1 Identification

- **Product identifier**
  
  **Trade name:** IPS e.max ZirPress

- **CAS Number:**
  66402-68-4

- **EC number:**
  266-340-9

- **Application of the substance / the mixture**
  Manufacture of dental prosthesis  
  Fluorapatite glass-ceramic ingot for the PRESS-ON technology

- **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 ZirPress

- HMIS-ratings (scale 0 - 4)
  - Health = 0
  - Fire = 0
  - Reactivity = 0

- Other hazards: Avoid breathing sanding dust /swarf.
- 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
- Description: Fluorapatite glass-ceramic ingot

4 First-aid measures

- Description of first aid measures
  - General information: No special measures required.
  - After inhalation: Grinding dust: Supply fresh air; consult doctor in case of complaints.
  - After skin contact: Generally the product does not irritate the skin.
  - After eye contact:
    - Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
    - Mechanical effects only.
  - After swallowing:
    - Grinding dust: 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.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures: Not required.
- Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up: Pick up mechanically.
Trade name: **IPS e.max ZirPress**

- **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.

- **Protective Action Criteria for Chemicals**
  - **PAC-1:**
    Substance is not listed.
  - **PAC-2:**
    Substance is not listed.
  - **PAC-3:**
    Substance is not listed.

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**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:** None.
    - **Specific end use(s)** No further relevant information available.

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**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 and dental laboratories.
  - **Breathing equipment:** Use respiratory protective device against the effects of dust.
  - **Protection of hands:** Not required.
  - **Material of gloves** -
  - **Penetration time of glove material** -
  - **Eye protection:**
    Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

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**9 Physical and chemical properties**

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
  - **Form:** Solid

(Contd. on page 4)
Trade name: IPS e.max ZirPress

According to product specification
Odorless
Not determined.

Not applicable.
Undetermined.
Undetermined.
Not applicable.
Product is not flammable.
Not determined.
Product does not present an explosion hazard.
Not determined.
Not determined.
Not applicable.
Insoluble.
Not determined.
Not applicable.
Not applicable.
No further relevant information available.

Reactivity
No further relevant information available.

Stable under normal handling and storage conditions.
No decomposition if used according to specifications. 
No dangerous reactions known.
No further relevant information available.
None under normal conditions of storage and use.

Acute toxicity:
No irritant effect.
No irritating effect.
No sensitizing effects known.
No further relevant information available.
Trade name: IPS e.max ZirPress

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: 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 Void
- Packing group
  - DOT, ADR/RID/ADN, IMDG, IATA Void
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user
  - 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": 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):
ACTIVE

Hazardous Air Pollutants
Substance is not 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

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**: 09/30/2019 / 4
- **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
  - 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.