

SAFETY DATA SHEETS

This SDS packet was issued with item:

077082738

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071026061 077082712 077082720 078911905

Safety Data Sheet
according to HPR, Schedule 1

Printing date 04/24/2018

Version number 8.1

Reviewed on 04/24/2018

1 Identification


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


- **Classification of the substance or mixture**
Flammable Liquids - Category 2 H225 Highly flammable liquid and vapour.
Skin Irritation - Category 2 H315 Causes skin irritation.
Eye Irritation - Category 2A H319 Causes serious eye irritation.
Carcinogenicity - Category 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
 - **Hazard statements**
Highly flammable liquid and vapour.
Causes skin irritation.

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Causes serious eye irritation.

May cause cancer.

· **Precautionary statements**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Keep container tightly closed.

Ground and bond container and receiving equipment.

Use explosion-proof [electrical/ventilating/lighting] equipment.

Use non-sparking tools.

Take actions to prevent static discharges.

Wash thoroughly after handling.

Wear protective gloves/protective clothing/eye protection/face protection.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

IF exposed or concerned: Get medical advice/attention.

Specific treatment (see on this label).

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

In case of fire: Use for extinction: CO₂, powder or water spray.

Store in a well-ventilated place. Keep cool.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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 Health = 1

FIRE 2 Fire = 2

REACTIVITY 0 Reactivity = 0

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

| | | |
|--------------|-------------------------|-------------|
| CAS: 64-17-5 | ethanol | 60-100% w/w |
| CAS: 89-83-8 | thymol | ≤1% w/w |
| CAS: 56-95-1 | chlorhexidine diacetate | ≤1% w/w |

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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.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting 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.

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· **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:****CAS: 64-17-5 ethanol**

EL Short-term value: 1000 ppm

EV Long-term value: 1.900 mg/m³, 1.000 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 and dental laboratories.

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**· **General Information**· **Appearance:**

Form: Fluid

Color: Colorless

· **Odor:** Like alcohol· **Odor threshold:** Not determined.

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| | |
|---|---|
| · pH-value: | <i>Not applicable.</i> |
| · Change in condition | |
| Melting point/Melting range: | <i>Undetermined.</i> |
| Boiling point/Boiling range: | <i>Undetermined.</i> |
| · Flash point: | <i>12 °C</i> |
| · Ignition temperature: | <i>425 °C</i> |
| · Auto igniting: | <i>Product is not selfigniting.</i> |
| · Danger of explosion: | <i>Product is not explosive. However, formation of explosive air/vapor mixtures are possible.</i> |
| · Explosion limits: | |
| Lower: | <i>3.5 Vol %</i> |
| Upper: | <i>15.0 Vol %</i> |
| · Vapor pressure at 20 °C: | <i>59 hPa</i> |
| · Density at 20 °C: | <i>0.84 g/cm³</i> |
| · Relative density | <i>Not determined.</i> |
| · Vapor density | <i>Not determined.</i> |
| · Evaporation rate | <i>Not determined.</i> |
| · Solubility in / Miscibility with Water: | <i>Partly miscible.</i> |
| · Partition coefficient (n-octanol/water): | <i>Not determined.</i> |
| · Viscosity: | |
| Dynamic: | <i>Not determined.</i> |
| Kinematic: | <i>Not determined.</i> |
| · Other information | <i>No further relevant information available.</i> |

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:** *No irritating effect.*
- **Sensitization:** *No sensitizing effects known.*

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· **Additional toxicological information:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

| | |
|----------------------|---|
| CAS: 64-17-5 ethanol | I |
|----------------------|---|

· **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

· **TDG, IMDG, IATA**

1170

· **UN proper shipping name**

· **DOT, IATA**

ETHANOL SOLUTION

· **TDG**

1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

· **IMDG**

ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

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· **Transport hazard class(es)**· **DOT**· **Class** 3 Flammable liquids· **Label** 3· **TDG (Transport dangerous goods):**· **Class** 3 (F1) Flammable liquids· **Label** 3· **IMDG, IATA**· **Class** 3 Flammable liquids· **Label** 3· **Packing group**· **DOT, TDG, IMDG, IATA** II· **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 MARPOL73/78 and the IBC Code** Not applicable.· **UN "Model Regulation":** UN1170, ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 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):**

CAS: 64-17-5 ethanol

CAS: 7732-18-5 water, distilled, conductivity or of similar purity

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Trade name: Cervitec Plus

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CAS: 89-83-8 thymol

· **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

· **Hazard statements**

Highly flammable liquid and vapour.

Causes skin irritation.

Causes serious eye irritation.

May cause cancer.

· **Precautionary statements**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Keep container tightly closed.

Ground and bond container and receiving equipment.

Use explosion-proof [electrical/ventilating/lighting] equipment.

Use non-sparking tools.

Take actions to prevent static discharges.

Wash thoroughly after handling.

Wear protective gloves/protective clothing/eye protection/face protection.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

IF exposed or concerned: Get medical advice/attention.

Specific treatment (see on this label).

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

In case of fire: Use for extinction: CO₂, powder or water spray.

Store in a well-ventilated place. Keep cool.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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** 04/24/2018 / 8

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· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· *** Data compared to the previous version altered.**

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