Firenze

SAFETY DATA SHEET FOR OPERATORS

(Information sheet)
CLOSOL 2%
Chlorhexidine 2% cavity cleanser

Sez. 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

1.1. Supplier identification: Product Code: ITD020IC1

Product name CLOSOL 2%

1.2. Relevant identified uses of the substance

or mixture and uses advised against Cavity Cleanser Solution

1.3. Details of the supplier of the safety

data sheet: Name: Italmed srl

Address: viale Mazzini, 15 – 50132

Firenze

Phone: 055 5003124

Safety data sheet n. 1 September 2019

1.4. **Emergency telephone number :** Nearest center poisons

In Italy: Centro Antiveleni Niguarda

Milano - tel. 02-66101029

Sez. 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture

Digluconate Chlorhexidine

CAS n. 18472-51-0 % 2%

2.1.1 Classification as per Regulation (CE) N. 1272/2008:

Hazard class and category codes Eye Irrit. 2

Hazards codes: H319 – Eye Irrit;

2.1.2 Classification as per Directive 1999/45/CEE:

Classification: Not dangerous
Nature of the specific risks attributed: None in particular

The product if in contact with skin and eyes can be irritating

Do not disperse in the environment

2.2. Label elements

Labels conforming to Regulation (CE) n. 1272/2008:

Precautionary statements:

environment

In contact with acids it releases toxic

gases

Reaction:

P305+P351+P338 - IN CASE OF CONTACT WITH EYES: Rinse thoroughly for several minutes. Remove any contact lenses if it is easy to do. Continue to rinse. P337+P313 - If eye irritation persists, consult a doctor.

For professional use only.

2.3. Other hazards

Very toxic to aquatic organisms

ॐH400

Sez. 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance:

3.2 **Mixture** Chlorhexidine Digluconate

CAS n. 18472-51-0 % 2%

Refer to item 16 for the full text of the risk phrases and hazard statements

Sez. 4. FIRST AID MEASURES

4.1. Description of first aid measures

After Inhalation: Allow the subject to breathe fresh air. If the

breathing is difficult, make oxygen inhale.

Consult a doctor

After Skin contact: Immediately wash with water.

Contact with mucous membranes: Rinse the part affected thoroughly

with water for at least 15 minutes. Contact a

doctor if irritation persists.

Eye contact: Remove contact lenses if worn.

Rinse opened eye for at least 15 minutes

under running water. Contact an

ophthalmologist if the irritation persists.

After swallowing: Consult a doctor.

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

No data available

4.3. Indication of any immediate medical attention and special treatment needed

If the irritation persists, contact a doctor

Sez. 5. FIRE-FIGHTING MEASURES

5.1 **Suitable extinguishing agents:** Foam, dry extinguishing powder, CO2

5.2. Special hazards arising from the substance or mixture

No data available

5.3. Advice for firefighters

Use respiratory protection.

Safety helmet and complete protective

clothing.

It is also advisable to use self-contained breathing apparatus, above all, if operating

in closed and poorly ventilated areas.

Sez. 6. <u>ACCIDENTAL REALEASE MEASURES</u>

6.1 **Personal precautions**

Protective equipment and emegency

procedure:

Wear appropriate protective clothing.

6.2 **Environmental precautions** Absorb the material with sand or

vermiculite and confine it in closed containers for subsequent disposal. Keep away from drains, surface water and groundwater. Contain contaminated

washing water and dispose of it.

6.3. Methods and material for containment and cleaning up:

6.3.1 For containment

Collect the product for re-use, if possible, or

for disposal. If necessary, absorb it with

inert material.

Prevent it from entering the drainage

system.

6.3.2 **For cleaning up** After collection, wash the affected area and

materials with water.

6.3.3 **Other information:** No further information available.

6.4. **Reference to other sections** Refer to steps 8 and 13 for more

Information

Sez. 7. <u>HANDLING AND STORAGE</u>

7.1 Preacutions for safe handlings

7.1.1 **General advises** Wear suitable protective clothing.

Tender far from the reach of children. Do not smoke during handling and use

7.2 Conditions for safe storage, including

any incompatibilities: Store in its original packaging

tightly closed, in a dry and cool place. Keep

away from heat and away from light.

7.3 **Specific end uses:** Store in a well ventilated place and away

From heat sources.

Sez. 8. <u>EXPOSURE CONTROLS/PERSONAL PROTECTION</u>

8.1. **Control Parameters** No data available.

8.2. **Exposure controls** No specific controls required

Personal protective equipment:

Use the product in well-ventilated

areas.

Use protective gloves

Use appropriate protective glasses

Use suitable protective clothing

Avoid contact with the mucous

membranes

Sez. 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

Solution:

Aspect: Liquid solution
Colour: Light yellow color

Odor: Characteristic

PH > 5,5 Boiling point: ND

Relative density 1,065 about (Water=1)

Solubility ND
Vapor pressure ND
Evaporation rate ND
Flash point ND

9.2. **Other information** No data available

Sez. 10. STABILITY AND REACTIVITY

10.1 **Reactivity** No reactivity risk

10.2 **Stability:** Stable if stored as instructed

10.3 **Possibility of dangerous reactions:** In contact with acids it releases toxic gases.

May cause violent reactions with ammonia,

methanol and amines

10.4 **Conditions to avoid:** Do not keep the product near heat sources.

Avoid exposure to light

10.5 **Incompatible materials:** Strong oxidizing agents

10.6 **Decomposition products**

dangerous: by thermal decomposition or in case of fire,

gases and vapors potentially harmful to

health can be released

Sez. 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects: May cause eye damage

Toxcity data: No data available

Local effects: After contact with the skin: contact may result in

an irritant effect.

After contact with the eyes: causes irritation

The product is a medical device and as such has been considered not dangerous or harmful both under normal conditions of use and for an improper use.

Sez. 12. ECOLOGICAL INFORMATION

12.1 **Toxicity:** Prevent soil contamination,

subsoil and groundwater: do not eliminate

the product using water courses,

sewage systems or land of any nature

12.2 Persistence and degradability: No available data

12.3. Bioaccumulative potential
12.4. Mobility in soil
12.5. Results of the assesment
No available data
No available data

12.6. Other adverse effects No adverse effects found

Sez. 13. DISPOSAL CONSIDERATION

13.1 **Waste treatment methods** Do not disperse in the environment, in the

drains, in waterways.

Very toxic to aquatic organisms.
The used packs must be eliminated according to local regulations in force.
To request information for this specific case, please contact an authorized waste

disposal company.

Sez. 14. TRANSPORT INFORMATION

14.1. **UN-number**Not included in the scope of the regulations

on the transport of dangerous goods: by road (ADR); by rail (RID); by air (ICAO /

IATA); by sea (IMDG)

14.2. UN shipping name
14.3. Transport hazard classes
14.4. Packing group
14.5. Environmental hazards

None
None

14.6. **Special recommendation for users** No data available

14.7. Transport in bulk according to the annex II of MARPOL 73/78 and the IBC code

It is not expected to transport bulk cargoes

For transport, applies the same to pharmaceutical products.

Sez. 15. <u>REGULATORY INFORMATION</u>

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

Regulation (CE) n. 1907/2006 (REACH), Regulation (CE) n. 1272/2008 (CLP),

15.2. Evaluation of chemical safety

The supplier has carried out a chemical safety assessment

Sez. 16. OTHER INFORMATION

16.1. Other information

Description of the risk phrases set out in point 2
H400 Very toxic to aquatic organisms
H319 = Causes serious eye damage
Description of the hazard statements set out in point 2
H319 = Causes serious eye damage
H400 Very toxic to aquatic organisms

Method of use: See the leaflet

16.2 **Last revision:** 20.09.2019

Reason for revision:

adaptation to regulation 830/2015/EU

Notice to users:

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