

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 3 (replaces version 2)

Revision: 22.02.2024

- **1.1 Product identifier**
- **Trade name:** *gigasept® pearls*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Life cycle stages** *PW Widespread use by professional workers*
- **Sector of Use** *SU20 Health services*
- **Application of the substance / the mixture** *Disinfectants for instruments*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*PRISMAN GmbH
 Otto-Hahn-Ring 6-18
 DE-64653 Lorsch
 Germany*
- Vertrieb durch/ Distributed by:*
*Schülke & Mayr GmbH
 Robert-Koch-Str. 2
 DE-22851 Norderstedt
 Germany
 Telefon: +49 (0)40/ 52100-0
 Telefax: +49 (0)40/ 52100318
 mail@schuelke.com
 www.schuelke.com*
- **Further information obtainable from:** *Alexander.Metz@prisman.de*
- **1.4 Emergency telephone number:** *+49 (0) 6251 - 866 980 - 0 , Mo-Fr 9-17 Uhr*

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
*Acute Tox. 4 H302 Harmful if swallowed.
 Eye Dam. 1 H318 Causes serious eye damage.*
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**



GHS05 GHS07

- **Signal word** *Danger*
- **Hazard-determining components of labelling:**
*disodium carbonate, compound with hydrogenperoxide (2:3)
 tetrasodium ethylenediaminetetraacetate*
- **Hazard statements**
*H302 Harmful if swallowed.
 H318 Causes serious eye damage.*
- **Precautionary statements**
*P280 Wear protective gloves / eye protection.
 P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
 P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*

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P310 *Immediately call a POISON CENTER/doctor.*
 P332+P313 *If skin irritation occurs: Get medical advice/attention.*
 P411 *Store at temperatures not exceeding 25°C.*
 P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 15630-89-4 EINECS: 239-707-6 Reg.nr.: 01-2119457268-30-xxxx	disodium carbonate, compound with hydrogenperoxide (2:3) ⚠ Eye Dam. 1, H318 ⚠ Acute Tox. 4, H302	25-50%
CAS: 77-92-9 EINECS: 201-069-1 Index number: 607-750-00-3 RTECS: GE 7350000 Reg.nr.: 01-2119457026-42-xxxx	citric acid ⚠ Eye Irrit. 2, H319; STOT SE 3, H335	10-25%
CAS: 139-33-3 EINECS: 205-358-3 Reg.nr.: 01-2119486775-20	disodium dihydrogenethylenediaminetetraacetate ⚠ STOT RE 2, H373 ⚠ Acute Tox. 4, H332	2.5-10%
CAS: 497-19-8 EINECS: 207-838-8 Index number: 011-005-00-2 Reg.nr.: 01-2119485498-19-xxxx	sodium carbonate ⚠ Eye Irrit. 2, H319	2.5-10%
CAS: 64-02-8 EINECS: 200-573-9 Index number: 607-428-00-2 RTECS: AH 5075000 Reg.nr.: 01-2119486762-27-0000	tetrasodium ethylenediaminetetraacetate ⚠ Eye Dam. 1, H318 ⚠ Acute Tox. 4, H302	≤2.5%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**
Immediately remove any clothing soiled by the product.
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Immediately rinse with water.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Call for a doctor immediately.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Use neutralising agent.
Dispose contaminated material as waste according to section 13.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Store in cool, dry place in tightly closed receptacles.
Thorough dedusting.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing

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*Wash hands before breaks and at the end of work.**Avoid contact with the eyes.**Avoid contact with the eyes and skin.*· **Respiratory protection:** Not required.· **Hand protection**

Protective gloves

*The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.**Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.**Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*· **Material of gloves***The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.*· **Penetration time of glove material***The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.*· **For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:***Rubber gloves*· **For the permanent contact gloves made of the following materials are suitable:** *Neoprene gloves*· **As protection from splashes gloves made of the following materials are suitable:***Butyl rubber, BR**Fluorocarbon rubber (Viton)**Nitrile rubber, NBR*· **Eye/face protection**

Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· **Physical state***Solid*· **Colour:***Blue*· **Odour:***Pleasant*· **Odour threshold:***Not determined.*· **Melting point/freezing point:***Undetermined.*· **Boiling point or initial boiling point and boiling range***Undetermined.*· **Flammability***Not determined.*· **Lower and upper explosion limit**· **Lower:***Not determined.*· **Upper:***Not determined.*· **Flash point:***Not applicable.*· **Decomposition temperature:***60 °C*· **pH at 20 °C***8 (20g/ltr.)*

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· Viscosity:	
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Slightly soluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density at 20 °C:	0.9 g/cm ³
· Relative density	Not determined.
· Bulk density:	650 kg/m ³
· Vapour density	Not applicable.

· 9.2 Other information	
· Appearance:	
· Form:	Solid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· VOC (EC)	0 %
· Solids content:	99.0 %
· Change in condition	
· Evaporation rate	Not applicable.

· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void

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· Oxidising liquids	Void
	Void
· Oxidising solids	Void
	Void
· Organic peroxides	Void
	Void
· Corrosive to metals	Void
	Void
· Desensitised explosives	Void
	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Oxygen

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Harmful if swallowed.

· **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)

Oral	LD50	1,000 mg/kg
Inhalative	LC50/4 h	50 mg/l

15630-89-4 disodium carbonate, compound with hydrogenperoxide (2:3)

Oral	LD50	500 mg/kg (ATE)
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139-33-3 disodium dihydrogenethylenediaminetetraacetate

Inhalative	LC50/4 h	1.5 mg/l (ATE)
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64-02-8 tetrasodium ethylenediaminetetraacetate

Oral	LD50	500 mg/kg (ATE)
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- **Serious eye damage/irritation** Causes serious eye damage.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

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SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

15630-89-4 disodium carbonate, compound with hydrogenperoxide (2:3)

EC50	7.7 mg/l (A)
	466 mg/l (Bel)
	4.9 mg/l (daphnia)
LC50/96h	70.7 mg/l (fish)

77-92-9 citric acid

LC50/48h	440 mg/l (fish)
	1,535 mg/l (daphnia)

139-33-3 disodium dihydrogenethylenediaminetetraacetate

EC50	500 mg/l (Bel)
	140 mg/l (daphnia)
LC50/96h	>100 mg/l (fish)

497-19-8 sodium carbonate

EC50	200-227 mg/l (daphnia)
LC50/96h	300 mg/l (fish)

64-02-8 tetrasodium ethylenediaminetetraacetate

LC50/96h	>100 mg/l (fish)
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· **12.2 Persistence and degradability** No further relevant information available.

· **12.3 Bioaccumulative potential** No further relevant information available.

· **12.4 Mobility in soil** No further relevant information available.

· 12.5 Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

· 12.7 Other adverse effects

· Additional ecological information:

· General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Must not reach sewage water or drainage ditch undiluted or unneutralised.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packaging:

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

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SECTION 14: Transport information

· 14.1 UN number or ID number	
· ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name	
· ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR, IMDG, IATA	
· Class	Void
· Label	-
· ADN/R Class:	Void
· 14.4 Packing group	
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	
· Hazard identification number (Kemler code):	-
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	Not dangerous according to the above specifications.

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Labelling according to Regulation (EC) No 1272/2008

GHS label elements

The product is classified and labelled according to the GB CLP regulation.

- Hazard pictograms



GHS05 GHS07

- Signal word *Danger*

- Hazard-determining components of labelling:

disodium carbonate, compound with hydrogenperoxide (2:3)

tetrasodium ethylenediaminetetraacetate

- Hazard statements

H302 Harmful if swallowed.

H318 Causes serious eye damage.

- Precautionary statements

P280 Wear protective gloves / eye protection.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

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

P310 Immediately call a POISON CENTER/doctor.

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P332+P313 *If skin irritation occurs: Get medical advice/attention.*
 P411 *Store at temperatures not exceeding 25°C.*
 P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H302 Harmful if swallowed.
 H318 Causes serious eye damage.
 H319 Causes serious eye irritation.
 H332 Harmful if inhaled.
 H335 May cause respiratory irritation.
 H373 May cause damage to organs through prolonged or repeated exposure.

- **Recommended restriction of use** Product only for professional use

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
 ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods
 IATA: International Air Transport Association
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 VOC: Volatile Organic Compounds (USA, EU)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 Acute Tox. 4: Acute toxicity – Category 4
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1
 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
 STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

- *** Data compared to the previous version altered.**