

Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product, and must be read in conjunction with the Safety Data Sheet (SDS) attached.

Product Name: Tehtyclean

Manufacturer: Cefla SC

SDS Expiry: 1 July 2023

Supplier Details: Henry Schein New Zealand
23 William Pickering Drive, Albany
PO Box 101 140, North Shore, Auckland 0745
Ph. 0800 808 855
www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre – 0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: Non Hazardous

HSNO Group Standard: Non Hazardous

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet is prepared on 22 April 2020

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

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SAFETY DATA SHEET

Reg. (CE) No. 1907/2006 - Reg. (CE) 1272/2008

Product: TETHYCLEAN
CONCENTRATED DETERGENT FOR MEDICAL AND DENTAL INSTRUMENTAL

Rev. No. 01

Date: 01.07.2018

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SECTION 1: IDENTIFICATION OF SUBSTANCE OR MIXTURE AND OF THE COMPANY OR COMPANY

- 1.1. PRODUCT IDENTIFIER
Tethyclean
Concentrated detergent for medical and dental instruments
- 1.2. RELEVANT USES
IDENTIFIED OF THE SUBSTANCE / MIXTURE
AND USES ADVISED
Use in instrument washing machines by spray or ultrasound for medical and dental instruments Do not use to wash different objects, surfaces or skin
- 1.3. DETAILS OF THE PROVIDER OF THE
SAFETY DATA SHEET
Maker
CEFLA SC Via Selice Provinciale 23 / A 40026 Imola
BO (Italy)
Tel. +39 0542 653111 - Fax +39 0542 653444
plinio.lenzi@cefla.it
Distributor
- 1.4. EMERGENCY NUMBER

SECTION 2: HAZARDS IDENTIFICATION

- 2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE The product has not been classified as dangerous according to Regulation (EC) 1272/2008 (CLP) and its subsequent modifications and integrations.
- 2.2. LABEL ELEMENTS
Hazard pictograms:
- - not applicable
Warnings:
- - not applicable Hazard statements:
- - not applicable Precautionary statements:
the product has not been classified as dangerous and does not require mandatory precautionary advice. However, as a precaution, the following precautionary statements are indicated on the label: Avoid contact with the eyes.
P305 + P351 + P338 IF ON EYES: Rinse carefully with water for several minutes. Remove contact lenses, if present and easy. Continue clarifying
- 2.3. OTHER DANGERS
According to the available data, the product does not contain PBT or vPvB substances in a percentage greater than 0.1%

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

- 3.1. SUBSTANCES
Not applicable

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3.2. BLENDS

Substances that make up the mixture	Concentration % m / m	Classification Regulation (EC) 1272/2008 + mod. and int.
CAS WATER 7732-18-5 CE 231-791-2 INDEX: - -	<70	Not qualified
PROTEASE - SUBTILISIN CAS 9014-01-1 CE - - INDEX - -	0.01 - 0.05	Acute Tox. 4 H302, STOT SE 3 - H335 Skin irritation 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 CE 215-185-5 INDEX 011-002-00-6	<0.01	Skin corr 1A H314
PROPYLENE GLYCOL CAS 57-55-6 CE - - INDEX - -	<0.01	Not qualified
OTHER COMPONENTS Amphoteric Surfactants Phosphonates	<5	Not qualified

SECTION 4: FIRST AID MEASURES**4.1. DESCRIPTION OF FIRST AID MEASURES****General instructions**

Normal use of the product does not give rise to an acute risk. Inhalation:

Normal use of the product does not give rise to an acute risk. Skin contact:

Normal use of the product does not give rise to an acute risk. Eye contact:

rinse carefully for several minutes. Remove contact lenses, if present and easy. Continue to clarify Ingestion:

Normal use of the product does not give rise to an acute risk.

Personal protective equipment for people who provide first aid:

Not provided for in normal use.

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**4.2. MAIN SYMPTOMS AND EFFECTS,
 ACUTE AND DELAYED**

Inhalation:
 acute: no specific known information about symptoms and
 delayed
 effects: no specific known information about symptoms and
 Skin contact
 effects:
 acute: no specific known information about symptoms and
 delayed
 effects: no specific known information about symptoms and
 Eye contact
 effects:
 acute: no specific known information about symptoms and
 delayed
 effects: no specific known information about symptoms and
 Ingestion
 effects:
 acute: no specific known information about symptoms and
 delayed
 effects: no specific known information about symptoms and
 effects

**4.3. INDICATION OF ALL MEDICAL CARE
 AND SPECIAL TREATMENTS THAT
 MUST BE DISPENSED IMMEDIATELY**

Notes to Physician
 Information not available
 Specific treatments: information not available Antidotes:
 information not available
 Contraindications: information not available
 Workplace: information not available

SECTION 5: FIGHTING MEASURES C ONTRA FIRE

5.1. EXTINGUISHING MEDIA

Suitable extinguishing media:
 Carbon dioxide fire extinguishers, foam, powder, water spray Unsuitable extinguishing media for
 safety reasons: none in particular

5.2. SPECIFIC HAZARDS

DERIVATIVES OF THE SUBSTANCE OR MIXTURE

Avoid breathing combustion products
 i

**5.3. RECOMMENDATIONS FOR FIRE
 FIGHTING PERSONNEL**

Special protective actions for firefighters:
 Keep all people away from the fire area.
 Spray the containers with water to avoid decomposition of the product and the development of substances potentially dangerous to health. Always use complete fire protection equipment. Collect the used water to extinguish the fire, which must not be discharged into the drains. Dispose of contaminated water used for extinguishing and fire residues in accordance with current regulations

Protective equipment for firefighters
 Fire fighting clothing, such as open circuit self contained air breathing apparatus (EN137) fire fighting protective clothing (EN469) fire fighting gloves (EN659) fire fighting boots (HO A29 or A30)

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SECTION 6: MEASURES IN CASE OF ACCIDENTAL SPILL

- 6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES For personnel who are not part of the emergency services: prevent the entry of strange and unprotected personnel. For emergency personnel:
 In case of vapors or dusts present in the air, adopt respiratory protection
- These indications are valid both for those in charge of processing and for emergency operations. Suitable materials for personal protective clothing:
 not available
- 6.2. PRECAUTIONS RELATED TO THE ENVIRONMENT Prevent product from entering drains, surface and ground water
- 6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING Ways to contain and clean up a spill:
 contain with earth or inert material
 Collect most of the material and remove the residue with jets of water. Eliminate according to the provisions of Section. 13
- 6.4. REFERENCES TO OTHER SECTIONS For more information on individual protection and disposal, see Sections 8 and 13

SECTION 7: HANDLING AND ALM GATHERING

- 7.1. PRECAUTIONS FOR SAFE HANDLING Safe handling
 Handle the product after consulting all the sections of this Safety Data Sheet. Protect the eyes.
- Avoid release of the product into the environment. Do not eat, drink or smoke while using the product. More information in section 8.
- 7.2. CONDITIONS OF SAFE STORAGE, INCLUDING POSSIBLE INCOMPATIBILITIES Keep in the original container, away from possible incompatible materials, of according to Secc. 10
- 7.3. END SPECIFIC USES The product is for professional use
 USE according to the instructions of the instrument washer

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. CONTROL PARAMETERS Reference

standards:
 GBR United Kingdom - EH40 / 2005 Workplace exposure llimits TLV-ACGIH 2017

PROPYLENE GLYCOL**Limit value**

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

Predicted concentration with no effect on the environment - PNEC

Reference value in fresh water	260 mg / L
Reference value in sea water	26 mg / L
Reference value for freshwater sediments	572 mg / kg

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Reference value for sediments in marine 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 the terrestrial environment	50 mg / kg

Derived no effect level - DNEL - DMEL Workers

Systemic effects - acute		Local effects - acute		Systemic - chronic effects		Local effects - chronic	
<i>Dermal</i>	<i>Inhalation</i>	<i>Dermal</i>	<i>Inhalation</i>	<i>Dermal</i>	<i>Inhalation</i>	<i>Dermal</i>	<i>Inhalation</i>
na	na	na	na	na	168 mg / m ³	na	10 mg / m ³

Consumers

Systemic effects - acute			Local effects - treble		Systemic - chronic effects			Local effects - chronic	
<i>Dermal</i>	<i>Inhalation</i>	<i>Oral</i>	<i>Dermal</i>	<i>Inhalation</i>	<i>Dermal</i>	<i>Inhalation</i>	<i>Oral</i>	<i>Dermal</i>	<i>Inhalation</i>
na	na	na	na	na	na 50 mg / m ³		na	na 10 mg / m ³	

SODIUM HYDROXIDE**Limit value**

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

Derived no effect level - DNEL - DMEL Workers

Systemic effects - acute		Local effects - acute		Systemic - chronic effects		Local effects - chronic	
<i>Dermal</i>	<i>Inhalation</i>	<i>Dermal</i>	<i>Inhalation</i>	<i>Dermal</i>	<i>Inhalation</i>	<i>Dermal</i>	<i>Inhalation</i>
na	na	na	na	na	1 mg / m ³	na	1 mg / m ³

Consumers

Systemic effects - acute			Local effects - treble		Systemic - chronic effects			Local effects - chronic	
<i>Dermal</i>	<i>Inhalation</i>	<i>Oral</i>	<i>Dermal</i>	<i>Inhalation</i>	<i>Dermal</i>	<i>Inhalation</i>	<i>Oral</i>	<i>Dermal</i>	<i>Inhalation</i>
na	na	na	na	na	na	na	na	na	1 mg / m ³

Legend:

(C) = Ceiling; INALAB = Inhalable fraction; RESPIR = Respirable fraction; TORAC = Thoracic Fraction

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8.2. EXPOSURE CONTROLS

Respect the usual safety measures for the handling of chemical substances. Appropriate technical controls.

the intended uses of the mixture do not imply the need for technical exposure controls

Individual protection measures, such as personal protective equipment

Eye / face protection

Wear protective glasses

Skin care

Wear normal work clothes

Protection of hands

Wear protective gloves made of butyl rubber, fluorinated rubber,
nitrile rubber, PVC

Respiratory protection Not required, except as otherwise specified in
chemical risk assessment

Protection against thermal hazards: not necessary for identified use Other: See Sect. 7.1

Environmental exposure controls:

Emissions from production processes, including from ventilation equipment, should be controlled to ensure they respect environmental protection standards

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES**

a) Appearance	Amber liquid
b) Odor	characteristic
c) Olfactory threshold	Not available
d) pH	> 10
e) Melting point / freezing point	Not available
f) Initial boiling point and boiling range	Not available
g) Flash point	> 60 ° C
h) Evaporation rate	Not available
i) Flammability (solid, gas)	Not available
j) Upper / lower flammability or explosive limits	Not available
k) Vapor pressure	Not available
l) Vapor density	Not available
m) Relative density	1.18 g / mL
n) Solubility (ies)	Soluble
o) Partition coefficient: n-octanol / water	Not available
p) Auto-ignition temperature	Not available
q) Decomposition temperature	Not available
r) Viscosity	Non viscous
s) Explosive properties	Non explosive
t) Oxidizing properties	Non-oxidizing

9.2. OTHER DATA

VOC (Volatile Organic Compounds) Absent (0.0%)

SECTION 10: STABILITY AND REACTIVITY**10.1. REACTIVITY**

There are no particular hazards of reaction with other substances under normal use conditions

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10.2. CHEMICAL STABILITY	Stable under normal conditions of use and storage
10.3. POSSIBILITY OF HAZARDOUS REACTIONS	Hazardous reactions are not expected under normal conditions of use and storage.
10.4. CONDITIONS TO AVOID None in particular-	Respect the usual precautions for the use of chemical products
10.5. INCOMPATIBLE MATERIALS	Information not available In general, avoid strong acids and strong oxidants
10.6. HAZARDOUS DECOMPOSITION PRODUCTS	Information not available

SECTION 11: TOXICOLOGICAL INFORMATION

There are no known episodes of health damage due to exposure to the product. In any case, it is recommended to operate according to the rules of good industrial hygiene

11.1. INFORMATION ON TOXICOLOGICAL EFFECTSMetabolism, kinetics, mechanism of action and other information

Information not available

Information on possible routes of exposure

Information not available

Delayed and immediate effects, as well as chronic effects caused by short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

CL50 (Inhalation) of the mixture: not classified (no relevant component)

DL50 (Oral) mixture: not classified (no relevant component)

DL50 (Dermal) of the mixture: not classified (no relevant component)

SKIN CORROSION OR IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE INJURY OR EYE IRRITATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTION TOXICITY

Does not meet the classification criteria for this hazard class

SPECIFIC TOXICITY IN CERTAIN ORGANS (STOT) SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

SPECIFIC TOXICITY IN CERTAIN ORGANS (STOT) REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

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SECTION 12: ECOLOGICAL INFORMATION

Ecological-toxicological data has not been determined specifically for this product. The information is based on the knowledge of the components and on the ecological-toxicological data of 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 THE SOIL	information not available
12.5. RESULTS OF THE PBT AND MPMB ASSESSMENT	According to the available data, the product does not contain PBT or vPvB substances in a percentage greater than 0.1%
12.6. OTHER SIDE EFFECTS	information not available

SECTION 13: CONSIDERATION IT IS RELATED TO DISPOSAL

13.1. METHODS FOR WASTE TREATMENT Product:	<p>Product waste should be considered as special non-hazardous waste. Disposal should be carried out by a company authorized to treat waste in accordance with European, national and local regulations on waste management.</p> <p>Avoid the release of product in the ground, in water courses, drains and sewers. Container: polyethylene bottle.</p> <p>Recycling preferred, rather than incineration or controlled discharge Contaminated packaging should be sent for recovery or disposal in accordance with European, national and local waste management regulations</p>
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SECTION 14: TRANSPORT INFORMATION

The product is not classified as dangerous goods according to the regulations in force on the transport of dangerous goods

	ADR / RID	DNA	IMDG	IATA / ICAO
14.1 UN NUMBER			Not applicable	
14.2 OFFICIAL DESIGNATION OF TRANSPORT OF THE UNITED NATIONS			Not applicable	
14.3. TRANSPORT HAZARD CLASS (S)			Not applicable	
14.4. PACKING GROUP			Not applicable	
14.5. ENVIRONMENTAL HAZARDS			Not applicable	
14.6. PRECAUTIONS INDIVIDUALS FOR USERS			Not applicable	
14.7. TRANSPORT IN BULK UNDER ANNEX II OF THE MARPOL 73/78 CONVENTION AND THE IBC CODE			Non-relevant information	

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SECTION 15: REGL INFORMATION AMENTARIA

15.1. REGULATION AND LEGISLATION IN THE
 FIELD OF SAFETY, HEALTH AND THE
 ENVIRONMENT SPECIFIC FOR THE
 SUBSTANCE OR MIXTURE

Directive 93/42 / EEC (Medical devices) Directive 99/13 / EC (Volatile organic compounds) Regulation (EC) 1272/2008 (Dangerous substances and mixtures) - Regulation (EC) 1907/2006 (REACH - Safety data sheets) Regulation (EC) 648/2004 (Detergents)

More legislative and regulatory sources that are not considered relevant to the product:

Regulation (EC) 1005/2009 (Substances that deplete the ozone layer) Regulation (EC) 850/2004 (Persistent organic pollutants) Regulation (EC) 649/2012 (Export and import of dangerous chemical products) Seveso Category - Directive 2012 / 18 / EC

none

Substance restrictions Annex XVII Reg CE 1907/2006

none

List of candidate substances Art. 59 REACH

According to the available data, the product does not contain SVHC substances in a percentage greater than 0.1%

Substances subject to authorization Annex XIV REACH:

none

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

none

Substances subject to the Rotterdam Convention:

none

Substances subject to the Stockholm Convention:

None Sanitary

controls:

information not available

15.2. CHEMICAL SAFETY ASSESSMENT

A chemical safety assessment has not been prepared for the mixtures and the substances it contains.

SECTION 16: OTHER INFORMATION

a) Revision of the safety data sheet

01 - full review

b) Abbreviations and acronyms

NA = not applicable ND = not available Gr = Group DNEL = derived no effect level PNEC = predicted no effect concentration

ADN = European agreement on the international transport of dangerous goods by inland waterways

ADR = European agreement on the international transport of dangerous goods by road

IATA = International Air Transport Association ICAO = International Civil Aviation Organization

IMDG = International Maritime Code on the Transport of Dangerous Goods IMO = International Maritime Organization

RID = regulation on the international transport of dangerous goods by rail

PBT = persistent, bioaccumulative and toxic substance vPvB = very persistent and very bioaccumulative

c) Bibliographic references Data sources

Safety data sheets for raw materials European directives and regulations (see 15.1)

d) Information evaluation methods

The criteria indicated in: Regulation (EC) 1272/2008 - Art. 9 sec. Have been applied. one: classification or differentiation criteria according to Annex I, parts 2 to 5

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e) List of applicable risk phrases

Risk phrases indicated in Sect. 3.2 on 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 difficulties

Respiratory in case of inhalation H400 - Very toxic to aquatic organisms

f) Training of workers

It is sufficient to comply with the indications for use on the labels and those supplied in this safety data sheet.

NOTE

The information in this safety data sheet is provided in good faith and is based on our current knowledge and experience of the product. It is used to describe the product from a security point of view.

In no case the user is considered exempt from the conservation, handling, storage and use of the product according to the instructions indicated on the label and / or supplied with the product, and in accordance with the laws, administrative rules and regulations on the product, the hygiene and safety at work. All responsibility is disclaimed for any incorrect use of the product.