Section: 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name : HYDREX SURGICAL SCRUB

Product code : 110825E

Use of the

Substance/Mixture

: Skin antiseptic

Substance type: : Mixture

For professional users only.

Product dilution information : No dilution information provided.

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

Identified uses : Drug

Recommended restrictions

on use

: Reserved for industrial and professional use.

1.3 Details of the supplier of the safety data sheet

Company : Ecolab Ltd.

PO Box 11; Winnington Avenue

Northwich, Cheshire, United Kingdom CW8 4DX

+ 44 (0)1606 74488 ccs@ecolab.com

1.4 Emergency telephone number

Emergency telephone : +441618841235

number +32-(0)3-575-5555 Trans-European

Poison Information Centre

telephone number

: For medical professionals only: 0344 892 0111

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Version : 1.4

Section: 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

According to the current legislation creation of Safety Data Sheets is not mandatory for medicinal products or cosmetics, This is a medicinal product according to Directive 2001/83/EC relating to

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medicinal products for human use and therefore is exempted from classification and labeling according to Regulation (EC) N° 1272/2008 (and their resp. amendments).

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

2.3 Other hazards

None known.

Section: 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous components

Chemical Name	CAS-No. EC-No. REACH No.	Classification REGULATION (EC) No 1272/2008	Concentration : [%]
Drug mixture		Not Classified;	>= 50 - <= 100

Section: 4. FIRST AID MEASURES

4.1 Description of first aid measures

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for

at least 15 minutes. Remove contact lenses, if present and easy

to do. Continue rinsing.

In case of skin contact : Rinse with water.

If swallowed : Rinse mouth. Get medical attention if symptoms occur.

If inhaled : Get medical attention if symptoms occur.

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 immediate medical attention and special treatment needed

Treatment : No specific measures identified.

Section: 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

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circumstances and the surrounding environment.

Unsuitable extinguishing

media

: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during

firefighting

: Fire Hazard

Keep away from heat and sources of ignition. Flash back possible over considerable distance.

Hazardous combustion

products

: Depending on combustion properties, decomposition products

may include following materials:

Carbon oxides

nitrogen oxides (NOx)

5.3 Advice for firefighters

for firefighters

Special protective equipment : Use personal protective equipment.

Further information : Fire residues and contaminated fire extinguishing water must be

disposed of in accordance with local regulations.

Section: 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency

personnel

: Remove all sources of ignition. Refer to protective measures listed

in sections 7 and 8.

Advice for emergency

responders

If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable

materials.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up Eliminate all ignition sources if safe to do so. Stop leak if safe to

> do so. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). Flush away traces with water. For large spills, dike spilled material or otherwise contain

material to ensure runoff does not reach a waterway.

6.4 Reference to other sections

See Section 1 for emergency contact information.

For personal protection see section 8.

See Section 13 for additional waste treatment information.

Section: 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

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Advice on safe handling : Keep away from fire, sparks and heated surfaces. Take necessary

action to avoid static electricity discharge (which might cause

ignition of organic vapours).

Hygiene measures : No specific measures identified.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage

areas and containers

: Keep away from heat and sources of ignition. Keep away from oxidizing agents. Keep out of reach of children. Keep container

tightly closed. Store in suitable labeled containers.

Storage temperature : 0 °C to 25 °C

7.3 Specific end uses

Specific use(s) : Drug

Section: 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls

Engineering measures : Good general ventilation should be sufficient to control worker

exposure to airborne contaminants.

Individual protection measures

: No specific measures identified. Hygiene measures

Eye/face protection (EN 166) : No special protective equipment required.

Hand protection (EN 374) : No special protective equipment required.

Skin and body protection

(EN 14605)

: No special protective equipment required.

Respiratory protection (EN

143, 14387)

: None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information. Use certified

respiratory protection equipment meeting EU

requirements(89/656/EEC, (EU) 2016/425), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods

or procedures of work organization.

Environmental exposure controls

General advice : Consider the provision of containment around storage vessels.

Section: 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

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Appearance : liquid

Colour : clear, red

Odour : Perfumes, fragrances

pH : 6.0, 100 %

Flash point : 70 °C closed cup

Odour Threshold : Not applicable and/or not determined for the mixture

Melting point/freezing point : Not applicable and/or not determined for the mixture

Initial boiling point and : Not applicable and/or not determined for the mixture

boiling range

Evaporation rate : Not applicable and/or not determined for the mixture

Flammability (solid, gas) : Not applicable and/or not determined for the mixture

Upper explosion limit : Not applicable and/or not determined for the mixture

Lower explosion limit : Not applicable and/or not determined for the mixture

Vapour pressure : Not applicable and/or not determined for the mixture

Not applicable and/or not determined for the mixture

Relative density : 1.03
Water solubility : soluble

Solubility in other solvents : Not applicable and/or not determined for the mixture Partition coefficient: n- : Not applicable and/or not determined for the mixture

octanol/water

Relative vapour density

Auto-ignition temperature : Not applicable and/or not determined for the mixture
Thermal decomposition : Not applicable and/or not determined for the mixture
Viscosity, kinematic : Not applicable and/or not determined for the mixture
Explosive properties : Not applicable and/or not determined for the mixture

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Not applicable and/or not determined for the mixture

Section: 10. STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Heat, flames and sparks.

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10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Depending on combustion properties, decomposition products may include following materials: Carbon oxides nitrogen oxides (NOx)

Section: 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

exposure

Information on likely routes of : Inhalation, Eye contact, Skin contact

Product

Acute oral toxicity : Acute toxicity estimate : > 2,000 mg/kg

Acute inhalation toxicity : There is no data available for this product.

: Acute toxicity estimate : > 2,000 mg/kg Acute dermal toxicity

Skin corrosion/irritation : There is no data available for this product.

Serious eye damage/eye

irritation

: There is no data available for this product.

Respiratory or skin

sensitization

: There is no data available for this product.

Carcinogenicity : There is no data available for this product.

Reproductive effects : There is no data available for this product.

Germ cell mutagenicity : There is no data available for this product.

: There is no data available for this product. Teratogenicity

STOT - single exposure : There is no data available for this product.

STOT - repeated exposure : There is no data available for this product.

Aspiration toxicity : There is no data available for this product.

Potential Health Effects

Eyes : Health injuries are not known or expected under normal use.

Skin : Do not use in the perineal or eyelid areas. Do not instill in the

middle ear - may cause deafness if ear drum is perforated.

Ingestion : Health injuries are not known or expected under normal use.

Inhalation : Health injuries are not known or expected under normal use.

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Chronic Exposure : Health injuries are not known or expected under normal use.

Experience with human exposure

Eye contact : No symptoms known or expected.

Skin contact : No symptoms known or expected.

Ingestion : No symptoms known or expected.

Inhalation : No symptoms known or expected.

Section: 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Environmental Effects : This product has no known ecotoxicological effects.

Product

Toxicity to fish : no data available

Toxicity to daphnia and other : no data available

aquatic invertebrates

Toxicity to algae : no data available

12.2 Persistence and degradability

Product

no data available

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

Product

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 Other adverse effects

no data available

Section: 13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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13.1 Waste treatment methods

Product : Diluted product can be flushed to sanitary sewer if regulations

permit.

Contaminated packaging : Dispose of in accordance with local, state, and federal regulations.

Guidance for Waste Code

selection

: Organic wastes containing dangerous substances. If this product is used in any further processes, the final user must redefine and assign the most appropriate European Waste Catalogue Code. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable European (EU Directive 2008/98/EC) and local regulations.

Section: 14. TRANSPORT INFORMATION

The shipper/consignor/sender is responsible to ensure that the packaging, labeling, and markings are in compliance with the selected mode of transport.

Land transport (ADR/ADN/RID)

14.1 UN number : 3082

14.2 UN proper shipping

name

: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Chlorhexidine digluconate)

14.3 Transport hazard : 9

class(es)

14.4 Packing group : III14.5 Environmental hazards : Yes

14.6 Special precautions for

user

: None

Air transport (IATA)

14.1 UN number : 3082

14.2 UN proper shipping

name

: Environmentally hazardous substance, liquid, n.o.s.

(Chlorhexidine digluconate)

14.3 Transport hazard

class(es)

: 9

14.4 Packing group : III 14.5 Environmental hazards : Yes

14.6 Special precautions for

user

: None

Sea transport (IMDG/IMO)

14.1 UN number : 3082

14.2 UN proper shipping : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

name N.O.S.

(Chlorhexidine digluconate) 14.3 Transport hazard : 9

class(es)

14.4 Packing group : III 14.5 Environmental hazards : Yes

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14.6 Special precautions for : None

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC

Code

Section: 15. REGULATORY INFORMATION

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

Not applicable.

: Not applicable.

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of majoraccident hazards involving dangerous substances.

Candidate List of Substances : Not applicable.

of Very High Concern for

Authorisation

National Regulations

Take note of Dir 94/33/EC on the protection of young people at work.

: The Chemicals (Hazard Information and Packaging for Supply) Other regulations

Regulations.

The Control of Substances Hazardous to Health Regulations.

Health and Safety at Work Act.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out on the product.

Section: 16. OTHER INFORMATION

Full text of other abbreviations

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; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx -Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx -Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA -International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO -International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO -International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 -Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population

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(Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Prepared by : Regulatory Affairs

Numbers quoted in the MSDS are given in the format: 1,000,000 = 1 million and 1,000 = 1 thousand. 0.1 = 1 tenth and 0.001 = 1 thousandth

REVISED INFORMATION: Significant changes to regulatory or health information for this revision is indicated by a bar in the left-hand margin of the SDS.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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