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

1.1 Product identifier

ORO CLEAN [®] Liquid
YQYW-J8J5-300Y-TH87
Mixture
Cleaner

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

	of dental suction units, spittoon bowls and amalgam separators. ORO ${\sf CLEAN}^{\circledast}$ Liquid has a touch of peppermint scent. Perfect for weekly cleaning.
Uses advised against:	Do not use for purposes other than those prescribed.
Recommended restrictions on	For professional use only.
use:	

ORO CLEAN[®] Liquid is a powerful concentrate for the cleaning and deodorisation

1.3 Details of the supplier of the safety data sheet

21 Vinohra Žižkov 130 00 Czech	ean Chemie s.r.o. adská 2828/151) Praha 3 Republic proclean.cz
	vroclean cz
om info@o	vroclean cz
	10010411.02
om www.oi	oroclean.cz
iser/importer/distributor	
ie s.r.o. 8/151	
<u>Z</u>	
	2

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: +358 1 2348 342

* 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 to Regulation (EC) No 1272/2008

Hazard type	Hazard category	Hazard statement code(s)	Classification procedure
Physical hazard	Met. Corr. 1	H290	On basis of test data.
Health hazard	Skin Irrit. 2	H315	Harmonised (legal) classification.
Health hazard	Eye Dam. 1	H318	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 Hazard pictograms:

	GH	S05	GHS07
Signal word:	Danger		
Hazard statements:	H290 H315 H318	May be corrosive to me Causes skin irritation. Causes serious eye dar	
Precautionary statements:	P280	Wear protective gloves/ protection.	protective clothing/eye protection/face
	P302 + P352	IF ON SKIN: Wash with	plenty of soap and water.
	P305 + P351 + P338		iously with water for several minutes. , if present and easy to do. Continue
	P310	Immediately call a POIS	SON CENTER or doctor/physician.
	P332 + P313	If skin irritation occurs:	Get medical advice/attention.
	P362	Take off contaminated of	clothing.
Supplemental information:	Not applicable.		
Other hazards			
PBT or vPvB properties:	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.		BT), or very persistent and very
Endocrine disrupting properties:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commissior Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/60		g to REACH Article 57(f) or Commission

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

See below.

3.2 Mixtures

2.3

Classification acc	ording to Regulation (E	C) No 1272/2008			
Substance name	Identification	Classification	SCL, M-factor, ATE	Concentration	

at levels of 0.1% or higher.

Potassium hydroxide	CAS no.: 1310-58-3 EC no.: 215-181-3 Index no.: 019-002-00-8 REACH no.: 01-2119487136-33-0000	Acute Tox. 4, H302 Skin Corr. 1A, H314	Eye Irrit. 2, H319: 0,5 % ≤ C < 2 %; Skin Corr. 1A, H314: C ≥ 5 %; Skin Corr. 1B, H314: 2 % ≤ C < 5 %; Skin Irrit. 2, H315: 0,5 % ≤ C < 2 %	
2-Ethylhexanol ethoxylate	CAS no.: 26468-86-0 EC no.: 607-943-2 Index no.: Not applicable. REACH no.: Not applicable.	Eye Irrit. 2, H319	No data available.	1% - < 2.5%

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. No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. When it is suspected, that there may still be harmful vapours/fumes present in the air, respiratory protection (mask; self contained breathing apparatus) must be used. Wash contaminated clothing with water before removing or use gloves.
After inhalation:	Remove patient to fresh air - move out of dangerous area. In case of unconsciousness bring patient into stable side position and seek medical attention. If breathing is irregular or respiratory arrest occurs provide artificial respiration. Keep at rest in a position comfortable for breathing. Seek medical help immediately.
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. Immediately obtain professional medical help.
After contact with eyes:	Immediately flush eyes with running water, keeping eyelids apart. After 5 minutes of rinsing, remove contact lenses, if present, and continue rinsing. Consult a physician immediately.
After ingestion:	Do not induce vomiting. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Immediately consult a doctor. 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
Potassium hydroxide CAS no.:1310-58-3	Worker (long term, local effects)	Inhalation	1 mg/m³
	Consumer (long term, local effects)	Inhalation	1 mg/m³
2-Ethylhexanol ethoxylate CAS no.:26468-86-0	No data available.	No data available.	No data available.
PNEC values			
Substance name	Route of exposure	Limit value	
Potassium hydroxide CAS no.:1310-58-3	No data available.	No data available.	
2-Ethylhexanol ethoxylate CAS no.:26468-86-0	No data available.	No data available.	

8.2 Exposure controls

Appropriate engineering controls

See section 7. No additional measures necessary.

Individual protection measures

Eye/face protection:	Wear protective glasses during refilling and/or preparation of working solution and during use.
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).
Body protection:	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.
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 skin, eyes and clothes. Do not eat, drink or smoke while working. Do not breathe vapours/aerosols.

Environmental exposure controls

Observe the usual precautions for handling chemicals. Do not empty concentrate into drains. Avoid releasing the concentrate to the environment. 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:	Yellow
Odour:	Peppermint
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):	12.5 - 14.5
pH-value (diluted product):	10.5 - 12.5 (2%)
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:	1.08 g/cm ³
Relative density:	1.08
Relative vapour density at 20 °C:	No data available.

9.2 Other information

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

Avoid contact with materials sensitive to strong acids or bases. Avoid contact with unhardened steel and sensitive non-ferrous metals.

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:	Causes burns.	
Component:	No data available.	
Serious eye damage/irritation		
Mixture:	Causes serious eye damage.	
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 expos	ure	
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.	
Information on oth	ner 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

11.2

The release of the diluted ready-to-use solution of this product is not expected to have any ecotoxic effects. Concentrated solutions can have temporary and localized toxic effects on aquatic and terrestrial organisms. This 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
Potassium hydroxide	Not applicable.	Not applicable.	Not applicable.
2-Ethylhexanol ethoxylate	No data available.	OECD 301 B	Readily biodegradable.

12.3 Bioaccumulative potential

	Mixture:	Based on available data, no product ingredient is expected to exhibit bioaccumulative potential.
	Component:	No data available.
12.4	Mobility in soil	
	Mixture:	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.
	Component:	No data available.

1

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 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.
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** UN 1760
- 14.2 UN proper shipping name CORROSIVE LIQUID, N.O.S. (Potassium hydroxide)
- 14.3 Transport hazard class(es) 8
- 14.4 Packing group III | Danger label: 8 | LQ: 5 L
- 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
 - UN 1760
- **14.2 UN proper shipping name** CORROSIVE LIQUID, N.O.S. (Potassium hydroxide)
- 14.3 Transport hazard class(es) 8
- 14.4 Packing group III | Danger label: 8 | LQ: 5 L
- 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** UN 1760
- 14.2 UN proper shipping name CORROSIVE LIQUID, N.O.S. (Potassium hydroxide)
- 14.3 Transport hazard class(es) 8
- 14.4 Packing group III | Danger label: 8 | LQ: 5 L
- 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
Met. Corr. 1	H290	On basis of test data.
Skin Irrit. 2	H315	Harmonised (legal) classification.
Eye Dam. 1	H318	Harmonised (legal) classification.

List of relevant phrases

H290 May be corrosive to metals.

- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

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.