## 1 Identification

- **Product identifier**
  - **Trade name:** **IPS Empress Direct**

- **Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.

- **Application of the substance / the mixture**
  - Light-curing resin-based dental restorative material

- **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**
  - **Skin Irrit. 2** **H315** Causes skin irritation.
  - **Eye Irrit. 2A** **H319** Causes serious eye irritation.
  - **Skin Sens. 1** **H317** May cause an allergic skin reaction.

- **Label elements**

- **GHS label elements**
  - The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**
  - **GHS07**

- **Signal word** Warning

- **Hazard-determining components of labeling:**
  - urethane dimethacrylate
  - Bis-GMA

(Contd. on page 2)
Material Safety Data Sheet
acc. to ISO 11014

Printing date 04/20/2015  Reviewed on 04/01/2015

Trade name: IPS Empress Direct

- **Hazard statements**
  - Causes skin irritation.
  - Causes serious eye irritation.
  - May cause an allergic skin reaction.

- **Precautionary statements**
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - Wash contaminated clothing before reuse.
  - If skin irritation or rash occurs: Get medical advice/attention.
  - If eye irritation persists: Get medical advice/attention.

- **Additional information:**
  - Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

- **Hazard description:**

- **WHMIS-symbols:**
  - D2B - Toxic material causing other toxic effects

- **Classification system:**
  - **NFPA ratings (scale 0 - 4)**
    - Health = 1
    - Fire = 0
    - Reactivity = 0

  - **HMIS-ratings (scale 0 - 4)**
    - Health = 1
    - Fire = 0
    - Reactivity = 0

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

- **3 Composition/information on ingredients**
  - **Chemical characterization:** Mixtures
  - **Description:** Mixture of the substances listed below with nonhazardous additions.

  **Dangerous components:**
  - 72869-86-4 urethane dimethacrylate 10-13%
  - 13760-80-0 ytterbium trifluoride 5-<10%
  - 43048-08-4 tricyclodocane dimethanol dimethacrylate 3-5%
  - 1565-94-2 Bis-GMA 1-<3%

- **4 First-aid measures**
  - **Description of first aid measures**
    - **After inhalation:**
      - Supply fresh air and to be sure call for a doctor.
      - In case of unconsciousness place patient stably in side position for transportation.

  (Contd. on page 3)
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.
  - 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.

- Further information about storage conditions:
  - Protect from exposure to the light.
  - Protect from heat and direct sunlight.
  - Keep receptacle tightly sealed.

- 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.
**Trade name: IPS Empress Direct**

- **Control parameters**
  - **Components with limit values that require monitoring at the workplace:**
    The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
  - **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.
      Avoid contact with the eyes and skin.
      Keep away from foodstuffs, beverages and feed.
    - **Breathing equipment:** Not required.
    - **Protection of hands:**
      Protect the glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
  - **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. 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.
  - **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

- **Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:**
    - **Form:** 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:** Not applicable.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.
## 10 Stability and reactivity

- **Reactivity**: No further relevant information available.
- **Chemical stability**: Stable under normal handling and storage conditions. Photoreactive (Danger of polymerization).
- **Thermal decomposition / conditions to be avoided**: No decomposition if used according to specifications.
- **Possibility of hazardous reactions**: No dangerous reactions known.
- **Conditions to avoid**: Protect from exposure to the light. Keep away from heat and direct sunlight.
- **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:
  - Primary irritant effect:
    - on the skin: No irritant effect.
    - on the eye: Irritating effect.
  - Sensitization: Sensitization possible through skin contact.
  - 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 3 (Self-assessment): extremely 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, TDG, ADN, IMDG, IATA Void
- UN proper shipping name
  - DOT, ADN, IMDG, IATA Void
  - TDG Void
- Transport hazard class(es)
  - DOT, TDG, ADN, IMDG, IATA Void
  - 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 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).
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)
      13760-80-0 ytterbium trifluoride A4
    - NIOSH-Ca (National Institute for Occupational Safety and Health)
      None of the ingredients is listed.
  - GHS label elements
    The product is classified and labeled according to the Globally Harmonized System (GHS).
  - Hazard pictograms
    GHS07
  - Signal word Warning
  - Hazard-determining components of labeling:
    urethane dimethacrylate
    Bis-GMA
  - Hazard statements
    Causes skin irritation.
    Causes serious eye irritation.
    May cause an allergic skin reaction.
**Trade name: IPS Empress Direct**

- **Precautionary statements**
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - Wash contaminated clothing before reuse.
  - If skin irritation or rash occurs: Get medical advice/attention.
  - If eye irritation persists: Get medical advice/attention.

- **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.

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**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** 04/20/2015 / 2

- **Abbreviations and acronyms:**
  - 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)
  - WHMIS: Workplace Hazardous Materials Information System (Canada)
  - Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
  - Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
  - Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

* Data compared to the previous version altered.