1 Identification

- **Product identifier**
- **Trade name:** IPS e.max Ceram: Dentin, Deep Dentin, Incisal, Transpa Incisal, Transpa, Essence, Gingiva, Margin, Intensive Margin, Add-On, Special Enamel, Light Reflector, Light Absorber, Power Dentin

- **CAS Number:** 66402-68-4
- **EC number:** 266-340-9
- **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
    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 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)**
    
    Health = 0
    Fire = 0
    Reactivity = 0

(Contd. on page 2)
Trade name: IPS e.max Ceram: Dentin, Deep Dentin, Incisal, Transpa Incisal, Transpa, Essence, Gingiva, Margin, Intensive Margin, Add-On, Special Enamel, Light Reflector, Light Absorber, Power Dentin

HMIS-ratings (scale 0 - 4)

<table>
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<tr>
<th>HEALTH</th>
<th>FIRE</th>
<th>REACTIVITY</th>
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<tbody>
<tr>
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<td>Fire</td>
<td>Reactivity</td>
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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.
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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
- General protective and hygienic measures:
  Vacuum clean contaminated clothing. Do not blow or brush off contamination.
  Keep away from foodstuffs, beverages and feed.
  Wash hands before breaks and at the end of work.
  Usual hygienic measures for dental practice and dental laboratories.
- Breathing equipment: Not required.
9 Physical and chemical properties

· Information on basic physical and chemical properties
  · General Information
  · Appearance:
    · Form: Powder
    · Color: According to product specification
  · Odor: Odorless
  · Odor 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.
  · Vapor density: Not applicable.
  · Evaporation rate: Not applicable.

· Solubility in / Miscibility with
  · Water: Insoluble.

· Partition coefficient (n-octanol/water): Not determined.
Trade name: IPS e.max Ceram: Dentin, Deep Dentin, Incisal, Transpa Incisal, Transpa, Essence, Gingiva, Margin, Intensive Margin, Add-On, Special Enamel, Light Reflector, Light Absorber, Power Dentin

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

11 Toxicological information

- Information on toxicological effects
  - Acute toxicity:
    - on the skin: No irritant effect.
    - 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.

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

14 Transport information

- UN-Number
  - DOT, ADR, RID, ADN, ADN, IMDG, IATA Void

- UN proper shipping name
  - DOT, ADR, RID, ADN, ADN, IMDG, IATA Void

- Transport hazard class(es)
  - DOT, ADR, RID, ADN, ADN, IMDG, IATA
  - Class Void

- Packing group
  - DOT, ADR, RID, ADN, ADN, IMDG, IATA Void

- Environmental hazards:
  - Marine pollutant: No

- Special precautions for user
  - Not applicable.

- 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": Void

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.
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· 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

· 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 09/20/2016 / 6

· 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
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - NFPA: National Fire Protection Association (USA)
  - HMIS: Hazardous Materials Identification System (USA)
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative

(Contd. of page 6)
Trade name: **IPS e.max Ceram: Dentin, Deep Dentin, Incisal, Transpa Incisal, Transpa, Essence, Gingiva, Margin, Intensive Margin, Add-On, Special Enamel, Light Reflector, Light Absorber, Power Dentin**

NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

* Data compared to the previous version altered.