

## SAFETY DATA SHEET

According to Regulation No. 830/2015

Created at : 23.02.2022

### 1. Identification of the substance / preparation and of the company / undertaking

#### Identification of the substance or preparation

Use of the substance / preparation: **HYGUSAN MED by Hygienium disinfectant wet wipes 80 pcs**

#### Identification of the company:

Grande Gloria Production S.A, Sat Costi, strada Tuluc, nr 1, Hala Nr. 68, Biroul nr 2, com. Vanatori,  
jud.Galati, Romania

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The National Institute of Public Health Bucharest, Romania , str. Dr. Leonte, nr.1-3, sector 5, +40213183606 /

**Additional information provided by:** Grande Gloria Production S.A, Tel.: 004 0236. 470890

### 2. Hazards identification

#### Classification according to EU directives:

The product is classified and coded according to European directives / norms regarding hazardous materials.  
This product meet the classification criteria according to Regulation (EC) No 1272/2008 (CLP).

**Danger symbol: doesn't present.**

#### Labeling items:

**Keep out of reach of children.**

**In case of contact with eyes: rinse thoroughly with plenty of water for several minutes.**

**Remove contact lenses, if necessary, and if done easily. Continue rinsing.**

**Content/container in accordance with local/national/international regulations. When handling the product, the instructions in accordance with the ordinance on dangerous substances in the CE safety data sheet must be followed.**

**Storage conditions: Protect yourself from sunlight. Do not expose to temperatures exceeding 5-30 ° C.**

**Danger symbol: does not present.**

## Dangers / side effects

### For human / health:

**Eye contact :** May cause temporary reddening of the eyes.

**In contact with skin:** No specific symptoms are known due to the product.

**In case of inhalation:** No side effects are known.

**In case of swallowing:** No secondary phenomena are known.

**Environmental hazards:** Do not discharge into surface water or soil.

### The classification system:

The classification is in accordance with the European directives and the information held by the company as well the resulting ones from the specialized bibliography.

## 3. Composition / information on ingredients (ingredients)

### Chemical characterization

Description: The product is a mixture containing the following components:

Nr crt.	Description of the substance si concentration.		Identification data			Classification (Regulation (CE) NR. 1272/2008
	The name/ description or the chemical nature	Conc. / the field of conc	Number CAS	Number EC	Number Index	Phrase H
1	Quaternary ammonium compounds, C12-14 alkyl[(ethylphenyl)methyl]dimethyl, Chlorides	0,065 %	68424-85-1	270-325-2	-	Skin Corr. 1B - H314; Acute Tox.4 - H302; Aquatic Acute 1 - H400, Aquatic Chronic 1 - H410
	ethyl alcohol	0,0013 %	64-17-5	200-578-6	603-002-00-5	Flam. Liq.2, H225
2	Amestec de: Alkyldimethylbenzylammonium Chloride	0,036 %	68391-01-5	<b>269-919-4</b>	-	Skin Corr. 1B - H314; Acute Tox.4 - H302; Aquatic Acute 1 - H400,
	Alkyl dimethyl ethylbenzyl ammonium chloride	0,036 %	85409-23-0	287-090-7	-	Skin Corr. 1B - H314; Acute Tox.4 - H302; Aquatic Acute 1 - H400, Aquatic Chronic 1 - H410

	ethyl alcohol	0,018 %	64-17-5	200-578-6	603-002-00-5	Flam. Liq.2, H225
3	1,1-hexamethyllenebis[5-(4-chloro biguanide]-di (D-digluconate) (Chlorhexidine Digluconate)	0,015 %	18472-5-0	242-354-0	-	Lez. oc. 1, H318 Aquatic Acute 1- H400 Aquatic Chronic 1: H410;
4	Mixture of 5-cloro-2-metil-2H-izotiazol-3-onă (EINECS 247-500-7) si 2-metil-2Hizotiazol-3-onă (EINECS 220-239-6)	0.1%	55965-84-9	-	613-167-00-5	Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 Skin Corr. 1B, H314 Eye Dam. 1, H 318 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
	(etilendioxi)dimetanol		3586-55-8	222-720-6	-	Acute Tox. 3 H301 Skin Irrit. 2, H315 Eye Dam. 1 H318

\*NC- not classified

#### **4. First aid measures**

**General information:** Remove stained clothing.

**After inhalation:**

No adverse effects are known.

**After skin contact:**

It is not irritating to skin contact.

**After eye contact:**

It is necessary to wash the eyes with running water for several minutes. If the symptoms persist, consult the doctor.

**After swallowing:**

It's not a normal route of exposure. Rinse mouth with plenty of water. If symptoms persist, consult your doctor

#### **5. Firefighting measures**

**Suitable extinguisher:**

CO2, dust or water jet. Strong fires should be extinguished with water jet or alcohol-resistant foam.

**Specific means of protection:**

In case of fire, wear full fire protection equipment.

**Other information:**

Dispose of debris and contaminated water in accordance with current regulations.

#### **6. Accidental release measures**

**Personal protection measures:**

- eliminate all possible sources of ignition (open fire, sparks); wear protective gloves; avoid inhaling vapors, stay away from areas where vapors may accumulate; keep containers tightly closed, out of the reach of children.

**Environmental protection measures:**

Prevent product from seeping into the sewer system.

**Means of cleaning / removal:**

In case of leakage of small quantities of the product, free evaporation or absorption is allowed with inert materials (earth, sand, textiles, etc.) which will then be collected in containers suitable for recovery or disposal. Continuously ventilate the contaminated area without using equipment electric or tools that produce sparks.

**7. Handling and storage****Handling:****Information for safe handling:**

Avoid inhalation of vapors, contact with eyes, skin or clothing.  
Wear appropriate equipment for leak or fire.  
No smoking in storage or handling areas.

**Storage:****Conditions for storage and packaging:**

The product will be stored in tightly closed containers / tanks, away from any heat source, in a well ventilated, dry and cool area. Storage temperature: between 5 and 30°C.

Compatible materials: plastic, PVC, polypropylene, stainless steel.

Incompatible materials: nylon, charcoal, neoprene.

**Advice on mixed storage:** Store product in the original package in a cool, well-ventilated place.

**8. Exposure controls/Personal protection****Exposure limit values:**

According to GD 1218/2006 the product contains the following substances listed in annex no. 1 with exposure limit values, which require monitoring at the workspace:

Nr.crt.	Name	Maximum limit value			
		8h		Short term (15 min.)	
		mg/mc	ppm	mg/mc	ppm
1	Ethyl alcohol	1900	1000	9500	5000

**Occupational exposure controls:****General rules of protection and hygiene during work:**

Remove stained clothing.

Wash hands before breaks and at the end of work.

**Hand protection:**

The material of the gloves must be waterproof and resistant to the product / substance / preparation.

**Glove material:** Nitrile rubber.

**Penetration time of glove material:** The exact penetration time must be determined and observed by the manufacturer of the protective gloves.

**Eye protection:**

Avoid contact with eyes.

## 9. Physical and chemical properties

### General information

**Aggregation state:** liquid

**Color:** characteristic

**Smell:** characteristic

**Melting point / Melting range:** Not defined

**Boiling point / Boiling range:** Not defined

**Ignition temperature:** Not defined

**Self-ignition:** The product is not self-igniting.

**Explosion hazard:** The product is not explosive.

**Solubility:** Soluble in water

**PH value at 20 ° C:** 5-6

## 10. Stability and reactivity

**Conditions to avoid:** Avoid high temperatures and fire sources in the immediate vicinity.

**Materials to Avoid:** Strong mineral acids, oxidizing agents.

**Hazardous decomposition products:** Combustion will generate carbon oxides.

## 11. Toxicological information

**Toxicological information and other health effects (for mixing):**

**Toxicokinetics, metabolism and distribution:** no data available

**Acute toxicity:** no data available

**Irritating effects:** no data are known

**Corrosive effects:** no corrosive effects are known

**Sensitization:** no sensitizing effects are known.

**Carcinogenic, mutagenic, reproductive toxicity:** no data available

**Toxicological information and other health effects (for surfactants):**

**Acute toxicity:**

**Primary irritability:** On the skin: irritates the skin and mucous membranes

Eyes: Severe irritation with risk of serious eye damage

**Toxicological information and other health effects (for chlorhexidine):**

Acute toxicity - oral: LD50 Oral (rat) > 2000 mg / kg (OECD 401)

Acute dermal toxicity: LD50 > 5000 mg / kg (rat)

Acute inhalation toxicity: Not available.

Serious eye damage / irritation: Causes serious eye damage.

Respiratory sensitization: Not sensitized.

Skin sensitization: Does not sensitize.

Germ cell mutagenicity:

- Genotoxicity - in vitro: Does not contain substances known to be mutagenic.

- Genotoxicity - in vivo: Does not contain substances known to be mutagenic.

Carcinogenicity: There is no evidence that the product may cause cancer.

Reproductive toxicity: No evidence of reproductive or teratogenic potential.

Specific target organ toxicity:

-Single exposure: STOT- No information available.

- Repeated exposure: No information available.

Aspiration hazard: No information available.

Inhalation: May be harmful by inhalation

Ingestion: May be harmful if swallowed. May cause irritation of the gastrointestinal tract.

Skin contact: May cause irritation. May cause sensitization or allergic reactions in susceptible persons.

Eye contact: Causes serious eye damage.

**Toxicological information and other health effects (for Quaternary ammonium compounds, benzyl-C12-14 (even-numbered)-alkyldimethyl, chlorides):**

• **Acute toxicity:**

• **LD / LC50 values relevant for classification:..**

**Quaternary ammonium compounds, benzyl-C12-14 (even-numbered)-alkyldimethyl, chlorides**

\* Oral, DL50: 344 mg/kg (rat)

\* Dermal, DL50: 3340 mg/kg (rabbit)

• **Primary irritability:**

• On the skin:

Corrosive to the skin and mucous membranes.

• at the eyes:

**Trade name: BTC 50 E / Barquat 50**

Particularly corrosive

**Additional toxicological information:**

corrosive

If swallowed, the product causes very strong corrosion of the oral cavity and pharynx with the risk of perforation of the esophagus and stomach.

• CMR effects (carcinogenic, mutagenic and toxic effects for reproduction)

Carcinogen: no data are known

Mutagen: no data are known

Reproductive toxicity: no data are known

**Acute toxicity (for BTC 80):**

LD / LC50 values relevant for classification:

68391-01-5 Alkyldimethylbenzylammonium chloride

Oral, LD50: 650 mg / kg (rat)

85409-23-0 Alkyl dimethyl ethylbenzyl ammonium chloride

Oral, LD50: <2000 mg / kg (rat)

64-17-5 ethyl alcohol

Oral, LD50: 7060 mg / kg (rat)

Inhalative, LC50 / 4h, 20000 mg / l (rat)

Primary irritability:

On the skin: Corrosive on the skin and mucous membranes.

To the eye: Particularly corrosive.

## 12. Ecological information

### **Ecotoxicity information (for mixing):**

**Ecotoxicity:** no data available

### **General information:**

Do not infiltrate into groundwater, water network or sewerage

### **Ecotoxicity information (for surfactants):**

From the biological point of view the product is easily biodegradable .

### **Ecotoxicity information (for Chlorhexidine):**

Acute aquatic toxicity:

LE (C) 50: 0.01 <L (E) C50 ≤ 0.1

M factor (acute): 10

Acute toxicity - fish: LC50, 96h: 2.08 mg / l

Acute toxicity - aquatic invertebrates: EC 50, 48 hours, DAPHNIA, 0.087 mg / l

Acute toxicity - aquatic plants: ErC50, 72 hours, ALGAE, 0.081 mg / l

Acute toxicity - microorganism EC50 3 hours, activated sludge, 25 mg / l

Chronic acute toxicity: M factor (chronic): 1

Persistence and degradability: Not readily biodegradable.

Bioaccumulative potential: Bioaccumulative factor (BCF): 42 l / kg Separation of chlorhexidine and gluconate base is expected during absorption in fish. Therefore, free chlorhexidine BCF was probably determined instead of chlorhexidine digluconate. Biomagnification through the aquatic food chain is not expected.

Partition coefficient: Not available.

Mobility in soil: the product is miscible with water.

Results of PBT and vPvB assessment: The product does not contain substances classified as PBT or vPvP.

Other side effects: Avoid release to the environment. Do not allow product to reach groundwater, watercourse or sewage system.

### **Information on toxic effects on the environment (for surfactants in the mixture):**

**Aquatic toxicity: The product label is "N", therefore the value of the lowest acute toxicity (LC50, IC50, EC50) is between 0.1 and 1 mg / l.**

### **Disposal data (persistence and biodegradability):**

**From a biological point of view, the product is easily biodegradable.**

### **General information:**

**It is forbidden to discharge undiluted product into the sewer system.  
Used as intended, this product will not cause any adverse effects in the environment.**

**Ecotoxicity information (for BTC 50):**

- *Toxicity*
- *Aquatic toxicity:*
  - \* *Quaternary ammonium compounds, benzyl-C12-14*
  - \* *(even-numbered) -alkyldimethyl, chlorides*
  - \* *fish, LC50: 0.515 mg / l*
  - daphnia, CE50: 0.016 mg / l*
  - \* *algae, IC 50: 0.03 mg / l*
  - \* *seaweed, NOEC: 0.009 mg / l*
- *Persistence and degradability*
- *Other indications:*

*The product is biologically readily biodegradable.*
- *Other ecological indications:*
- *General information:*

*Do not infiltrate groundwater, water system or sewage system.*  
*The product contains environmentally harmful substances.*
- *Results of PBT and vPvB assessment*
- *PBT:*

*not applicable*
- *vPvB:*

*not applicable*

**13. Disposal considerations**

**The product:**

**Recommendation:**

**Dispose of in accordance with local regulations.**

**Do not spill into soil or surface water. In case of accidental spillage, remove material.  
absorbent (sand or sawdust) and then wash the surface with plenty of water.**

**Uncleaned packaging:**

**Recommendation: Empty packs should be rinsed with water and disposed of as waste in containers.  
special collection ..**

**Recommended cleaning agents: Water**

**Waste disposal legislation:**

**Law no. 211/2011 on the waste regime.**

**Legislation according to which product packaging is eliminated: Law no. 249/2015 on the  
management of packaging and packaging waste**

**14. Transport information**

UN-number not assigned.



The preparation does not present specific risks for transport. It is transported by covered means of transport.

ADR / RID - Not classified.

## **15. Regulatory information**

**Classification according to EU directives:**

**The product is classified and coded according to European directives / regulations on hazardous materials.**

**Community / national legislation:**

- Regulation (EC) no. 1272/2008 regarding the classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548 / EEC and 1999/45 / EC, as well as amending Regulation (EC) no 1907/2006;
- Law no.319 / 2006- the law of safety and health at work;
- HG no.1218 / 2006 on establishing minimum safety and health requirements at work to ensure the protection of the workers against the risks related to the presence of chemical agents;
- GG no.856 / 2002 regarding the evidence of the waste management and for the approval of the list containing the waste, including the hazardous waste;
- Law no.211 / 2011 regarding the waste regime.
- Regulation no.453 / 2010 with subsequent amendments and completions.

## **16.Other informations:**

The information presented is based on our current knowledge. These are not guarantees for the characteristics of the product and does not motivate any contractual legal relationship

**Made by:**

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