

SAFETY DATA SHEETS

This SDS packet was issued with item:

070963835

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070889311 070963785 070963793 070963801 070963819 070963827 070963843 070963850 071099571 071099589
071099779 071099787 071099878 071099944 071099985 071099993 071100064 071100072 071100080 071100098
071100189 071100197 071166180 071166222 071166230 071166271 071166305 071166313 071252352 071450345
071450352 071450360 071450378 071450394 071450402 071450410 510021879 510021886 510021893 510021900

1 Identification

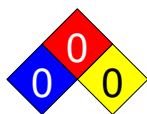
- **Product identifier**
- **Trade name:** **IPS e.max ZirCAD (Block/Disc)**
- **CAS Number:**
66402-68-4
- **EC number:**
266-340-9
- **Application of the substance / the mixture**
Manufacture of dental prothesis
Yttrium-stabilized zirconium oxide block for the CAD/CAM technology
Yttrium-stabilized zirconium oxide disc 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 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)**



Health = 0
Fire = 0
Reactivity = 0

(Contd. on page 2)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/20/2017

Version number 5

Reviewed on 03/17/2017

Trade name: **IPS e.max ZirCAD (Block/Disc)**

(Contd. of page 1)

· **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 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

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 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.

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.
- **Reference to other sections**
See Section 7 for information on safe handling.

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/20/2017

Version number 5

Reviewed on 03/17/2017

Trade name: **IPS e.max ZirCAD (Block/Disc)**

See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

(Contd. of page 2)

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 and dental laboratories.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
- **Breathing equipment:**
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 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).

US

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/20/2017

Version number 5

Reviewed on 03/17/2017

Trade name: **IPS e.max ZirCAD (Block/Disc)**

(Contd. of page 3)

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.
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.
Vapor 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.

· 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.

US

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/20/2017

Version number 5

Reviewed on 03/17/2017

Trade name: **IPS e.max ZirCAD (Block/Disc)**

(Contd. of page 4)

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **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.
- **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, 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

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/20/2017

Version number 5

Reviewed on 03/17/2017

Trade name: **IPS e.max ZirCAD (Block/Disc)**

(Contd. of page 5)

· Packing group	
· DOT, ADR, RID, ADN, 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	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):**

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.

· **GHS label elements** Void· **Hazard pictograms** Void· **Signal word** Void· **Hazard statements** Void

(Contd. on page 7)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/20/2017

Version number 5

Reviewed on 03/17/2017

Trade name: **IPS e.max ZirCAD (Block/Disc)**

(Contd. of page 6)

- **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** 03/20/2017 / 4
- **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)
 ICAO: International Civil Aviation Organisation
 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)
 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*
- *** Data compared to the previous version altered.**

US