

PART I

SAFETY DATA SHEET
Regulation on Safety Data Sheets for Hazardous Substances and Mixtures
(R.G. 13.12.2014 – 29204)
PROCHEX

Date : 01.12.2012
Revision Date : 31.03.2016
Versiyon 2.
FORM No: A00196

PART II

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

1.1. Product identifier

Product code : A00196

Product name : PROCHEX

Product description : Excipients for Dentistry; %2 CHLOREXİDİNDİGLUCONATE

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

Relevant identified uses : Professional Dental Cleaning Solution

1.3. Details of the supplier of the safety data sheet

Manufacturer : Promida Diş Malzemeleri San Tic. Ltd. Şti.

75. Yıl Mah. 3. Cd. (Küçük Organize Sanayi) No: 6/A Odunpazarı/Eskişehir

TEL: 0 222 205 34 84

info@promida.com.tr

1.4. Emergency telephone number

Turkey : UZEM (114)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation(EC) No 1272/2008 [CLP]

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Skin Irritation, Category 2

Eye Irritation, Category 2

Aquatic Acute Category 2

2.2. Label elements

Classification according to Regulation(EC) No 1272/2008 [CLP]

The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

Hazard pictogram(s) :



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Signal Word : Warning

Hazard statement(s) :

H315: Causes skin irritation.

H319: Causes serious eye irritation.

H401: Toxic to aquatic life.

Precautionary statement(s)

P264: Wash {hands} thoroughly after handling.

P280: Wear {protective gloves/protective clothing/eye protection/face protection}.

P273: Avoid release to the environment

Response Phrases:

P302+352: IF ON SKIN: Wash with plenty of soap and water.

P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312: Call a POISON CENTER or doctor/physician if you feel unwell.

P332+313: If skin irritation occurs, get medical advice/attention.

P337+313: If eye irritation persists, get medical advice/attention.

P362+364: Take off contaminated clothing and wash it before reuse.

Storage and Disposal Phrases:

Please refer to Section 7 for Storage and Section 13 for Disposal information.

2.3. Other hazards

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The most significant routes of overexposure for this product are by contact with skin or eyes, inhalation and ingestion. The symptoms of overexposure are described below:

ACUTE:

INHALATION: Inhalation of mist or spray may cause respiratory irritation.

CONTACT WITH SKIN: Contact with the skin may cause irritation.

EYE CONTACT: Contact may cause serious eye irritation.

INGESTION: Under normal conditions of intended use, this material is not expected to be an ingestion hazard.

Ingestion may cause gastrointestinal irritation, nausea and vomiting.

CHRONIC: Prolonged contact with skin may cause defatting and dermatitis.

TARGET ORGANS: Acute: Eyes, Skin, Respiratory tract Chronic: Skin

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical material	Cas No	Clasifications	Wt %
Chlorhexidine Gluconate	18472-51-0	H318 Serious Eye Dam Cat 1, Aquatic Acute Cat 1	2

For full text of H-statements: see SECTION 16.

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SECTION 4: First aid measures

4.1 DESCRIPTION OF FIRST AID MEASURES:

EYE CONTACT: If product enters the eyes, open eyes while under gentle running water for at least 15 minutes. Seek medical attention if irritation persists or blurred vision occurs.

SKIN CONTACT: Wash skin thoroughly with soap and water after handling. Seek medical attention if irritation develops and persists.

INHALATION: If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

INGESTION: If product is swallowed, call physician or poison control center for most current information. If Professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or SDS with the victim to the health professional.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Some individuals may develop skin sensitization from exposure.

4.2 SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

Contact with eyes and skin may cause irritation.

4.3 RECOMMENDATIONS TO PHYSICIANS:

Treat symptoms and eliminate overexposure

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Water spray, fog, or mist, foam, dry chemical, carbon dioxide (CO₂)

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : None known.

5.3. Advice for firefighters

Fire fighting procedures : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire. This product is a non-combustible liquid with a flash point > 200°F (93°C).

Water Spray: Yes Carbon Dioxide: Yes

Foam: Yes Dry Chemical: Yes

Halon: Yes Other: Any "C" Class

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures : Refer to Section 8 for Personal Protective Equipment. Ensure adequate ventilation

6.2. Environmental precautions

Water spill : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

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Small Spill : ONLY PEOPLE WEARING PPE SHOULD CLEANUP SPILLS. Wipe up small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.

Large Spill : ONLY PEOPLE WEARING PPE SHOULD CLEAN UP SPILLS. Absorb with inert, damp non-combustible material, then flush area with water.

6.4. Reference to other sections

Additional information : PPE MUST BE WORN WHILE CLEANING UP ANY SPILLS. IF PEOPLE ARE NOT WEARING PPE THEY MUST BE EVACUATED FROM THE AREA OF THE SPILL.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Use suitable protective equipment.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Endodontic Cleaning Solution

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

None known.

8.2. Exposure controls

Eye/face protection : Wear eye protection.

Skin protection : Wear suitable protective clothing and gloves.

Respiratory protection : Use only in a well ventilated area.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Appearance : Clear

Colour : Light orange,

Odour : Odorless

9.2. Other information

Additional information : No further relevant information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

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10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : No dangerous reactions known.

10.4. Conditions to avoid

Conditions to avoid : No further relevant information available.

10.5. Incompatible materials

Incompatible materials : Oxidizing agents,

10.6. Hazardous decomposition products

Hazardous decomposition products : Thermal decomposition products include oxides of carbon and nitrogen.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

LD/LC50 no available

Primary irritant effect:

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

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

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

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

STOT-single exposure Based on available data, the classification criteria are not met.

STOT-repeated exposure Based on available data, the classification criteria are not met.

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

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute) : Chlorhexidine Gluconate 18472-51-0 EC50 - 0.087 mg/l 96h Daphnia

12.2. Persistence and degradability

Persistence and degradability : Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential : Not classified

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12.4. Mobility in soil

Mobility in soil : Not available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment :

Not applicable.

12.6. Other adverse effects

Environmental data : No specific data available on this product.

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

Not water endangering in accordance with EU Guideline 91/155-EWG.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal method : Dispose of container and unused contents in accordance with local requirements.

SECTION 14: Transport information

This product is not considered as dangerous goods.

14.1. UN number

UN number : not regulated

14.2. UN proper shipping name

UN proper shipping name : not regulated

14.3. Transport hazard class(es)

Primary hazard class/division : not regulated

Hazard classification : not regulated

14.4. Packing group

Packing group : not regulated

14.5. Environmental hazards

Marine pollutant #1 : Not applicable.

14.6. Special precautions for user

ADR - road : Not applicable.

RID - rail : Not applicable.

IMDG - sea : Not applicable.

IATA - air : Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : Not applicable.

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SECTION 15: Regulatory information

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

Directive 2012/18/EU · Named dangerous substances - ANNEX I None of the ingredients is listed.
REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

15.2. Chemical safety assessment

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H401: Toxic to aquatic life.

Department issuing SDS: Regulatory Affairs

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International

Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Prepared by : İlke Özyurt

Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.