

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 Empress CAD IPS Empress CAD Multi

Product number: 266-340-9

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

Leucite-reinforced glass-ceramic blocks for the CAD/CAM

technique

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 Ivoclar Vivadent Pty Ltd

1- 5 Overseas Drive Noble Park North VIC 3174 Tel: + 61 3 9795 9599 Fax: + 61 3 9795 9645

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1.5 Emergency phone number: 13 11 26

Poisons Hotline (24 hours / 7 days)

2. HAZARD(S) IDENTIFICATION

2.1 GHS Classification:-

Importer:

Void

2.2 GHS Label elements, including precautionary statements:-

Hazard Pictogram: Void Void Hazard-determining components of Void

labelling:

Hazard statements: Void Void Void

Additional information:

2.3 V

Other hazards:-

Results of PBT and vPvB assessment;

PBT: Not applicable. vPvB: Not applicable.



COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of substances listed below with nonhazardous additions.

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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.

FIRST AID MEASURES

Description of necessary first aid measures:-4.

4.1

If inhaled: Grinding dust: Supply fresh air; consult doctor in case of

complaints.

In case of skin contact: Generally the product does not irritate the skin. In case of eye contact:

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

doctor.

Mechanical effects only.

Grinding dust: Rinse out mouth and then drink plenty of If swallowed:

If symptoms persist consult doctor.

Rinse out mouth and then drink plenty of water. Symptoms caused by exposure:-

If symptoms persist consult doctor.

4.2 Medical attention and special treatment:-No further relevant information available.

4.3

No further relevant information available.

FIRE FIGHTING MEASURES

5. Suitable extinguishing equipment:-

5.1 Suitable extinguishing media:

> Unsuitable extinguishing media: Specific hazards arising from the

substance/mixture/product:-

The product is not flammable.

No further relevant information available.

5.2

5.3 Special protective equipment and precautions for fire fighters:-

Special personal protective equipment: No further relevant information available No further relevant information available

Precautions:

6. **ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures:-6.1

Particular danger of slipping on leaked/spilled product.

Environmental precautions:-6.2

No special measures required.

6.3 Methods and materials for containment and cleaning up:-

Pick up mechanically.

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.

For use in dentistry only.

7.2 Conditions for safe storage, including any incompatibilities:-

Store only in the original receptacle

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:

Usual hygienic measures for dental practice.

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 Required



Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling). Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337.

Skin protection: Not Required



Respiratory protection:Use respiratory protective device against the effects of dust.

9. PHYSICAL/CHEMICAL PROPERTIES

9.1 Information on physical/chemical properties:-

a) Appearance/Form: Solid

b) Colour: According to product specification

c) Odour: Odourless

d) Odour threshold: Not determined.



pH value: Not applicable. e) Not determined. Melting point/melting range: f) Boiling point/boiling range: Not determined. g) Flash point: Not determined. h) Ignition temperature: i) Not determined.

Self-igniting: Product is not self-igniting.

Danger of explosion: Not determined.

Upper/lower flammability or explosive Lower Not determined. limits: Not determined. Upper

Vapour pressure 20°C: Not determined. m) Density at 20°C: Not determined. n) Relative density: o) Not determined. p)

Vapour density: Not applicable. **Evaporation rate:** Not applicable. q)

Solubility in/miscibility with water: Insoluble. r) Partition coefficient: n- octanol/water: Not determined. s)

t) Viscosity: Dvnamic Not applicable. Kinematic Not applicable.

Solids content: Not applicable. u)

STABILITY AND REACTIVITY 10.

10.1 Reactivity:-

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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.

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.

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 irritant effect. Serious eye damage/eye irritation: No irritant effect.

Respiratory or skin sensitization: No sensitizing effects known

Germ cell mutagenicity: No further relevant information available. No further relevant information available. Carcinogenicity: Reproductive toxicity: No further relevant information available. No further relevant information available.

No further relevant information available.

Specific target organ toxicity - single

exposure:

Specific target organ toxicity - repeated

exposure:

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: No further relevant information available.

Swallowed:No further relevant information available. **Eyes:**No further relevant information available.

Skin: No further relevant information available.

Inhaled:
Long Term (Chronic) Exposure:

No further relevant information available.
No further relevant information available.

Swallowed:

Eyes:

No further relevant information available.

No further relevant information available.

Skin:

No further relevant information available.

11.3 Early onset symptoms related to exposure:
No further relevant information available.

11.4 Delayed health effects from exposure:- No further relevant information available.

11.5 Exposure levels and health effects:- No further relevant information available.

11.6 Interactive effects:- No further relevant information available.

11.7 Other:- 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):
Label:
Void.
Packaging group:
Void.
Void.

Environmental hazards:Special precautions for user:
Not applicable.
Not applicable.

Danger code: Void.



EMS Number:

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

Transport/Additional information:

Void.

Not applicable.

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. Lig. 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.

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

^{*} Data compared to the previous version altered



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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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