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Material Safety Data Sheet acc. to ISO 11014

Version number 3

Reviewed on 04/15/2015

Printing date 05/18/2015

1 Identification
· Product identifier
• Trade name: <u>IPS e.max Ceram Glaze Powder / FLUO</u>
• CAS Number: 66402-68-4
· EC number:
266-340-9 • 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
• Details of the supplier of the safety data sheet • Manufacturer/Supplier:
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228 USA
<i>Tel.</i> +1 800 533 6825
Fax +1 716 691 2285
Ivoclar Vivadent Inc. 1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada Phone: +1 905 670 8499
<i>Fax:</i> +1 905 670 3102
• Information department: Quality Assurance / Regulatory Affairs • Emergency telephone number:
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053 Emergency-Call Canada - Canutec: 1-613-996-6666
Emergency-Can Canada - Canadec. 1-015-990-0000
General SDS Assistance: US: 1-800-533-6825
Canada: 1-800-263-8182
2 Hazard(s) identification
· Classification of the substance or mixture
The substance is not classified according to the Globally Harmonized System (GHS).
• Label elements • GHS label elements Void
• Hazard pictograms Void
• Signal word Void • Hazard statements Void
· Classification system:
• NFPA ratings (scale 0 - 4)
$\begin{array}{c} 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ $
0 0 Reactivity = 0
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· HMIS-ratings (scale 0 - 4)

HEALTHImage: OFIREImage: OFIREFire = 0REACTIVITYReactivity = 0

· Other hazards

- Dust generation
- Particular danger of slipping on leaked/spilled product.
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description
- 66402-68-4 ceramic materials
- Identification number(s)
- EC number: 266-340-9

4 First-aid measures

- · 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.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- Suitable extinguishing agents: The product is not flammable.
- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: No special measures required.

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6 Accidental release measures

- *Personal precautions, protective equipment and emergency procedures Particular danger of slipping on leaked/spilled product.*
- · Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up: Pick up mechanically.
- *Ensure adequate ventilation.* • **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.

7 Handling and storage

· Handling:

- **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 protection against explosions and fires: No special measures required.
- · 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:
- *Keep receptacle tightly sealed. Store in dry conditions.*
- Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- Components with limit values that require monitoring at the workplace: Not required.
- Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- · Personal protective equipment:
- 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.
- Breathing equipment:
- In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- 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.

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· 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

Physical and chemical proper	rties
Information on basic physical and	chemical properties
General Information	chemical properties
· Appearance:	
Form:	Powder
Color:	According to product specification
· Odor:	Odorless
• 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.
Auto igniting:	Not determined.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor 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/wat	ter): Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Other information	No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant information available.

· 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.

 \cdot Conditions to avoid No further relevant information available.

· Incompatible materials: No further relevant information available.

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· Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- Primary irritant effect:
- on the skin: No irritant effect.
- \cdot on the eye: Mechanical effects only.
- Sensitization: No sensitizing effects known.
- Additional toxicological information: No further relevant information available.

· Carcinogenic categories

· NTP (National Toxicology Program)

Substance is not listed.

· OSHA-Ca (Occupational Safety & Health Administration)

Substance is not listed.

12 Ecological information

- · Toxicity
- Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- *Mobility in soil* No further relevant information available.
- · Additional ecological information:
- · General notes: Generally not hazardous for water
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- **vPvB:** Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

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

Void

Void

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

14 Transport information

- · UN-Number
- · DOT, TDG, ADN, IMDG, IATA
- · UN proper shipping name · DOT, TDG, ADN, IMDG, IATA

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· Transport hazard class(es)	
· DOT, TDG, ADN, IMDG, IATA	
· Class	Void
· Packing group · DOT, TDG, IMDG, IATA	Void
• Environmental hazards: • Marine pollutant:	No
· Special precautions for user	Not applicable.
• Transport in bulk according to Annex I MARPOL73/78 and the IBC Code	I of Not applicable.
• Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· Sara

· Section 355 (extremely hazardous substances):
Substance is not listed.
· Section 313 (Specific toxic chemical listings):
Substance is not listed.
· TSCA (Toxic Substances Control Act):
Substance is listed.
Proposition 65
· Chemicals known to cause cancer:
Substance is not listed.
· Chemicals known to cause reproductive toxicity for females:
Substance is not listed.
· Chemicals known to cause reproductive toxicity for males:
Substance is not listed.
· Chemicals known to cause developmental toxicity:
Substance is not listed.
· Carcinogenic categories
· EPA (Environmental Protection Agency)
Substance is not listed.
· TLV (Threshold Limit Value established by ACGIH)
Substance is not listed.
· NIOSH-Ca (National Institute for Occupational Safety and Health)
Substance is not listed.
· GHS label elements Void
· Hazard pictograms Void
• Signal word Void • Hazard statements Void
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· National regulations:

• Other regulations, limitations and prohibitive regulations The product is a medical device according to the Directive 93/42/EEC. This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

• Date of preparation / last revision 05/18/2015 / 2

• Abbreviations and acronyms:

ICAO: International Civil Aviation Organisation IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

 \cdot * Data compared to the previous version altered.