

SAFETY DATA SHEETS

This SDS packet was issued with item:

077175813

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

071074384 071074608 071075670

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071074335 071074343 071074350 071074368 071074376 071074525 071075662 071075688 071075696 071075704
071075712 071075720 071075738 077143589 077143597 077143696 077143779 077143787 077143795 077143803
077143811 077143845 077143852 077143860 077143878 077143886 077143894 077144769 077144777 077144785
077144793 077144801 077144819 077144827 077144835 077174857 077174865 077174873 077174881 077175508
077175516 077175524 077175532 077175540 077175557 077175565 077175573 077175581 077175599 077175607
077175615 077175623 077175631 077175805 077175821 077175839 077175847 077175854 077175862 077175870
077175888 077175896 077175904 077175912 077175920 077175938 077175946 077175953

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 18.05.2015

Version number 4

Revision: 15.04.2015

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

- **1.1 Product identifier**
- Trade name: **IPS e.max ZirCAD**
- CAS Number:
66402-68-4
- EC number:
266-340-9
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture**
Manufacture of dental prothesis
Yttrium-stabilized zirconium oxide block for the CAD/CAM technology
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
-
- Tel: +423 235 35 35
Fax: +423 235 33 60
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The substance is not classified according to the CLP regulation.
-
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 Void**
- **Hazard pictograms Void**
- **Signal word Void**
- **Hazard statements Void**
- **2.3 Other hazards** Avoid breathing sanding dust /swarf.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.1 Chemical characterisation: Substances**
- CAS No. Description
66402-68-4 ceramic materials
- Identification number(s) ---
- EC number: 266-340-9
- **Description:** Yttrium-stabilized zirconium oxide block

GB

(Contd. on page 2)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 18.05.2015

Version number 4

Revision: 15.04.2015

Trade name: **IPS e.max ZirCAD**

(Contd. of page 1)

SECTION 4: First aid measures

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** The product is not flammable.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

-GB-

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 18.05.2015

Version number 4

Revision: 15.04.2015

Trade name: **IPS e.max ZirCAD**

(Contd. of page 2)

SECTION 8: Exposure controls/personal protection

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

SECTION 9: Physical and chemical properties

- **9.1 Information on basic 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/Melting range:** Undetermined.
- Boiling point/Boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Product is not flammable.
- **Self-igniting:** Not determined.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
- Lower:** Not determined.
- Upper:** Not determined.
- **Vapour 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/water):** Not determined.
- **Viscosity:**
- Dynamic:** Not applicable.

(Contd. on page 4)

-GB-

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 18.05.2015

Version number 4

Revision: 15.04.2015

Trade name: **IPS e.max ZirCAD**

(Contd. of page 3)

| | |
|--------------------------------|--|
| Kinematic: | Not applicable. |
| · 9.2 Other information | No further relevant information available. |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitisation:** No sensitising effects known.
- **Additional toxicological information:** No further relevant information available.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 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.

GB
(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 18.05.2015

Version number 4

Revision: 15.04.2015

Trade name: **IPS e.max ZirCAD**

(Contd. of page 4)

SECTION 14: Transport information

| | |
|---|--|
| · 14.1 UN-Number · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | Void |
| · 14.4 Packing group · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 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": | - |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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)
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
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
- *** Data compared to the previous version altered.**

GB

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)**



(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)

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 2)

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 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)

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 5)

| | |
|--|--|
| · Packing group | Void |
| · 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