SAFETY DATA SHEET

according to Regulation (EC) No 1907/2006 (REACH) Article 31, Annex II as amended

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE **COMPANY/UNDERTAKING**

Product identifier 1.1

Product name:	DENTIRO [®] Zero
UFI:	MA00-C0F3-200X-QFHV
Substance type:	Mixture
Use of the substance/mixture:	Surface disinfectant

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

use:

Identified uses:	DENTIRO [®] Zero is an alcohol-free, ready-to-use solution for the fast disinfection and cleaning of non-invasive medical devices with sensitive surfaces such as dental chairs. DENTIRO [®] Zero is particularly suitable for the disinfection of alcohol-sensitive materials such as artificial leather, Plexiglas [®] , and PVC.
Uses advised against:	Do not use for purposes other than those prescribed.
Recommended restrictions on	For professional use only.

1.3 Details of the supplier of the safety data sheet

	Manufacturer	EU only representative
Address:	Oro Clean Chemie AG Allmendstrasse 21 8320 Fehraltorf Switzerland	Oro Clean Chemie s.r.o. Vinohradská 2828/151 Žižkov 130 00 Praha 3 Czech Republic
Telephone:	+41 (0)44 226 44 44	
Email:	info@oroclean.com	info@oroclean.cz
Website:	www.oroclean.com	www.oroclean.cz
	Downstream user/importer/di	stributor
Address:	Oro Clean Chemie s.r.o. Vinohradská 2828/151 Žižkov 130 00 Praha 3 Czech Republic	
Telephone:		
Email:	info@oroclean.cz	

Person responsible for preparing the SDS

Lee Moi Wong | Research & Development | Chief Research Officer (CRO) Telephone: +41 (0)44 226 44 44 Email: ra@oroclean.com

1.4 Emergency telephone number

Emergency telephone number: 112

* Please check the above numbers regularly as they might be subject to change.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according	lassification according to Regulation (EC) No 1272/2008		
Hazard type Hazard category Hazard statement code(s) Classification procedure			Classification procedure
Environmental hazard	Aquatic Chronic 3	H412	Harmonised (legal) classification.

The full text for all H-statements is displayed in section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

	0 0 0	· · ·	
	Hazard pictograms:	None.	
	Signal word:	No signal word	according to Regulation (EC) 1272/2008.
	Hazard statements:	H412	Harmful to aquatic life with long lasting effects.
	Precautionary statements:	P273 P305 + P351 + P338 P501	Avoid release to the environment. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Dispose of contents/container in accordance with local and
		F301	national regulations.
	Supplemental information:	Not applicable.	
3	Other hazards		
	PBT or vPvB properties:	persistent, bioa	mixture contains no components considered to be either ccumulative and toxic (PBT), or very persistent and very (vPvB) at levels of 0.1% or higher.
	Endocrine disrupting properties:	endocrine disru	mixture does not contain components considered to have pting properties according to REACH Article 57(f) or Commission ulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 6 or higher.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

See below.

3.2 Mixtures

2.3

Classification according to Regulation (EC) No 1272/2008

Substance name	Identification	Classification	SCL, M-factor, ATE	Concentration
Alkyl (C12-16) dimethylbenzyl ammonium chloride	CAS no.: 68424-85-1 EC no.: 939-253-5 Index no.: No data available. REACH no.: 01-2119965180-41-0000	Acute Tox. 4, H302 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Eye Dam. 1, H318 Skin Corr. 1B, H314	M = 10, M (chronic) = 1	< 1%
Amines, N-C10-16- alkyltrimethylenedi,-reaction oroducts with chloroacetic acid	CAS no.: 139734-65-9 EC no.: 701-317-3 Index no.: Not applicable. REACH no.: 01-2120050368-56-0000	Acute Tox. 4, H302 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314	No data available.	< 1%

The full text for all H-statements is displayed in section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Never give anything by mouth to an unconscious person. Place patient in recovery position and ensure airway patency. When in doubt or if feeling unwell seek medical assistance. Show the safety data sheet and label to the physician.
After inhalation:	Remove patient to fresh air - move out of dangerous area. Obtain professional medical help.
After contact with skin:	Take off all contaminated clothing. Areas of the body that have come into contact with the product must be rinsed with water. If symptoms develop and persist, seek medical attention.
After contact with eyes:	Immediately flush eyes with running water, keeping eyelids apart. If irritation persists, seek professional medical attention.
After ingestion:	Do not induce vomiting. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Consult a physician. Show the physician the safety data sheet or label.

4.2 Most important symptoms and effects, both acute and delayed

See section 11 for more detailed information on health effects and symptoms.

4.3 Indication of any immediate medical attention and special treatment needed Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:Carbon dioxide. Dry chemical powder. Water spray. Alcohol resistant foam.Unsuitable extinguishing media:Full water jet.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:	In case of a fire toxic gases can be generated; do not inhale gases/smoke.
Hazardous combustion products:	No data available.

5.3 Advice for firefighters

Special protective equipment for
firefighters:Firefighters should wear appropriate protective clothing for firefighters (including
helmets, protective boots and gloves) (BS EN 469) and self-contained breathing
apparatus (SCBA) with a full face-piece (BS EN 137).Additional information:In case of fire or heating do not breathe fumes/vapours. No action shall be taken
involving any personal risk or without suitable training. Contaminated firefighting
water and fire residues must be disposed of in accordance with the local
regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures



Advice for non-emergency personnel:	Use personal protective equipment (section 8). Ensure adequate ventilation. No action shall be taken involving any personal risk or without suitable training. Prevent access to unprotected personnel. Evacuate the danger zone. Do not breathe vapour or mist. Avoid contact with skin, eyes and clothing.
Advice for emergency responders:	Use personal protective equipment.

6.2 Environmental precautions

Do not allow to enter drains or waterways. Prevent product from getting into subsoil/soil.

6.3 Methods and material for containment and cleaning up

Stem the spill if this does not pose risks. Absorb product (with inert material), collect it in special container and dispose it to a licensed hazardous-waste disposal contractor. Prevent release into the sewer, water, basements or confined areas. Ventilate the premises. Clean contaminated area with plenty of water.

6.4 Reference to other sections

See also sections 7, 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

General advice:	Use general or local exhaust ventilation to prevent inhaling vapours and aerosols. Do not discharge into drains, surface water and soil. After use immediately close container tightly.
Instructions for protection against fire and explosion:	Ensure adequate ventilation.
Advice on general occupational hygiene:	Use good personal hygiene practices – wash hands at breaks and when done working with material. Do not eat, drink or smoke while working. Do not breathe vapours/mist. Avoid contact with skin, eyes and clothes. Remove contaminated clothes and wash them before reuse. Wear suitable protective equipment; see section 8.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage room and containers:	Close opened containers after use. Put the containers upright to prevent from leaking. Do not store in unlabelled containers.
Further information about storage conditions:	Keep in a cool, dry and well ventilated place. Keep away from food, drink and animal feeding stuffs. Store only in original container.
Stocking with different products:	Store separately from beverages, food and feed. Store separately from strong acids, bases and oxidation agents.

7.3 Specific end use(s)

See identified uses in section 1.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits

Please refer to the latest edition of the appropriate source text and consult an industrial hygienist or similar professional, or local agencies, for further information.

Biological limit values

No biological exposure limits noted for the ingredient(s).

DNEL values

Substance name	Pattern of exposure	Route of exposure	Limit value
Alkyl (C12-16) dimethylbenzyl ammon- ium chloride CAS no.:68424-85-1	No threshold derived.	No threshold derived.	No threshold derived.
Amines, N-C10-16-alkyltrimethylened- i,-reaction products with chloroacetic acid CAS no.:139734-65-9	Worker (long term, systemic effects)	Inhalation	280 µg/m³
	Consumer (long term, systemic effects)	Inhalation	50 µg/m³
	Worker (long term, systemic effects)	Dermal	4 mg/kg bw/day
	Consumer (long term, systemic effects)	Dermal	286 µg/kg bw/day
	Consumer (long term, systemic effects)	Oral	29 µg/kg bw/day
PNEC values			
Substance name	Route of exposure	Limit value	
Alkyl (C12-16) dimethylbenzyl ammon- ium chloride CAS no.:68424-85-1	Fresh water	420 ng/L	
	Marine water	96 ng/L	
	Intermittent release (fresh water)	160 ng/L	
	Intermittent release (marine water)	207 ng/L	
	Sewage treatment plant	160 µg/L	
	Sediment (fresh water)	68 mg/kg dw	
	Intermittent release (marine water)	15.75 mg/kg dw	
	Soil	1.66 mg/kg dw	
Amines, N-C10-16-alkyltrimethylened- i,-reaction products with chloroacetic acid CAS no.:139734-65-9	Fresh water	230 ng/L	
	Marine water	23 ng/L	
	Intermittent release (fresh water)	237 ng/L	
	Sewage treatment plant	220 µg/L	
	Sediment (fresh water)	2.67 mg/kg dw	
	Sediment (marine water)	534 µg/kg dw	
	Soil	6.4 mg/kg dw	

8.2 Exposure controls

Appropriate engineering controls

See section 7. No additional measures necessary.

Individual protection measures	3	
Eye/face protection:	Not required during normal use.	
Hand protection:	Not required during normal use.	
Body protection:	Not required during normal use.	
Respiratory protection:	Avoid aerosol formation. Use respiratory protection if aerosol is formed.	
Thermal hazards:	No data available.	
Hygiene measures:	Use good personal hygiene practices – wash hands at breaks and when done working with material. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes. Do not eat, drink or smoke while working. Do not breathe vapours/aerosols.	

Environmental exposure controls

Observe the usual precautions for handling chemicals.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Form:	Clear, non-viscous liquid
Colour:	Colourless
Odour:	Apple
Melting point:	No data available.
Freezing point:	No data available.
Boiling point or initial boiling point and boiling range:	No data available.
Flammability:	The product is not flammable.
Lower explosion limit:	Not applicable.
Upper explosion limit:	Not applicable.
Flash point:	No data available.
Auto-ignition temperature:	Not self-igniting.
Decomposition temperature:	Not applicable.
pH-value (undiluted product):	8.2 - 8.8
pH-value (diluted product):	Not applicable (ready-to-use solution).
Kinematic viscosity:	No data available.
Solubility:	Completely miscible with water.
Partition coefficient n- octanol/water:	Not applicable.
Vapour pressure at 50 °C:	No data available.
Density:	1.00 g/cm ³
Relative density:	1.00
Relative vapour density at 20 °C:	No data available.

9.2 Other information

Oxidising properties: Explosive properties: Evaporation rate: Miscibility: Other information: Not oxidising. Product is not explosive. No data available. Completely miscible with water. No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The mixture is not reactive.

10.2 Chemical stability

Stable at normal temperatures and pressure at least up to the expiry date printed on the container.

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Avoid conditions beyond those mentioned in section 7.

10.5 Incompatible materials

No specific materials to avoid during intended use.

10.6 Hazardous decomposition products

No dangerous decomposition products occur under normal storage and use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Inhalation:	Information on effects are given below.
Skin contact:	Information on effects are given below.
Eye contact:	Information on effects are given below.
Ingestion:	Information on effects are given below.
Acute toxicity	
Mixture:	ATEmix: LD50 (rat, ingestion) > 5000 mg/kg
Component:	No data available.
Skin corrosion/irritation	
Mixture:	No irritation is expected.
Component:	No data available.
Serious eye damage/irritation	
Mixture:	Irritating to eyes.
Component:	No data available.
Respiratory or skin sensitization	
Mixture:	The product is not classified as sensitising.
Component:	No data available.
Germ cell mutagenicity	
Mixture:	Not a mutagen. Does not contain ingredients with known mutagenic properties.
Component:	No data available.
Carcinogenicity	
Mixture:	Does not contain ingredients with known carcinogenic properties.
Component:	No data available.
Reproductive toxicity	
Mixture:	This product contains no ingredients with known reproductive toxicity effects.
Component:	No data available.
STOT-single exposure	
Mixture:	This product exhibits no known STOT-single exposure.
Component:	No data available.
STOT-repeated exposure	
Mixture:	This product exhibits no known STOT-repeated exposure.
Component:	No data available.
Aspiration hazard	
Mixture:	This product exhibits no known aspiration hazard.
Component:	No data available.

11.2 Information on other hazards

Endocrine disrupting properties	
Mixture:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
Component:	No data available.
Other hazards	
Mixture:	No data available.
Component:	No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

This product has no known ecotoxic effect. The product is not expected to negatively affect the function of sewage treatment plants. There is no data available from ecotoxicological tests regarding the entire product. The ecotoxicological risk has been estimated based on available data on product ingredients and concentrations, where available.

12.2 Persistence and degradability

The product ingredients possess good biodegradation properties. The surfactants included in the product comply with the requirements for the biological decomposition of Regulation (EC) No. 648/2004 on detergents. Based on available data, the biodegradability in sewage treatment plants can be categorized as high.

Substance name	Biodegradation	Basis	Remark
Alkyl (C12-16) dimethylbenzyl ammonium chloride	Ca. 60%	OECD 301 D, 28 D	Readily biodegradable.
Amines, N-C10-16-alkyltrimethylenedi,- reaction products with chloroacetic acid	94%	OECD 301 A	Readily biodegradable.

12.3 Bioaccumulative potential

Mixture:

Based on available data, no product ingredient is expected to exhibit bioaccumulative potential. No data available.

Component:

12.4 Mobility in soil Mixture:

Mixture: The product is not expected to be mobile over long distances because all product ingredients possess good biodegradability. Surface tension and absorption / desorption kinetics are not relevant to the product. No data available.

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

The product contains no ingredients with ozone depletion potential or global warming potential. The product contains no heavy metals or their compounds as defined in 2006/11/EG. The product contains no absorbable organic halogens (AOX) or volatile organic compounds (VOC).

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal methods:

Dispose of according to national and regional provisions. Waste code EWC Nr: 070699 (Group: waste material of MFSU from fats, lubricants, soaps, detergents, disinfectants and personal protection products). Small amounts of the product (up to about 500 ml per day) can be disposed of via the sewage system after dilution 1:5 with tap water.

Contaminated packaging:

Empty packaging can be treated like household waste or recycled after cleaning with water. Handle the packaging containing the product in the same way as the product itself. Where available, references to local regulations regarding disposal are given in section 15 of the SDS. The user has sole responsibility for acquaintance and compliance with the applicable regulations.

SECTION 14: TRANSPORT INFORMATION

Land transport (ADR/ADN/RID)

14.1 UN number

Not regulated as a dangerous good.

- **14.2 UN proper shipping name** Not applicable.
- 14.3 Transport hazard class(es) Not applicable.

14.4 Packing group

Not regulated as a dangerous good. | Danger label: Not applicable. | LQ: Not applicable.

14.5 Environmental hazards

Environmental hazards: No

14.6 Special precautions for user See sections 6 to 8.

Sea transport (IMDG/IMO)

14.1 UN number

Not regulated as a dangerous good.

14.2 UN proper shipping name Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not regulated as a dangerous good. | Danger label: Not applicable. | LQ: Not applicable.

14.5 Environmental hazards

Environmental hazards: No Marine pollutant: No

14.6 Special precautions for user See sections 6 to 8.

14.7 Maritime transport in bulk according to IMO instruments Not applicable for product as supplied.

Air transport (IATA)

- **14.1 UN number** Not regulated as a dangerous good.
- **14.2 UN proper shipping name** Not applicable.
- **14.3 Transport hazard class(es)** Not applicable.
- **14.4 Packing group** Not regulated as a dangerous good. | Danger label: Not applicable. | LQ: Not applicable.

14.5 Environmental hazards

Environmental hazards: No

14.6 Special precautions for user

See sections 6 to 8.

SECTION 15: REGULATORY INFORMATION

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

The product has been classified and marked in accordance with Regulation (EC) No.1272/2008 (CLP). The product complies with requirements of Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 648/2004 (Detergents Regulation), Regulation (EU) No. 528/2012 (Biocides Regulation), Directive 93/42/EC (Medical Devices Directive), and Regulation (EU) No. 2017/745 on medical devices (MDR), if applicable.

15.2 Chemical safety assessment

No chemical safety assessment was carried out for this product.

SECTION 16: OTHER INFORMATION

Indication of changes

1.1 Product identifier - Updated.

- 1.2 Relevant identified uses of the substance or mixture and uses advised against Updated.
- 1.3 Details of the supplier of the safety data sheet Updated.
- 1.4 Emergency telephone number Updated.
- 4.1 Description of first aid measures Updated.
- 5.2 Special hazards arising from the substance or mixture Updated.
- 5.3 Advice for firefighters Updated.
- 6.1 Personal precautions, protective equipment and emergency procedures Updated.
- 6.2 Environmental precautions Updated.
- 7.1 Precautions for safe handling Updated.
- 7.2 Conditions for safe storage, including any incompatibilities Updated.
- 8.1 Control parameters Updated.
- 8.2 Exposure controls Updated.
- 9.1 Information on basic physical and chemical properties Updated.
- 9.2 Other information Updated.

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008 / Information on toxicological effects - Updated.

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

Abbreviations and acronyms

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road ASTM - American Society for Testing and Materials AwSV - Ordinance on facilities for handling substances that are hazardous to water **BOD** - Biochemical Oxygen Demand c.c. - Closed cup CAS - Chemical Abstract Services CESIO - European Committee of Organic Surfactants and their Intermediates COD - Chemical Oxygen Demand DMEL - Derived Minimum Effect Level DNEL - Derived No Effect Level EbC50 - Median concentration in terms of reduction of growth EC - Effective concentration EINECS - European Inventory of Existing Commercial Chemical Substances EN - European Norm ErC50 - Median concentration in terms of reduction of growth rate GGVSEB - German ordinance for road, rail and inland waterway transportation of dangerous goods GGVSee - German ordinance for sea transportation of dangerous goods GLP - Good Laboratory Practice GMO - Genetic Modified Organism IATA - International Air Transport Association ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods ISO - International Organization For Standardization LD/LC - Lethal dose/concentration LOAEL - Lowest Observed Adverse Effect Level LOEL - Lowest Observed Effect Level LQ - Limited Quantity M-Factor - Multiplying factor NOAEL - No Observed Adverse Effect Level NOEC - No Observed Effect Concentration NOEL - No Observed Effect Level o.c. - Open cup



OECD - Organisation for Economic Cooperation and Development OEL - Occupational Exposure Limit PBT - Persistent, bioaccumulative, toxic PNEC - Predicted No Effect Concentration REACH - REACH registration RID - Convention concerning International Carriage by Rail SVHC - Substances of Very High Concern TA - Technical Instructions TRGS - Technical Rules for Hazardous Substances vPvB - Very persistent, very bioaccumulative WGK - Water Hazard Class

Key literature references and sources for data

No data available.

Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

Hazard category	Hazard statement code(s)	Classification procedure
Aquatic Chronic 3	H412	Harmonised (legal) classification.

List of relevant phrases

- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H318 Causes serious eye damage.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.

Training information

Comply with national laws regulating employee instruction.

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.