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

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

· **1.1 Product identifier**

· **Trade name: Omnisept**
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
· **Sector of Use** SU20 Health services
· **Technical function** Biocide
· **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

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SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**


GHS05 corrosion

Skin Corr. 1B H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.


GHS09 environment

Aquatic Acute 1 H400 Very toxic to aquatic life.
Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.


GHS07

Acute Tox. 4 H302 Harmful if swallowed.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.

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· ***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.*
· ***Labelling of packages where the contents do not exceed 125 ml***
· ***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***
H314 Causes severe skin burns and eye damage.
· ***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.*

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SECTION 3: Composition/information on ingredients

· ***3.2 Chemical characterisation: Mixtures***
· ***Description:*** *Mixture of substances listed below with nonhazardous additions.*

· ***Dangerous components:***		
CAS: 7173-51-5 *EINECS: 230-525-2* *Index number: 612-131-00-6*	*didecyldimethylammonium chloride* *Skin Corr. 1B, H314; Aquatic Chronic 2, H411; Acute Tox. 4, H302*	*2.5-10%*
CAS: 2372-82-9 *EINECS: 219-145-8*	*N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine* *Acute Tox. 3, H301; STOT RE 2, H373; Skin Corr. 1A, H314; Aquatic Acute 1, H400; Aquatic Chronic 1, H410*	*2.5-10%*
	fatty alcohol polyglycol ethers *Eye Irrit. 2, H319*	*≤2.5%*
CAS: 139-33-3 *EINECS: 205-358-3*	*disodium dihydrogenethylenediaminetetraacetate* *STOT RE 2, H373; Acute Tox. 4, H332*	*≤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:*** *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.*
· ***After swallowing:***
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*** *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 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.

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· **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 item 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.
· **7.3 Specific end use(s)** No further relevant information available.

*
SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**
· **Additional information about design of technical facilities:** No further data; see item 7.
· **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**
· **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.
· **Protection of hands:**

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.

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· ***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:***
Polychloropren - CR (0,5 mm): Durchbruchzeit > 4 h
Nitrilkautschuk/Nitrillatex - NBR (0,35 mm): Durchbruchzeit > 4h
Butylkautschuk - Butyl (0,5 mm): Durchbruchzeit > 8 h
Fluorkautschuk - FKM (0,4 mm): Durchbruchzeit > 8 h
Polyvinylchlorid - PVC (0,5 mm): Durchbruchzeit > 4 h
Diese Empfehlung beruht ausschließlich auf der chemischen Verträglichkeit und dem Test nach EN 374 unter Laborbedingungen.
Je nach Anwendung können sich unterschiedliche Anforderungen ergeben . Daher sind zusätzlich die Empfehlungen des Schutzhandschuhlieferanten zu berücksichtigen.
Neoprene gloves
· ***As protection from splashes gloves made of the following materials are suitable:***
Butyl rubber, BR
Fluorocarbon rubber (Viton)
· ***Eye protection:***
Safety glasses

Tightly sealed goggles

*
SECTION 9: Physical and chemical properties

· ***9.1 Information on basic physical and chemical properties***	
· ***General Information***	
· ***Appearance:***	
Form:	*Fluid*
Colour:	*According to product specification*
· ***Odour:***	*Amine-like*
· ***Odour threshold:***	*Not determined.*
· ***pH-value at 20 °C:***	*>11 (1%)*
· ***Change in condition***	
Melting point/freezing point:	*Undetermined.*
Initial boiling point and boiling range:	*0 °C*
· ***Flash point:***	*>100 °C*
· ***Flammability (solid, gas):***	*Not applicable.*
· ***Decomposition temperature:***	*Not determined.*
· ***Auto-ignition temperature:***	*Product is not selfigniting.*
· ***Explosive properties:***	*Product does not present an explosion hazard.*
· ***Explosion limits:***	
Lower:	*Not determined.*
Upper:	*Not determined.*
· ***Vapour pressure at 20 °C:***	*23 hPa*
· ***Density at 20 °C:***	*1.01 g/cm³*
· ***Relative density***	*Not determined.*

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· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with water:**	Fully miscible.
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
Dynamic:	Not determined.
Kinematic:	Not determined.
· **Solvent content:**	
Water:	87.0 %
VOC (EC)	0 %
Solids content:	7.0 %
· **9.2 Other information**	No further relevant information available.

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 toxicological effects**
· **Acute toxicity**
Harmful if swallowed.

· **LD/LC50 values relevant for classification:**		
ATE (Acute Toxicity Estimates)		
Oral	LD50	1,148 mg/kg
Inhalative	LC50/4 h	100 mg/l

7173-51-5 didecyldimethylammonium chloride		
Oral	LD50	500 mg/kg (ATE)
2372-82-9 N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine		
Oral	LD50	100 mg/kg (ATE)
139-33-3 disodium dihydrogenethylenediaminetetraacetate		
Inhalative	LC50/4 h	1.5 mg/l (ATE)

· **Primary irritant effect:**
· **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
· **Serious eye damage/irritation**
Causes serious eye damage.
· **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
· **Additional toxicological information:**
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.

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· ***STOT-single exposure*** *Based on available data, the classification criteria are not met.*
· ***STOT-repeated exposure*** *Based on available data, the classification criteria are not met.*
· ***Aspiration hazard*** *Based on available data, the classification criteria are not met.*

*
SECTION 12: Ecological information

· ***12.1 Toxicity***
· ***Aquatic toxicity:*** *No further relevant information available.*
· ***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.*
· ***Ecotoxical effects:***
· ***Remark:*** *Very toxic for fish*
· ***Additional ecological information:***
· ***General notes:***
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
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
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.
· ***12.5 Results of PBT and vPvB assessment***
· ***PBT:*** *Not applicable.*
· ***vPvB:*** *Not applicable.*
· ***12.6 Other adverse effects*** *No further relevant information available.*

*
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.

· ***European waste catalogue***	
07 00 00	*WASTES FROM ORGANIC CHEMICAL PROCESSES*
07 06 00	*wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics*
07 06 99	*wastes not otherwise specified*

· ***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***	
· ***ADR, IMDG, IATA***	*UN1903*
· ***14.2 UN proper shipping name***	
· ***ADR***	*1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine, Didecylmethylpolyoxyethylammoniumpropionat)*

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· **IMDG**	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine, didecyldimethylammonium chloride), MARINE POLLUTANT
· **IATA**	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine, 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 Symbol (fish and tree)
· **Special marking (ADR):**	Symbol (fish and tree)
· **14.6 Special precautions for user**	Warning: Corrosive substances.
· **Hazard identification number (Kemler code):**	8
· **EMS Number:**	F-A,S-B
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Excepted quantities (EQ):**	E1
· **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
· **Transport category**	3
· **Tunnel restriction code**	E
· **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

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· **UN "Model Regulation":**	UN1903, DISINFECTANT, LIQUID, CORROSIVE, N.O.S., 8, III

*
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

· **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
· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **Regulation (EU) No 649/2012**		
7173-51-5	didecyldimethylammonium chloride	Annex I Part 1

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
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.
Customs tariff No.: 3808 94 90

· **Relevant phrases**
H301 Toxic if swallowed.
H302 Harmful if swallowed.
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.
H400 Very toxic to aquatic life.
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 européen sur le transport 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 - oral – Category 3
Acute Tox. 4: Acute toxicity - oral – Category 4
Skin Corr. 1A: Skin corrosion/irritation – Category 1A

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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.***