

CEFLA S.C.

Via Selice Provinciale 23/A,
40026 Imola BO (Italy)
Ph. +39 0542 653111 – Fax +39 0542 653444
www.cefla.com

SAFETY DATA SHEET

(EC) Reg no. 1907/2006 – (EC) Reg. 1272/2008

Product: **TETHYCLEAN**
CONCENTRATED DETERGENT
FOR MEDICAL AND DENTAL TOOLS AND INSTRUMENTS

rev.2

Date: 05.10.2018

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SECTION 1: SUBSTANCE OR MIXTURE IDENTIFICATION AND COMPANY/FIRM DATA

- 1.1. PRODUCT IDENTIFICATION NAME Tethyclean
Concentrated detergent for medical and dental tools and instruments
- 1.2. APPROPRIATE USE AND NOT RECOMMENDED USE OF THE SUBSTANCE OR MIXTURE Use in spray or ultrasound washing machines for medical and dental tools and instruments.
Do not use to wash other objects, surfaces or skin
- 1.3. INFORMATION REGARDING THE SUPPLIER OF THE SAFETY DATA SHEET Manufacturer
CEFLA S.C. Via Selice Provinciale 23/A
40026 Imola BO (Italy)
Ph. +39 0542 653111 – Fax +39 0542 653444
ceflaimola@cefla.it
- 1.4. EMERGENCY TELEPHONE NUMBER **Australia**
Poisons Information Centre
Ph: 13 11 26 (24hr/7days)
New Zealand
Poison Information Centre
Ph: 0800 POISON (0800 764 766)

SECTION 2: DANGER IDENTIFICATION

- 2.1. SUBSTANCE OR MIXTURE CLASSIFICATION The product is not classified as hazardous pursuant to (EC) Regulation 1272/2008 (CLP) and subsequent amendments and additions.
- 2.2. LABEL ELEMENTS
Danger pictogram:
-- not applicable
Warnings:
-- not applicable
Danger information:
-- not applicable
Precautionary statements: the product is not classified as hazardous and there is no related compulsory precautionary Statement.
However, as a precaution, the following Precautionary statements are mentioned on the label:
P262 Do not get in eyes.
P305+P351+P338 IF IN EYES: rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing
- 2.3. OTHER DANGERS Based on available data PBT or vPvB substance content in the product does not exceed 0.1%

SECTION 3: COMPOSITION / INFORMATION ON THE INGREDIENTS

- 3.1. SUBSTANCES Not applicable
- 3.2. MIXTURE

Substances composing the mixture	Concentration % m/m	Classification (EC) Regulation 1272/2008 and subsequent amendments and additions
WATER CAS 7732-18-5 EC 231-791-2 INDEX: --	< 70	Unclassified

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PROTEASE – SUBTILISIN CAS 9014-01-1 EC -- INDEX --	0.01 – 0.05	Acute Tox. 4 H302, STOT SE 3 – H335 Skin irrit 2 H315, Eye Dam 1 H318 Resp Sens 1 H334 Aquatic Acute 1 H400
1.2 BENZISOTHIAZOLIN-3-ONE CAS 2634-33-5 EC 220-120-9 INDEX --	0.01 – 0.03	Acute Tox. 4 H302, Skin Irrit 2 H315, Eye Dam 1 H318 Skin Sens 1 H317 Aquatic Acute 1 H400
SODIUM HYDROXIDE CAS 1310-73-2 EC 215-185-5 INDEX 011-002-00-6	< 0.01	Skin corr 1A H314
PROPYLENE GLYCOL CAS 57-55-6 EC -- INDEX --	< 0.01	Unclassified
OTHER INGREDIENTS Amphoteric surfactants Phosphonates	< 5	Unclassified

SECTION 4: FIRST-AID MEASURES

4.1. DESCRIPTION OF FIRST-AID MEASURES	<p>General Indications It is not expected that normal use of the product leads to acute risk.</p> <p>Inhalation: It is not expected that normal use of the product leads to acute risk.</p> <p>Dermal contact: It is not expected that normal use of the product leads to acute risk.</p> <p>Eye contact: rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing</p> <p>If swallowed: It is not expected that normal use of the product leads to acute risk.</p> <p>Personal protective equipment for anybody providing first-aid: It is not expected for normal use.</p>
4.2. MAIN ACUTE AND DELAYED SYMPTOMS AND EFFECTS	<p>Inhalation:</p> <p>acute: specific information regarding symptoms and effects is not known</p> <p>delayed: specific information regarding symptoms and effects is not known</p> <p>Dermal contact:</p> <p>acute: specific information regarding symptoms and effects is not known</p> <p>delayed: specific information regarding symptoms and effects is not known</p> <p>Eye contact:</p> <p>acute: specific information regarding symptoms and effects is not known</p> <p>delayed: specific information regarding symptoms and effects is not known</p> <p>If swallowed:</p> <p>acute: specific information regarding symptoms and delayed effects is not known</p> <p>is not known: specific information regarding symptoms and effects is not known</p> <p>known</p>

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4.3. INDICATIONS REGARDING
NEED TO SEEK MEDICAL
ADVICE IMMEDIATELY AND
OF SPECIAL TREATMENT

Notes for the physician
Information not available

Special treatments: information not available
Antidote: information not available
Contraindications: information not available
Workplace: information not available

SECTION 5: FIRE SAFETY MEASURES

5.1. FIRE-EXTINGUISHING APPLIANCES

Suitable fire-extinguishing appliances:
CO₂, Foam, Dry powder, Water spray fire extinguishers

Unsuitable fire-extinguishing appliances for safety reasons: no one in particular

5.2. SPECIAL DANGERS RESULTING FROM THE SUBSTANCE OR THE MIXTURE

Avoid inhaling combustion products
i

5.3. RECOMMENDATIONS FOR FIRE-EXTINGUISHING PERSONNEL

Special protection actions for firefighters:
Take everybody away from the fire area.
Cool the containers using water jets to prevent product from decomposing and potentially developing health harmful substances.
Always wear complete fire protecting equipment. Collect water used to extinguish the fire as it must not be discharged in the sewage system. Dispose of the contaminated water used to extinguish the fire and of the fire residual according to the laws in force

Protecting equipment for fire-extinguishing personnel
Normal fire protecting equipment, as open- circuit compressed air breathing apparatus (EN137)
protective clothing (EN469)
protective gloves (EN 659)
Firefighters boots (HO A29 or A30)

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. PERSONAL PRECAUTIONS, PROTECTION EQUIPMENT AND EMERGENCY PROCEDURES

For non-emergency personnel:
Keep unnecessary and unprotected personnel from entering.
For emergency personnel:
Use breathing equipment if fumes or powders are released into the air.
These indications refer to operating conditions as well as for emergency events
Suitable material for personal protection equipment:
not available

6.2. ENVIRONMENTAL PRECAUTIONS

Prevent the product from flowing into the sewage system, into surface water, into ground water

6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEAN-UP

Modes to contain leakage and to clean-up:
dam with earth or inert material
Pick up as much material as possible and eliminate the residues with water jets.
Dispose of according to the provisions in Sect. 13

6.4. REFERENCE TO OTHER SECTIONS

Other information regarding individual protection and disposal are included in Section 8 and 13

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SECTION 7: HANDLING AND STORAGE**7.1. PRECAUTIONS FOR SAFE HANDLING****Safe handling**

Handle the product after having consulted all the sections of this Safety Data Sheet
Provide eye protection.
Avoid disposing of the product in the environment
Do not eat, drink or smoke when using the product.

Other information in section 8.

7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING POSSIBLE INCOMPATIBILITIES

Store in the original container
far from material which may be incompatible, refer to Sect. 10

7.3. SPECIFIC FINAL USE

The product is for professional use only
USE according to the instructions of the tool washing machine

SECTION 8: EXPOSURE CONTROL / INDIVIDUAL PROTECTION**8.1. CONTROL PARAMETERS**

Regulatory references:

GBR United Kingdom – EH40/2005 Workplace exposure limits
TLV-ACGIH 2017

PROPILENGLICOL**Threshold Limit Values**

Type	Country	TWA/8h		STEL/15 min	
		mg/m3	ppm	mg/m3	ppm
WEL	GBR	474	150		

Predicted No Effect Concentration - PNEC

Reference value in fresh water	260 mg/L
Reference value in sea water	26 mg/L
Reference value for sediments in fresh water	572 mg/kg
Reference value for sediments in sea water	57.2 mg/kg
Reference value for water, intermittent release	183 mg/L
Reference value for STP microorganisms	20000 mg/L
Reference value for earth environment	50 mg/kg

Derived no-effect level DNEL - DMEL**Workers**

Systemic effects - acute		Local effects - acute		Systemic effects - long term		Local effects - long term	
<i>Dermal contact</i>	<i>Inhalation</i>	<i>Dermal contact</i>	<i>Inhalation</i>	<i>Dermal contact</i>	<i>Inhalation</i>	<i>Dermal contact</i>	<i>Inhalation</i>
n.a.	n.a.	n.a.	n.a.	n.a.	168 mg/m3	n.a.	10 mg/m3

Consumers

Systemic effects - acute			Local effects - acute		Systemic effects - long term			Local effects - long term	
<i>Dermal contact</i>	<i>Inhalation</i>	<i>Oral contact</i>	<i>Dermal contact</i>	<i>Inhalation</i>	<i>Dermal contact</i>	<i>Inhalation</i>	<i>Oral contact</i>	<i>Dermal contact</i>	<i>Inhalation</i>
n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	50 mg/m3	n.a.	n.a.	10 mg/m3

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SODIUM HYDROXIDE**Threshold Limit Values**

Type	Country	TWA/8h		STEL/15 min	
		mg/m ³	ppm	mg/m ³	ppm
WEL	GBR			2	
TLV-ACGIH				2(C)	

Derived no-effect level DNEL - DMEL**Workers**

Systemic effects - acute		Local effects - acute		Systemic effects - long term		Local effects - long term	
<i>Dermal contact</i>	<i>Inhalation</i>	<i>Dermal contact</i>	<i>Inhalation</i>	<i>Dermal contact</i>	<i>Inhalation</i>	<i>Dermal contact</i>	<i>Inhalation</i>
n.a.	n.a.	n.a.	n.a.	n.a.	1 mg/m ³	n.a.	1 mg/m ³

Consumers

Systemic effects - acute			Local effects - acute		Systemic effects - long term			Local effects - long term	
<i>Dermal contact</i>	<i>Inhalation</i>	<i>Oral contact</i>	<i>Dermal contact</i>	<i>Inhalation</i>	<i>Dermal contact</i>	<i>Inhalation</i>	<i>Oral contact</i>	<i>Dermal contact</i>	<i>Inhalation</i>
n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1 mg/m ³

Key:

(C) = Ceiling; INALAB = Fraction that can be inhaled; RESPIR = Fraction that can be breathed; TORAC = Thorax fraction

8.2. EXPOSURE CONTROLS

Comply with usual safety measures when handling chemical substances

Suitable technical checks

the intended use for the mixture does not require the need to provide exposure technical checks

Individual precautionary measures, such as individual protection equipment

Eye / face protections	Wear safety glasses
Skin protection	Wear normal working clothes
Hand protection	wear rubber butyl, fluorocarbon rubber, nitrile, PVC protection gloves
Respiratory protection	not necessary, unless otherwise indicated by chemical risk evaluation

Protections against thermal dangers: not expected for the intended use

Other: See Sect. 7.1

Environmental exposure controls:

Emissions due to operating processes, including emissions due to ventilation systems, should be controlled for the sake of compliance with the legislation for environmental protection

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1. INFORMATION REGARDING PHYSICAL AND CHEMICAL PROPERTIES**

a) Aspect	Amber coloured liquid
b) Characteristic	odour
c) Odour threshold	Not available

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d) pH	> 10
e) melting point / freezing point	Not available
f) initial boiling point and boiling range	Not available
g) flashpoint	> 60 °C
h) evaporation rate	Not available
i) flammability (solid/gas)	Not available
j) upper / lower flammability or explosive limits	Not available
k) vapour pressure	Not available
l) vapour density	Not available
m) relative density	1.18 g/mL
n) solubility	Soluble
o) partition coefficient: n-octanol on water	Not available
p) auto ignition temperature	Not available
q) decomposition temperature	Not available
r) viscosity	Not viscous
s) explosive properties	Not explosive
t) oxidizing properties	Non oxidizing

9.2. OTHER INFORMATION

VOC (Volatile Organic Compounds)

Absent (0.0 %)

SECTION 10: STABILITY AND REACTIVITY

10.1. REACTIVITY	No particular reactivity dangers with other substances in normal intended use conditions have to be reported
10.2. CHEMICAL STABILITY	It is stable in normal use and storage conditions
10.3. POSSIBILITY OF HAZARDOUS REACTIONS	Hazardous reactions are not expected in normal use and storage conditions.
10.4. CONDITIONS TO AVOID	None in particular - Please refer to usual precautions when using chemical products
10.5. INCOMPATIBLE MATERIALS	Information not available As a general rule avoid strong acids and strong oxidizing agents
10.6. HAZARDOUS DECOMPOSITION PRODUCTS	Information not available

SECTION 11: TOXICOLOGICAL INFORMATION

No episodes of damage to health due to exposure to the product have been reported.
In any case it is recommended to work according to safety and hygiene regulations of good industrial practice

11.1. INFORMATION ON TOXICOLOGIC EFFECTS

Metabolism, kinetics, mechanism of action and other information

Information not available

Information regarding the probable exposure routes

Information not available

Immediate, delayed and chronic effects due to short and long term exposure

Information not available

Interactive effects

Information not available

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ACUTE TOXICITY

LC50(Inhaling) of the mixture: unclassified (no significant component)
LD50 (Oral) of the mixture: unclassified (no significant component)
LD50 (Skin) of the mixture unclassified (no significant component)

SKIN CORROSION / SKIN IRRITATION

It does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / SKIN IRRITATION

It does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

It does not meet the classification criteria for this hazard class

CARCINOGENICITY

It does not meet the classification criteria for this hazard class

TOXICITY FOR REPRODUCTION

It does not meet the classification criteria for this hazard class

SPECIFIC TOXICITY FOR TARGET ORGANS (STOT) SINGLE EXPOSURE

It does not meet the classification criteria for this hazard class

SPECIFIC TOXICITY FOR TARGET ORGANS (STOT) REPEATED EXPOSURE

It does not meet the classification criteria for this hazard class

DANGER IN CASE OF ASPIRATION

It does not meet the classification criteria for this hazard class

SECTION 12: ENVIRONMENTAL PROTECTION INFORMATION

Eco-toxicological data for this product have not been specifically determined. Data are based on knowledge relevant to components and eco-toxicological information on similar products.

12.1. TOXICITY	information not available
12.2. PERSISTENCE AND DEGRADABILITY	information not available
12.3. BIOACCUMULATION POTENTIAL	information not available
12.4. MOBILITY IN SOIL	information not available
12.5. PBT AND VPVB EVALUATION RESULTS	based on available data pbt or vpvb substance content in the product does not exceed 0.1%
12.6. OTHER NEGATIVE EFFECTS	information not available

SECTION 13: CONSIDERATIONS ON DISPOSAL

13.1. PROCEDURES FOR WASTE MANAGEMENT	<p>Product:</p> <p>Product residues have to be considered as not hazardous Medical Waste It must be disposed of through an authorized waste management firm, in compliance with European, National and local regulations regarding waste disposal Avoid dispersing the product in the soil, rivers and lakes, drains and sewage system</p> <p>Container:</p> <p>Polyethylene bottle. Recycling instead of incineration or landfilling has to be preferred Contaminated packages must be sent to recycling stations or disposal plants in compliance with European, National and local regulations regarding waste disposal</p>
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SECTION 14: INFORMATIONS REGARDING TRANSPORT

The product is not classified as Hazardous Good pursuant to the laws in force regarding transport of dangerous substances

	ADR/RID	ADN	IMDG	IATA/ICAO
14.1 UNO CODE	Not applicable			
14.2 UNO SHIPPING NAME	Not applicable			
14.3. HAZARD CLASS FOR TRANSPORT	Not applicable			
14.4. PACKING GROUP	Not applicable			
14.5. HAZARDS FOR THE ENVIRONMENT	Not applicable			
14.6. SPECIAL PRECAUTIONS FOR THE USERS	Not applicable			
14.7. TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not relevant information			

SECTION 15: INFORMATION ON REGULATIONS

15.1. SPECIFIC LAWS AND REGULATIONS REGARDING HEALTH, SAFETY AND ENVIRONMENT FOR THE SUBSTANCE OR THE MIXTURE

Directive 93/42/EEC (Medical Devices)
Directive 99/13/EC (Volatile organic compound)
(EC) Regulation 1272/2008 (Hazardous substances and mixtures) -
(EC) Regulation 1907/2006 (REACH – Safety Data Sheets)
(EC) Regulation 648/2004 (detergents)

Other law and regulation references judged not relevant for the product:
(EC) Regulation 1005/2009 (ozone-depleting substances)
(EC) Regulation 850/2004 (persistent organic pollutants)
(EC) Regulation 649/2012 (export and import of dangerous chemicals)

Seveso Category – Directive 2012/18/EC
None

Restrictions for Substances Annexe XVII EC Reg 1907/2006
none

Candidate substance for List according to Art. 59 REACH

Based on available data SVHC content in the product does not exceed 0.1%

Substances subject to authorization Annex XIV REACH:

none

Substances subject to export notification obligation (EC) Reg 649/2012

none

Substances subject to Rotterdam Convention:

none

Substances subject to Stockholm Convention:

None

Sanitary Checks:

information not available

15.2. EVALUATION OF CHEMICAL SAFETY

No evaluation for chemical safety has been issued for the mixture and the substances contained in the mixture

SECTION 16: OTHER INFORMATION

a) Revision of Safety Data Sheet

Revision 2: Sections n 1.

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b) Legend

NA = not applicable ND = not available Gr = Group
DNEL = Derived no-effect level
PNEC = Predicted no-effect concentration
ADN - European Agreement concerning the international carriage of dangerous goods by waterways
ADR - European Agreement concerning the international carriage of dangerous goods by road
IATA – International air transport association
ICAO ..- International civil aviation organization
IMDG – International maritime dangerous goods code
IMO – International maritime organisation
RID – Regulations concerning the international carriage of dangerous goods by rail
PBT – persistent, bioaccumulative, toxic substance
vPvB – very Persistent, very Bioaccumulative substance

c) Bibliographic references
Data Sources

Safety Data Sheets for Raw Materials
European Directives and Regulations (see 15.1)

d) Information evaluation methods

The criteria mentioned in the following regulations have been applied:
(EC) Regulation 1272/2008 – Art. 9 paragraph 1:
classification or differentiation criteria as per Annex I, parts from 2 to 5

e) List of relevant risk phrases

Risk phrases listed in Sect. 3.2 relevant to ingredients

H302 – Harmful if swallowed
H314 – Causes severe skin burns and eye damage
H315 – Causes skin irritation
H317 – May cause an allergic skin reaction
H318 - Causes serious eye damage.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H400 – Very toxic to aquatic life

f) Formation for employees

Compliance with the indications for use mentioned in the labels and with the indications given in this Safety Data Sheet is enough

NOTE

The information supplied in this Safety Data Sheet is provided in good faith and based upon our present knowledge and experience with the product. Its purpose is to describe the product from the safety standpoint.

In no case the user is exempted from keeping, handling, storing and using the product according to the instructions given in the label and/or supplied with the product and in compliance with laws, administrative and regulatory standards regarding the product and occupational safety. The producer therefore declines all responsibility for any eventual improper or incorrect use.