

PART I

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

Date : 27.05.2024
Revision Date :
Versiyon 2.
FORM No: RK01

PART II

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

1.1. Product identifier

Product code : RK01

Product name : PROFILLER UNICOMP

Product description : Excipients for Dentistry

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

Relevant identified uses : Professional Dental Universal Composite

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.

Met. Corr. 1 H290

Skin Corr. 1B H314

Eye Dam. 1 H318

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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GHS07

Signal Word: Warning

Hazard statement(s) :

- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H317 May cause an allergic skin reaction
- H335 May cause respiratory irritation.
- H335 May cause respiratory irritation.

Precautionary statement(s)

- P264 Wash hands thoroughly after handling
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P271 Use only outdoors or in a well-ventilated area
- P272 Contaminated work clothing should not be allowed out of the workplace

2.3. Other hazards

No additional information available

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical material	Cas No	Classifications	Wt %
BIS-GMA BISPHENOL A-GLYCIDYL METHACRYLATE	1565-94-2	Skin Irrit. 2: H315 Eye Irrit. 2: H319; Skin Sens. 1: H317	0-10
TEGDMA TRIETHYLENE GLYCOL DIMETHACRYLATE	109-16-0	Skin Sens. 1: H317	0-10
UDMA URETHANE- DIMETHACRYLATE	72869-86-4	Skin Irrit. 2: H315 Skin Sens. 1: H317 Eye Irrit. 2: H319 STOT SE 3 ; H335	0-10
Silicone Oxide	7631-86-9	Skin Irrit. 2: H315 Eye Irrit. 2: H319; Acute Tox. 4; H332 STOT SE 3 ; H335	20-40
Ytterbium Oxide	1314-37-0	Skin Irrit. 2: H315	20-40

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		Eye Irrit. 2: H319; STOT SE 3 ; H335	
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For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1 DESCRIPTION OF FIRST AID MEASURES:

First-aid measures general : If medical advice is needed, have product container or label at hand.

First-aid measures after inhalation : If inhaled, remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

First-aid measures after skin contact : Remove contaminated clothing. Immediately rinse with plenty of water for at least 60 minutes. Obtain medical attention if irritation persists.

First-aid measures after eye contact : Immediately rinse with water for a prolonged period. Remove contact lenses, if present and easy to do.

Continue rinsing for at least 60 minutes. If eye irritation persists: Get medical advice and attention.

First-aid measures after ingestion : If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label.

4.2 SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

Symptoms/injuries : Corrosive. Causes burns.

Symptoms/injuries after inhalation : Inhalation may cause immediate severe irritation progressing quickly to chemical burns.

Symptoms/injuries after skin contact : Prolonged skin contact may result in severe irritation leading to chemical burns.

Symptoms/injuries after eye contact : Causes serious eye damage.

Symptoms/injuries after ingestion : Ingestion is likely to be harmful or have adverse effects.

4.3 RECOMMENDATIONS TO PHYSICIANS:

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

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Suitable extinguishing media : Not considered flammable but will burn at high temperatures. Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : If involved in a fire the following toxic and/or corrosive fumes may be produced by thermal decomposition: Oxides of phosphorus.

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Explosion hazard : Product is not explosive.
Reactivity : Stable at ambient temperature and under normal conditions of use.

5.3. Advice for firefighters

Firefighting instructions : Do not breathe fumes from fires or vapours from decomposition. All firefighting personnel must wear safety suits.

Protection during firefighting : Use normal individual fire protective equipment. Use self-contained breathing apparatus when fighting fire in an enclosed area.

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

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 etching gel

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

None known.

8.2. Exposure controls

Eye/face protection : Wear eye protection.

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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 : gel
Appearance : clear
Colour : blue,
Odour : Odorless

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 : Metal. Bases. Oxidizers.

10.6. Hazardous decomposition products

Under conditions of fire this material may produce: Oxides of phosphorus..

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified
Phosphoric acid (7664-38-2)
LD50 oral rat 1530 mg/kg
LD50 dermal rabbit 2730 mg/kg
LC50 inhalation rat (mg/l) > 850 mg/m³ (Exposure time: 1 h)
ATE (oral) 1530.000 mg/kg body weight
ATE (dermal) 2730.000 mg/kg body weight
Skin corrosion/irritation : Causes severe skin burns and eye damage. pH: 1.7 - 2
Serious eye damage/irritation : Causes serious eye damage. pH: 1.7 - 2

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SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute) : Not classified

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 : No specific data available on this product.

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

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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.

Relevant phrases

Acute Tox. 4 (Oral) Acute toxicity (oral) Category 4
----- Eye Dam. 1 Serious eye damage/eye irritation Category 1
----- Met. Corr. 1 Corrosive to metals Category 1
----- Skin Corr. 1B Skin corrosion/irritation Category 1B
----- H290 May be corrosive to metals
----- H302 Harmful if swallowed
----- H314 Causes severe skin burns and eye damage
----- H318 Causes serious eye damage

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

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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.