1 Identification

- **Product identifier**
- **Trade name:** Cervitec Plus

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

- **Application of the substance / the mixture** Protective varnish

- **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**
  - Flam. Liq. 2 H225 Highly flammable liquid and vapor.
  - Skin Irrit. 2 H315 Causes skin irritation.
  - Eye Irrit. 2A H319 Causes serious eye irritation.
  - Carc. 1A H350 May cause cancer.

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

- **Hazard pictograms**
  - GHS02
  - GHS07
  - GHS08

- **Signal word** Danger

- **Hazard-determining components of labeling:**
  - ethanol

(Contd. on page 2)
Trade name: Cervitec Plus

Hazard statements
- Highly flammable liquid and vapor.
- Causes skin irritation.
- Causes serious eye irritation.
- May cause cancer.

Precautionary statements
- Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
- Avoid breathing dust/fume/gas/mist/vapors/spray
- Wear protective gloves/protective clothing/eye protection/face protection.
- Keep container tightly closed.
- 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).

Classification system:
- NFPA ratings (scale 0 - 4)
  - Health = 1
  - Fire = 2
  - Reactivity = 0

- HMIS-ratings (scale 0 - 4)
  - Health = 1
  - Fire = 2
  - 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:
  - 64-17-5 ethanol 50-100%
  - 89-83-8 thymol 1-<2.5%
  - 56-95-1 chlorhexidine diacetate 1-<2.5%

4 First-aid measures
- Description of first aid measures
  - After inhalation: Supply fresh air; consult doctor in case of complaints.
  - After skin contact: Immediately wash with water and soap and rinse thoroughly.
  - After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
  - After swallowing: If symptoms persist consult doctor.
- Information for doctor:
  - Most important symptoms and effects, both acute and delayed: 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.
  - For safety reasons unsuitable extinguishing agents: Water with full jet
  - Special hazards arising from the substance or mixture: No further relevant information available.
- **Advice for firefighters**
  - Protective equipment: No special measures required.
  - Additional information: Cool endangered receptacles with water spray.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
  - Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
  - Do not allow to enter sewers/surface or ground water.
- **Methods and material for containment and cleaning up:**
  - Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  - 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.
  - Information about protection against explosions and fires:
    - Keep ignition sources away - Do not smoke.
    - Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
  - Requirements to be met by storerooms and receptacles: Store in a cool location.
  - Information about storage in one common storage facility: Not required.
- **Further information about storage conditions:**
  - Keep receptacle tightly sealed.
  - Store in cool, dry conditions in well sealed receptacles.
  - 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:
    - 64-17-5 ethanol
      - PEL: Long-term value: 1900 mg/m³, 1000 ppm

(Contd. on page 4)
40.1.5

**REL Long-term value:** 1900 mg/m³, 1000 ppm

**TLV Short-term value:** 1880 mg/m³, 1000 ppm

- **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.
  - **Breathing equipment:**
    - Not required.
    - 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:**
    - **Protective gloves**
      - 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**

<table>
<thead>
<tr>
<th><strong>General Information</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance:</strong></td>
</tr>
<tr>
<td><strong>Form:</strong> Fluid</td>
</tr>
<tr>
<td><strong>Color:</strong> Colorless</td>
</tr>
<tr>
<td><strong>Odor:</strong> Like alcohol</td>
</tr>
<tr>
<td><strong>Odor threshold:</strong> Not determined.</td>
</tr>
<tr>
<td><strong>pH-value:</strong> Not applicable.</td>
</tr>
</tbody>
</table>

**Change in condition**

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

| **Flash point:** 12 °C (54 °F) |
| **Ignition temperature:** 425 °C (797 °F) |

(Contd. on page 5)
Trade name: Cervitec Plus

- Auto igniting: Product is not self-igniting.

- Danger of explosion: Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

- Explosion limits:
  - Lower: 3.5 Vol %
  - Upper: 15.0 Vol %

- Vapor pressure at 20 °C (68 °F): 59 hPa (44 mm Hg)

- Density at 20 °C (68 °F): 0.84 g/cm³ (7.01 lbs/gal)
- Relative density: Not determined.
- Vapour density: Not determined.
- Evaporation rate: Not determined.

- Solubility in / Miscibility with Water: Partly miscible.

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

- Viscosity:
  - Dynamic: Not determined.
  - Kinematic: Not determined.

- Solvent content: VOC content: 79.6 %
- 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.
- 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: No irritating effect.
    - Sensitization: No sensitizing effects known.
    - Additional toxicological information:
- Carcinogenic categories
  - IARC (International Agency for Research on Cancer)
    - 64-17-5 ethanol
  - NTP (National Toxicology Program)
    - 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:
    Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - DOT UN1170
  - ADR, IMDG, IATA 1170
- UN proper shipping name
  - ADR 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
  - IMDG ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
  - IATA ETHANOL SOLUTION
- Transport hazard class(es)
  - DOT
    - Class 3 Flammable liquids
Trade name: Cervitec Plus

- **Label**
  - 3

- **ADR**
  - Class 3 (F1) Flammable liquids
  - Label 3

- **IMDG, IATA**
  - Class 3 Flammable liquids
  - Label 3
  - Packing group II
  - DOT, ADR, IMDG, IATA
  - Environmental hazards:
  - Marine pollutant: No
  - Special precautions for user: Warning: Flammable liquids
  - Danger code (Kemler): 33
  - EMS Number: F-E,S-E
  - Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.
  - UN "Model Regulation": UN1170, Ethanol solutions (Ethyl alcohol solutions), 3, II

### 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):**
    - 64-17-5 ethanol
    - 7732-18-5 water, distilled, conductivity or of similar purity
    - 89-83-8 thymol
  - **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.

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Chemicals known to cause reproductive toxicity for males:
None of the ingredients is listed.

Chemicals known to cause developmental toxicity:
- 64-17-5 ethanol

Carcinogenic categories
- EPA (Environmental Protection Agency)
  None of the ingredients is listed.
- TLV (Threshold Limit Value established by ACGIH)
  - 64-17-5 ethanol - A3
- 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).

Signal word: Danger

Hazard-determining components of labeling:
- ethanol

Hazard statements
- Highly flammable liquid and vapor.
- Causes skin irritation.
- Causes serious eye irritation.
- May cause cancer.

Precautionary statements
- Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
- Avoid breathing dust/fume/gas/mist/vapors/spray
- Wear protective gloves/protective clothing/eye protection/face protection.
- Keep container tightly closed.
- 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.

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 05/19/2015 / 7

Abbreviations and acronyms:
- 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
Trade name: Cervitec Plus

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)
VOC: Volatile Organic Compounds (USA, EU)
Flam. Liq. 2: Flammable liquids, Hazard Category 2
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
Carc. 1A: Carcinogenicity, Hazard Category 1A

* Data compared to the previous version altered.