

Printing date 05/18/2015 Version number 5 Reviewed on 04/15/2015

1 Identification

- · Product identifier
- · Trade name: IPS e.max Ceram ZirLiner: Intensiv, Gingiva
- · 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.
- $\cdot \textbf{\textit{Application of the substance / the mixture}} \ \textit{Manufacture of dental prothesis}$
- · 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 substance 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)



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· HMIS-ratings (scale 0 - 4)



· Other hazards

Dust generation

Particular danger of slipping on leaked/spilled product.

- · 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

4 First-aid measures

- · Description of first aid measures
- · General information: No special measures required.
- · After inhalation:

Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Rinse with water.

Generally the product does not irritate the skin.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

Mechanical effects only.

· After swallowing:

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 Fire-fighting 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.

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6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Particular danger of slipping on leaked/spilled product.

- · Environmental precautions: No special measures required.
- · Methods and material for containment and cleaning up:

Pick up mechanically.

Ensure adequate ventilation.

· 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.

Prevent formation of dust.

Ensure good ventilation/exhaustion at the workplace.

- · 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:

Keep receptacle tightly sealed.

Store in dry conditions.

· 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.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Vacuum clean contaminated clothing. Do not blow or brush off contamination.

Do not inhale dust / smoke / mist.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

- · Recommended filter device for short term use: Filter P2
- · Protection of hands: Not required.
- · Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

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· 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: Safety glasses

9 Physical and chemical properties

· General Information

· Appearance:

Form: Powder

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.

· 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.

- $\cdot \textit{Partition coefficient (n-octanol/water):} \ \textit{Not determined}.$
- · 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.

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· 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: Mechanical effects only.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information: No further relevant information available.
- · Carcinogenic categories
- · NTP (National Toxicology Program)

Substance is not listed.

· OSHA-Ca (Occupational Safety & Health Administration)

Substance is not listed.

12 Ecological information

- Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- $\cdot \textit{Behavior in environmental systems:}$
- · 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.
- · 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, TDG, ADN, IMDG, IATA Void
- · UN proper shipping name
- · DOT, TDG, ADN, IMDG, IATA Void

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· Transport hazard class(es)	
· DOT, TDG, ADN, IMDG, IATA · Class	Void
· Packing group · DOT, TDG, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	f Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	-

15 Regulatory information

- $\cdot \textit{Safety, health and environmental regulations/legislation specific for the substance or \textit{mixture} \\$
- · 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 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.

- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void

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- · 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.

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 05/18/2015 / 4
- · Abbreviations and acronyms:

ICAO: International Civil Aviation Organisation

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)

* * Data compared to the previous version altered.

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