

Material Safety Data Sheet

according to Regulation (EC) No 1907/2006 (REACH)

DENTIRO® Zero

Version: 5.0.0 | Date: 09.06.2016 || Replaces version: 4.1.0 | Date: 01.06.2015 || English

1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 **PRODUCT IDENTIFIER**
DENTIRO® Zero

1.2 **RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST**
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 abdominal and vaginal ultrasound probes and infusion pumps. DENTIRO® Zero is particularly suitable for the disinfection of alcohol-sensitive materials such as natural and artificial leather, Plexiglas®, and soft PVC. The active compounds of DENTIRO® Zero do not evaporate and therefore, reduce surface re-contamination.

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	Address:	Medical OCC Deutschland GmbH Wickhofstrasse 12 13467 Berlin Germany
Telephone:	Switzerland +41 (0)44 226 44 44	Telephone:	Germany +49 (0)30 1207 61 18
Fax:	Switzerland +41 (0)44 226 44 00	E-Mail:	info@oroclean.com
E-Mail:	info@oroclean.com	Website:	www.oroclean.com
Website:	www.oroclean.com		

Downstream users / importer / distributor

Address:	Oro Clean Chemie AG Allmendstrasse 21 8320 Fehraltorf Switzerland
Telephone:	+41 (0)44 226 44 44
Fax:	+41 (0)44 226 44 00
E-Mail:	info@oroclean.com
Website:	www.oroclean.com

1.3.1 **PERSON RESPONSIBLE FOR PREPARING THE MSDS**

Ms Wong Lee Moi
Research & Development Manager
E-Mail: leemoi.wong@oroclean.com

1.4 **EMERGENCY TELEPHONE NUMBERS**

Emergency information: +41 (0)44 512 49 89
Toxicological center*: +41 (0)44 251 51 51 (Switzerland)

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

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2 HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

2.1.1 CLASSIFICATION ACCORDING TO REGULATION (EC) NO 1272/2008

HAZARD CLASSES AND CATEGORIES	HAZARD STATEMENTS:	CLASSIFICATION PROCEDURE
Aquatic Chronic 3	H412 Harmful to aquatic life with long lasting effects.	Harmonised (legal) classification.

2.2 LABEL ELEMENTS

2.2.1 LABELING OF THE MIXTURE ACCORDING TO REGULATION (EC) NO 1272/2008

Hazard pictograms:

–

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 Avoid release to the environment.

P305+P351 IF IN EYES: Rinse cautiously with water for several minutes.

P501 Dispose of contents/container in accordance with relevant regulations.

Supplemental hazard information (EU):

– No supplementary labelling requirements according to Regulation (EC) 1272/2008.

2.3 OTHER HAZARDS

This mixture does not meet the PBT/vPvB criteria of REACH, annex XIII.

3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

This product is a mixture (see section 3.2).

3.2 MIXTURES

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3.2.1 HAZARDOUS INGREDIENTS CLASSIFICATION ACCORDING TO REGULATION (EC) NO 1272/2008

Name	CAS number	EINECS number	Index number	REACH number	Hazard categories	Hazard statements	Concentration
Benzyl-C12-16-alkyldimethylammonium chloride	68424-85-1	270-325-2	n.a.	05-2115874530-46-0000	Acute Tox. 4, Skin Corr. 1B, Aquatic Acute 1, Aquatic Chronic 1	H302, H314, H400, H410	< 1%
Amines, N-C10-16-alkyltrimethylenedi-, reaction products with chloro acetic acid	139734-65-9	n.a.	n.a.	No obligations under REACH.	Acute Tox. 4, Skin Corr. 1C, Aquatic Acute 1	H302, H314, H400	< 1%

3.2.2 ADDITIONAL INFORMATION

For the full wording of the listed R- and H-phrases see section 16.

4 FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

4.1.1 GENERAL INSTRUCTIONS

Ensure self-protection. When seeking medical attention show this material safety data sheet.

4.1.2 AFTER INHALATION

Ensure self-protection against product vapors or aerosols. Move any person involved from exposure area to fresh air. Do not leave the person(s) alone. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop. Loosen tight clothing such as a collar, tie, belt or waistband.

4.1.3 AFTER SKIN CONTACT

Immediately remove contaminated clothing . Wash skin with plenty of cold water. Do not use solvents. Seek medical attention if irritation or other symptoms develop. Wash clothing before reuse.

4.1.4 AFTER EYE CONTACT

Flush eyes out with running water. Obtain medical attention if symptoms such as redness, irritation or pain develop.

4.1.5 AFTER INGESTION

Rinse mouth with water and make victim drink plenty of water. Do not induce vomiting. If vomiting occurs naturally, have victim lean forward and give water again. Do not attempt to give anything to a semi-conscious or unconscious person. Immediately seek medical attention.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The following symptoms may occur: IN CASE OF INGESTION nausea, vomiting, abdominal pain, gastrointestinal complaints, pulmonary irritation.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Treat symptomatically.

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5 FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

5.1.1 SUITABLE EXTINGUISHER

Water spray, carbon dioxide, foam, solid extinguishing agents. Product itself does not burn, take appropriated fire-fighting measures regarding the whole fire.

5.1.2 UNSUITABLE EXTINGUISHER FOR SAFETY REASONS

None

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

No special danger to be expected.

5.3 ADVICE FOR FIREFIGHTERS

5.3.1 PROTECTIVE DEVICE FOR FIREFIGHTING

Use suitable respiratory equipment.

5.3.2 FURTHER INDICATIONS

Do not inhale any explosion or fire fumes. Take appropriated fire-fighting measures regarding the whole fire. Any fire substance and contaminated fire-fighting water have to be disposed according to instructions of the local authority.

6 ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Wear suitable protective equipment. Slippery when spilled. Do not open the primary container unless authorised to do so. Restrict access to area until completion of cleanup.

6.2 ENVIRONMENTAL PRECAUTIONS

Contain spill with absorbent material, such as sand, vermiculite or universal binding material.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Wipe up with absorbent material (e.g. cloth, fleece).

6.4 REFERENCE TO OTHER SECTIONS

For instructions for safe handling, disposal, and personal protection equipment see sections 07, 08, and 13.

7 HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Read product instructions before use. Wear suitable protective equipment (please see section 08). Open container carefully. Avoid breathing fumes / aerosols. Avoid contact with eyes and mucous membranes. Do not mix with other products. Retain all warning and identity labels.

7.1.1 INSTRUCTIONS FOR PROTECTION AGAINST FIRE AND EXPLOSION

The product is not combustible. No special protective measures against fire and explosion are required.

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- 7.1.2 ADVICE ON GENERAL OCCUPATIONAL HYGIENE**
Do not eat, drink, or smoke while working. Before breaks and after work wash hands thoroughly. Use cream to care for your skin. Handle the product in accordance with good industrial hygiene and safety practices.
- 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES**
- 7.2.1 REQUIREMENTS FOR STORAGE ROOM AND CONTAINERS**
Keep out of reach of children. Keep in the original container only. Full pallets must not be stacked.
- 7.2.2 FURTHER INFORMATION ABOUT STORAGE CONDITIONS**
Keep container tightly closed. Store at room temperature. Keep from freezing and temperature greater than 30°C. Store in a dry place. Do not store for prolonged periods in direct sunlight.
- 7.2.3 STOCKING WITH DIFFERENT PRODUCTS**
Store separately from beverages, food and feed.
- 7.3 SPECIFIC END USE(S)**
See section 01 or technical data sheet.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

8.1.1 COMPONENTS WITH OCCUPATIONAL EXPOSURE LIMIT VALUES

SUBSTANCE	CAS NUMBER	LONG TERM LIMIT VALUES (MG/M3)	SHORT TERM LIMIT VALUES (MG/M3)
BENZYL-C12-16-ALKYLDIMETHYLAMMO- NIUM CHLORIDE	68424-85-1	NO OCCUPATIONAL EXPOSURE LIMITS.	NO OCCUPATIONAL EXPOSURE LIMITS.
AMINES, N-C10-16-ALKYLTRIMETHYL- ENEDI,-REACTION PRODUCTS WITH CHLORO ACETIC ACID	139734-65-9	NO OCCUPATIONAL EXPOSURE LIMITS.	NO OCCUPATIONAL EXPOSURE LIMITS.

8.1.2 COMPONENTS WITH BIOLOGICAL LIMIT VALUES

SUBSTANCE	CAS NUMBER	LIMIT VALUES (MG/M3)
BENZYL-C12-16-ALKYLDIMETHYLAMMO- NIUM CHLORIDE	68424-85-1	NO BIOLOGICAL LIMIT VALUES.
AMINES, N-C10-16-ALKYLTRIMETHYL- ENEDI,-REACTION PRODUCTS WITH CHLORO ACETIC ACID	139734-65-9	NO BIOLOGICAL LIMIT VALUES.

8.2 EXPOSURE CONTROLS

8.2.1 APPROPRIATE ENGINEERING CONTROLS

See section 07. No additional measures necessary.

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8.2.2 PERSONAL PROTECTIVE EQUIPMENT

Eye / face protection:

Not required during normal use.

Skin protection:

Hand protection

Not applicable..

Other

Not required during normal use.

Respiratory protection:

Avoid aerosol formation. Use respiratory protection if aerosol is formed.

General protection measures:

Avoid contact with eyes.

8.2.3 ENVIRONMENTAL EXPOSURE CONTROLS

Observe the usual precautions for handling chemicals.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

9.1.1 GENERAL INFORMATION

Colour: Colourless

Physical state: Clear, non-viscous liquid

Scent: Apple

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9.1.2 IMPORTANT HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

pH-value:	8 - 8.5
pH-value in aqueous solution:	Not applicable (ready-to-use solution)
Melting point (°C):	No data available.
Boiling point (°C):	No data available.
Flash point (°C):	No data available.
Flammability:	The product is not flammable.
Explosive properties:	The product does not pose any danger of explosion.
Lower explosion limit (%):	Not applicable.
Upper explosion value (%):	Not applicable.
Oxidizing properties:	The product has no oxidizing properties
Vapor pressure (kPa):	No data available.
Relative density (g/cm ³):	1
Solubility / Miscibility:	Fully miscible with water
Partition coefficient n-octanol/water (log Pow):	Not applicable.
Viscosity (mPas):	No data available.
Vapor density in relation to water:	No data available.
Evaporation rate:	No data available.
Auto-ignition temperature (°C):	This product does not possess autoignition properties.
Decomposition temperature (°C):	Not applicable.

9.2 OTHER INFORMATION

Conductivity (mS/cm):	No data available.
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The temperature and / or pressure sensitive values are normalized to 20 °C and 1013 hPa.

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 hazardous reactions such as polymerization are expected.

10.4 CONDITIONS TO AVOID

Avoid conditions beyond those mentioned in section 07.

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- 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.

11 TOXICOLOGICAL INFORMATION

- 11.1 **INFORMATION ON TOXICOLOGICAL EFFECTS**
- 11.1.1 **ACUTE ORAL TOXICITY**
LD50 (rat) > 5000 mg/kg
- 11.1.2 **ACUTE DERMAL TOXICITY**
No data available.
- 11.1.3 **ACUTE INHALATIVE TOXICITY**
No data available.
- 11.1.4 **SKIN / MUCOSA IRRITATION AND CORROSIVITY**
No irritation is expected.
- 11.1.5 **EYE IRRITATION AND CORROSIVITY**
Irritating to eyes.
- 11.1.6 **SENSITIZATION**
No sensitization is expected.
- 11.1.7 **REPEATED DOSE TOXICITY**
This product exhibits no known chronic toxicity.
- 11.1.9 **CMR-EFFECTS (CARCINOGENICITY, MUTAGENICITY AND REPRODUCTIVE TOXICITY)**
This product contains no ingredients with known carcinogenicity, mutagenicity or reproductive toxicity effects.
- 11.1.10 **ADDITIONAL ADVICE ON TOXICOLOGY**
The product was classified in toxicological terms on the basis of the results of the calculation procedure outlined within Regulation (EC) No. 1272/2008 (CLP). There are no data from toxicological tests regarding the entire product. The values for acute toxicity, irritation and sensitization on skin and mucosa and for the mutagenic potential of the product were estimated based on available data on product ingredients. There is a lack of relevant data for some ingredients. According to the experience of the manufacturer, no dangers other than the ones declared on the label are to be expected.

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.

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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.

BIODEGRADATION OF RELEVANT SUBSTANCES IN THE MIXTURE

SUBSTANCE	CAS NUMBER	BIODEGRADATION
BENZYL-C12-16-ALKYLDIMETHYLAMMONIUM CHLORIDE	68424-85-1	CA. 60% (28 D, METHOD OECD 301 D, READILY BIODEGRADABLE).
AMINES, N-C10-16-ALKYLTRIMETHYLENE, -REACTION PRODUCTS WITH CHLOROACETIC ACID	139734-65-9	94% (METHOD OECD 301 A, READILY BIODEGRADABLE).

12.3 BIOACCUMULATIVE POTENTIAL

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

12.4 MOBILITY IN SOIL

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.

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

This product does not contain a PBT-/vPvB-substance according to REACH, Annex XIII.

12.6 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).

13 DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

13.1.1 DISPOSAL OF PRODUCT

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.

13.1.2 DISPOSAL OF 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 MSDS. The user has sole responsibility for acquaintance and compliance with the applicable regulations.

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14 TRANSPORT INFORMATION

- 14.1 **UN NUMBER**
Transportation and shipping of this product is not restricted.
- 14.2 **UN PROPER SHIPPING NAME**
- 14.2.1 **ADR/RID/SDR**
- (-)
- 14.2.2 **IMDG CODE / ICAO-TI / IATA-DGR**
- (-)
- 14.3 **TRANSPORT HAZARD CLASS(ES)**
- (-)
- 14.4 **PACKING GROUP**
- (-)
- 14.4.1 **HAZARD LABEL**
-
- 14.4.2 **LQ**
Transportation and shipping of this product is not restricted.
- 14.5 **ENVIRONMENTAL HAZARDS**
ADR/RID / IMDG-Code / ICAO-TI / IATA -DGR: No
Marine pollutant: No
- 14.6 **SPECIAL PRECAUTIONS FOR USER**
See sections 06 to 08.
- 14.7 **TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL73/78 AND THE IBC CODE**
This product is not delivered in bulk according to Annex II of MARPOL73/78 and the IBC Code.

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), and Directive 93/42/EC (Medical Devices Directive) if applicable.
- 15.1.1 **NATIONAL REGULATIONS**
For further information, please refer to local law.
- 15.2 **CHEMICAL SAFETY ASSESSMENT**
Chemical safety assessments for substances in this mixture were not carried out.

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16 OTHER INFORMATION

LIST OF RELEVANT R-PHRASES, HAZARD STATEMENTS, SAFETY PHRASES AND/OR PRECAUTIONARY STATEMENTS

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

TRAINING ADVICE

Thoroughly read this material safety data sheet before using this product. For detailed information refer to the technical data sheet.

SOURCES OF KEY DATA

The material safety data sheets from suppliers of ingredients, scientific literature, as well as the current regulations were used as a basis for the preparation of this material safety data sheet.

INDICATION OF CHANGE	REASON FOR REVISION
1.3.1 Person responsible for preparing the MSDS	Change in company contact information
1.4 Emergency telephone numbers	Change in emergency contact information.
2.2.1 Labelling according to Directive 1999/45/EC	Adaptation.
13.1.1 Disposal of product	Adaptation.
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	Adaptation to change in regulations.
16 Other information	Adaptation to change in regulations.

ABBREVIATIONS AND ACRONYMS

Abbreviations and acronyms used in this document can be looked up on www.wikipedia.org.

FURTHER INFORMATION

The information in this material safety data sheet is based on the present state of the Manufacturer's knowledge and experience. This information is given for safety reasons only. It is given in good faith and shall not constitute a guarantee for any specific product properties. The information does not imply a legally valid contractual relationship. Users should make their own investigations to determine how suitable the information provided in this material safety data sheet is for their own purposes. It is the responsibility of the user to comply with all applicable laws and regulations. Any use of the product which does not conform to this material safety data sheet or which involves using the product in combination with any other products or processes is the responsibility of the user. The data in sections 04 to 08 and 10 to 12 refer in part to the release of large quantities and not to the proper product application or use. The information in this material safety data sheet should be provided to all those who will use, handle, store, transport or otherwise be exposed to this product. No responsibility is taken as to the accuracy or the completeness of the provided information in all cases.

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MSDS Update Alert

You are legally obliged to always have the most recent MSDS from your suppliers on hand. Sign-up now for MSDS Update Alerts and OCC Switzerland will immediately notify you if there is a change in a MSDS.

Visit: www.oro-clean.com