Revision: 04.01.2023

Start

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

Printing date 04.01.2023

Version number 5 (replaces version 4)

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: Research and Development
- 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 GB 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.

· Additional information:

As this product is a medical device in the meaning of Directive 93/42/EEC and regulation (EC) 2017/745 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.

(Contd. on page 2)

Printing date 04.01.2023 Version number 5 (replaces version 4) Revision: 04.01.2023

Trade name: ChemVarnish

(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 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, EUH066

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.
- · Information for doctor No further relevant information available.
- 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, 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.

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

(Contd. on page 3)

Printing date 04.01.2023 Version number 5 (replaces version 4)

Trade name: ChemVarnish

(Contd. of page 2)

Revision: 04.01.2023

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.

Information about fire - and explosion protection:



Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · Handling Product is intended for dental use only.
- · 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

· 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/m³, 400 ppm Long-term value: 734 mg/m³, 200 ppm

- Regulatory information WEL: EH40/2020
- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see item 7.
- · Individual protection measures, such as 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.

· Hand protection



Protective gloves.

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

(Contd. on page 4)

Printing date 04.01.2023 Version number 5 (replaces version 4) Revision: 04.01.2023

Trade name: ChemVarnish

(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.

Butyl rubber, BR Permeation: Level ≥ 2

Recommended thickness of the material: ≥ 0.3 mm

Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye/face 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

Physical state
Colour:
Odour:
Odour threshold:
Melting point/freezing point:

Fluid

Colourless
Ester-like
Not determined
undetermined

· Boiling point or initial boiling point and boiling

range 77 °C (Ethylacetat)
• Flammability Not applicable.

· Lower and upper explosion limit

Lower: 2.1 Vol %
Upper: 11.5 Vol %
Flash point: -5 °C (Ethylacetat)
Ignition temperature: 427 °C (Ethylacetat)
Decomposition temperature: Not determined.
pH
Not determined.

· Viscosity:

Kinematic viscositydynamic:Not determined.Not determined.

· Solubility

· Water: Not miscible or difficult to mix

97 hPa

· Partition coefficient n-octanol/water (log value) Not determined.

· Vapour pressure at 20 °C:

Density and/or relative density

Density:

Density:

Relative density

Vapour density

Not determined.

Not determined.

Not determined.

- · 9.2 Other information
- · Appearance:
- · Form: Liquid

(Contd. on page 5)

Printing date 04.01.2023 Version number 5 (replaces version 4) Revision: 04.01.2023

Trade name: ChemVarnish

(Contd. of page 4)

Important information on protection of health and

environment, and on safety.

· Auto-ignition temperature: Product is not selfigniting.

• Explosive properties: Product is not explosive. However, formation of

explosive air/vapour mixtures are possible.

· Solvent content:

• Organic solvents: 90.0 %

· Change in condition

· Evaporation rate Not determined.

· Information with regard to physical hazard classes

Explosives Void
Flammable gases Void
Aerosols Void
Oxidising gases Void
Gases under pressure Void

· Flammable liquids Highly flammable liquid and vapour.

· Flammable solids Void
· Self-reactive substances and mixtures Void
· Pyrophoric liquids Void
· Pyrophoric solids Void
· Self-heating substances and mixtures Void
· Substances and mixtures, which emit flammable

Substances and mixtures, which emit flammable gases in contact with water Void
Oxidising liquids Void
Oxidising solids Void
Organic peroxides Void
Corrosive to metals Void
Desensitised explosives Void

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 hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity

· LD/LC50	values	relevant	for c	classi	fication:
-----------	--------	----------	-------	--------	-----------

CAS: 141-78-6 ethyl acetate

Oral | LD50 | 5,620 mg/kg (rat)

Dermal | LD50 | > 180,000 mg/kg (rabbit)

- · Serious eye damage/irritation Causes serious eye irritation.
- · STOT-single exposure May cause drowsiness or dizziness.

(Contd. on page 6)

Version number 5 (replaces version 4) Printing date 04.01.2023 Revision: 04.01.2023

Trade name: ChemVarnish

· 11.2 Information on other hazards

(Contd. of page 5)

· Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity

1 amatia tamiaitu

· Aquatic toxicity). <u>.</u>	
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.
- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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

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

SECTION 14: Transport information

· 14.1	UN	number	or ID	number
--------	----	--------	-------	--------

· ADR, IMDG, IATA UN1173

· 14.2 UN proper shipping name

1173 ETHYL ACETATE mixture $\cdot ADR$ ETHYL ACETATE mixture · IMDG, IATA

(Contd. on page 7)

Printing date 04.01.2023 Version number 5 (replaces version 4) Revision: 04.01.2023

Trade name: ChemVarnish

(Contd. of page 6) · 14.3 Transport hazard class(es) $\cdot ADR$ 3 (F1) Flammable liquids. · Class · Label · IMDG, IATA 3 Flammable liquids. ·Label 3 · 14.4 Packing group II· ADR, IMDG, IATA · 14.5 Environmental hazards: Not applicable. Warning: Flammable liquids. · 14.6 Special precautions for user · Hazard identification number (Kemler code): F-E,S-D· EMS Number: · Stowage Category · 14.7 Maritime transport in bulk according to IMO instruments Not applicable. · Transport/Additional information: · Limited quantities (LQ) Code: E2 · Excepted quantities (EQ) Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml · Transport category · Tunnel restriction code D/E· Limited quantities (LQ) 1L· 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

(Contd. on page 8)

Printing date 04.01.2023 Version number 5 (replaces version 4)

Trade name: ChemVarnish

(Contd. of page 7)

Revision: 04.01.2023

· 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.

EUH066 Repeated exposure may cause skin dryness or cracking.

- · Department issuing SDS: Research & Development
- · Contact: HotLine for urgent technical support: +49-7531-583-350
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international 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.

GB