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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

EndoPreZyme

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

PC35 Washing and cleaning products (including solvent based products)

1.3. Details of the supplier of the safety data sheet

Address:

Surgical Innovations (Pty) Ltd
Northlands Deco Park, Stand 326
10 New Market Street
Design Boulevard
21890 Northriding - South Africa
Telephone no. +27 11 462 4221

E-mail address of person responsible for this SDS:

sida@drweigert.de

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Supplemental information

EUH210 Safety data sheet available on request.

2.3. Other hazards

No special hazards have to be mentioned. The product contains no PBT or vPvB substances.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients

2-phenoxyethanol

CAS No. 122-99-6 EINECS no. 204-589-7

Registration no. 01-2119488943-21

Concentration >= 1 < 10 %

Classification (Regulation (EC) No. 1272/2008)

Acute Tox. 4 H302 Eye Irrit. 2 H319

propan-2-ol

CAS No. 67-63-0 EINECS no. 200-661-7

Registration no. 01-2119457558-25

Concentration >= 1 < 10 %



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Classification (Regulation (EC) No. 1272/2008)

Flam. Liq. 2 H225 Eye Irrit. 2 H319 STOT SE 3 H336

Other information

Complete text of hazard statements in chapter 16

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of persistent symptoms consult doctor.

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment.

After skin contact

In case of contact with skin wash off with warm water. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

After ingestion

Rinse out mouth and give plenty of water to drink.

Adhere to personal protective measures when giving first aid

First aider: Pay attention to self-protection!

4.2. Most important symptoms and effects, both acute and delayed

Until now no symptoms known so far.

4.3. Indication of any immediate medical attention and special treatment needed Hints for the physician / hazards

In the case of swallowing with subsequent vomiting, aspiration of the lungs can occur which can lead to chemical pneumonia or asphyxiation.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.

5.2. Special hazards arising from the substance or mixture

In case of combustion evolution of dangerous gases possible.

5.3. Advice for firefighters

Special protective equipment for fire-fighting

In case of combustion use a suitable breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Do not discharge into surface waters/groundwater.

6.3. Methods and material for containment and cleaning up



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Pick up with absorbent material. Clean contaminated floors and objects thoroughly, observing environmental regulations. Dispose of as prescribed.

6.4. Reference to other sections

Refer to protective measures listed in Sections 7 and 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on protection against fire and explosion

No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Recommended storage temperature

Value > 0 < 25 °C

Requirements for storage rooms and vessels

Store product in closed containers.

Hints on storage assembly

Do not store together with foodstuffs.

Further information on storage conditions

Protect from heat and direct sunlight. Keep container tightly closed and dry.

7.3. Specific end use(s)

no data

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limit values

propan-2-ol

List OEL

Skin resorption / sensibilisation: skin; Status: 09/2019

Other information

There are not known any further control parameters.

8.2. Exposure controls

General protective and hygiene measures

Observe the usual precautions for handling chemicals.

Respiratory protection

Not necessary, but do not inhale vapours. If workplace limits are exceeded, a respiratory protection approved for this particular job must be worn.

Hand protection

Chemical resistant gloves

Use Permanent hand contact Appropriate Material neoprene

Appropriate Material neoprene

Material thickness >= 0,65 mm

Breakthrough time > 480 min

Appropriate Material nitrile

Material thickness >= 0,4 mm Breakthrough time > 480 min

Appropriate Material butyl



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Use Short-term hand contact

Appropriate Material nitrile

Material thickness >= 0,11 mm

Hand protection must comply with EN 374.

Eye protection

Safety glasses with side protection shield; Eye protection must comply with EN 166.

Body protection

Not necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form liquid, clear

Colour colourless to yellowish

Odour alcohol-like

Odour threshold

Remarks not determined

pH value

Value 7,1

Temperature 20 °C

Melting point

Remarks not determined

Freezing point

Remarks not determined

Initial boiling point and boiling range

Remarks not determined

Flash point

Value > 60 °C

Method closed cup

Evaporation rate (ether = 1):

Remarks not determined

Flammability (solid, gas)

evaluation Not applicable

Upper/lower flammability or explosive limits

Remarks Not applicable

Vapour pressure

Remarks not determined

Vapour density

Remarks not determined

Density

Value 1,03 g/cm³

Temperature 20 °C

Solubility in water

Remarks miscible in all proportions

Solubility(ies)

Remarks not determined



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Partition coefficient: n-octanol/water

Remarks not determined

Ignition temperature

Remarks Not applicable

Decomposition temperature

Remarks not determined

Viscosity

dynamic

Value < 10 mPa.s

Temperature 20 °C

Explosive properties

evaluation not determined

Oxidising properties

evaluation None known

9.2. Other information

Other information

None known

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reactions when stored and handled according to prescribed instructions.

10.2. Chemical stability

No hazardous reactions known.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

No hazardous reactions known.

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute oral toxicity

ATE > 10.000 mg/kg Method calculated value (Regulation (EC) No. 1272/2008)

Remarks Based on available data, the classification criteria are not met.

Acute oral toxicity (Components)

2-phenoxyethanol

Species rat

LD50 1850 mg/kg

propan-2-ol

Species rat

LD50 5840 mg/kg



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Method OECD 401

Acute dermal toxicity

Remarks Based on available data, the classification criteria are not met.

Acute dermal toxicity (Components)

propan-2-ol

Species rabbit

LD50 13900 mg/kg

Method OECD 402

Acute inhalational toxicity

Remarks Based on available data, the classification criteria are not met.

Acute inhalative toxicity (Components)

propan-2-ol

Species rat

LC50 > 25 mg/l

Duration of exposure 6 h

Administration/Form Vapors
Method OECD 403

Skin corrosion/irritation

Remarks Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Remarks Based on available data, the classification criteria are not met.

Sensitization

Remarks Based on available data, the classification criteria are not met.

Subacute, subchronic, chronic toxicity

Remarks Based on available data, the classification criteria are not met.

Mutagenicity

Remarks Based on available data, the classification criteria are not met.

Reproductive toxicity

Remarks Based on available data, the classification criteria are not met.

Carcinogenicity

Remarks Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity (STOT)

Single exposure

Remarks Based on available data, the classification criteria are not met.

Repeated exposure

Remarks Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Other information

There is no data available on the product apart from the information given in this subsection.

SECTION 12: Ecological information

12.1. Toxicity

General information

not determined

Fish toxicity (Components)



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2-phenoxyethanol

Species golden orfe (Leuciscus idus)

LC50 220 to 460 mg/l

Duration of exposure 96 h

propan-2-ol

Species Fathead minnow (Pimephales promelas) LC50 9640 mg/l

Duration of exposure 96 h

Daphnia toxicity (Components)

2-phenoxyethanol

Species Daphnia magna

EC50 > 500 mg/l

Duration of exposure 48 h

propan-2-ol

Species Daphnia magna

LC50 appr. 10000 mg/l

Duration of exposure 48 h

Algae toxicity (Components)

2-phenoxyethanol

Species Scenedesmus subspicatus

ErC50 > 500 mg/l

Duration of exposure 72 h

propan-2-ol

Species Scenedesmus subspicatus

IC50 > 1000 mg/l

Duration of exposure 72 h

Bacteria toxicity (Components)

propan-2-ol

Species activated sludge

EC50 > 100 mg/l

12.2. Persistence and degradability

General information

not determined

12.3. Bioaccumulative potential

General information

not determined

Partition coefficient: n-octanol/water

Remarks not determined

12.4. Mobility in soil

General information

not determined

12.5. Results of PBT and vPvB assessment

Evaluation of persistance and bioaccumulation potential

The product contains no PBT or vPvB substances.

12.6. Other adverse effects

General information



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not determined

General information / ecology

Do not discharge product unmonitored into the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations for the product

Allocation of a waste code number, according to the European Waste Catalogue (EWC), should be carried out in agreement with the regional waste disposal company.

Disposal recommendations for packaging

Packaging that cannot be cleaned should be disposed off in agreement with the regional waste disposal company.

SECTION 14: Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

Information for all modes of transport

14.6. Special precautions for user

See Sections 6 to 8

Other information

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Other information

The product does not contain substances of very high concern (SVHC).

15.2. Chemical safety assessment

For this preparation a chemical safety assessment has not been carried out.

SECTION 16: Other information

Hazard statements listed in Chapter 3

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

CLP categories listed in Chapter 3

Acute Tox. 4 Acute toxicity, Category 4
Eye Irrit. 2 Eye irritation, Category 2
Flam. Liq. 2 Flammable liquid, Category 2

STOT SE 3 Specific target organ toxicity - single exposure, Category 3

Abbreviations



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ADR: Accord européen relatif au transport international des marchandises Dangereuses par Route RID: Règlement concernant le transport international ferroviaire de marchandises dangereuses

IMDG: International Maritime Code for Dangerous Goods

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

VOC: Volatile Organic Compound

LD: Lethal dose

LC: Lethal concentration

PBT: Persistent, Bioaccumulative and Toxic vPvB: Very persistent and very bioaccumulative SVHC: Substances of very high concern

UN: United Nations

CAS: Chemical Abstracts Service

OECD: Organisation for Economic Co-operation and Development

GHS: Globally Harmonized System of classification and Labelling of Chemicals REACH: Registration, Evaluation, Autohorisation and Restriction of Chemicals

MARPOL 73/78: International Convention for the Prevention of Pollution From Ships, 1973 as modified

by the Protocol of 1978 (MARPOL: Marine Pollution)

IBC: Intermediate Bulk Container

ASTM: American Society for Testing And Materials

TSCA: Toxic Substances Control Act (USA)

WHO: World Health Organization IMO: International Maritime Organization

IUCLID: International Uniform Chemical Information Database

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: *** This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.