Revision: 22.11.2023

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 22.11.2023 Version number 6 (replaces version 5)

· 1.1 Product identifier

· Trade name: Omnisept

· 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the mixture Disinfectants for instruments
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Hersteller/Lieferant:

PRISMAN GmbH

Otto Hahn Ring 6-18

D-64653 Lorsch - Germany

Vertrieb durch:

OMNIDENT DentalHandelsgesellschaft mbH

Gutenbergring 5 D-63110 Rodgau

Tel.: +49 (0) 6106 874-0

· Further information obtainable from:

Produktmanagement

Fon: +49 (6106) 8 74 - 0

· 1.4 Emergency telephone number:

Erreichbar werktags von: 8.00 - 16.30 Uhr

Tel: +49 (6106) 874 -0 Fax: +49 (6106) 874 -265

info@omnident.de

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.

Skin Corr. 1B H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage. Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

- · 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:

didecyldimethylammonium chloride

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine

· Hazard statements

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H410 Very toxic to aquatic life with long lasting effects.

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· Precautionary statements

P273 Avoid release to the environment.
P280 Wear protective gloves / eye protection.

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

[or shower].

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.

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: 7173-51-5	didecyldimethylammonium chloride	2.5-10%
EINECS: 230-525-2	♦ Skin Corr. 1B, H314	
Index number: 612-131-00-6	🔖 Aquatic Chronic 2, H411	
Reg.nr.: 01-2119457558-25-XXXX	♦ Acute Tox. 4, H302	
CAS: 2372-82-9	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2.5-10%
EINECS: 219-145-8	♠ Acute Tox. 3, H301; Acute Tox. 3, H311	
Reg.nr.: 01-2119980592-29-xxxx	♦ STOT RE 2, H373	
	Skin Corr. 1A, H314	
	4 Aquatic Chronic 1, H410	
	fatty alcohol polyglycol ethers	≤2.5%
	♠ Eye Irrit. 2, H319	
CAS: 139-33-3	disodium dihydrogenethylenediaminetetraacetate	≤2.5%
EINECS: 205-358-3	♦ STOT RE 2, H373	
Reg.nr.: 01-2119486775-20	♦ Acute Tox. 4, H332	

[·] 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:

Take affected persons into fresh air and keep quiet.

Seek medical treatment in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

If skin irritation continues, consult a doctor.

Immediately wash with water and soap and rinse thoroughly.

· After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

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· After swallowing:

Rinse out mouth and then drink plenty of water.

Call for a doctor immediately.

Drink plenty of water and provide fresh air. Call for a doctor immediately.

- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 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

In case of fire, the following can be released:

Carbon monoxide (CO)

- · 5.3 Advice for firefighters
- · Protective equipment: Do not inhale explosion gases or combustion gases.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Use respiratory protective device against the effects of fumes/dust/aerosol.

Particular danger of slipping on leaked/spilled product.

Ensure adequate ventilation

Wear protective clothing.

Wear protective equipment. Keep unprotected persons away.

· 6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Dilute with plenty of water.

Do not allow to enter sewers/surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Use neutralising agent.

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

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 Keep receptacles tightly sealed.
- · 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.

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· 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

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:

Polychloroprene - CR (0.5 mm): Breakthrough time > 4 h

Nitrile rubber/nitrile latex - NBR (0.35 mm): Breakthrough time > 4h

Butyl rubber - Butyl (0.5 mm): Breakthrough time > 8 h

Fluororubber - FKM (0.4 mm): Breakthrough time > 8 h

Polyvinyl chloride - PVC (0.5 mm): Breakthrough time > 4 h

This recommendation is based exclusively on the chemical compatibility and the test according to EN 374 under laboratory conditions.

Depending on the application, different requirements may arise. Therefore the

Therefore, the recommendations of the protective glove supplier must also be taken into account.

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Neoprene gloves

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· As protection from splashes gloves made of the following materials are suitable:

Butyl rubber, BR

Fluorocarbon rubber (Viton)

· Eye/face protection Safety glasses



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state Fluid

· Colour: According to product specification

Odour: Amine-like
Odour threshold: Not determined.
Melting point/freezing point: Undetermined.

· Boiling point or initial boiling point and boiling range $0~^{\circ}C$

· Flammability Not applicable.

· Lower and upper explosion limit

· Lower:
 · Upper:
 · Upper:
 · Flash point:
 · Decomposition temperature:
 · pH at 20 °C
 · Not determined.
 · volume of the performance of the photography of th

· Viscosity:

Kinematic viscosityDynamic:Not determined.Not determined.

·Solubility

• water: Fully miscible.
• Partition coefficient n-octanol/water (log value) Not determined.

· Vapour pressure at 20 °C: 23 hPa

Density and/or relative density

Density at 20 °C:
 Relative density
 Vapour density
 Not determined.
 Not determined.

· 9.2 Other information

· Appearance:

· Form: Fluid

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:

• Water: 87.0 %
 • VOC (EC) 0 %
 • Solids content: 7.0 %

· Change in condition

· Evaporation rate Not determined.

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Information with regard to physical hazard cla	isses	
· 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 flammal	ole gases	
in contact with water	Void	
Oxidising liquids	Void	
Oxidising solids	Void	
· Organic peroxides	Void	
· Corrosive to metals	Void	
Desensitised explosives	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: No dangerous decomposition products known.

SECTION 11: Toxicological information

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

· Acute toxi	city Harmf	ful if swallowed.	
· LD/LC50	values rele	evant for classification:	
ATE (Acu	te Toxicity	Estimates)	
Oral	LD50	I,148 mg/kg	
Inhalative	LC50/4 h	100 mg/l	
7173-51-5	didecyldin	methylammonium chloride	
Oral	LD50	238 mg/kg (rat)	
Dermal	LD50	3,342 mg/kg (rat)	
2372-82-9	N-(3-amir	nopropyl)-N-dodecylpropane-1,3-diamine	
Oral	LD50	261 mg/kg (rat)	
Dermal	LD50	>600 mg/kg (rat)	
139-33-3 c	lisodium d	lihydrogenethylenediaminetetraacetate	
Oral	LD50	>2,000 mg/kg (rat)	
Inhalative	LC50/4 h	>1-5 mg/l (rat)	
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- · Skin corrosion/irritation Causes severe skin burns and eye damage.
- · Serious eye damage/irritation Causes serious eye damage.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic to	Aquatic toxicity:			
7173-51-5	7173-51-5 didecyldimethylammonium chloride			
EC50	mg/kg (rat)			
EC50	0.062 mg/l (daphnia)			
LC50/96h	0.19 mg/l (fish)			
2372-82-9	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine			
EC50	0.01- $0.1 mg/l (A)$			
	18 mg/l (Bel)			
	0.073 mg/l (daphnia)			
LC50/96h	0.68 mg/l (fish)			
139-33-3 a	lisodium dihydrogenethylenediaminetetraacetate			
EC50	500 mg/l (Bel)			
	140 mg/l (daphnia)			
LC50/96h	>100 mg/l (fish)			

- · 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
- · Remark: Very toxic for fish
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

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

Danger to drinking water if even small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

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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.

SECTION 14: Transport information	
14.1 UN number or ID number ADR, IMDG, IATA	UN1903
· 14.2 UN proper shipping name · ADR · IMDG	1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Naminopropyl) - N - dodecylpropane - 1, 3 - diamindidecyldimethylammonium chloride), ENVIRONMENTAI HAZARDOUS DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (N-
· IATA	aminopropyl)-N-dodecylpropane-1,3-diamin didecyldimethylammonium chloride), MARINE POLLUTA DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Naminopropyl)-N-dodecylpropane-1,3-diamin didecyldimethylammonium chloride)
· 14.3 Transport hazard class(es)	
· ADR, IMDG	
Class	8 Corrosive substances.
· Label	8
·IATA	
· Class	8 Corrosive substances.
· Label	8
· 14.4 Packing group · ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	
Marine pollutant:	Yes
· Special marking (ADR):	Symbol (fish and tree) Symbol (fish and tree)
14.6 Special precautions for user Hazard identification number (Kemler code):	Warning: Corrosive substances.

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· EMS Number:	F- A , S - B
· 14.7 Maritime transport in bulk accord	ing to IMO
instruments	Not applicable.
· Transport/Additional information:	
· ADR	
· Excepted quantities (EQ)	Code: E1
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
· IMDG	
· Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: E1
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml

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 GHS09

- · Signal word Danger
- · Hazard-determining components of labelling:

didecyldimethylammonium chloride

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine

· Hazard statements

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H410 Very toxic to aquatic life with long lasting effects.

· Precautionary statements

P273 Avoid release to the environment.
P280 Wear protective gloves / eye protection.

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

[or shower].

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.

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.
- · Seveso category E1 Hazardous to the Aquatic Environment
- · Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t

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· Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t

· 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.

Customs tariff No.: 3808 94 90

· Relevant phrases

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H373 May cause damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

· 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)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

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. 3: Acute toxicity - Category 3

Acute Tox. 4: Acute toxicity - Category 4

Skin Corr. 1A: Skin corrosion/irritation - Category 1A

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2

* * Data compared to the previous version altered.

GB