## SAFETY DATA SHEET according to regulation 1907/2006/EC PINK CAD-CAM DISC

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/UNDERTAKING

#### INFORMATION ON THE PRODUCT

#### 1.1 Product identifier

Trade name

## PINK CAD-CAM DISC

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

#### Recommended use

Discs have been used for fabrication of dentures by using CAD/CAM techniques.

**Details of the supplier of the Safety Data Sheet** 

## 1.3 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: <a href="mailto:polident.si">polident@polident.si</a>
<a href="mailto:Information provided by">Information provided by</a>

00386 5 3304859

## **Emergency telephone number**

**1.4** 00386 5 3304840

#### 2. HAZARDS IDENTIFICATION

## 2.1 Classification of the substance or mixture

Classification according to Regulation 1272/2008/EC: Not applicable

## 2.2 Label elements

Labelling according to Regulation 1272/2008/EC:

Not applicable

#### 2.3 Other hazards:

None.

#### Results of PBT and vPvB assessment

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

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Chemical characterization: Mixtures

## **Description**

Material on the base of polymethylmethacrylate, dimethacrylates and pigments.

#### Hazardous ingredients according to Regulation 1272/2008/EC:

Not applicable

## 4. FIRST AID MEASURES

## 4.1 Description of first aid measures

## **General information**

No special measures required.

#### Inhalation

Remove the casualty into fresh air. In case of complaints get medical advice.

#### Skin contact

Wash off with water and soap. Consult a physician if irritation persists.

#### **Eve contact**

Rinse eye with plenty of water if it is necessary seek medical attention: only mechanical effect.

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#### Ingestion

Wash out mouth with water and drink water. In case of complaints get medical advice.

## 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, foam, dry powder, carbon dioxide.

## Unsuitable extinguishing media for safety reasons

None.

## 5.2 Special hazards arising from the substance or mixture

May be released in case of fire: carbon monoxide, carbon dioxide, organic products of decomposition.

## 5.3 Advice for firefighters

Wear self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

## 6.1 Personal precautions, protective equipment and emergency procedures

Not required.

#### **6.2** Environmental precautions

No special measures required.

## 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

Only adequate trained persons may deal with product. For use in dentistry only.

Keep away from children.

Ensure the area is well ventilated.

No eating, drinking or smoking during handling with product.

Follow the usual good standards of occupational hygiene.

## Information on fire and explosion protection

No special measures required.

## 7.2 Conditions for safe storage, including any incompatibilities

Storage

## Requirements for storage areas

Keep in dry storage.

#### 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.

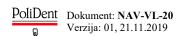
#### 8.2 Exposure controls

#### **General protective measures**

Provide adequate ventilation.

## **Hygiene measures**

Follow the usual good standards of occupational hygiene and dental practice.



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#### **Respiratory protection**

Avoid contact with powder generated by final working.

Wear respiratory protective device in case of dust formation.

#### Hand protection

Not reguired.

#### **Eve protection**

Wear safety goggles during mechanical processing.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

## 9.1 Information on basic physical and chemical properties

**Appearance: Form**: firm disc

Colour: different colours
Odour: odourless
Changes in condition: /
Melting point: Undetermined
Boiling point: Undetermined

Flash point: >250°C

Ignition temperature: not applicable Lower explosion limit: not determined Upper explosion limit: not determined Vapour pressure: not applicable

**Density:** 1,17 g/cm<sup>3</sup>

Viscosity (dynamic): not applicable Solubility in water: insoluble pH – value: not applicable

#### 9.2 Other information

None.

#### 10. STABILITY AND REACTIVITY

#### 10.1 Reactivity

No relevant information available.

#### 10.2 Chemical stability

The product is stable under normal handling and storage conditions.

#### 10.3 Possibility of hazardous reactions

No hazardous reactions known.

#### 10.4 Conditions to avoid

Decompositions begins at appr. 250°C.

## 10.5 Incompatible materials

No relevant information available.

#### 10.6 Hazardous decomposition products

None when used as prescribed.

May be released in case of fire: carbon monoxide, carbon dioxide, organic products of decomposition

## 11. TOXICOLOGICAL INFORMATION

## 11.1 Information on toxicological effects

## Acute oral toxicity

The similar product has been tested according to EN ISO 10993-5 (2009): Tests for in vitro cytotoxicity. The test article extract met the requirements of the EN ISO 10993-5 (2009).

#### Irritation

The similar product has been tested according to EN ISO 10993-10 (2010): Tests for irritation and skin sensitization. An intracutaneous irritation test by intradermal injection in the rabbit has been performed and the test article extract met the requirements of the ISO 10993-10 (2010).

#### Sensitization

The similar product has been tested according to EN ISO 10993-10 (2010): Tests for irritation and skin sensitization. According to the EN ISO 10993-10 (2010) the product did not induce delayed sensitization.

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#### 12. ECOLOGICAL INFORMATION

#### 12.1 Toxicity

**Hazardous to the aquatic environment:** No further relevant information available, no evidence for hazardous properties

- **12.2 Persistence and degradability:** No further relevant information available, no evidence for hazardous properties
- **12.3 Bioaccumulative potential:** No further relevant information available, no evidence for hazardous properties
- **12.4 Mobility in soil:** No further relevant information 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:** 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.

Code of waste EWC: 18 01 07

#### 14. TRANSPORT INFORMATION

## 14.1 UN Number: see section 14.2

## 14.2 UN proper shipping name

Land transport ADR: Not dangerous according to transport regulations.

Land transport RID: Not dangerous according to transport regulations.

Inland waterway transport ADN: Not dangerous according to transport regulations.

**Shipment by sea IMDG:** Not dangerous according to transport regulations.

Air transport ICAO/IATA: Not dangerous according to transport regulations.

- 14.3 Transport hazard class(es): see section 14.2
- **14.4** Packing group: see section 14.2
- 14.5 Environmental hazards: None.
- **14.6** Special precautions for user: see section 14.2
- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: None.
- **14.8** Transport additional information: None

#### 15. REGULATORY INFORMATION

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

#### Other regulations, limitations and prohibitive regulations

The product is Class IIa medical device according to the EC Directive 93/42/EEC.

#### 15.2 Chemical Safety Assessment

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

## 16. OTHER INFORMATION

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.

Pripravil: Janja Lipušček Pregledal: Janja Lipušček Odobril: Janja Lipušček