

Printing date 10/31/2012 Version number 3 Reviewed on 10/31/2012

1 Identification of the substance/mixture and of the company/undertaking

· Product identifier

· Trade name: IPS e.max ZirCAD

· CAS Number:

66402-68-4

· EC number:

266-340-9

· Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· Application of the substance / the preparation

Manufacture of dental prothesis

Yttrium-stabilized zirconium oxide block 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 MSDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazards identification

· Classification of the substance or mixture

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

- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.
- · Information concerning particular hazards for human and environment: Not applicable.
- · Label elements
- · Labelling according to EU guidelines:

The substance is not subject to classification according to the sources of literature known to us.

- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0 Fire = 0Reactivity = 0

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Safety Data Sheet acc. to ISO/DIS 11014

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· HMIS-ratings (scale 0 - 4)

HEALTH0Health = 0FIRE0Fire = 0REACTIVITY0Reactivity = 0

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

3 Composition/information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description

66402-68-4 ceramic materials

- · Identification number(s) ---
- EC number: 266-340-9
- · Description: Yttrium-stabilized zirconium oxide block

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.

If symptoms persist consult doctor.

- · 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 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents: The product is not flammable.
- · 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.
- · Methods and material for containment and cleaning up: Pick up mechanically.

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· 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.

- · 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: None.
- · 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: Not required.
- · 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.
- · Breathing equipment: Use respiratory protective device against the effects of dust.
- · **Protection of hands:** Not required.
- · Material of gloves -
- · Penetration time of glove material -
- · 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: OdorlessOdour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/Melting range: Undetermined.
Boiling point/Boiling range: Undetermined.

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· Flash point:	Not applicable.	
· Flammability (solid, gaseous):	Product is not flammable.	
· Auto igniting:	Not determined.	
· Danger of explosion:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not applicable.	
Density:	Not determined.	
· Relative density	Not determined.	
· Vapour 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.
- · 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:
- · Primary irritant effect:
- · on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information: The substance is not subject to classification.
- · Carcinogenic categories
- · NTP (National Toxicology Program)

Substance is not listed.

-USA

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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: Generally not hazardous for water
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- $\cdot \textit{Other adverse effects} \ \textit{No further relevant information available}.$

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.

· UN-Number	17 - 1	
· DOT, ADR, ADN, IMDG, IATA	Void	
· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	Void	
· Transport hazard class(es)		
· DOT, ADR, ADN, IMDG, IATA	V-: J	
· Class	Void	
· Packing group		
· DOT, ADR, IMDG, IATA	Void	
· Environmental hazards:		
· Marine pollutant:	No	
· Special precautions for user	Not applicable.	
· Transport in bulk according to Annex I	II of	
MARPOL73/78 and the IBC Code	Not applicable.	
· UN ''Model Regulation'':	-	

USA

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15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- Sara
- · Section 355 (extremely hazardous substances):

Substance is not listed.

· Section 313 (Specific toxic chemical listings):

Substance is not listed.

· TSCA (Toxic Substances Control Act):

Substance is not listed.

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

Substance is not listed.

· Chemicals known to cause reproductive toxicity for females:

Substance is not listed.

· Chemicals known to cause reproductive toxicity for males:

Substance is not listed.

· Chemicals known to cause developmental toxicity:

Substance is not listed.

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

Substance is not listed.

· TLV (Threshold Limit Value established by ACGIH)

Substance is not listed.

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

Substance is not listed.

· OSHA-Ca (Occupational Safety & Health Administration)

Substance is not listed.

· Product related hazard informations:

The substance is not subject to classification according to the sources of literature known to us.

- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the EC-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.

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.

· Abbreviations and acronyms:

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

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ICAO: International Civil Aviation Organization

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 CAS: Chemical Abstracts Service (division of the American Chemical Society)

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

USA