

PART I

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

Date : 01.12.2012
Revision Date : 12.07.2021
Versiyon 2.
FORM No: RC0200

PART II

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

1.1. Product identifier

Product code : RC0200

Product name : PROCAL

Product description : Excipients for Dentistry

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

Relevant identified uses : Professional Dental endodontic temporary products

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.

Acute Tox. 4 H332 Harmful if inhaled.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

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.

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Hazard pictogram(s) :



Signal Word : Irritating

Hazard statement(s) :

H335: STOT SE. 3. May cause respiratory irritation.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statement(s)

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves / eye protection / face protection.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 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/doctor if you feel unwell.

P321 Specific treatment (see on this label).

2.3. Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable. vPvB: Not applicable.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical material	Cas No	Classifications	Wt %
Calcium hydroxide	1305-62-0	Irritant (Xi) R 36 / 37 / 38 Skin irritation; 2 STOT SE; 2 Eye irritation, 2	>50

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information:

Immediately remove any clothing soiled by the product. Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

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After inhalation:

This product is a viscous gel, therefore chance of inhalation is extremely low. Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. In case of unconsciousness place patient stably in side position for transportation.

After skin contact:

Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing: If swallowed in large quantities seek medical attention.

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

No further relevant information available.

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

No further relevant information available.

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.

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

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

Reference to other sections :

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information

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

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 : powder

Colour : white

Odour : Characteristic

9.2. Other information

Additional information : No further relevant information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

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.

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10.4. Conditions to avoid

Conditions to avoid : No further relevant information available.

10.5. Incompatible materials

Incompatible materials : No further relevant information available.

10.6. Hazardous decomposition products

Hazardous decomposition products : Flor, Nitrogen oxides, Ammonia, Carbon monoxide and carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

No data

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

12.2. Persistence and degradability

Persistence and degradability : Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential : Not classified

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.

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12.6. Other adverse effects

Environmental data : Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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

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.

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

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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.

H335 May cause respiratory irritation.

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)

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

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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.