

# **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 ZirPress

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

Fluorapatite glass-ceramic ingot for the PRESS-ON

technology

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 Ptv Ltd

Importer: Ivoclar Vivadent Pty Ltd

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

Email: info@ivoclarvivadent.com

1.5 Emergency phone number: 13 11 26

Poisons Hotline (24 hours / 7 days)

2. HAZARD(S) IDENTIFICATION

2.1 GHS Classification:-

Void

2.2 GHS Label elements, including precautionary statements:-

Hazard Pictogram: Void Void Hazard-determining components of Void

labelling:

Hazard statements: Void Precautionary statements: Void

2.3 Additional information:

Other hazards:- Avoid breathing sanding dust /swarf

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

Description: Fluorapatite glass-ceramic ingot



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: 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.

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

water. If symptoms persist consult doctor No further relevant information available No further relevant information available.

4.2 Symptoms caused by exposure:-4.3 Medical attention and special

treatment:-

5.2

## 5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing equipment:-

Suitable extinguishing media: Unsuitable extinguishing media:

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

The product is not flammable

No further relevant information available.

No further relevant information available.

5.3 Special protective equipment and precautions for fire fighters:-

**Special personal protective equipment:** 

Precautions:

No further relevant information available No further relevant information available

#### 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:-

No special measures required.

6.2 Environmental precautions:-

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

#### 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:-

Void

8.5 Individual protection measures include PPE:-

Eye/face protection:



Safety glasses

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:



Protection of hands:

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: Appearance/Form. According to product specification

c) Odour: Odourless

d) Odour threshold:
e) pH value:

Not determined.
Not applicable.

f) Melting point/melting range:
g) Boiling point/boiling range:
h) Flash point:

Not determined.
Not applicable.
Not determined.

i) Ignition temperature: Not determined.

j) **Self-igniting:** Product is not self-igniting.

k) Danger of explosion: Not determined.

Upper/lower flammability or explosive limits:

Lower Upper Not determined.
Not determined.

m) Vapour pressure 20°C: Not determined.



n) Density at 20°C:
o) Relative density:
p) Vapour density:
q) Evaporation rate:
r) Solubility in/miscibility with water:

Not applicable.
Not applicable.
Insoluble.

s) Partition coefficient: n- octanol/water: Not determined.
t) Viscosity: Not applicable.

Kinematic Not applicable.

u) Solids content: Not determined.

# 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:-

exposure:

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:

Skin corrosion/irritation:

Serious eye damage/eye irritation:

No irritant effect
No irritant effect

**Respiratory or skin sensitization:**No sensitizing effects known

Germ cell mutagenicity:

Carcinogenicity:

Reproductive toxicity:

No further relevant information available.

No further relevant information available.

No further relevant information available.

Specific target organ toxicity - single
exposure:

No further relevant information available.

**Specific target organ toxicity - repeated** No further relevant information available.

Aspiration hazard:

Additional information:

No further relevant information available.

No further relevant information available

# 11.2 Information on possible routes of exposure:-

Short Term (Acute) Exposure:

No further relevant information available.

No further relevant information available.

Eyes:
No further relevant information available.
Skin:
No further relevant information available.
No further relevant information available.

Inhaled:

Long Term (Chronic) Exposure:

No further relevant information available.

No further relevant information available.

Swallowed:

No further relevant information available.



Eyes:
Skin:
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:-

No further relevant information available.

## Additional ecological information / General notes:-

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system

12.6 Other adverse effects:-

Generally not hazardous for water

## 13. DISPOSAL CONSIDERATIONS

# 13.1 Disposal methods:-

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.

# 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:**Special precautions for user:
Not applicable.
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.

#### 16. OTHER INFORMATION

Key to abbreviations/acronyms used in SDS:-

Void

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

Void

## Copyright statement:-

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:-

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.

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

#### Disclaimer:-

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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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<sup>\*</sup> Data compared to the previous version altered