

Safety Data Sheet according to WHS Regulations

Printing date 04.04.2024

Version number 2

Revision: 02.04.2024

Not classified as hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **Product identifier**
- **Trade name: *Ivotion***
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** CAD/CAM disc for removable prosthetics
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent AG
Bendererstrasse 2
9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
Tel: +423 235 35 35 / Fax: +423 235 33 60
- **Importer:**
Ivoclar Vivadent Pty. Ltd.
1- 5 Overseas Drive
Noble Park North VIC 3174
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclar.com
- **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

- **Classification of the substance or mixture**
The substance is not classified, according to the Globally Harmonised System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards** Avoid breathing sanding dust /swarf.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- **Chemical characterisation: Substances**
- **CAS No. Description**
CAS No.: 9011-14-7 Polymethylmethacrylate

4 First Aid Measures

- **General information:** No special measures required.
- **After inhalation:** Grinding dust: Supply fresh air; consult doctor in case of complaints.

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- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:**
Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
Mechanical effects only.
- **After swallowing:** Grinding dust: Rinse out mouth and then drink plenty of water.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Mechanical processing:
Wear protective clothing.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
Provide suction extractors if dust is formed.
- **Information about fire - and explosion protection:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.

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Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

· **Respiratory protection:**

Mechanical processing:

Use respiratory protective device against the effects of dust.

· **Recommended filter device for short term use:** Filter P1

· **Protection of hands:**

Protective gloves should always be worn during mechanical and thermal processing.

After use of gloves apply skin-cleaning agents and skin cosmetics.

· **Material of gloves**

Mechanical processing:

Leather gloves

Strong material gloves

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

9 Physical and Chemical Properties

· **General Information**

· **Appearance:**

· **Form:**

Solid

· **Colour:**

According to product specification

· **Odour:**

Odourless

· **Odour threshold:**

Not determined.

· **pH-value:**

Not applicable.

· **Change in condition**

· **Melting point/freezing point:**

150 °C

· **Initial boiling point and boiling range:**

Undetermined.

· **Flash point:**

Not applicable.

· **Flammability (solid, gas):**

Product is not flammable.

· **Ignition temperature:**

Not determined.

· **Explosive properties:**

Product does not present an explosion hazard.

· **Vapour pressure:**

Not applicable.

· **Density at 20 °C:**

1.2 g/cm³

· **Relative density**

Not determined.

· **Vapour density**

Not applicable.

· **Evaporation rate**

Not applicable.

· **Solubility in / Miscibility with**

· **water:**

Insoluble.

· **Partition coefficient: n-octanol/water:**

Not determined.

· **Viscosity:**

· **Dynamic:**

Not applicable.

· **Kinematic:**

Not applicable.

· **Solids content:**

100.0 %

· **Other information**

No further relevant information available.

10 Stability and Reactivity

· **Reactivity** No further relevant information available.

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- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
Can decompose slowly with localised heating above 150°C.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **ADG, ADN, IMDG, IATA** Void

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· UN proper shipping name · ADG, ADN, IMDG, IATA	Void
· Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class	Void
· Packing group · ADG, IMDG, IATA	Void
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Industrial Chemicals**

Substance is listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

Substance is not listed.

· **Australia: Priority Existing Chemicals**

Substance is not listed.

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** Substance is not listed.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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.

· **Contact:**

· **Abbreviations and acronyms:**

IMO: International Maritime Organization

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

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IATA: International Air Transport Association
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
· *** Data compared to the previous version altered.**

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