# 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND

**COMPANY/UNDERTAKING** 

INFORMATION ON THE PRODUCT

1.1 Product identifier

Trade name

# K-30 S POWDER

### 1.2 Relevant identifier uses of the substance or mixture and uses advised against

Recommended use

Material for the fabrication of full and partial dentures.

# 1.3 Details of the supplier of the Safety Data Sheet

#### Manufacturer/supplier

Polident d.o.o.,

**Dental Products Industry** 

Volčja Draga 42, 5293 Volčja Draga,

Slovenija

Tel.:00386 5 3304840, Fax: 00386 5 3304870

E-mail: polident@polident.si
Information provided by

00386 5 3304859

### 1.4 Emergency telephone number

00386 5 3304840

#### 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

Clasification according to Regulation (EC) No. 1272/2008

The mixture is not classified according to Regulation.

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008

Not applicable.

2.3 Other hazards

### Results of PBT and vPvB assessment

**PBT:** Not applicable. **vPvB:** Not applicable.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Chemical characterization: Mixtures

#### Description

Product contents polymethylmethacrylate, pigments and dibenzoyl peroxide.

#### Hazardous ingredients according to Regulation (EC) No. 1272/2008

Not applicable.

#### 4. FIRST AID MEASURES

### 4.1 Description of first aid measures

### **General information**

Remove contaminated clothing.

#### Inhalation

Remove the casualty into fresh air. In case of complaints obtain medical attention.

#### Skin contact

Wash off immediately with water. If skin irritation occurs obtain medical attention.

### Eye contact

Rinse opened eye with plenty of water and if it is necessary obtain medical attention.

#### Ingestion

Do not induce vomiting. Rinse mouth. In case of complaints obtain medical attention.

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

None known.

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

Treat symptomatically.

### 5. FIRE – FIGHTING MEASURES

### 5.1 Extinguishing media

### Suitable extinguishing media

Water spray, foam, dry powder, carbon dioxide.

#### Unsuitable extinguishing media for safety reasons

Water with full yet.

### 5.2 Special hazards arising from the substance or mixture

Dangerous gases may be released in case of fire.

#### 5.3 Advice for firefighters

Wear self-contained breathing apparatus and suitable protective clothing.

#### 6. ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation.

Ensure suitable personal protection (including respiratory protection) during removal of spillages.

### **6.2** Environmental precautions

Prevent product from getting into drains, surface water or ground water.

### 6.3 Methods and material for containment and cleaning up

Pick up mechanically. Dispose of in accordance with regulations.

#### 6.4 Reference to other sections

For information on safe handling see Section 7.

For information on personal protection equipment see Section 8.

For information on disposal information see Section 13.

#### 7. HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

#### Safe handling advice

Avoid the formation and deposition of dust.

### Information on fire and explosion protection

No special precautions required.

# 7.2 Conditions for safe storage, including any incompatibilities

Storage

#### Requirements for storage areas

Keep the powder only in the original vessel in cool and dry place.

#### **Empiry date**

Considering the instructions for safety storage and handling the expiry date of the powder is five years.

# 7.3 Specific end use(s)

None.

# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### 8.1 Control parameters

# Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

### 8.2 Exposure controls

### **Appropriate engineering controls**

Do not eat, drink or smoke at the work place. Follow the usual good standards of occupational hygiene and dental practise. Ensure adequate ventilation of work place.

Store work clothing separately. Remove contaminated clothing.

### Individual protection measures, such as personal protective equipment

Eye/face protection

Wear tightly sealed goggles.



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### SAFETY DATA SHEET according to regulation 1907/2006/EC K-30 S POWDER

#### Skin protection

Wear suitable protective gloves.



Material of gloves: Butyl rubber; EN 374

Suitability of gloves should be confirmed with glove manufacturer. Change gloves, if contamination occurs or duration of activity exceed break through time. Breakthrough time of the glove material: refer to the information provided by the glove's producer.

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

Respiratory protection

By normal use is not required.

Thermal hazards

None.

**Environmental exposure controls** 

Ensure effective control measures when working within the boundaries as specified in section 6.2.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance
Form: powder
Colour: pink shades
Odour: odourless

pH – value: not applicable Changes in condition: / Softening point (°C): ca. 110 Boiling point (°C): not applicable

Flash point ( $^{\circ}$ C): > 250

Relative evaporation rate (Ether=1): Not available

Flammability (solid, gas): Not applicable Auto Ignition temperature(°C): > 400

**Decomposition temperature** (°C): Not applicable **Lower explosion limit** (%vv/v): Not available **Upper explosion limit** (%vv/v): Not available

Vapour pressure (Pa): Not applicable Vapour density (Air=1): Not applicable

**Density** ( $g/cm^3$ ): 1,2 at 20 °C

Bulk density (kg/m³): Not applicable Viscosity (dynamic): Not applicable Solubility in water: insoluble

Solubility (quantitative): in e.g. esters, ketones and chlorinated hydrocarbons: readily soluble

Partition coefficient (n-Octanol/water): Not applicable

Explosive properties: Not applicable Oxidising properties: Not applicable

### 9.2 Other information

None.

### 10. STABILITY AND REACTIVITY

# 10.1 Reactivity

See Section 10.2.

#### 10.2 Chemical stability

The product is stable under normal handling and storage conditions. Depolymerization begins at 250°C.

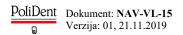
# 10.3 Possibility of hazardous reactions

No dangerous reactions known.

#### 10.4 Conditions to avoid

Operations that create dust.

#### 10.5 Incompatible materials



Strong oxidizing agents.

### 10.6 Hazardous decomposition products

None when used and stored as prescribed.

Dangerous gases may be released in case of fire.

#### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

#### **Acute toxicity**

No specific test data available.

No evidence for hazardous properties.

#### **Skin irritation**

No specific test data available.

No evidence for hazardous properties.

#### **Eve contact**

No specific test data available.

No evidence for hazardous properties.

#### Sensitization

No specific test data available.

No evidence for hazardous properties.

#### **CMR** effects

No.

# Repeated dose toxicity

No specific test data available.

No evidence for hazardous properties.

### Further information on toxicology

When the product is used and storage as directed, the product does not have any toxicological effects. The fine particles contained in the product may cause mechanical irritation of the skin, eyes and mucous membranes.

Avoid product contact with skin and eyes and inhalation of dust.

### 12. ECOLOGICAL INFORMATION

#### 12.1 Toxicity

#### Hazardous to the aquatic environment

No specific test data available.

No evidence for hazardous properties.

### 12.2 Persistence and degradability

No specific test data available.

No evidence for hazardous properties.

#### 12.3 Bioaccumulative potential

No specific test data available.

No evidence for hazardous properties.

### 12.4 Mobility in soil

No specific test data available.

No evidence for hazardous properties.

### 12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

**12.6** Other adverse effects: No further relevant information available.

### 13. DISPOSAL CONSIDERATIONS

# 13.1 Waste treatment methods

**Product:** Must not be disposed together with household garbage. Do not allow product to reach sewage system. Disposal should be made in accordance with local, state and national legislation. **Uncleaned packaging:** Disposal should be made in accordance with local, state and national legislation.

#### 14. TRANSPORT INFORMATION

**14.1 UN number:** Not applicable. The product is not dangerous according to transport regulations.

### 14.2 UN proper shipping name

Stran 5 od 5

See Section 14.1.

#### 14.3 **Transport hazard class(es)**

See Section 14.1.

#### 14.4 Packing group

ADR, IMDG, IATA:

See Section 14.1.

#### 14.5 **Environmental hazards**

Marine pollutant: Not classified as a marine pollutant.

#### 14.6 Special precautions for user

Not applicable.

#### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

#### 14.8 **Transport additional information**

Not applicable.

#### REGULATORY INFORMATION 15.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Product is a medical device class IIa according to Directive 93/42/EEC.

#### 15.2 **Chemical Safety Assessment**

A chemical safety assessment has not been carried out for this micture.

#### OTHER INFORMATION 16.

This information is based on our present knowledge and experience. They are intended as a description of the products safety requirements and are not to be seen as a quarantee of certain product's features.

New versions of Safety Data Sheet will be *laying printed* for the data compared to the previous version altered.

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