

Printing date 07.01.2021 Version number 8 Revision: 07.01.2021

Hazardous according to criteria of Australian Safety and Compensation Council.

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 AG Bendererstrasse 2 9494 Schaan

PRINCIPALITY OF LIECHTENSTEIN
Tel: +423 235 35 35 / Fax: +423 235 33 60

Importer:

Ivoclar Vivadent Pty. Ltd. 1- 5 Overseas Drive Noble Park North VIC 3174

Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

Further information obtainable from:

Regulatory Affairs sds@ivoclarvivadent.com

Emergency telephone number: 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

· Classification of the substance or mixture

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

- · Label elements
- · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms





GHS02

GHS07

- · Signal word Danger
- · Hazard statements

Highly flammable liquid and vapour.

Causes skin irritation.

Causes serious eye irritation.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Keep container tightly closed.

Avoid breathing dust/fume/gas/mist/vapours/spray.

(Contd. on page 2)

Printing date 07.01.2021 Version number 8 Revision: 07.01.2021

Trade name: Cervitec Plus

(Contd. of page 1)

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

If skin irritation or rash occurs: Get medical advice/attention.

If eve irritation persists: Get medical advice/attention.

· Additional information:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

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

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.

	Dangerous components:			
	CAS: 64-17-5	ethanol	Flam. Liq. 2, H225	50-100%
	CAS: 56-95-1	chlorhexidine diacetate	Eye Dam. 1, H318	<2.5%
Γ	CAS: 89-83-8	thymol	Skin Corr. 1B, H314; Acute Tox. 4, H302	<2.5%

[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

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 Fire Fighting Measures

- Extinguishing media
- · Suitable extinguishing agents:

CO2, 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.

(Contd. on page 3)

Printing date 07.01.2021 Version number 8 Revision: 07.01.2021

Trade name: Cervitec Plus

(Contd. of page 2)

· 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 fire and explosion protection:

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 container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

· Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · Control parameters

Ingredients with limit values that require monitoring at the workplace:

CAS: 64-17-5 ethanol

WES Long-term value: 1880 mg/m³, 1000 ppm

- · Additional information: The lists valid during the making 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.

Respiratory protection:

Not required.

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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.

(Contd. on page 4)

Printing date 07.01.2021 Version number 8 Revision: 07.01.2021

Trade name: Cervitec Plus

(Contd. of page 3)

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

Information on basic physical and chemical properties			
General Information Appearance:			
Form:	Fluid		
Colour:	Colourless		
Odour:	Like alcohol		
Odour threshold:	Not determined.		
pH-value:	Not applicable.		
Change in condition			
Melting point/freezing point:	Undetermined.		
Initial boiling point and boiling range:	Undetermined.		
Flash point:	12 ℃		
Ignition temperature:	425 °C		
Auto-ignition temperature:	Product is not selfigniting.		
Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.		
Explosion limits:			
Lower:	3.5 Vol %		
Upper:	15.0 Vol %		
Vapour pressure at 20 °C:	59 hPa		
Density at 20 °C:	0.84g/cm^3		
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.		
Other information	No further relevant information available.		

Printing date 07.01.2021 Version number 8 Revision: 07.01.2021

Trade name: Cervitec Plus

(Contd. of page 4)

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
- Skin corrosion/irritation No irritant effect.
- · Serious eye damage/irritation No irritating effect.
- · Respiratory or skin sensitisation No sensitising effects known.

12 Ecological Information

- · Toxicity
- Aquatic toxicity: No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- Behaviour 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 (German Regulation) (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 together with household garbage. Do not allow product to reach sewage system.

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

14 Transport information

- · UN-Number
- · ADG, IMDG, IATA

1170

(Contd. on page 6)

Printing date 07.01.2021 Version number 8 Revision: 07.01.2021

Trade name: Cervitec Plus

	(Contd. of page
· UN proper shipping name · ADG	1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
· IMDG	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
· IATA	ETHANOL SOLUTION
· Transport hazard class(es)	
· ADG	
· Class · Label	3 (F1) Flammable liquids.
· IMDG, IATA	3 Flammable liquids.
· Label	3
· Packing group · ADG, IMDG, IATA	II
· Environmental hazards: · Marine pollutant:	No
Special precautions for user Hazard identification number (Kemler code):	Warning: Flammable liquids. 33
· Hazchem or Emergency Action Code: · EMS Number:	•2YE F-E,S-E
Transport in bulk according to Annex II of Mar and the IBC Code	<u> </u>
· Transport/Additional information:	
· ADG	
Limited quantities (LQ)	LQ4
Transport category	2
Tunnel restriction code	D/E
· UN "Model Regulation":	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Industrial Chemicals

All ingredients are listed.

Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

(Contd. on page 7)

Printing date 07.01.2021 Version number 8 Revision: 07.01.2021

Trade name: Cervitec Plus

(Contd. of page 6)

Australia: Priority Existing Chemicals

None of the ingredients is listed.

GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms





GHS02

GHS07

· Signal word Danger

· Hazard statements

Highly flammable liquid and vapour.

Causes skin irritation.

Causes serious eye irritation.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Keep container tightly closed.

Avoid breathing dust/fume/gas/mist/vapours/spray.

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

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category P5c FLAMMABLE LIQUIDS
- Qualifying quantity (tonnes) for the application of lower-tier requirements 5000 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 50000 t
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

· 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.

Relevant phrases

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

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

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 4: Acute toxicity - oral - Category 4

Skin Corr. 1B: Skin corrosion/irritation - Category 1B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

(Contd. on page 8)

Printing date 07.01.2021 Version number 8 Revision: 07.01.2021

Trade name: Cervitec Plus

Eye Dam. 1: Serious eye damage/eye irritation – Category 1 Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A (Contd. of page 7)

ATT