

SAFETY DATA SHEET (GHS)

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER

1.1 Product identifier:-

Product name:

IPS e.max Ceram: Dentin, Deep Dentin, Incisal,
Transpa Incisal,
Transpa, Essence, Gingiva, Margin,
Intensive Margin, Add-On, Special Enamel, Light
Reflector, Light
Absorber, Power Dentin

Product number:

Void

1.2 Other means of identification:-

Not applicable.

1.3 Recommended use of the chemical and restrictions on use:-

Not applicable.

Identified uses:

Manufacture of dental prosthesis

1.4 Details of the manufacturer and importer:-

Manufacturer:

Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
Tel: +423 235 35 35
Fax: +423 235 33 60

Importer:

Ivoclar Vivadent Ltd
12 Omega St, Rosedale, Auckland, New Zealand
Phone +64 9 914 9999 Fax +64 9 914 9990
www.ivoclarvivadent.co.nz
0800 764 766 (National Poison Centre)
Poisons Hotline (24 hours / 7 days)

1.5 Emergency phone number:

2. HAZARD(S) IDENTIFICATION

2.1 GHS Classification:-

2.2 GHS Label elements, including precautionary statements:-

Hazard Pictogram:

Void

Signal word:

Void

Hazard-determining components of labelling:

Void

Hazard statements:

Void

Precautionary statements:

Void

2.3 Additional information:

Dust generation

Particular danger of slipping on leaked/spilled product.

Other hazards:-

Results of PBT and vPvB assessment;

PBT: Not applicable.

vPvB: Not applicable.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of substances listed below with nonhazardous additions.

| Ingredient name | CAS No. | Classification | Concentration |
|-------------------|------------|----------------|---------------|
| ceramic materials | 66402-68-4 | | |

For the full text of the H-Statements mentioned in this Section, refer to Section 16.

4. FIRST AID MEASURES

4.1 Description of necessary first aid measures:-

If inhaled:

Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.

In case of skin contact:

Rinse with water.

In case of eye contact:

Generally the product does not irritate the skin.
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

If swallowed:

Mechanical effects only.
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.

4.2 Symptoms caused by exposure:-

No further relevant information available.

4.3 Medical attention and special treatment:-

No further relevant information available.

5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing equipment:-

Suitable extinguishing media:

The product is not flammable.

Unsuitable extinguishing media:

No further relevant information available.

5.2 Specific hazards arising from the substance/mixture/product:-

No further relevant information available.

5.3 Special protective equipment and precautions for fire fighters:-

Special personal protective equipment:

No further relevant information available

Precautions:

No further relevant information available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:-

Particular danger of slipping on leaked/spilled product.

6.2 Environmental precautions:-

No special measures required.

6.3 Methods and materials for containment and cleaning up:-

Pick up mechanically.

Ensure adequate ventilation

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

7.1 Precautions for safe handling:-

Only adequately trained personnel should handle this product.

Prevent formation of dust.

Ensure good ventilation/exhaustion at the workplace.

7.2 Conditions for safe storage, including any incompatibilities:-

Store only in the original receptacle
Keep container tightly sealed.
Store in dry conditions.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure control measures:-

Occupational exposure limits:

| Component | CAS No. | Value | Parameters | Basis |
|-----------|---------|-------|------------|-------|
| Void | Void | Void | Void | Void |

Ingredients with biological limit values:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Biological monitoring:-

The lists valid during the making were used as basis.

Exposure controls / Personal protective equipment / General protective and hygienic measures:

Vacuum clean contaminated clothing. Do not blow or brush off contamination.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Usual hygienic measures for dental practice and dental laboratories.

8.3 Control banding:-

Use good industrial hygiene practice and general ventilation.

8.4 Engineering controls:-

In case of intensive contact, wear protective gloves (EN 374).
Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties).
Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves.
Protective gloves shall be replaced immediately when physically damaged or worn.

8.5 Individual protection measures include PPE:-

Eye/face protection:



Safety glasses

Not Required

Skin protection:

Not Required



Respiratory protection:

Not Required

Recommended filter device for short term use: Filter P2

9. PHYSICAL/CHEMICAL PROPERTIES

9.1 Information on physical/chemical properties:-

| | | |
|----|--|------------------------------------|
| a) | Appearance/Form: | Powder |
| b) | Colour: | According to product specification |
| c) | Odour: | Odourless |
| d) | Odour threshold: | Not determined. |
| e) | pH value: | Not applicable. |
| f) | Melting point/melting range: | Not determined. |
| g) | Boiling point/boiling range: | Not determined. |
| h) | Flash point: | Not determined. |
| i) | Ignition temperature: | Not determined. |
| j) | Self-igniting: | Product is not self-igniting. |
| k) | Danger of explosion: | Not determined. |
| l) | Upper/lower flammability or explosive limits: | Lower Not determined. |
| | | Upper Not determined. |
| m) | Vapour pressure 20°C: | Not determined. |
| n) | Density at 20°C: | Not determined. |
| o) | Relative density: | Not determined. |
| p) | Vapour density: | Not applicable. |
| q) | Evaporation rate: | Not applicable. |
| r) | Solubility in/miscibility with water: | Insoluble. |
| s) | Partition coefficient: n- octanol/water: | Not determined. |
| t) | Viscosity: | Dynamic Not applicable. |
| | | Kinematic Not applicable. |
| u) | Solids content: | Not applicable. |

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.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:-

Acute toxicity / Values relevant for classification:

No further relevant information available.

Skin corrosion/irritation:

No further relevant information available.

Serious eye damage/eye irritation:

No further relevant information available.

Respiratory or skin sensitization:

No further relevant information available.

Germ cell mutagenicity:

No further relevant information available.

Carcinogenicity:

No further relevant information available.

Reproductive toxicity:

No further relevant information available.

Specific target organ toxicity - single exposure:

No further relevant information available.

Specific target organ toxicity - repeated exposure:

No further relevant information available.

Aspiration hazard:

No further relevant information available.

Additional information:

No further relevant information available.

11.2 Information on possible routes of exposure:-

Short Term (Acute) Exposure:

Swallowed:

Eyes:

Skin:

Inhaled:

Long Term (Chronic) Exposure:

Swallowed:

Eyes:

Skin:

Inhaled:

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

11.3 Early onset symptoms related to exposure:-

11.4 Delayed health effects from exposure:-

11.5 Exposure levels and health effects:-

11.6 Interactive effects:-

11.7 Other:-

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity:-

No further relevant information available.

12.2 Persistence/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.

12.5 Other adverse effects:-

Generally not hazardous for water

Additional ecological information / General notes:-

Generally not hazardous for water.

12.6 Other adverse effects:-

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods:-

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

Disposal must be made according to official regulations.

14. TRANSPORT INFORMATION

UN number ADR / IMDG / IATA:-

Void.

UN proper shipping name or technical name:-

ADR:

Void.

IMDG, IATA:

Void.

Transport hazard class(es):

Void.

Label:

Void.

Packaging group:

Void.

| | |
|---|--|
| Environmental hazards: | Not applicable. |
| Special precautions for user: | Not applicable. |
| Danger code: | Void. |
| EMS Number: | Void. |
| 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). |

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture/product:-

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.

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.

16. OTHER INFORMATION

| | |
|--|------|
| Key to abbreviations/acronyms used in SDS:- | Void |
|--|------|

Key literature references/data sources used to compile SDS:-

Standard EN420:2003 General requirements for protective gloves: disposable gloves, e.g. nitrile rubber, material thickness 0.1 mm (Australian Standard 2161).

Long-term exposure (Level 6: < 480 min): protective gloves, e.g. nitrile rubber, material thickness 0.7 mm (Australian Standard 2161).

Personal eye protection - Eye and face protectors for occupational applications: safety glasses (Australian Standard AS 1336 and AS/NZS 1337.1:2010).

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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.

IATA: International Air Transport Association.

GHS: Globally Harmonised System of Classification and Labelling of Chemicals.

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).

LC50: Lethal concentration, 50 percent.

LD50: Lethal dose, 50 percent.

Flam. Liq. 2: Flammable liquids, Hazard Category 2.

Flam. Liq. 3: Flammable liquids, Hazard Category 3.

Acute Tox. 4: Acute toxicity, Hazard Category 4.

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2.

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2.

Repr. 2: Reproductive toxicity, Hazard Category 2.

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3.

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2.

IPS e.max Ceram: Dentin, Deep Dentin, Incisal, Transpa Incisal,
Transpa, Essence, Gingiva, Margin, Intensive Margin, Add-On, Special
Enamel, Light Reflector, Light Absorber, Power Dentin



Asp. Tox. 1: Aspiration hazard, Hazard Category 1.

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Users should rely on their own knowledge and inquiries and make their own determination as to the applicability of this information in relation to their particular purposes and specific circumstances. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace and in conjunction with other substances or products.

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