

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.01.2019

Version number 4

Revision: 03.01.2019

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

- **1.1 Product identifier**
- **Trade name: ChemVarnish**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Varnish for glass-ionomer restorative material
- **Uses advised against** No further relevant information available.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
DENTSPLY DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsplysirona.com
- **Further information obtainable from:**
 - Departement Research & Development for technical information
 - Departement Marketing & Sales for distribution of the safety data sheets
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

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.
Eye Irrit. 2 H319 Causes serious eye irritation.
STOT SE 3 H336 May cause drowsiness or dizziness.
- **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-determining components of labelling:**
ethyl acetate
- **Hazard statements**
H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
- **Precautionary statements**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241	Use explosion-proof [electrical/ventilating/lighting] equipment.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

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· Additional information:

As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation (EC) 1272/2008.

- **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: 141-78-6	ethyl acetate	50 – 100%
EINECS: 205-500-4	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	

· **Additional information** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· 4.1 Description of first aid measures

- **General information** Immediately remove any clothing soiled by the product.
- **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. If symptoms persist, consult a doctor.
- **After swallowing** Do not induce vomiting; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Information for doctor** 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, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents**
Water with full jet.
Water.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Self-contained respiratory protective device.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Keep away from ignition sources

· 6.2 Environmental precautions:

Prevent seepage into sewage system, workpits and cellars.

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).

Dispose contaminated material as waste according to item 13.

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- Ensure adequate ventilation.
- Do not flush with water or aqueous cleansing agents
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
- Ensure good ventilation/exhaustion at the workplace.
- Prevent formation of aerosols.
- Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.
- **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.
- Store only in the original receptacle.
- **Information about storage in one common storage facility:** Store away from oxidising agents.
- **Further information about storage conditions:** 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:**

CAS: 141-78-6 ethyl acetate

WEL	Short-term value: 1468 mg/m ³ , 400 ppm
	Long-term value: 734 mg/m ³ , 200 ppm

- **Regulatory information** WEL: EH40/2018
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**
- Keep away from foodstuffs, beverages and feed.
- Immediately remove all soiled and contaminated clothing
- Wash hands before breaks and at the end of work.
- Avoid contact with the eyes and skin.
- **Respiratory protection:**
- 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.
- Not necessary if room is well-ventilated.

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· Protection of hands:

Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
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.

Butyl rubber, BR

Permeation: Level ≥ 2 Recommended thickness of the material: ≥ 0.3 mm**· 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:

Tightly sealed goggles.

· Body protection: Protective work clothing.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties**· General Information****· Appearance:**

Form:	Liquid
Colour:	Colourless
Odour:	Ester-like
Odour threshold:	Not determined.

· pH-value: Not determined.**· Change in condition**

Melting point/freezing point:	undetermined
Initial boiling point and boiling range:	77 °C

· Flash point: -5 °C**· Flammability (solid, gaseous)** Not applicable.**· Ignition temperature:** 427 °C (Ethylacetat)**· Decomposition temperature:** Not determined.**· 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:	2.1 Vol %
Upper:	11.5 Vol %

· Vapour pressure at 20 °C: 97 hPa (Ethylacetat)

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· Density:	Not determined
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Not miscible or difficult to mix
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
dynamic:	Not determined.
kinematic:	Not determined.
· Solvent content:	
Organic solvents:	90.0 %
· 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**
- **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.
- **10.6 Hazardous decomposition products:**
Ethanol
Ethanoic acid

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

CAS: 141-78-6 ethyl acetate

Oral	LD50	5,620 mg/kg (rat)
Dermal	LD50	> 180,000 mg/kg (rabbit)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**
May cause drowsiness or dizziness.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

CAS: 141-78-6 ethyl acetate

LC50/48h 560 mg/l (daphnia magna)

LC50/96h 350 mg/l (Fish acute toxicity study)

EC50/24h 2,300 mg/L (daphnia magna)

· **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:**

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 hazardous substances

HP 3 Flammable

HP 4 Irritant - skin irritation and eye damage

HP 5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

· **Uncleaned packaging:**

· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

UN1173

· **14.2 UN proper shipping name**

· **ADR**

1173 ETHYL ACETATE mixture

· **IMDG, IATA**

ETHYL ACETATE mixture

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· 14.3 Transport hazard class(es)

· ADR



· Class 3 (F1) Flammable liquids.
· Label 3

· IMDG, IATA



· Class 3 Flammable liquids.
· Label 3

· 14.4 Packing group

· ADR, IMDG, IATA II

· 14.5 Environmental hazards: Not applicable.

· 14.6 Special precautions for user Warning: Flammable liquids.

· Danger code (Kemler): 33
· EMS Number: F-E,S-D
· Stowage Category B

· 14.7 Transport in bulk according to Annex II of

Marpol and the IBC Code Not applicable.

· Transport/Additional information:

· ADR

· Limited quantities (LQ) IL
· Excepted quantities (EQ) Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml

· Transport category 2
· Tunnel restriction code D/E

· IMDG

· Limited quantities (LQ) IL
· Excepted quantities (EQ) Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml

· UN "Model Regulation": UN 1173 ETHYL ACETATE MIXTURE, 3, II

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- 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 5,000 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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· **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.

*The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.
For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.*

· **Relevant phrases**

*H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.*

· **Department issuing SDS:** Research & Development

· **Contact:** HotLine for urgent technical support: +49-7531-583-350

· **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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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

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