

**Safety Sheet**

*(CE Directive 2001/58)*

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## 1. PREPARATION AND COMPANY IDENTIFICATION

- 1.1 Product Identification:** "NEX CLOREX C2 4% BRUSH-SPONGE"
- 1.2 Use:** Disinfectant, to be used on surgeon's hands. Disinfecting detergent solution ready to use, packed with a sponge-brush and nailcleaner.
- 1.3 Company:** **NEX MEDICAL s.a.s**  
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## 2. COMPOSITION AND INGREDIENTS

- 2.1 Ingredients:** Chlorhexidine Digluconate, Isopropyl Alcohol, Oxo-ethylate Alcohol, Perfume, Colouring, Water.
- 2.2 Substances contained in the preparation and classified as dangerous** (CE Directive 1999/45)

| CHEMICAL NAME (OR COMMON NAME) | %    | CAS no.    | EINECS no | Symbols | Risk Phrases |
|--------------------------------|------|------------|-----------|---------|--------------|
| Chlorhexidine Digluconate 20%  | 20   | 18472-51-0 | 242-354-0 | Xi-N    | 36/37-50/53  |
| Oxo-ethylate Alcohol           | 3,75 | 68439-54-3 | Polymer   | Xn      | 22-41        |
| Isopropyl Alcohol              | 2,6  | 67-63-0    | 200-661-7 | Xi-F    | 11-36-67     |

## 3. HAZARD IDENTIFICATION

- 3.1 Classification of the solution:** the solution is classified as dangerous according to CE DIRECTIVE 1999/45.

**Warning symbol:** **X** Xi (IRRITATING)

**R phrases :** **R – 36** irritating to the eyes

**S phrases :** **S – 2 – 25 – 26**

- keep away from the reach of children
- avoid eyes contact
- in case of contact with eyes, rinse immediately with plenty of water and seek for medical advice

### 3.2 Effects on human health:

- Ingestion:** stomach ache and nausea; the product may cause irritation to mucous membrane of the oral cavity and to the upper digestive system
- Inhalation:** none under normal conditions of use
- Skin contact:** the product does not cause dermal sensitisation
- Eyes contact:** the product may cause irritation, lacrimation, flush and blurred sight.

- 3.3 Environmental effects:** surfactants are biodegradable, therefore a build up in the environment is unlikely to happen; losses of the product in aquatic environment may cause fishes and other aquatic organisms death.

### 4. FIRST AID MEASURES

- 4.1 Ingestion:** in case of massive ingestion, wash the mouth with water, do not induce vomiting, seek for medical advice and show this Safety Sheet. Administer albuminate milk with 1-2 ml of dimethicone: milk protects mucous membrane from irritation while dimethicone prevents the formation of foam (which may occlude airflow and lead to suffocation).
- 4.2 Inhalation:** inhalation of the product is quite improbable; however, in case of inhalation, the injured person should be made breath pure air in case of the accidental formation of aerosol or vapours.
- 4.3 Skin contact** remove contaminated clothes. Wash with plenty of water
- 4.4 Eyes contact** the product may cause irritation to the eyes: rinse with plenty of water for at least 10 minutes. If necessary, seek for medical advice.

### 5. FIRE-FIGHTING MEASURES

- 5.1 Extinguishing devices:** powder, foam, nebulised water, CO<sub>2</sub>
- 5.2 Unsuitable extinguishing devices:** N.A.
- 5.3 Risk of exposure:** the product is a no flammable aqueous solution; the residue burns after water evaporation only in large fires. In this case, smoke will contain also CO, CO<sub>2</sub>, ...
- 5.4 Precautions:** water cools the surfaces exposed to a fire; if possible and not risky, remove containers that are not in the fire area yet and ensure to not feed the fire any longer.
- 5.5 Protective equipment:** staff must be evacuated; self-contained breathing apparatus and protective clothing should be available for fire-fighters.

### 6. MEASURES IN CASE OF ACCIDENTAL RELEASE

#### 6.1 Personal precautions:

**In case of massive losses:** before proceeding with the collection of the spilled product, evacuate people and wear rubber gloves. If possible, stop them without exposing to risk; remove materials and substances that are incompatible with the product (see sec.10).

#### 6.2 Cleaning methods:

**In case of large losses:** if possible, stop them with sand, collect material with mechanical devices and put it in closed containers labelled for later disposal. Dispose according to state and local regulations. Wash residues with plenty of water. Do not mix with other waste material. For disposal instructions, see local authorities standards (see sec.13).

**In case of small losses:** wash with plenty water.

### 7. HANDLING AND WAREHOUSING

**7.1 Handling:** there are no special precautions regarding handling. Follow current regulations regarding cleaning, safety and industrial health (see sections 3 and 4). Read product label carefully.

**7.2 Warehousing:** the product has been packed in PE or PP containers. Keep containers closed before the use. Keep the product in a cold place, away from direct sunlight and at a temperature between 5 and 40°C.

**7.3 Special use:** NONE

### 8. PERSONAL PROTECTION/ CONTROL OF EXPOSURE

**8.1 Threshold values for exposure:** the product does not release vapours, aerosols or significant particles in the air, considering the minimal amount of the product that could be used.

**8.1.1 Exposure control:** not applicable

**8.1.2 Exposure control in profession:** not applicable

**8.2.1.1 Respiration protection:** none required for this specific use.

**8.2.1.2 Hand protection:** none required for this specific use.

**8.2.1.3 Eye protection:** protective eyewear to be worn only during pouring and/or handling of spilled product

**8.2.1.4 Skin protection:** none required for this specific use.

**8.2.2 Environment exposure control:** N.A.

### 9. CHEMICAL AND PHYSICAL PROPERTIES

#### 9.1 General information

*Appearance:* imbibed liquid

*Smell:* that typical of the components

### 9.2 Important information regarding human health, safety and environment

|        |                            |                                  |
|--------|----------------------------|----------------------------------|
| 9.2.1  | pH (tel quel)              | 5,5                              |
| 9.2.2  | pH (1% solution):          | 6,5 ± 0,5                        |
| 9.2.3  | Boiling point interval:    | 100°C approx.                    |
| 9.2.4  | Flash point:               | non flammable                    |
| 9.2.5  | Flammability (solid, gas): | non flammable                    |
| 9.2.6  | Explosive properties:      | no                               |
| 9.2.7  | Combustion properties:     | no                               |
| 9.2.8  | Vapor pressure:            | not classified                   |
| 9.2.9  | Relative density (20/4):   | 1,02 ca.                         |
| 9.2.10 | Solubility:                | water-soluble in all proportions |
| 9.2.11 | Vapor density (aria= 1):   | not applicable                   |

9.2.12 Viscosity: not determined

9.2.13 Evaporation speed: not classified

9.2.14 Division coefficient P (n-octanol/water): not determined

### 9.3 Further information

|       |                                      |                |
|-------|--------------------------------------|----------------|
| 9.3.1 | Mixability:                          | not applicable |
| 9.3.2 | Explosiveness threshold (% in vol.): | not applicable |
| 9.3.3 | Conductivity:                        | not applicable |
| 9.3.4 | Decomposition temperature:           | not applicable |
| 9.3.5 | Explosion danger:                    | none           |
| 9.3.6 | Self-ignition temperature:           | not applicable |

## 10. STABILITY AND REACTIVITY

10.1 **Conditions to be avoided:** heat sources; temperature < 5° and > 40°C; direct sunlight

10.2 **Materials to be avoided:** acids and strong oxidants

10.3 **Dangerous decomposition by-products:** at high temperature (see section 5) as those likely to occur in a fire, there can be toxic and irritating gases and vapours of various kinds deriving from the partial or total combustion of the product components.

## 11. TOXICOLOGICAL INFORMATION

- 11.1 Acute oral toxicity:** LD50 > 2000mg/kg on rats.  
The product components have the following acute oral toxicity values on rats LD50:  
Chlorhexidine digluconate: > 2000mg/Kg  
Oxo-ethylate alcohol: > 200 < 2000mg/Kg  
Isopropyl alcohol: > 5.840 mg/Kg
- 11.2 Acute irritation:** no rash
- 11.3 Primary irritation index:** light 0,5
- 11.4 Draize scale:** 0
- 11.5 Sensitisation:** none, neither rashes nor edema
- 11.6 Contact with eyes:** "irritating to the eyes"
- 11.7 Contact with skin:** not classified as "irritating to the skin"
- 11.8 Ingestion:** not classified as "harmful after ingestion"; however the product may cause irritation to mouth and upper digestive tract.
- 11.9 Inhalation:** not classified

## 12. ECOLOGICAL INFORMATION

- 12.1 Eco-toxicity:** the product contains Chlorhexidine digluconate (classified as dangerous for the environment) on which some toxicological data are provided.  
Toxicity on bacteria : EC50 0,49 mg/l 30 min Photobacterium phosphoreum (DIN 38412 T34)  
Ichthyotoxicity: LC50 10,4 mg/l 96 h Brachydanio rerio (OECD 203)  
Algae toxicity: LC50 0,011 mg/l 72 h Scenedesmus subspicatus (DIN 38412 T34)
- 12.2 Mobility:** not determined
- 12.3 Persistence and degradability:** the product is biodegradable. However, it should not reach superficial watercourses without prior treatment in a water purification plant.
- 12.4 Environment** losses of large quantities of the product in aquatic environment may be toxic for fishes and other aquatic organisms.
- 12.5 Other adverse effects:** not determined

## 13. REMARKS ON DISPOSAL

- 13.1 Waste treatment:** dispose in a suitable purification plant or outsource in compliance with national/local regulations.

**13.2 Container treatment:** rinse accurately with water by giving to effluents the above mentioned consideration. Once empty and clean, containers can be recycled or disposed in compliance with national/local regulations.  
Do not dump containers in environment after use.

**13.3 Purification plants:** the product should not reach watercourses before being treated in a biological purification plant. In order to avoid problems for active sludge biological purification plants, it has to be remembered that the product contains Chlorhexidine Digluconate which has bactericidal effects.

### 14. TRANSPORT INFORMATION

**14.1** ONU number: not classified  
**14.2** IATA class: not classified  
**14.3** RID class: not classified  
**14.4** ADR class: not classified

### 15. REGULATORY INFORMATION

**15.1** In compliance with CE directive 2001/58, legislative decrees 3-2-97 n.52, 16-7-98 n.285 and further amendments regarding the labelling of dangerous substances and preparations. According to these legislative references, the product must be classified as **“irritating to the eyes”**.

**15.2 Warning symbol:** **X** Xi (IRRITATING)

**15.3 R Phrases (type of risk) :** **R – 36**  

- irritating to eyes

**15.4 S Phrases (prevention):** **S– 2 – 25 – 26**  

- keep away from the reach of children
- avoid contact with eyes.
- in case of contact with eyes, rinse immediately with plenty of water and seek for medical advice

**15.5 List of basic regulations:**  
**“since applicable”**  
D.P.R. 547/55 e D. L. 626/94: regulations for accident prevention and workers safety  
D.P.R. 303/56 General industrial health regulations  
L.319/76 e D.L. 133/92: water drainage  
D.P.R. 175/88: business with high accident risk  
D.P.R. 203/88: emissions in atmosphere  
D.P.R. 277/91: exposure to chemical agents  
D.P.R. 250/89: labelling of detergents  
D.M. 25/6/90: medical surgical devices  
(enforcement of DPR 223/88).  
D.L. 3/2/97 n.52: classification, packing, labelling of dangerous substances  
D.L.16/7/98 n.285 classification packing, labelling of

|   |  |   |
|---|--|---|
|  | <p align="center"><b>SAFETY DATA<br/>SHEET</b></p> | <p align="center"><b>NEX CLOREX C2 4%<br/>BRUSH-SPONGE</b></p> <p align="right">Revised: January 2012 - REV. 2      Pagg. 8/9</p> |
|---|--|---|

dangerous preparations.

Directive 2001/58/CE and further amendments and enforcement provisions.

## **16. OTHER INFORMATION**

16.1 The person in charge or its substitute should keep operators informed about the specific risk they may face while using the product.

16.2 Read product label carefully, follow directions and recommendations before using the product.

16.3 Do not use the product improperly.

### **16.4 Here are some phone numbers of intoxication centres in Italy operating 24hrs:**

- OSPEDALE NIGUARDA CA' GRANDA (MILANO) Tel. 02166101029
- CENTRO ANTIVELENI UNIVERSITÀ' DI TORINO Tel. 01126637637.
- CENTRO ANTIVELENI OSPEDALE CMI,E (PORDENONE) Tel. 04341550301
- CENTRO ANTIVELENI OSPEDALE CIVILE SANT'ANDREA (LA SPEZIA) Tel. 01871533296
- CENTRO ANTIVELENI OSPEDALE S. MARTINO (GENOVA) Tel. 0101352808
- PRONTO SOCCORSO UNITA' TOSSICOLOGICA (BOLOGNA) Tel. 0511333333
- SERVIZIO AUTONOMO DI TOSSICOLOGIA USL IO D (FIRENZE) Tel. 05514277238
- CENTRO ANTIVELENI OSPEDALE S.S. ANNUNZIATA (CHIETI) Tel. 08711345362
- CENTRO ANTIVELENI OSPEDALE CARDARELLI (NAPOLI) Tel. 08117472870
- OSPEDALE VITO FAZLI (LECCE) Tel. 08321665374
- POLICLINICO A. GEMELLI (ROMA) Tel. 0613054343
- POLICLINICO UMBERTO I (ROMA) Tel.06490663
- CENTRO ANTIVELENI OSPEDALE GARIBALDI (CATANIA) Tel. 095/7594120.

**16.5** *The sources used for the compilation of this Safety Sheet consist of literature, data from the suppliers of raw materials, current legislation on dangerous substances and preparations. We recommend you to review the data sheet or to contact the firm for any other further information. The information in this Safety Sheet is based on our present knowledge and is provided in accordance with the requirements of CE Regulations 1907/2006 of 18/12/2006 (REACH). The product must adhere to the standards and rules of hygiene, safety and environmental provisions according to the existing legislation. The information contained here refers to the product in the state and conditions under which it has been provided in compliance with Safety Standards and Methods.*





## SAFETY DATA SHEET

## NEX CLOREX C2 4% BRUSH-SPONGE

Revised: January 2012 - REV. 2      Pagg. 9/9

**16.7** For further information and details, please contact:

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