

PART I

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

Date : 01.12.2012
Revision Date : 31.03.2016
Versiyon 2.
FORM No: C10620

PART II

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

1.1. Product identifier

Product code : C10620

Product name : PROPHY P

Product description : Excipients for Dentistry, Prophylaxis paste

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

Relevant identified uses : Professional Dental prophylaxis paste

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 under CLP: Skin Irrit. 2: H315; STOT RE 1: H372

Most important adverse effects: Causes damage to organs [lungs] through prolonged or repeated exposure [inhalation (dust/mist)].

Causes skin irritation

2.2. Label elements

Label elements: Hazard statements: H372: Causes damage to organs [lungs] through prolonged or repeated exposure [inhalation (dust/mist)]. H315: Causes skin irritation. Hazard pictograms: GHS07: Exclamation mark GHS08: Health hazard

Hazard pictogram(s) :



Signal words: Danger

Precautionary statements:

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P260: Do not breathe dust.

P262: Do not get in eyes, on skin, or on clothing.

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

P285: In case of inadequate ventilation wear respiratory protection

P342: If experiencing respiratory symptoms:

P314: Get medical advice/attention if you feel unwell.

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

Various non hazardous pigments at < 0.1% total value

Blend of flavours*; <0.6%

Silica and silica based products; 50-70%; H373

Glycerine; CAS 56-81-5; 20-30%

Water, CAS 7732-18-5,

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.

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.

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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.

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

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7.3. Specific end use(s)

Specific end use(s) : Professional Dental Endodontic Lubricant 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 : Paste

Appearance : viscose

Colour : different colours,

Odour : different Odor

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.

10.4. Conditions to avoid

Conditions to avoid : No further relevant information available.

10.5. Incompatible materials

Incompatible materials : Oxidizing agents, Alkalis, Acids.

10.6. Hazardous decomposition products

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

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Harmful if inhaled.

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 (carcinogenicity, 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.

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.

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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

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.

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

* indicates text in the SDS which has changed since the last revision

Phrases used in s.2 and s.3: H315: Causes skin irritation.

H372: Causes damage to organs <or state all organs affected, if known> through

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prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

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.