1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND

COMPANY/UNDERTAKING

INFORMATION ON THE PRODUCT

1.1 Product identifier

Trade name

X-RAY CAD-CAM DISC

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

Recommended use

Discs are used for fabrication of diagnostic stents on dental milling machines. Diagnostic stents are used for correct implant positioning planning on the basis of the analysis of the radiographs or within 3D planning software.

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 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: Not applicable.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Chemical characterization: Mixtures

Description

Material based on polymethylmethacrylate with barium sulfate.

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.

Ingestion

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

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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

None.

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 adequante ventilation.

Hygiene measures

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

Respiratory protection

Avoid contact with powder generated by final working.

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Wear respiratory protective device in case of dust formation.

Hand protection

Not reguired.

Eye 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: white
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: not applicable

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

No toxiciting effects known.

Irritation

No irritating effects known.

Sensitization

No sensitizating effects known.

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

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- **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

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.

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