

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

Printing date 09.03.2022

Version number 3

Revision: 15.07.2021

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

- **1.1 Product identifier**
- **Trade name:** DTK-Adhesive
- **Article number:** 540 0118 5, 540 0119 5
- **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:** Dual-hardening luting composite.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
bredent GmbH & Co.KG
Weißenhörner Straße 2
89250 Senden
Tel: +49 (0) 7309/872-0
Fax: +49 (0) 7309/872-24
- **Further information obtainable from:**
R & D
e-mail: R.D@bredent.com
- **1.4 Emergency telephone number:** (001) 352 323 3500

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Remark**
The device is a medical device pursuant to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. No safety data sheet is required for the device, so no claim is made to full compliance with the relevant statutory requirements.
- **Classification according to Regulation (EC) No 1272/2008**



- Skin Irrit. 2 H315 Causes skin irritation.
- Eye Irrit. 2 H319 Causes serious eye irritation.
- Skin Sens. 1 H317 May cause an allergic skin reaction.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
Medical products and medical devices within the meaning of Directives 90/385/EEC and 93/42/EEC used in an invasive manner or in direct contact with the body as well as medical products and medical devices falling under Directive 98/79/EC are fully exempt from the provisions of the CLP Regulation and therefore do not need to be classified, packaged or labelled.
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Bisphenol-A-Diglycidyl-Methacrylate
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves / eye protection / face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.

(Contd. on page 2)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 3

Revision: 15.07.2021

Trade name: DTK-Adhesive

P501 Dispose of contents/container in accordance with local/regional/national/international regulations. (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:** Paste of dimethacrylates, inorganic fillers, catalysts, stabilizers and pigments.

· **Dangerous components:**

CAS: 1565-94-2	Bisphenol-A-Diglycidyl-Methacrylate	2.5-10%
EINECS: 216-367-7	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	

- **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**
- **After inhalation:** Take affected persons into fresh air and keep quiet.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** Call a doctor immediately.
- **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.
Foam
Sand
- **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.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective clothing.
Ensure adequate ventilation
- **6.2 Environmental precautions:**
Dilute with plenty of water.
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).
- **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.

GB

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 3

Revision: 15.07.2021

Trade name: DTK-Adhesive

(Contd. of page 2)

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Keep receptacles tightly sealed.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
 - **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** Protect from exposure to the light.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Do not eat, drink, smoke or sniff while working.
The usual precautionary measures are to be adhered to when handling chemicals.
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **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**

Nitrile rubber, NBR

Recommended thickness of the material: ≥ 0.5 mm

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 penetration time has to be at least 480 minutes (Permeation according to EN 374 Part 3: Level 6).

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

- **Eye protection:** Goggles recommended during refilling

GB

(Contd. on page 4)

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

Printing date 09.03.2022

Version number 3

Revision: 15.07.2021

Trade name: DTK-Adhesive

(Contd. of page 3)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Pasty
· Colour:	Yellowish
· Odour:	Ester-like
· Odour threshold:	Not determined.

· pH-value at 20 °C: 2.5

· Change in condition

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	> 200 °C

· Flash point: Not applicable.

· Flammability (solid, gas): Not applicable.

· Decomposition temperature: > 60 °C

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

· Lower:	Not determined.
· Upper:	Not determined.

· Vapour pressure at 20 °C: 1 hPa

· Density at 20 °C:	1.9 g/cm ³
· Relative density	Not determined.
· Vapour density at 20 °C	> 1
· Evaporation rate	Not determined.

· Solubility in / Miscibility with water at 20 °C: 5 g/L

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

· Dynamic:	Not determined.
· Kinematic:	Not determined.

· Solvent content:

· Organic solvents: 0.0 %

· 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:

The following may be given off during a fire:
Corrosive gases/vapours

GB

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 3

Revision: 15.07.2021

Trade name: DTK-Adhesive

(Contd. of page 4)

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:** LD50: rat 1000 mg/kg
- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Additional toxicological information:**
- **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** Based on available data, the classification criteria are not met.
- **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.

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:**
Avoid transfer into the environment.
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
- **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**
After prior treatment product has to be disposed of in an incinerator for hazardous waste adhering to the regulations pertaining to the disposal of particularly hazardous waste.
Smaller quantities of cured material may be disposed off together with household waste.
Can be burned with household garbage after consulting with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.
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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

GB

(Contd. on page 6)

Safety data sheet
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Trade name: DTK-Adhesive

(Contd. of page 5)

SECTION 14: Transport information

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Labelling according to Regulation (EC) No 1272/2008
The product is classified and labelled according to the CLP regulation.
- Hazard pictograms GHS07
- Signal word Warning
- Hazard-determining components of labelling:
Bisphenol-A-Diglycidyl-Methacrylate
- Hazard statements
H315 Causes skin irritation.
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H317 May cause an allergic skin reaction.
- Precautionary statements
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves / eye protection / face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- 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
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.

(Contd. on page 7)

GB

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

Printing date 09.03.2022

Version number 3

Revision: 15.07.2021

Trade name: DTK-Adhesive

(Contd. of page 6)

H319 Causes serious eye irritation.

· **Department issuing SDS:** R & D

· **Contact:** R & D

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

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

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

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

Skin Sens. 1: Skin sensitisation – Category 1

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

GB