

Printing date 19.05.2015 Version number 8 Revision: 29.04.2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- · 1.1 Product identifier
- · Trade name: Cervitec Plus
- · 1.2 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
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent AG Bendererstrasse 2

FL-9494 Schaan

PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35 *Fax:* +423 235 33 60

· Further information obtainable from:

Regulatory Affairs

sds@ivoclarvivadent.com

• 1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

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

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms





GHS02

GHS07

- · Signal word Danger
- · Hazard statements

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P233 Keep container tightly closed.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye 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 Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

(Contd. on page 2)

Printing date 19.05.2015 Version number 8 Revision: 29.04.2015

Trade name: Cervitec Plus

(Contd. of page 1)

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

SECTION 3: Composition/information on ingredients

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

· Dangerous components:				
CAS: 64-17-5		50-100%		
EINECS: 200-578-6	Flam. Liq. 2, H225			
	thymol	1-<2.5%		
EINECS: 201-944-8	Skin Corr. 1B, H314; Aquatic Chronic 2, H411; Acute Tox. 4, H302			
	chlorhexidine diacetate	1-<2.5%		
EINECS: 200-302-4	Eye Dam. 1, H318; Aquatic Chronic 2, H411			

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

SECTION 4: First aid measures

- · 4.1 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.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 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
- · 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.
- · Additional information Cool endangered receptacles with water spray.

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures
- Wear protective equipment. Keep unprotected persons away.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

(Contd. on page 3)

Printing date 19.05.2015 Version number 8 Revision: 29.04.2015

Trade name: Cervitec Plus

(Contd. of page 2)

See Section 13 for disposal information.

SECTION 7: Handling and storage

- 7.1 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.

- · 7.2 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.

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

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

64-17-5 ethanol

WEL Long-term value: 1920 mg/m³, 1000 ppm

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 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.

· 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.

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.

(Contd. on page 4)

Printing date 19.05.2015 Version number 8 Revision: 29.04.2015

Trade name: Cervitec Plus

(Contd. of page 3)

· 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

SECTION 9: Physical and chemical properties	1

· 9.1	Information	ı on basid	: physical	l and c	hemical	properties

· General Information

· Appearance:

Form: Fluid Colour: Colourless · Odour: Like alcohol · Odour threshold: Not determined. · pH-value:

· Change in condition

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

12 °*C* · Flash point:

425 °C · Ignition temperature:

· Self-igniting: Product is not selfigniting.

· Danger of explosion: Product is not explosive. However, formation of explosive air/

3.5 Vol %

15.0 Vol %

Not applicable.

vapour mixtures are possible.

· Explosion limits: Lower:

Upper: 59 hPa · Vapour pressure at 20 °C: · Density at 20 °C: 0.84 g/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.

· 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability Stable under normal handling and storage conditions.
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.

(Contd. on page 5)

Printing date 19.05.2015 Version number 8 Revision: 29.04.2015

Trade name: Cervitec Plus

(Contd. of page 4)

· 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity:
- · Primary irritant effect:
- on the skin: No irritant effect.on the eye: No irritating effect.
- · Sensitisation: No sensitising effects known.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 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.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

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

SECTION 14: Transport information			
· 14.1 UN-Number · ADR, IMDG, IATA	1170		
· 14.2 UN proper shipping name			
$\cdot ADR$	1170 ETHANOL SOLUTION (ETHYL ALCOHOL		
	SOLUTION)		
· IMDG	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION		
· IATA	ETHANOL SOLUTION		

Printing date 19.05.2015 Version number 8 Revision: 29.04.2015

Trade name: Cervitec Plus

(Contd. of page 5) · 14.3 Transport hazard class(es) $\cdot ADR$ 3 (F1) Flammable liquids. · Class · Label · IMDG, IATA · Class 3 Flammable liquids. · Label · 14.4 Packing group · ADR, IMDG, IATA II · 14.5 Environmental hazards: · Marine pollutant: No · 14.6 Special precautions for user Warning: Flammable liquids. · Danger code (Kemler): · EMS Number: F-E,S-E· 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable. · Transport/Additional information: · Limited quantities (LQ) LQ4 · Transport category 2 · Tunnel restriction code D/E· UN "Model Regulation": UN1170, ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · National regulations:
- · Other regulations, limitations and prohibitive regulations
 The product is a medical device according to the Directive 93/42/EEC.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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.

(Contd. on page 7)

Printing date 19.05.2015 Version number 8 Revision: 29.04.2015

Trade name: Cervitec Plus

(Contd. of page 6)

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

H411 Toxic to aquatic life with long lasting effects.

· 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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

Flam. Liq. 2: Flammable liquids, Hazard Category 2 Acute Tox. 4: Acute toxicity, Hazard Category 4

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2

* Data compared to the previous version altered.