1 Identification

- Product identifier
  - Trade name: IPS e.max Ceram Glaze Paste / FLUO, Shades
- Relevant identified uses of the substance or mixture and uses advised against
  - No further relevant information available.
- Application of the substance / the mixture
  - Auxiliary for 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
      Tel. +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
      Fax: +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
    - General SDS Assistance:
      US: 1-800-533-6825
      Canada: 1-800-263-8182

2 Hazard(s) identification

- Classification of the substance or mixture
  - The product 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)
      Health = 0
      Fire = 0
      Reactivity = 0
  - HMIS-ratings (scale 0 - 4)
    - Health = 0
    - Fire = 0
    - Reactivity = 0

(Contd. on page 2)
Trade name: *IPS e.max Ceram Glaze Paste / FLUO, Shades*

- **Other hazards**
  - Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization:** Mixtures
  - **Description:** dental ceramic
  - **Dangerous components:**
    - 56-81-5 glycerol 10–<25%

### 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:**
    - CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - **Special hazards arising from the substance or mixture** No further relevant information available.
  - **Advice for firefighters**
  - **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
  - **Environmental precautions:** Do not allow to enter sewers/surface or ground water.
  - **Methods and material for containment and cleaning up:** Pick up mechanically.
  - **Reference to other sections**
    - See Section 7 for information on safe handling.
    - See Section 8 for information on personal protection equipment.
Trade name: IPS e.max Ceram Glaze Paste / FLUO, Shades

See Section 13 for disposal information.

7 Handling and storage

· Handling:
  · Precautions for safe handling
    Only adequately trained personnel should handle this product.
    For use in dentistry only.
  · 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:
    This product is hygroscopic.
    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:

    | Substance          | PEL Long-term value | TLV |
    |--------------------|--------------------|-----|
    | 56-81-5 glycerol   | 15* 5** mg/m³      |     |
    | mist               | *total dust **respirable fraction |
    |                    | TLV withdrawn-insufficient data human occup. exp. |

· 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.
  Keep away from foodstuffs, beverages and feed.
  Wash hands before breaks and at the end of work.

· 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.

· Protection of hands:
  The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
  After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves
  Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
  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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

(Contd. on page 4)
· **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

### 9 Physical and chemical properties

#### General Information

- **Appearance**: Pasty
- **Color**: According to product specification
- **Odor**: Characteristic
- **Odour threshold**: Not determined.
- **pH-value**: Not determined.

#### Change in condition

- **Melting point/Melting range**: Undetermined.
- **Boiling point/Boiling range**: Undetermined.

#### Flash point:

- **Undetermined.**
- **Not applicable.**

#### Auto igniting:

- **Product is not selfigniting.**

#### Danger of explosion:

- **Product does not present an explosion hazard.**

#### Explosion limits:

- **Lower**: Not determined.
- **Upper**: Not determined.

#### Vapor pressure:

- **Not determined.**

#### Density:

- **Not determined.**
- **Relative density**: Not determined.
- **Vapour density**: Not determined.
- **Evaporation rate**: Not determined.

#### Solubility in / Miscibility with

- **Water**: Partly soluble.

#### Partition coefficient (n-octanol/water): Not determined.

#### Viscosity:

- **Dynamic**: Not determined.
- **Kinematic**: Not determined.

#### 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.
- **Conditions to avoid**: No further relevant information available.
- **Incompatible materials**: No further relevant information available.
11 Toxicological information

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

- Carcinogenic categories
  - NTP (National Toxicology Program)
    None of the ingredients is listed.
  - OSHA-Ca (Occupational Safety & Health Administration)
    None of the ingredients is 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:
    Water hazard class 1 (Self-assessment): slightly hazardous for water
    Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
  - 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.

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

14 Transport information

- UN-Number
- DOT, ADR, ADN, IMDG, IATA: Void
Trade name: **IPS e.max Ceram Glaze Paste / FLUO, Shades**

| · UN proper shipping name | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | Void |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | No |
| · Marine pollutant: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · 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": | - |

### 15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Sara
    - **Section 355 (extremely hazardous substances):**
      None of the ingredients is listed.
    - **Section 313 (Specific toxic chemical listings):**
      None of the ingredients is listed.
    - **TSCA (Toxic Substances Control Act):**
      All ingredients are listed.
  - **Proposition 65**
    - **Chemicals known to cause cancer:**
      None of the ingredients is listed.
    - **Chemicals known to cause reproductive toxicity for females:**
      None of the ingredients is listed.
    - **Chemicals known to cause reproductive toxicity for males:**
      None of the ingredients is listed.
    - **Chemicals known to cause developmental toxicity:**
      None of the ingredients is listed.
  - **Carcinogenic categories**
    - **EPA (Environmental Protection Agency)**
      None of the ingredients is listed.
    - **TLV (Threshold Limit Value established by ACGIH)**
      None of the ingredients is listed.
    - **NIOSH-Ca (National Institute for Occupational Safety and Health)**
      None of the ingredients is listed.
Trade name: IPS e.max Ceram Glaze Paste / FLUO, Shades

- GHS label elements Void
- Hazard pictograms Void
- Signal word Void
- Hazard statements Void
- 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:
  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
  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
  ELINCS: European List of Notified Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  NFPA: National Fire Protection Association (USA)
  HMIS: Hazardous Materials Identification System (USA)

* Data compared to the previous version altered.