

Printing date 07/06/2020 Version number 1 Reviewed on 07/06/2020

1 Identification

- · Product identifier
- · Trade name: Ivotion Base
- · Application of the substance / the mixture Denture base material for the CAD/CAM technology
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

175 Pineview Drive, Amherst, N.Y. 14228

USA

Tel. +1 800 533 6825 Fax +1 716 691 2285

Ivoclar Vivadent Inc. 1-6600 Dixie Road Mississauga, Ontario L5T 2Y2 Canada

Phone: +1 905 670 8499 Fax: +1 905 670 3102

- · Information department: Quality Assurance / Regulatory Affairs
- Emergency telephone number: 24 Hour Emergency Assistance:

Emergency-Call USA - Infotrac: 1-800-535-5053 Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazard(s) identification

· Classification of the substance or mixture

The product is not classified, according to the Globally Harmonized System (GHS).

- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0 Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



- · Other hazards Avoid breathing sanding dust /swarf.
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.

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· vPvB: Not applicable.

3 Composition/information on ingredients

· Chemical characterization: Mixtures

· **Description:** > 90% polymethylmethacrylate

· Dangerous components: Void

4 First-aid measures

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

- · Extinguishing media
- · Suitable extinguishing agents:

CO2, extinguishing 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.
- · Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions:

No special measures required.

Do not allow to enter sewers/surface or ground water.

- · 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.

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For use in dentistry only.

- · Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · 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/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components 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.

- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures:

Usual hygienic measures for dental practice and dental laboratories.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

- · Breathing equipment: 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 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

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Solid

Color: According to product specification

· Odor: Odorless
· Odor threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/Melting range: Undetermined.

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Boiling point/Boiling range:	Undetermined.	
Flash point:	Not applicable.	
Flammability (solid, gaseous):	Not determined.	
Decomposition temperature:	Not determined.	
Auto igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Vapor pressure:	Not applicable.	
Density at 20 °C (68 °F):	~ 1.2 g/cm³ (~ 10.014 lbs/gal)	
Relative density	Not determined.	
Vapor density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
Water:	Insoluble.	
Partition coefficient (n-octanol/wa	ter): Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
Other information	No further relevant information available.	

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · 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 localized heating above 150°C.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid Keep away from heat and direct sunlight.
- · Incompatible materials: acetone
- · Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · on the skin: No irritant effect.
- · on the eye:

No irritating effect.

Mechanical effects only.

- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

CAS: 9011-14-7 polymethylmethacrylate

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· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · 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 packagings:
- · Recommendation: Disposal must be made according to official regulations.

14 Transport information

- · UN-Number
- · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void
- · UN proper shipping name
- · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void
- · Transport hazard class(es)
- · DOT, ADR/RID/ADN, ADN, IMDG, IATA
- · Class Void
- · Packing group
- · DOT, ADR/RID/ADN, IMDG, IATA Void
- · Environmental hazards:
- · Marine pollutant: No
- · Special precautions for user Not applicable.

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· Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II of 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
- · Sara
- · Section 355 (extremely hazardous substances):

None of the ingredients is listed.

Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

CAS: 9011-14-7 polymethylmethacrylate

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

- · Carcinogenic categories
- · EPA (Environmental Protection Agency)

None of the ingredients is listed.

TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

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

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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.

- · Date of preparation / last revision 07/06/2020 / -
- · 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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists 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)

NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit

-US