers.

5.2. Special hazards arising from the substance or mixture

In case of fire the following gases may be released: CO (Carbon monoxide), CO₂ (Carbon dioxide).

Combustion of polyethylene packaging can form: CO, CO₂, ethylene, methane, propane, propylene, formaldehyde, acetaldehyde, cycloaliphatic hydrocarbons.

5.3. Advice for firefighters

Special protective equipment: Wear self-contained breathing apparatus. Wear full protective equipment in case of fire.

Additional information:

Collect contaminated fire extinguishing water separately. Do not dispose of in the city sewer system. Dispose of fire residues and contaminated fire extinguishing water in accordance with the regulations of the competent authorities.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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Wear personal protective equipment. Work clothes, goggles, providing good general or local ventilation. Do not breathe vapor. Avoid contact with eyes.
Remove all ignition sources and ventilate the area. Do not breathe vapour. Use protective equipment as referred to in section 8.

6.2. Environmental precautions

Do not allow the product to enter water sources.
Collect contaminated fire extinguishing water separately.
Do not allow to enter into sewer, water system or soil.

6.3. Methods and material for containment and cleaning up

Limit spillage.
It is absorbed with inert materials (sand, sawdust or soil). Wash with water and detergent.

6.4. Reference to other sections

See SECTION 8 for exposure control information and personal protective equipment.
See SECTION 13 for information on waste disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Take the necessary measures not to exceed the limit values for the working environment. Avoid contact with eyes.
Do not pour the excess preparation into the sewer, but use it as intended.
See SECTION 8 for protective equipment.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed original packaging, in dry and well ventilated rooms, away from food, beverages and at temperatures not exceeding 30 °C. Do not expose to direct sunlight. Do not store with strong oxidizing agents and concentrated acids.

Recommended storage temperature: 5 - 25 °C.

7.3. Specific end use(s)

The preparation is intended mainly for mass and professional use - hygienic disinfection of hands and skin.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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Limit values for exposure in the air of the working environment (according to Ordinance № 13 of the Ministry of Health, SG No. 8/2004)

Ethanol , CAS No 64-17-5 - 1000.0 mg/m³/ 8 h;

8.2. Exposure controls

Limitation of exposure on workplace

Provide adequate ventilation is recommended in order to control the exposure limit values for the components of the preparation.

Respiratory protection

Do not breathe vapor. Provide general ventilation.

Hand protection

There are no special requirements.

Eye protection

There are no special requirements.

Body protection

Protective work clothing.

Appropriate environmental exposure control

Excess detergent should not be discharged into the sewer, but should be used only for its intended purpose. Avoid contamination of soil, air, water sources

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Gel-like mass
Odour	Specific, of ethanol
Colour	Colourless
pH	5.9-6.1
Melting point	Not applicable
Boiling point / boiling range	78°C
Flash point	23.5°C
Auto-ignition point	363°C
Evaporation rate	Not determined



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Flammability (solid, gas)	Not determined
Lower / upper limit of flammability and explosion	Not determined
Vapor pressure	Not determined
Vapour density	Not determined
Density at 20 °C	Not determined
Solubility	Solubility in water/Soluble
Partition coefficient: n-octanol / water	0,35 at 20°C
Specific gravity	0,820 -0.900
Decomposition Temperature	No information available
Viscosity	Not determined
Explosive properties	Not determined
Oxidising properties	No information available

9.2. Other information Other physical and chemical properties

No further information is available.

SECTION 10: Stability and reactivity

10.1. Reactivity: flammable

10.2. Chemical stability: Stable under normal temperature conditions and recommended use.

Thermal decomposition / conditions to be avoided: Chemically stable under the conditions of storage, handling and use specified in the technical specification.

10.3. Possibility of hazardous reactions: No

10.4. Conditions to avoid: Avoid heat, flames and other sources of ignition.

10.5. Incompatible materials: Strong oxidising substances and acids.

10.6. Hazardous decomposition products: None under normal conditions. See also section 5.2.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Information on likely routes of exposure:

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Visual contact
Skin contact
Potential health effects
Mixture: No data available

Components: Ethanol
CAS №:64-17-5
EO number: 200-578-6
Index number : 603-002-00-5

Acute toxicity

Based on available data, the classification criteria are not met.

- LD/LC50 (lethal dose/ lethal dose) relevant for categorization concentration)
Quantitative data on the toxicological effect of this product are not available.
- Component Type Value Biological species
Orally LD50 8.350 мг/кг (mouse); 10.470 мг/кг (rat)
Inhalation LC50/4 ч. 116,9 мг/л (rat)
- Primary irritation:
Based on available data, the classification criteria are not met.
- Skin corrosion / irritation
Based on available data, the classification criteria are not met.
- Serious eye damage / eye irritation
Causes serious eye irritation.
- Respiratory or skin sensitization
Based on available data, the classification criteria are not met.
- Information on the following groups of potential consequences:
-CMR-effects (carcinogenic effects and those affecting hereditary mass and reproductive capacity)
-Germ cell mutagenicity
Based on available data, the classification criteria are not met.
- Carcinogenicity
NOAEL >3.000 мг/кг bw/day (rat)
Based on available data, the classification criteria are not met.
- Reproductive toxicity
NOAEL 13.800 мг/кг bw/day (mouse)
Based on available data, the classification criteria are not met.
- STOT-single exposure (Specific target organ toxicity)
Based on available data, the classification criteria are not met.
- STOT-repeated exposure (Specific target organ toxicity)
Based on available data, the classification criteria are not met.
- Aspiration hazard
Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

The product has not been tested. The data are for the active substance Ethyl alcohol

Fish: LC50 > 1000 mg/ l (96 h)



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Daphnia magna: EC50 > 10000 mg/ l (48 h)

Algae: EC50 - 275 mg/l (72h)

12.2. Persistence and degradability

Biodegradability: No data available on the preparation. Easy biodegradability of the active substance.

Hydrolysis, Oxidation: Rapid oxidation.

12.3. Bioaccumulative potential

Not expected to bioaccumulate.

Bioconcentration factor factor No data available

Octanol-water partition coefficient No data available

12.4. Mobility in soil

Absorption coefficient: No data available

12.5. Results of PBT and vPvB assessment According to Annex XIII of Regulation (EC) No 1907/2006

The chemical contains no PBT-substances.

The chemical contains no vPvB substances.

12.6. Other adverse effects: No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recommendations:

Recycling of used packaging is only possible after rinsing it completely with water. Do not empty into drains or the environment.

See specials

Waste: According to national legislation.

Packaging / container waste: Waste code according to Ordinance №3 on Classification of the waste / State Gazette No. 44/2004

Waste treatment according to the current legislation: The waste should be handed over to licensed companies for activities with hazardous waste.



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SECTION 14: Transport information

14.1. UN number ADR, IMDG, IATA: 1170

14.2. UN proper shipping name:

ADR ETHANOL (ETHYL ALCOHOL)
IMDG ETHANOL (ETHYL ALCOHOL)
IATA ETHANOL

14.3. Transport hazard class(es)

Transport label: ADR, IMDG, IATA
3 (F1) flammable liquids

14.4. Packing group: II

14.5. Environmental hazards: The product is not dangerous for the environment.

14.6. Special precautions for user: Caution: Flammable liquids

Kemler's number 33, EmS number: F-S, S-D. Do not transport together with food for humans and animals.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulations and EU legislation

REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 (REACH).

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).



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COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).

REGULATION (EC) No 1271/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on classification, labelling and packaging of substances and mixtures.

DIRECTIVE 1999/45/EC of the European Parliament concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the on classification, labelling and packaging of substances and mixtures.

DIRECTIVE 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations.

ECB-ESIS-European chemicals - information system, IUCLD.

DIRECTIVE 98/24 / EC on the protection of the health and safety of workers and the risks related to chemical agents at work.

DIRECTIVE 2000/39/EC establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24 / EC on the protection of the health and safety of workers and the risks related to chemical agents at work.

DIRECTIVE 89/656 / EEC on the minimum health and safety requirements for the use of personal protective equipment at the workplace.

DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste.

DIRECTIVE 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy.

Council Directive 91/689/EEC of 12 December 1991 on hazardous waste.

Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.

Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste.

15.2. Chemical safety assessment

No safety assessment has been performed for this product and the substances contained in it.

SECTION 16: Other information



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This information is based on the current level of our knowledge at the time of writing. However, it does not guarantee the specific properties of the product and does not constitute a legal basis for a relationship. The information provides basic guidelines for safe handling of this product regarding its storage, processing, transport and disposal. Data cannot be transferred to other products. If the product is mixed or processed with other materials, or if it is subjected to treatment, the data in this Safety Data Sheet may not be transferred to the new material unless otherwise stated.

List of relevant H-phrases Section 3

Hazard warnings:

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

H411 Toxic to aquatic life with long-lasting effects.

Basic references and data sources

REGULATION (EC) No 1907/2006 (REACH).

REGULATION (EC) No 1272/2008 (CLP, EC GHS)

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre,
Commission of the European Communities

<http://esis.jrc.ec.europa.eu>

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Training tips:

Minimum training of personnel who will work with this product is recommended in order to facilitate the understanding and interpretation of this safety data sheet and the labeling of the product.

END of SAFETY DATA SHEET