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

Printing date 18.05.2015

Version number 5

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 CAD Crystall./Add-On Connect, Dentin, Incisal · 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 · 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 Dust generation Particular danger of slipping on leaked/spilled product. · 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

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SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information: No special measures required.
- · After inhalation:
- Supply fresh air; consult doctor in case of complaints.
- In case of unconsciousness place patient stably in side position for transportation.
- · After skin contact:
- Rinse with water.
- Generally the product does not irritate the skin.
- · After eye contact:
- *Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor. Mechanical effects only.*
- *After swallowing: 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 Particular danger of slipping on leaked/spilled product.
- 6.2 Environmental precautions: No special measures required.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically. Ensure adequate ventilation.
- **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. Prevent formation of dust. Ensure good ventilation/exhaustion at the workplace.
- 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.

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• Further information about storage conditions:

Keep container tightly sealed.

Store in dry conditions.

• 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.

- 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:
- \cdot General protective and hygienic measures:
- Usual hygienic measures for dental practice.

Wash hands before breaks and at the end of work.

- Keep away from foodstuffs, beverages and feed.
- Vacuum clean contaminated clothing. Do not blow or brush off contamination.

Do not inhale dust / smoke / mist.

• Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- Recommended filter device for short term use: Filter P2
- · Protection of hands: Not required.
- · Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· 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: Safety glasses

SECTION 9: Physical and chemical properties

| General Information | | |
|--------------------------------|------------------------------------|--|
| Appearance: Form: | Powder | |
| Form: Colour: | 1 0 // 0 // | |
| 0000 | 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. | |

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^{· 8.1} Control parameters

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|------------------------------------|---|--------------------|
| • 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. | |
| \cdot 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.

- 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: Mechanical effects only.
- 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.

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· **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.

· European waste catalogue

08 02 99 wastes not otherwise specified

· Uncleaned packaging:

· Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

| · 14.1 UN-Number | | |
|---|--|--|
| · 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.

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 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.