

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

ULTRACLEAN-3

Version: 5.0.0 | Date: 09.06.2016 || Replaces version: 4.2.0 | Date: 01.06.2015 || English

IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAK-1 ING

1.1 **PRODUCT IDENTIFIER**

Telephone:

ULTRACLEAN-3

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST ULTRACLEAN-3 is a powerful concentrate for the cleaning of surgical and dental instruments in an ultrasonic cleaning device. The alkaline-based concentrate facilitates the removal of residual protein, blood, plaster, and

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET 1.3

Manufacturer		EU only representati	ve
Address:	Oro Clean Chemie AG	Address:	Oro

Oro Clean Chemie AG Allmendstrasse 21 8320 Fehraltorf Switzerland

Switzerland +41 (0)44 226 44 44

Fax: Switzerland +41 (0)44 226 44 00 E-Mail: info@oroclean.com Website: www.oroclean.com

Address:

Oro Clean Chemie s.r.o. Vinohradská 2828/151 Žižkov

130 00 Praha 3 Czech Republic

F-Mail: info@oroclean.cz Website: www.oroclean.cz

Downstream users / importer / distributor

Address: Oro Clean Chemie AG

Allmendstrasse 21 8320 Fehraltorf

Switzerland

+41 (0)44 226 44 44 +41 (0)44 226 44 00 Telephone: Fax E-Mail: info@oroclean.com Website: www.oroclean.com

1.3.1 PERSON RESPONSIBLE FOR PREPARING THE MSDS

Quality Assurance Department E-Mail: qa@oroclean.com

EMERGENCY TELEPHONE NUMBERS 1.4

Emergency information: +41 (0)44 512 49 89

+41 (0)44 251 51 51 (Switzerland) Toxicological center*:

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





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2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

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

HAZARD CLASSES AND CATE- HAZARD STATEMENTS: CLASSIFICATION PROCEDURE GORIES

Met. Corr. 1	H290	May be corrosive to metals.	On basis of test data.
Skin Corr. 1A	H314 eye da		Harmonised (legal) classification.

2.2 LABEL ELEMENTS

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

Hazard pictograms:



GHS05

Signal word:

Danger

Hazard statements:

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

Precautionary statements:

P260 Do not breathe dust or mist.

P280 Wear protective gloves, protective clothing and eye protection.

P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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

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

Supplemental hazard information (EU):

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





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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

3.2.1 HAZARDOUS INGREDIENTS

CLASSIFICATION ACCORDING TO REGULATION (EC) NO 1272/2008

Name	CAS number	EINECS number	Index num- REACH num ber	per Hazard categories	Hazard statements	Concentra- tion
Potassium hydroxide	1310-58-3	215-181-3	019-002-00- 01-2119487 8 0000	136-33- Acute Tox. 4, Skin Cori 1A	H302, H314	15% - < 30%

3.2.2 ADDITIONAL INFORMATION

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

4 FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

4.1.1 GENERAL INSTRUCTIONS

Ensure self-protection. Wear appropriate personal protective equipment. Immediately remove contaminated clothing. Bring any person out of the danger zone. In case of unconsciousness or danger of loss of consciousness immediately seek medical attention and administer first aid measures. First aid measures should be administered by a trained person. 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. Immediately seek medical attention. Wash clothing before reuse.

4.1.4 AFTER EYE CONTACT

Immediately flush out eyes with plenty of running water, while separating eyelids with fingers, for at least 15 minutes or as long as irritation continues. Remove contact lenses, if present, after first 5 minutes, and then continue rinsing eyes. Do not allow victim to rub eyes or keep them closed. Always immediately seek medical attention and consult an ophtalmologist, even if there is no apparent damage.





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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: skin and eye redness, skin burns, nausea, vomiting, abdominal pain, gastrointestinal complaints.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED Treat symptomatically.

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

Water jet.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Burning material may release dense smoke containing irritating and /or toxic gases, vapours and /or fumes.

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. Do not allow to get into water course, ground water or sanitary sewer system, otherwise inform responsible officials.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Stop leak if safe to do so. Small spills: Absorb with an inert material and place in an appropriatly labeled waste disposal container. Large spills: Collect for later disposal according to local, provincial, state or federal regulations. For disposal considerations please see section 13. Use cold water rinse for final clean-up.





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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 contact with eyes and skin. Do not mix with other products. Retain all warning and identity labels. Read label carefully and follow dilution chart on container to prepare correct solution strength. Do not use undiluted. Any non-intended or non-authorised use of this product may result in personal injury or damage to equipment.

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.

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 and persons unfamiliar with proper product use. Keep in the original container only. Do not use empty container with any other product or for any other purpose. Full pallets must not be stacked. Ensure dense floor covering which is resistant against acids, bases and solvents. Use ground tub without waste-draining.

7.2.2 FURTHER INFORMATION ABOUT STORAGE CONDITIONS

Keep container tightly closed. Store at room temperature. Keep from freezing and temperatures greater than 30°C. Store in a dry and well-ventilated place. Do not store for prolonged periods in direct sunlight. The user has sole responsibility for acquaintance and compliance with the regulations.

7.2.3 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 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)
POTASSIUM HYDROXIDE	1310-58-3	2 (BREATHABLE DUST; MAK CH; SUVA 2015).	NO SHORT-TERM EXPOSURE LIMIT (CH; SUVA 2015).





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8.1.2 COMPONENTS WITH BIOLOGICAL LIMIT VALUES

SUBSTANCE	CAS NUMBER	LIMIT VALUES (MG/M3)
POTASSIUM HYDROXIDE	1310-58-3	NO BIOLOGICAL LIMIT VALUES.

8.2 EXPOSURE CONTROLS

8.2.1 APPROPRIATE ENGINEERING CONTROLS

See section 07. No additional measures necessary.

8.2.2 PERSONAL PROTECTIVE EQUIPMENT

Eye / face protection:

Wear tightly fitting safety goggles or protective face shield.

Skin protection:

Hand protection

Short-term contact: Gloves with Protection Index of at least Class 2 (Norm EN 374, permeation time > 30 min) for substances of Classes G and K. Long-term contact: Gloves with Protection Index of at least Class 6 (Norm EN 374, permeation time > 480 min) for substances of Classes G and K. (Class G: amines; Class K: inorganic bases).

Other

Apron and work shoes or boots. Emergency responders should wear appropriate body protection.

Respiratory protection:

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

General protection measures:

Avoid contact with eyes, skin and clothing.

8.2.3 ENVIRONMENTAL EXPOSURE CONTROLS

Observe the usual precautions for handling chemicals. Do not empty concentrate into drains. Avoid releasing the concentrate to the environment.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

9.1.1 GENERAL INFORMATION

Colour:	Light yellow
Physical state:	Clear, non-viscous liquid
Scent:	Aromatic





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9.1.2 IMPORTANT HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

pH-value:	14
pH-value in aqueous solution:	12.5 - 13.5 (5%)
Melting point (°C):	No data available.
Boiling point (°C):	No data available.
Flash point (°C):	Not applicable.
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/cm3):	1.16
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.
OTHER INFORMATION	
Conductivity (mS/cm):	No data available.

9.2

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.

CONDITIONS TO AVOID 10.4

Avoid conditions beyond those mentioned in section 07.





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10.5 INCOMPATIBLE MATERIALS

Avoid contact with strong acids, bases or oxidation agents, danger of exothermic reactions.

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) > 1400 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

Causes severe burns.

11.1.5 EYE IRRITATION AND CORROSIVITY

Risk of serious damage to eyes.

11.1.6 SENSITIZATION

No sensitization is expected.

11.1.7 STOT-SINGLE EXPOSURE, STOT-REPEATED EXPOSURE, ASPIRATION HAZARD

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.





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12 ECOLOGICAL INFORMATION

12.1 TOXICITY

The release of the diluted ready-to-use solution of this product is not expected to have any ecotoxic effects. The concentrated solution can have prolonged and widespread toxic effects on aquatic and terrestrial organisms. The release of concentrated solution may 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. High product concentrations can affect the biodegradability potential of the activated sludge. Obtain the consent of the local authorities before discharging the concentrated solution to wastewater treatment plants.

BIODEGRADATION OF RELEVANT SUBSTANCES IN THE MIXTURE

SUBSTANCE	CAS NUMBER	BIODEGRADATION
POTASSIUM HYDROXIDE	1310-58-3	NOT APPLICABLE (THE SUBSTANCE IS AN INORGANIC MINERAL).

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 most of the product ingredients possess good biodegradability. The remaining ingredients (e.g. mineral salts) are absorbed into the soil without negative ecological effects. This product reduces the surface tension of water.

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





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13.1.1 DISPOSAL OF PRODUCT

Dispose of this product 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). The correctly diluted ready-to-use solution of this product can be disposed of via the sewage system. Small amounts of the product (up to about 100 ml per day) can be disposed of via the sewage system after dilution 1:30 with tap water.

13.1.2 DISPOSAL OF CONTAMINATED PACKAGING

Dispose of packaging according to national and regional provisions. 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.

14 TRANSPORT INFORMATION

14.1 UN NUMBER

1814

- 14.2 UN PROPER SHIPPING NAME
- 14.2.1 ADR/RID/SDR

POTASSIUM HYDROXIDE SOLUTION (Potassium hydroxide)

14.2.2 IMDG CODE / ICAO-TI / IATA-DGR

POTASSIUM HYDROXIDE SOLUTION (Potassium hydroxide)

14.3 TRANSPORT HAZARD CLASS(ES)

8 (Corrosive substances)

14.4 PACKING GROUP

II (Substances presenting medium danger)

14.4.1 HAZARD LABEL

8

14.4.2 LQ

1 |

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 MARPOL AND THE IBC CODE

This product is not delivered in bulk according to Annex II of MARPOL73/78 and the IBC Code.





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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 H- AND P-PHRASES, HAZARD STATEMENTS, SAFETY PHRASES AND/OR PRECAUTIONARY STATEMENTS

H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.

TRAINING ADVICE

Thoroughly read this material safety data sheet before using this product. For detailed information refer to the technical data sheet. This product must only be used by a trained person.

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.

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.

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