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

1.1 Product identifier

Trade name: THERMASEAL PLUS RIBBON PASTE A

1.2 Relevant identified uses of the substance or mixture and uses advised against

Application of the substance / the mixture  root canal filling 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
e-mail: KonstanzDEU.info-sdb@dentsply.com

Further information obtainable from:
- Departement Analytical Research / 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
Aquatic Chronic 2  H411  Toxic to aquatic life with long lasting effects.
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
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 1272/2008.
The product is classified and labelled according to the CLP regulation.

Hazard pictograms

![GHS07]  ![GHS09]

GHS07  GHS09

Signal word Warning

Hazard-determining components of labelling:
Bisphenol A Diglycidylether
Bis-[4-(2,3-epoxypropoxy)phenyl]-methane

Hazard statements
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H411 Toxic to aquatic life with long lasting effects.

(Contd. on page 2)
Trade name: THERMASEAL PLUS RIBBON PASTE A

- Precautionary statements
  P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  P280 Wear protective gloves/protective clothing/eye protection/face protection.
  P273 Avoid release to the environment.
  P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  P321 Specific treatment (see on this label).
  P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- Additional information:
  Contains epoxy constituents. May produce an allergic reaction.

- 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: 25068-38-6 Bisphenol A Diglycidylether
      Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317
      25-50%
    - CAS: 9003-36-5 Bis-[4-(-2,3-epoxypropoxy)phenyl]-methane
      Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317
      3-<10%

- 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
    - General information No special measures required.
    - After inhalation Supply fresh air and to be sure call for a doctor.
    - 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 Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.
  - 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, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective clothing.
- 6.2 Environmental precautions:
  Inform respective authorities in case of seepage into water course or sewage system.
  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.
  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.
- 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: 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:
    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
    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:** Not necessary if room is well-ventilated.
- **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**
  Nitrile rubber, NBR

  Recommended thickness of the material: ≥ 0,38 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**

  Value for the permeation: Level ≤ 3

  The exact break trough 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.

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### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

**General Information**

- **Appearance:**
  - Form: Pasty
  - Colour: Yellow

- **Odour:** Characteristic

- **Odour threshold:** Not determined.

- **pH-value:** Not determined.

- **Change in condition**

  - Melting point/Melting range: Undetermined
  - Boiling point/Boiling range: Undetermined

- **Flash point:** Not applicable

- **Flammability (solid, gaseous):** Not applicable

- **Ignition temperature:**

  - Decomposition temperature: Not determined

- **Self-igniting:** Product is not self-igniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

  - Lower: Not determined.
Trade name: THERMASEAL PLUS RIBBON PASTE A

Upper: Not determined.

- Vapour pressure: Not determined.
- 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: 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: Void

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
- Acute toxicity:
- LD/LC50 values relevant for classification:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Dermal LD50</th>
<th>Oral LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>AH Plus Paste A</td>
<td>7692 mg/kg (ATE)</td>
<td>&gt;5000 mg/kg (rat)</td>
</tr>
<tr>
<td>25068-38-6 Bisphenol A Diglycidylether</td>
<td>&gt;2000 mg/kg (rabbit)</td>
<td>&gt;5000 mg/kg (rat)</td>
</tr>
<tr>
<td>9003-36-5 Bis-[4-(2,3-epoxypropoxy)phenyl]-methane</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Primary irritant effect:
  - on the skin: Irritant to skin and mucous membranes.
  - on the eye: Irritating effect.
  - Sensitisation: Sensitisation possible through skin contact.
  - Additional toxicological information:
    The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
**SECTION 12: Ecological information**

12.1 Toxicity

- **Aquatic toxicity:**
  - 25068-38-6 Bisphenol A Diglycidylether
    - EC50/24h: 3.6 mg/L (daphnia magna)
    - LC50/96h: 1.5 mg/l (Fish acute toxicity study)
  - 9003-36-5 Bis-[4-(-2,3-epoxypropoxy)phenyl]-methane
    - EC50/24h: 2 mg/L (daphnia magna)
    - LC50/96h: 2 mg/l (Fish acute toxicity study)

- **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.
- **Ecotoxicical effects:**
  - **Remark:**
    - Toxic for water fleas
    - Toxic for fish
- **Additional ecological information:**
- **General notes:**
  - 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.
  - Also poisonous for fish and plankton in water bodies.
  - Toxic for aquatic organisms
- **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.

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

**SECTION 14: Transport information**

- **14.1 UN-Number**
  - **ADR, IMDG, IATA**
    - UN3082
· 14.2 UN proper shipping name
  · ADR 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Bisphenol A Diglycidylether)
  · IMDG ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight = 700), Bis-[4-(-2,3-epoxypropoxy)phenyl]-methane), MARINE POLLUTANT
  · IATA ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight = 700), Bis-[4-(-2,3-epoxypropoxy)phenyl]-methane)

· 14.3 Transport hazard class(es)
  · ADR Class 9 (M6) Miscellaneous dangerous substances and articles.
    · Label 9
  · IMDG, IATA Class 9 Miscellaneous dangerous substances and articles.
    · Label 9

· 14.4 Packing group
  · ADR, IMDG, IATA III

· 14.5 Environmental hazards:
  Product contains environmentally hazardous substances: reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight = 700)
  · Marine pollutant: Yes
  · Special marking (ADR): Symbol (fish and tree)
  · Special marking (IATA): Symbol (fish and tree)

· 14.6 Special precautions for user
  Warning: Miscellaneous dangerous substances and articles.
  · Danger code (Kemler): 90
  · EMS Number: F-A,S-F

· 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

· Transport/Additional information:
  · ADR Limited quantities (LQ) 5L
    · Excepted quantities (EQ) Code: E1
      Maximum net quantity per inner packaging: 30 ml
      Maximum net quantity per outer packaging: 1000 ml
  · Transport category 3
Section 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
No further relevant information available.

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
  H315 Causes skin irritation.
  H317 May cause an allergic skin reaction.
  H319 Causes serious eye irritation.
  H411 Toxic to aquatic life with long lasting effects.

- Department issuing MSDS: Analytical Research
- 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
  Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
  Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
  Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
  Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2
- * Data compared to the previous version altered.