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

1.1 Product identifier

Trade name: **IPS Empress Cosmo**

- **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 prosthesis

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
- **EC number(s):** ---

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.
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.

· 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.

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: Not determined.
  - 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.
  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.

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.

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

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- 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 MARPOL 73/78 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

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.