

Material Safety Data Sheet

In compliance with Regulation (EU) 2015/830 from 28th May 2015 for amending and supplementing Annex II of 1907/2006/EC/REACH/ and Regulation 1272/2008/EC Company, manufacturing the product:

BATERIA Plc.

Date of issue: 31.03.2020

Promisclena 23 Str. 6000 Stara Zagora

Edition: 02

Packaged by: ADVA International LTD Promisclena 23 Str. 6000 Stara Zagora

Manufactured for: ADVA International LTD Promisclena 23 Str. 6000 Stara Zagora

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/ESTABLISHMENT

1.1. Product identifier:

The SDS relates to **Disinfecting hand gel “ADVA Max Cleaner Gel”**.

1.2. Relevant identified uses of the substance or mixture and uses advised against: **Disinfecting hand gel “Max Cleaner”** is a biocidal product for active hand cleaning without water. The product is suitable for hand hygiene when travelling, after using public transport, when walking in nature, etc.

Permission for releasing a biocidal product onto the market No 0918-1/29.03.2010.

Group 1 Disinfectants and general biocides;

Subgroup 1. Biocides for personal hygiene.

Application scope: Biocide with bactericidal properties for hand hygiene disinfection

Type of biocidal product: Liquid, gel

Application: Mass and professional

1.3. Details of the supplier of the Safety Data Sheet:

Company, manufacturing and supplying the market – name and address:

BATERIA Plc. Nikopol, 26 Hristo Botev Str., postcode 5940

Additional information can be obtained at: +359 2 936 15 15

Email of the individual in charge of the Safety Data Sheet: *max-am@spnet.net*.

1.4. Emergency telephone number

National toxicological information centre, Multifunctional hospital for active healthcare and emergency medicine "N.I.Pirogov“:

Emergency telephone number/fax: +359 2 9154 233

Email: *poison_centre@mail.orbitel.bg*

<http://www.pirogov.bg>

Access restrictions: no access restrictions 24 hours per day.




SECTION 2. HAZARD DESCRIPTION

BATERIA Plc. offers with a preventive purpose the following classification and labeling of **Disinfecting hand gel “ADVA Max Cleaner Gel”** based on personal information relating to its ingredients.

2.1. Classification of the substance or mixture

In compliance with Regulation (EC) No 1272/2008 (Regulation CLP) the product with trade name **Disinfecting hand gel “Max Cleaner”** is a mixture, according to Article 2, paragraph 8 and has the following classification in hazard classes/categories with the corresponding hazard warnings (Look at table 1).

Table 1

Hazard class/Hazard category:	Hazard warnings:	Pictogram, signal word:	Safety recommendations:
Flammable liquids, hazard category 2.	H 225 Highly flammable liquid and vapours.	Pictogram: GHS02  Signal word: Dangerous!	Safety recommendation for prevention: P210, P233, P240, P241, P242, P243, P280 Safety recommendation for reaction: P303 + P361 + P353, P370 + P378 Safety recommendation for storage: P403 + P235 Safety recommendation for discharge: P501
Serious eye harm/irritation, hazard category 2	H 319 Causes serious eye irritation.	Pictogram: GHS07  Signal word: Caution!	Safety recommendation for prevention: P264, P280 Safety recommendation for reaction: P305 + P351 + P338, P337 + P313
Specific toxicity for certain organs – single time exposure – category 3.	H 336: May cause drowsiness or dizziness.	Pictogram: GHS07  Signal word: Caution!	Safety recommendation for prevention: P261, P271 Safety recommendation for reaction: P304 + P340, P312 Safety recommendation for storage: P403 + P233, P405 Safety recommendation for discharge: P501

For the full text of hazard warnings and safety recommendations, included in this section, look at Section 16.

2.2.Label elements: in compliance with Regulation 1272/2008/EO (CLP) the following information should be put on the product's label: **Pictograms for hazard**



GHS02: FLAME



GHS07: EXCLAMATION MARK

Signal word: Dangerous!

Hazard warnings:

H 225 Highly flammable liquid and vapours.

H 319 Causes serious eye irritation.

H 336 May cause drowsiness or dizziness.

Safety recommendations:

P 101 If medical help is needed, have product container or label at hand.

P 102 Keep away from children reach.

Safety recommendation for prevention:

P 210 Keep away from heat/sparks/open flame/hot surfaces. Smoking is prohibited.

P 233 Container should be stored tightly closed.

P 261 Avoid inhalation of evaporations/aerosols.

Safety recommendations for reaction:

P370 + P378 In case of fire: Use air-mechanical foam, carbon dioxide, dry powder extinguisher.

P305 + P351 + P338 IN CASE OF EYE CONTACT: Wash carefully with water for a few minutes. Remove contact lenses, if you have such and as far as possible.

Keep washing.

Safety recommendation for storage:

P403 + P235 Should be stored at a well aired place. Should be stored at a cool place.

Safety recommendation for discharge:

P 501- The content/container should be discharged in compliance with legislation.

Additional information:

EUH 210 – Safety Data Sheet available at request.

Disinfecting hand gel “ADVA Max Cleaner Gel” has biocidal and cosmetic properties and therefore is under Regulations: REGULATION (EU) 528/2012 of the European Parliament and the Council from 22th May 2012 regarding releasing onto the market and use of biocidal products (BPR) and REGULATION (EU) No 1223/2009 of the European Parliament and the Council from 30th November 2009 regarding cosmetic products. According to their requirements, the product ingredients and the active substance content should be put on the packing label:

INGREDIENTS /INCI: ALCOHOL DENAT, AQUA, TRIETHANOLAMINE, CARBOMER, PROPYLENE GLYCOL, GLYCERIN, PARFUM. **Name of the active substance: Ethanol (ethyl alcohol)**

Ethanol content: 62,0 g /100g.

Application: Pump and rub palms vigorously for 60 seconds, so that the skin remains moist during the whole exposure time. It is not necessary to wash with water after use.

2.3. Other hazards:

PBT/vPvB substances: The product does not contain substances PBT/vPvB (resistable, bioaccumulating and toxic/very resistable and very bioaccumulating) according to Annex XIII of REACH (Regulation (EC) No 1907/2006).

Substances, included in Annex XIV and Annex XVII of REACH: Irrelevant.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances – irrelevant.

3.2. Mixtures:

General characteristic of chemical substances: Disinfecting hand gel “ADVA Max Cleaner Gel” is a mixture of denatured ethyl alcohol, skin moisturizing agents, perfume and water.

3.2.1. Information on mixture ingredients, important for classifying the mixture in hazard classes/categories in compliance with the criteria of Regulation (EC) № 1272/2008, look at table 2.

Table 2

Chemical name under IUPAC / INCI	CAS № / <u>EC №</u>	Concentration, mass procents w/w %	Classification according to Regulation (EC) № 1272/ 2008 (CLP) /Hazard classes and categories, hazard warnings, pictogram, signal word/
Ethyl alcohol Ethanol / Alcohol REACH Registration number: 01-2119457610-43-XXXX	64-17-5/ <u>200-578-6/</u>	62,00 (69,6 content %)	Flam. Liq. 2 H225 /Flammable liquids, hazard category 2: H225/; Eye Irrit. 2 H319 /Serious eye harm/irritation, hazard category2: H 319/ STOT SE 3 H336 /Specific toxicity for certain organs – single time exposure, hazard category 3, drug effects: H 336/. Danger! / GHS 02 – flame GHS 07 – caution
Butanone / MEK Methyl ethyl ketone <i>/used as a denaturant in ethyl alcohol/</i>	78-93-3 <u>201-159-0</u>	≤ 0,62	Flam. Liq.2 H225 /Flammable liquids, hazard category 2: H 225/; Eye Irrit.2 H319 /Serious eye harm/irritation, hazard category 2: H 319/; STOT SE 3 H336 / Specific toxicity for certain organs – single time exposure, hazard category 3, drug effects: H 336: H 336/. Danger! / GHS02, GHS07

Isopropyl Alcohol /Propan-2-ol REACH Registration number: 01-2119457558-25-XXXX <i>/used as a denaturant in ethyl alcohol/</i>	67-63-0 <u>200-661-7</u>	$\leq 0,62$	Flam. Liq.2 H225 /Flammable liquids, hazard category 2: H 225/; Eye Irrit.2 H319 / Serious eye harm/irritation, hazard category 2: H 319/; STOT SE 3 H336 / Specific toxicity for certain organs – single time exposure, hazard category 3, drug effects/. Danger! GHS02, GHS07
2,2',2''-nitrilotriethanol TRIETHANOLAMINE	102-71-6/ <u>203-049-8</u>	0,60	Eye Irrit. 2 H 319 / Serious eye harm/irritation, hazard category 2: H 319/ Caution! GHS07
Perfume composition Coconut TH	Manufacturer: CARINSA Pol. Ind. Can Llobet	0,05	Skin Sens. 1, H 317 /Sensitivity — skin, hazard category 1: H 317/
	C/J. Cuatrecasas i Arumh, 2 08192 Sant Quirze del Vallès (Barcelona) SPAIN Tel. + 34 93 712 32 33 Fax + 34 93 711 23 64 carinsa@carinsa.com www.carinsa.com		Aquatic Chronic 3, H412 /Dangerous for water environment, chronic danger, category 3 H412/, Warning! GHS 07

The text of hazard warnings (H-phrases) is in Section 16 of SDS.

3.2.2. Information on substances, not classified as hazardous, as not being dangerous for the health or environment, according to Regulation (EC) № 1272/2008 or their content in the product is in concentrations, lower than the general limit amounts, indicated in table 1.1 in Regulation (EC) No 1272/2008 and of the general limit concentration, indicated in parts 3-5 from Annex I of Regulation (EC) № 1272/2008.

Trade/Chemical name according to IUPAC, INCI	CAS № / <u>EC №</u>	Concentration, (%)	Classification according to Regulation (EU) № 1272/2008 (CLP)
Water, Aqua	7732-18-5 <u>231-791-2</u>	Up to 100,0	It is not classified as dangerous substance
Synthalen® L/Carbomer	9007-20-9 <u>618-435-5</u>	0,40	It is not classified as dangerous substance
Glycerol, Glycerine	56-81-5 <u>200-289-5</u>	0,20	It is not classified as dangerous substance

Propane-1,2-diol PROPYLENE GLYCOL	57-55-6 <u>200-338-0</u>	0,20	It is not classified as dangerous substance
Denatonium Benzoate <i>/used as a denaturant in ethyl alcohol/</i>	3734-33-6 <u>223-095-2</u>	< 0,001	Severe toxicity (oral), hazard category 4 H302; Skin irritation, category 2 H315; Eyes irritation, category 2, H319; Specific toxicity for certain organs – single time exposure, hazard category 3, irritation of respiratory tract: H 335.

3.2.3. Substances, corresponding to the criteria for resistance, bioaccumulation and toxicity according to Regulation 253/2011 for amending Regulation (EC) № 1907/2006 of the European Parliament and the Council regarding registration, assessment, permission and restriction of chemicals (REACH), specifically Annex XIII – look at Section 12, paragraph 5.

SECTION 4. FIRST AID MEASURES

4.1. First aid measures description

In case of inhalation: In case of accidental inhalation of the product, the patient should be moved out at fresh air. Body temperature should be kept normal. If not feeling well or symptoms of intoxication, cough or hard breathing occur and develop, find medical help immediately and show the label or the safety data sheet of the product.

In case of skin contact: Take off contaminated clothes. Wash immediately the affected area with plenty of cold or lukewarm water and neutral soap or use appropriate product for cleaning the skin. In case of skin or rash, contact doctor immediately.

In case of eyes contact: Take off contact lens. Rinse while eye is open for at least 15 minutes under running water or shower aiming direct water stream. Rinse eyes with saline solution. Consult doctor.

In case of ingestion: Rinse mouth with water. Don't provoke vomiting. Don't give milk or fizzy drinks. Never give anything in mouth to unconscious person. If symptoms don't disappear and severe vomiting or other complications occur, lay the affected person steadily sideways. Call a doctor immediately.

4.2. Most important severe and occurring after certain period of time symptoms and effects: In contact with eyes: irritation, redness, possible occurrence of watery fluid, blurred eyesight. In case of skin contact: irritation, redness, rash. In case of aerosol inhaling: respiratory tract irritation. Inhaling of highly concentrated vapours may cause dizziness and vertigo. In case of ingestion: mouth and throat irritation, dizziness, vertigo, головоболит.

4.3. Indication of necessity for any urgent medical care and special treatment.

Mandatory qualified medical attention if swallowed and in contact with eyes, recommended – in case of inhalation and skin contact.

In case of ingestion: Drain copious salivation. Hemodynamic stabilization - infusion resuscitation, CS. Parenteral nutrition in the early days of intoxication. H2 blockers.

In case of eye contact: Immediately seek emergency medical help. Ophthalmoscope examination is recommended. Symptomatic treatment.

Special first-aid measures: No specific antidote. Treatment is symptomatic.

SECTION 5. FIRE-FIGHTING MEASURES

5.1. Fire extinguishers

Suitable Fire extinguishers:

The mixture meets the criteria of the CLP Regulation for the classification of Flammable Liquids. There is no risk of fire if the safety precautions and conditions of use and storage are observed.

In case of ignition if improperly used, stored or used, apply heavy spray with alcohol-resistant mechanical foam; extinguishing powder; water aerosol spray; carbon dioxide (CO₂) in accordance with the Fire Safety Regulations. Add more foam as it is partially destroyed by the product. Consideration should also be given to materials in the vicinity of the fire. Cool endangered vessels with a dispersed water jet.

Unsuitable fire fighting means for safety reasons:

Not recommended: Thick water jet, inert gases, halons.

5.2. Special hazards arising from the substance or mixture

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

5.3. Firefighters advice.

While in danger zone: Wear self-contained breathing apparatus and protective suit! The minimum required equipment in case of fire should be provided (fire blankets, portable first aid kits) in accordance with Directive 89/654/EEC. Incineration residues and contaminated extinguishing water must be disposed of in accordance with local administrative requirements.

SECTION 6. ACCIDENTAL RELEASE MEASURES.

6.1. Personal precautions, protective equipment and emergency procedures.

6.1.1. For non-emergency staff

Small Spill Response: Wear PPE for skin and eye protection. Allow spillage to evaporate if safe or absorb with soil, sand or other inert material, then transfer to suitable containers for recovery or disposal. Air the contaminated area well. Use non-spark forming tools. Do not use electrical equipment unless it is spark safe.

Large Spill Response: Wear a complete PPE kit according to Section 8. Restrict spill distribution by constructing a dike using absorbent materials that are then submitted for disposal. Inform emergency responders and relevant authorized bodies.

6.1.2. For emergency responders: Full PPE kit should be provided for use. The spill should be stopped if this can be achieved without risk. Wear suitable protective clothing. Non-emergency responders should stay away, danger area should be isolated and access should be denied. Low areas should be avoided, where vapours can accumulate and get burning.

If necessary, evacuation of workers should be organized. Those who do not have protective equipment should beware. Regional treatment plant and RIEW should be informed.

6.2. Environmental precautions

Take measures to prevent contamination of surface and groundwater, soil, and discharge into sewage systems.

a) Proper storage: Store product in original tightly closed containers in a ventilated place, at a temperature below 25°C without access to light and heat.

b) Prevention of sewage pollution: Cover drainage shafts with suitable materials such as Polyvinyl chloride, Polyethylene and others.

c) Environmental Pollution Prevention: Locate the spill by constructing barriers of soil, sand and other aggregates. In the event of an accident and/or spillage of the mixture, measures should be taken to locate and limit it, and the collected quantity of the mixture to be temporarily stored in special tightly closed and labeled containers, and then handed over to persons holding a permit according to Article 67 of the Waste Management Act.

6.3. Methods and materials for containment and cleaning.

Methods for spill cleaning:

- eliminate the cause (source) of the leak;

- exposure control: Provide local and general room ventilation, maintaining product concentrations below acceptable limits;
- limit the spread of spills through aggregates;
- collect waste from the mixture using a suitable adsorbent;
- waste from the mixture and from the spent adsorbent to be stored in containers for temporary storage and to be handed over to authorized persons for waste management.
- Restriction and cleaning materials:
 - a) spill containment materials: soil, sand, clay and other aggregates;
 - b) spill cleaning materials: adsorbents/eg. Chemizorb®, inert adsorbents/absorbents such as kieselguhr, silica gel and others. For subsequent disposal, follow the recommendations in section 13.

SECTION 7. HANDLING AND STORAGE OF SUBSTANCE/MIXTURE

7.1. Safety work precautions

For safe work of workers and employees: Provide sufficient ventilation in the work premises.

Avoid spilling the product. Do not eat, drink or smoke while working. Electrical equipment must be protected in accordance with the relevant standard. Wash your hands before each break and after work.

For other users of this product: Read the label before handling the product and follow the instructions for use and storage. Keep away from children! Avoid direct eye contact! For external use only! Use on irritated and damaged hand skin is not recommended!

7.2. Conditions for safe storage, incl. incompatibilities.

a) Product storage:

Keep the packaged product in a dry, well-ventilated place in tightly closed original packages. Recommended storage temperatures from 0°C до 30°C. Do not leave the product near flammable sources. Keep away from oxidizers and strong mineral acids. Keep away from food, drinks and children. Provide adequate ventilation. See section 10 of the SDS.

Compatible materials: stainless steel, titanium, cast bronze, cast iron, carbon steel, polypropylene, neoprene, nylon, viton, ceramics, carbon, glass. b) **Incompatibilities:**

Incompatible substances and materials: strong mineral acids, oxidizing agents, aluminum, copper and zinc at high temperatures and their alloys, natural rubber.

Incompatible packaging: Do not store in metallic or methyl methacrylate plastic containers.

Conditions to avoid:

Incompatible with the following products: Strong mineral acids, oxidizing agents. High temperature aluminum, reducing agents, combustible materials (wood, cellulose), organic materials, metals, acids.

7.3. Specific end use (s): Specific end use refers to the identified use as a biocidal product referred to in Section 1.2.

SECTION 8. EXPOSURE CONTROL AND PERSONAL PROTECTION EQUIPMENT

8.1. Control parametres

- **National occupational exposure limit values**

Substances with concentration in the air of the working environment is to be monitored in accordance with the requirements of REGULATION No 13 of 30 December 2003 on the protection of workers from the risks associated with exposure to chemical agents at work/Ref. DV. Issue 8 from 30 January 2004, amend. DV. Issue 71 from 1 September 2006, amend. DV. Issue 67 from 17 August 2007, amend. DV. Issue 2 from 6 January 2012, amend. and ext. DV. Issue 46 from 23 June 2015/:

Chemical agent /Substance/	Work environment air limit value (mg/m ³)	Type of exposure
Ethyl alcohol	1000,0 mg/m ³ -	8 hours 15 minutes
Isopropanol /Isopropyl alcohol/	980 1225	8 hours 15 minutes
Methylethylketone	590 mg/m ³ – for 8 hours 885 mg/m ³ – for 15 minutes	8 hours 15 minutes

- **Specific informaiton** /DNEL: calculated no-effect level, inactive dose and PNEC: estimated inactive concentration for the relevant ways of exposure (short-term/long-term exposure)/, provided for the main ingredients of the product:

Data refer to ethyl alcohol /Ethanol/:
DNEL values

Method of absorption	Exposure duration	Action	Value

Dermal	Prolonged (chronic)	systematical	343 mg/kg weight/day
Inhalation	Short (acute)	local	1900mg/m ³ (1000 ppm)
Inhalation	Prolonged (chronic)	systematical	950mg/m ³ (500ppm)

PNEC values

- PNEC aqua(freshwater): 0.96 mg/L
- PNEC aqua (sea water): 0.79 mg/L (ethanol)
- PNEC aqua (with intermittent release): 2.75 mg/L
- PNEC STP (Waste water treatment plant): 580 mg/L
- PNEC precipitate (freshwater): 3.6 mg/kg dw
- PNEC precipitate (sea water): 2.9 mg/kg dw
- PNEC soil: 0,63 mg/kg dry weight
- PNEC oral: 0.72 g/kg food

Data refer to Butanone/Methylethylketone /:

Long-term Exposure Limit (LTEL) - 600 mg/m³; 200 ppm Short-term Exposure Limit (STEL) - 900 mg/m³; 300 ppm

Data refer to Propan-2-ol:

DNEL values

DNEL Long-term inhalation exposure, workers = 500.0 mg/m³

DNEL Long-term dermal exposure, workers = 888.0 mg/ kg bw/day (mg/kg body weight per day)

DNEL Long-term inhalation exposure, population / End users / = 89.0 mg/m³

DNEL Long-term exposure dermal way, population / End users / = 319.0 mg/kg bw/day (mg/kg body weight per day)

End users, Long-term - organic effects, Ingestion = 26 mg/kg body weight per day

PNEC values

PNEC for aquatic organisms, fresh water = 140,9 mg/l

PNEC for aquatic organisms, seawater = 140,9 mg/l

Occasional release: 140,9 mg/l

Wastewater treatment plant: 2251 mg/l

Sediment, dry weight = 552 mg/kg

Soil = 28 mg/kg

(values are derived from the Chemical Safety Report).

8.2 Exposure control

8.2.1. Appropriate engineering control:

a) Provide adequate local exhaust ventilation or natural ventilation of the premises where the product is manufactured, packaged, stored or used. Provide water sources and eyewash stations near the work area. Need for ventilation in emergencies.

Do not smoke at the workplace. Avoid contact with eyes and skin. Work with the substance in a predominantly closed system equipped with exhaust ventilation.

b) Ventilation operation is not required for identified use of the mixture.

8.2.2. Individual protection measures

Workers must be fully equipped with personal protective equipment. The type and material of the protective gear must comply with the national/European legal provisions in force with regard to health and safety at work. It is advisable to use basic personal protective equipment marked "CE" in accordance with Directive 89/686/EC. For more information on **personal protective equipment** for exposure to the mixture during identified use, production and accident (use, cleaning, maintenance, protective class), see the table:

Ways of exposure	Identified use	Manufacturing: PPE Category I, according to Directive 89/686/EIC	Accident: PPE Category II, according to Directive 89/686/EIC
Eyes/Face	Protective glasses, according to standart BIS EN 166:2003.	Protective glasses. EN 1662003	Protective glasses. EN 166-2003 Tight with side shield
Hands	Not required.	Protective gloves, EN 374-2015 Material: Butyl rubber, Natural rubber, Neoprene Protection index: class 5; Breakthrough time > 240 min.	Protective gloves, EN 374-2015 Material: Neoprene; Nitrile or Butyl rubber; Protection index: class 6; Breakthrough time > 480 min.
Body	Not required.	Use chemical resistant gloves, boots and apron (where there is a risk of splashing).	Waterproof protective clothing. Work clothes should not be made of synthetic textiles (fabrics) which, in the event of fire, melt.
Respiratory tract	Not required.	Not required if ethyl alcohol concentration is under 1000,0 mg/m ³ . Respiratory tract protection required when increasing the concentration of ethyl alcohol and vapour/aerosol formation.	Entire respiratory system mask, EN 14387: 2004 Protection factor 50 or 100: B-1 P or B-2 P. /To be used if the concentration of ethyl alcohol is higher than the limit values

			given in section 8.1./
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8.2.3. Control of the effects of the substance/mixture on the environment

Do not allow product to be released into the environment. Avoid leaks and soil/water contamination caused by leaks. All contaminated wastewater must be treated at an industrial or municipal wastewater treatment plant that includes primary and secondary treatment. Ethanol is classified as VOC (volatile organic compound) according to **COUNCIL DIRECTIVE 1999/13/EC from 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations**. Pollution control measures, such as the combustion or recovery of solvent, should be used in combination with rapid emission control to ensure compliance with this Directive.

The site must have an action plan for spills to ensure that adequate precautions are taken to minimize the impact of episodic releases.

Risk management measures related to the use of the product by consumers: Follow the safety recommendations on the label.

a) Chemical safety report: Not required.

b) Environmental exposure controls: Adherence to good manufacturing practice. Store the mixture in original closed packages. Disposal of waste from the mixture in accordance with the provisions of the Waste Management Act.

Norms for Limit Concentrations (MACs) of harmful substances in ambient air of settlements according to REGULATION No 14 from 23 September 1997 on norms for limit values of harmful substances in ambient air of settlements.

Harmful substances (pollutants)	Average annual concentration, mg/m ³	Average annual concentration, mg/m ³	Maximum one-time Concentration, mg/m ³ (30-minute short-term exposure)
Ethanol	ND	5.0	5.0

Isopropyl alcohol	ND	0.6	0.6
Metylethylketon	ND	ND	ND
Denatonium benzoate	ND	ND	ND

ND – no data

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on main physical and chemical properties

Appearance: Transparent gel mass

Odor: Ethanol and product-specific perfume

Color: colorless

Explosive properties: none

Solubility in water at 20°C: solubility unlimited

pH (directly at 20°C): 6,5 – 7,5

Vapor pressure: at 19,6°C = 57.26 hPa, at 25°C = 78,7 hPa (ethanol).

Relative density: 0,8864 g/cm³ at 20°C

Flash point: 21°C (indoor crucible), 21,3°C (outdoor crucible)

Auto-ignition temperature: from 363°C to 425°C (ethanol)

Melting point/freezing point (°C): About minus 114°C (ethanol)

Boiling point/range: 80°C (at 1013 hPa)

Self-igniting: The product is not self-igniting

Flammability: Flammable product

Explosion hazard: The product is not explosive but explosive mixtures of vapor and air may form.

Explosion limits:

Bottom: 3,7% vol (ethanol)

Upper: 13,5% vol (ethanol)

Vapor density: no information available

Partition coefficient – 0,35 (n-octanol/water) Bioaccumulation is not expected

Viscosity:

Dynamic: No information available

Kinematic: No information available

Organic solvent content: 62.0% w/w

VOC (EC): 62,0%

SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity: No dangerous reactions are to be expected if the chemical storage instructions are followed. /See section 7/. Possible interactions:

- Vapors form explosive mixture with air.
- May react violently with very strong oxidants (eg. perchlorates, peroxides).
- Violent reaction is possible with alkaline and alkaline earth metals, strong acids and strong bases, metal salts, halogens, flammable materials.

10.2. Chemical stability

Stable under the proposed conditions of use, transport and storage (protected from sunlight, in a cool place, separate from incompatible substances).

10.3. Possibility of dangerous reactions

Possible chemical reactions in contact with metals (aluminum) at high temperature. Combustion of the mixture produces toxic gas - carbon dioxide.

10.4. Conditions to avoid

When working with the product, avoid low temperatures as well as heating of closed packages (temperatures above 400C, open fire, heat, direct sunlight); hit on the packaging, contact with flammable substances, strong oxidants, acids and bases, open packaging.

10.5. Incompatible materials

Reducing substances, metals - aluminum, at high temperatures, strong mineral acids, oxidizing agents, rubber.

10.6. Hazardous decomposition products.

Does not decompose if stored and used as intended! Carbon dioxide (CO₂) is released during fire or thermal decomposition.

SECTION 11. TOXICOLOGICAL INFORMATION

The toxicological properties of the product have not been tested. The main toxicological information is based on the toxicological data of the ingredients:

Information on the main hazard classes for the main component of the product – Ethyl alcohol /Ethanol/:

• **Acute toxicity:**

ORAL (Test method: OECD 401 equivalent): Rat LD50: 6.2 - 15g/kgbw INGESTION:
Ingestion of ethanol may have the following effects: central nervous system - depression, nausea/vomiting, symptoms similar to alcohol intoxication.

INHALATION (Test method: OECD 403 equivalent): Rat LC50 (4hr) > 50 mg/l

DERMAL: LD50: 15800 mg/kg.

The available data indicate that the criteria for classification of the substance in the Hazard Class Acute toxicity are not met.

• **Skin corrosion/irritation**

Studies, with all available acute four-hour ethanol exposures, showed no irritation in animals (OECD404 or equivalent) and humans. In humans, multiple-dose (ethanol) studies do not indicate irritation with repeated administration of the whole day at closed conditions for 12 days.

Additional exposures (ethanol) cause irritation. Available data indicate that the classification criteria are not met.

• **Serious eye damage/eye irritation**

Studies according to OECD Guideline 405 indicate that overall ethanol causes moderate eye irritation. All effects disappear within 8-14 days. The level of response is insufficient to classify under Directive 67/548 but sufficient with respect to a conjunctive response that meets the requirements for classification as Category 2 eye irritant under Regulation 1272/2008.

• **Respiratory or skin sensitization**

Skin and respiratory sensitivity: no data available. Available data indicate that the criteria for classification in this hazard class are not met.

• **CMR impacts**

Carcinogenicity: Rat: NOAEL > 3000mg/kg,

Mice: NOAEL female > 4400mg/kg, NOAEL male > 4250mg/kg based on historical control data, BMDL10 = 1400mg/kg based on harmonized data control. In humans, alcohol consumption is associated with increased frequency of some tumors. There is no evidence that humans exposure to ethanol, unless in case of repeated consumption of alcoholic beverages may cause increased frequency of cancer. From available data, criteria for the classification in this class are not met.

Mutagenicity: In vitro tests do not show mutagenic effects In vivo tests do not show mutagenic effects

Terragenicity: Not classified due to lack of abundant data.

- **Reproductive toxicity**

NOAEL (oral, mouse) = 13.8 g/kg (Test method: OECD 416 equiv.)

NOAEC (rat inhalation) > 16000 ppm

DEVELOPMENT TOXICITY (Test method: OECD 414 equiv.):

NOAEL (oral) = 5.2 g/kgbw/day

NOAEC (inhalation) = 39 mg/l

In humans, excessive consumption of alcoholic beverages during pregnancy is associated with the induction of fetal alcohol syndrome in the generation leading to weight loss at birth and the appearance of a physical and mental defect. There is no evidence that these effects can be caused by exposure solely to direct ingestion of alcoholic beverages.

Specific target organs toxicity - single exposure: Ethanol is classified in this hazard class, category 3 and with risk warning H 336:

May cause drowsiness or dizziness.

- **Specific target organ toxicity - repeated exposure:** studies in rats under sub-chronic nutrition or drinking water, NOAELs ranged from 1.73g/kg to 3.9g/kg body weight per day (ethanol). The most sensitive effect, above these doses, was observed on the kidneys in males. Effects were observed only at doses well above the levels that classification would require.

- **Inhalation hazard:** Inhalation of high concentrations of vapor (ethanol) may cause respiratory irritation, headache, nausea, dizziness.

Information on the major hazard classes for Isopropyl alcohol/Propan-2-ol: Oral LD50

(rat) - 5480 mg/kg (OECD Test Guideline 401);

Oral LD50 (rabbit) - 7990 mg/kg;

Dermal LD50 (rabbit) - 12870 mg/kg (OECD Test Guideline 402); Inhalation LC50 (rat, 6 h;) - 46740 mg/m³ (OECD Test Guideline 403).

Toxicological characteristics of the mixture “Max Cleaner” Active Hand Cleaning

Spray:

- **Acute toxicity** - no acute toxicity test of the product has been performed. The acute toxicity score (ATE) is calculated based on the lowest available values for lethal doses of the substances: LD50 (oral and/or dermal) and/or LC50 (inhalation). According to the acute

toxicity data of the product components, the mixture does not meet the criteria for classification in the acute toxicity class.

- **Skin/eye irritation** - the product may cause serious eye irritation when contacted /H 319/.
- **Sensitization** - the mixture contains a lemon ingredient that may cause allergic skin reactions to sensitive persons (EUH 208).
- **Do not swallow the product.** Ingestion may cause irritation to the mouth, throat and stomach.
- **Inhalation** - Inhalation of aerosol (a suspension of microscopic fine particles of the product dispersed in the air in the form of dust or mist): the product may cause respiratory irritation.
- **Specific target organ toxicity - single exposure**: according to the calculation method (content of substances in this hazard class above 20%) the mixture is classified in the same hazard class, category 3 and with risk warning H 336: May causes drowsiness or dizziness.
- **Chronic effects**: no harmful effects are expected from repeated exposure.
- **Carcinogenicity, mutagenicity and toxicity for reproduction** - The product does not contain substances classified as carcinogens, mutagens and toxic for reproduction.

Proper storage and use of the product do not show any known harmful effects on human health.

Section 12. SECTION ECOLOGICAL INFORMATION

No ecotoxicological studies have been performed on the product. Quantitative data on the environmental effects of this product is lacking. Its environmental assessment is based on its constituent data.

12.1. Toxicity

According to the calculation method, the product is not environmentally hazardous. Ecotoxicity data of certain ingredients (exposure [h], toxic doses and toxic concentrations [mg/l]):

Data refer to Ethyl alcohol/Ethanol/:

FISHES: LC50 (96hr) Salmo gairdneri: 13 g/l (ethanol); Pimephales promelas: 13,5; 14,2 и 15,3 g/l (ethanol).
Exposure time: 96 hours, Method: US EPA method E03-05

INVERTEBRATES - fresh water, Method: ASTM E729-80
EC50 (48 hours) Daphnia Magna: 12,34 g/l (ethanol); NOEC (reproduction, 21 дни): > 10 mg/l (ethanol). Ceriodaphnia dubia: EC50 (48 hours): 5,012 g/l (ethanol); NOEC (reproduction, 10 days): 9,6mg/l (ethanol).
Palaemonetes pugio NOEC (development, 10 days): 79mg/l (ethanol).

INVERTEBRATES – salty water:
EC50 (24h) Artemia Salina 23,9 > 10g/l (ethanol);
EC50 (48 hours) Artemia Salina nauplii: 857mg/l(ethanol)

SEAWEED – fresh water:
Chlorella vulgaris, 72hr: EC50 275mg/l, EC10 11,5mg/l (ethanol);
Selenastrum capricornutum, 72hr, EC50: 12,9g/l, EC10 = 0,44g/l (ethanol);
Chlamydomonas eugametos, 48 hours, EC50: 18g/l, NOEC = 7.9 g/l (ethanol)

SEAWEED – salty water:
Skeletonema costatum, NOEC (5 days): 3,24 g/l (ethanol).

The data is for Propan-2-ol:

LC50: 9714 mg/l (Daphnia - Daphnia magna; 24 h)

LC50: 9640 mg/l (Fishes - Pimephales promelas; 96 h)

LC50: 903 mg/l (Crangon crangon; 96h)

12.2. Persistence and degradability

According to manufacturers data, the substances included in the product meet the criteria for ultimate biodegradability (mineralization) under aerobic conditions as required by Regulation (EC) No 648/2004 on detergents.

The main component of the mixture - Ethanol is easily biodegradable: 94% Easily biodegradable
Method: OECD Guideline 301 B. The substance is expected to be easily degradable in wastewater treatment plants.

Isopropyl alcohol (IPA) meets the criteria for rapid biodegradability according to CLP Regulation: 95%; 21d (OECD 301E).

12.3. Bioaccumulative potential

Data refer to Ethanol: Assessment of bioaccumulation: The substance has low bioaccumulation potential. Bioconcentration factor (BCF): 3.2; LogKow <4

Based on the n octanol/water partition coefficient for the main component of the mixture, the product has low bioaccumulation potential.

12.4. Portability in soil

No product tests have been performed. For the main component of the mixture, ethanol, data show that the elimination in wastewater treatment plants is over 99%, based on standard methods.

Ethanol if released into the air will dissipate quickly. If released into the soil, it will evaporate at a rapid rate. It is soluble in water and dissociates.

12.5. Results of PBT and vPvB assessment

“Max Cleaner” Active Hand Cleansing Spray does not contain substances that meet the criteria of Regulation (EU) No 253/2011 for classification as PBT or vPvB.

12.6. Other adverse effects

No other important information is available.

SECTION 13. WASTE DISPOSAL

13.1. Waste treatment methods

It is carried out according to the official regulations for waste disposal.

13.1.1. The terms and procedure for the classification of waste by types and properties shall be determined by REGULATION No 2 from 23.07.2014 on the classification of waste. Waste from the mixture and packaging waste does not qualify for classification as hazardous waste in accordance with Article 6, paragraph 2 of Regulation No 2.

Waste identification in accordance with Article 5, paragraph 2 by selection of the six-digit code indicated in the list of wastes, Appendix No. 1 of Regulation No 2 from 23.07.2014 on waste classification:

a) Waste code of the mixture:	07 04 - wastes from PFCs of organic plant protection products (excluding 02 01 08 and 02 01 09), wood preservatives (excl. 03 02) and other biocides
	07 04 01* - washing water and mother lyes
b) Waste code of the packaging:	15 01 01*, meaning: plastic packaging containing residues of dangerous substances or contaminated with dangerous substances.

13.1.1. Recommendations regarding waste treatment methods:

a) Waste recovery: in order to make possible the recovery of packaging waste by recycling, it is recommended to be separately collected from the waste of the mixture and the total waste stream. Do not allow product waste generated by accident to be disposed of via wastewater into the sewage system.

b) Waste disposal:

Product: Use the full amount of the open original container. Do not discharge into drains. It is recommended that the waste from the biocidal product as residues should be diluted with water and collected temporarily in special tightly closed and labeled containers, after which it is handed over to persons holding a permit in accordance with Art. 67 of the Law on Waste Management (promulgated, SG, issue 53 from 13.07.2012).

Package. Packages which cannot guarantee the qualitative and quantitative integrity of the product shall be disposed of through specific measures in accordance with the applicable local regulations. It is recommended to use special containers. **Do not use contaminated packaging waste to store other products.**

After use, rinse the packaging thoroughly with water, collecting the rinsing water in special containers for residual quantities of the product, and collect the packaging in tightly closed and labeled containers and store it temporarily on the company territory, after which it is handed over to persons holding a permit under Art. 67 of the Waste Management Act.

Dispose of in compliance with local legislation if necessary.

SECTION 14. TRANSPORTATION INFORMATION

The product is transported by any type of covered vehicles, providing storage conditions. It is classified as dangerous in terms of road, sea, air and rail transport rules.

ADR/RID/ADN transportation:

Consignment name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

UN number UN 1170

Class 3 Flammable liquids

F1 classification code

Packing group: II

Tunnel Restriction Code: D/E

Labels: 3

Special provisions: 144, 601

IMDG Sea transport:

Consignment name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

UN number UN 1170

Class 3 Flammable liquids

F1 classification code

Packing group: II

Labels: 3

Special provisions (SP): 144

Air Transport (IATA)

Consignment name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

UN number UN 1170

Class 3 Flammable liquids

F1 classification code

Packing group: II

Labels: 3

Special provisions (SP): A3, A58, A180

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

Environmental hazards: no

SECTION 15. INFORMATION ON THE REGULATION

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

- Law on protection against the harmful effects of chemicals and mixtures,
- Environmental Protection law,
- Regulation (EU) No 453/2010,
- Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006
- on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH),
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council (CLP),
- Regulation on the order and way of classification, packaging and labeling of chemicals and mixtures. In force from 31.08.2010. Adopted by Decree No 182 from 20.08.2010. Two. Issue 68 from 31 August 2010,
- REGULATION No 13/2003 (promulgated, SG No 8/2004) on the protection of workers from the risks associated with exposure to chemical agents at work,
- Waste Management Act (promulgated SG, issue 53/13.07.2012),

- COMMISSION REGULATION (EC) No 552/2009 from 22 June 2009 amending Regulation (EC) № 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regarding appendix XVII,
- Commission Directive 91/322/EEC laying down indicative limit values in application of Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work,
- Council Directive 98/24/EC on the protection of the health and safety of workers from the risks posed by chemical agents at work (Fourteenth Special Directive within the meaning of Article 16 (1) of Directive 89/391/ EEC),
- Commission Directive 2000/39/EC establishing the first list of occupational exposure limit values for the implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks posed by chemical agents at work,
- Commission Directive 2006/15/EC establishing a second list of indicative occupational exposure limit values in application of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC.
- COUNCIL DIRECTIVE 1999/13/EC from 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations.
- Seveso III Directive: Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso III Directive (Directive 2012/18/EU repealing Directive 96/82/EC (Seveso II) from 1 June 2015) - Ethanol: P5c
- Thresholds for minimum quantities (in tons) for the application of: Requirements for low risk potential 5,000 t. Thresholds for minimum quantities (in tons) for the application of: Requirements for high risk potential 50,000 t.

15.2. Safety assessment of a chemical substance or mixture

No product safety assessment has been performed.

Section 16. OTHER INFORMATION

LIST OF PICTOGRAMS, SIGNAL WORDS, WARNINGS FOR DANGER AND SAFETY RECOMMENDATIONS RELATING TO THE PRODUCT

Pictograms:



GHS02



GHS07

Signal word

/indicated in section 2/:

DANGER!

Danger warnings:

H 225 Highly flammable liquid and vapours.

H 319 Causes serious eye irritation.

H 336 May cause drowsiness or vertigo.

Safety recommendations:

General:

P 101 In case of medical help, have product packaging or label at hand.

P 102 – Keep away of children.

Safety recommendation for prevention:

P 210 Keep away of heat/sparks/open flame/hot surfaces. Smoking is forbidden.

P 233 Container should be stored tightly closed.

P 240 Earthing/equipotential bonding of container and receiving device.

P 241 Use explosion-proof electrical/ventilating/lighting/ equipment.

P 242 Use only non-sparking tools.

P 243 Take precautionary measures against static discharges.

P 261 Avoid breathing vapors/aerosols.

P 264 Wash hands thoroughly after handling.

P 280 Wear protective gloves/protective clothing/eye protective goggles/face protecting shield.

P 271 Use only outdoors or in a well-ventilated area.

P 280 Wear protective gloves/safety goggles/face shield.

Response safety recommendations:

P303 + P361 + P353 IN CASE WITH SKIN CONTACT (or Hair): Take off all contaminated clothing immediately. Wash skin with water/take a shower.

P304 + P340 IF INHALED: Take patient at fresh air and keep at rest in a position comfortable for breathing.

P312 If you feel unwell, call a TOXICOLOGY CENTER or doctor.

P370 + P378 In the event of fire: Use air-mechanical foam, carbon dioxide, powder extinguishing media.

P305 + P351 + P338 IN CASE OF EYES CONTACT: Rinse cautiously with water for several minutes. Remove contact lenses, if any, as far as possible. Continue to rinse.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

Storage Safety Recommendation:

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

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

P405 Store locked up.

Disposal Safety Recommendation:

P 501 Dispose of contents/container according to legislation.

FULL TEXT OF DANGEROUS WARNINGS CONCERNING

THE RAW MATERIALS (referred to in section 3):

H-phrase text:

H 225 Highly flammable liquid and vapor.

H 226 Flammable liquid and vapor.

H 304 May be fatal if swallowed and entering airways.

H 315 Causes skin irritation.

H 317 May cause an allergic skin reaction.

H 319 Causes serious eye irritation.

H 335 May cause respiratory irritation.

H 336 May cause drowsiness or dizziness.

H 412 Harmful to aquatic life with long lasting effects.

LIST OF ABBREVIATIONS AND ACRONYMS USED, WHICH ARE NOT EXPLAINED IN THE TEXT:

ADR/RID - European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)/Regulations concerning the International Carriage of Dangerous Goods by Rail (RID);
ADN/ADNR - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)/Agreement on the Carriage of Dangerous Goods by the Rhine (ADNR).

IMDG - International Maritime Dangerous Goods Code (IMDG).

IATA - Technical Instructions for safe transport of dangerous goods by air.

MARPOL 73/78 - International Convention for the Prevention of Pollution from Ships, 1973, as amended by the Protocol of 1978.

IBC Code - International standard for the safe transportation of dangerous and noxious liquid chemicals in bulk by sea.

GHS: Global Harmonized System for Classification and Labeling of Chemicals and Preparations/Mixtures /. IUPAC: International Union of Pure and Applied Chemistry

INCI: International Nomenclature of Cosmetic Ingredients CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50% LD50: Lethal dose, 50%.

NOAEL: No-observed-adverse-effect level: The highest exposure level at which there are no biologically significant increases in the frequency or severity of adverse effect between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered adverse or precursors of adverse effects.

NOEC: NOEC stands for - no observed effect level and is the highest concentration of the toxicant tested which has no effect on the organisms exposed to it or more formally that yields no statistically significant deviation from a control.

NOEC: Concentration without observed effect means the concentration at the test that is immediately below the lowest tested concentration at which a statistically significant adverse effect is observed.

VOC: Volatile Organic Compounds (USA, EU) - Volatile organic compounds.

The classification of **“ADVA Max Cleaner Gel” Hand Disinfectant Gel** is done according to the manufacturer's data and materials and the original Material Safety Data Sheets, applicable legislation, EU directives and regulations. The information contained in this Safety Data Sheet is at the best of our knowledge at the time of publication. This information is only for proper and safer handling, storage, transportation and disposal of the product.

Sheet should not be viewed as a guarantee or clarification of product quality. This information applies only to the product specifically stated and does not apply if it has been used in combination with other materials or with other processes not explicitly mentioned in the text of the Safety Data Sheet.

We provide our clients with individual advice and, if desired, will also provide testing tests.

The Safety Data Sheet is issued for the second time.