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

1.1 Product identifier
- Trade name: AH Plus 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
  email: KonstanzDEU.info-sdb@dentsplysirona.com

- Further information obtainable from:
  - Département Research & Development for technical information
  - Département 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
  - 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.
  - Aquatic Chronic 2  H411  Toxic to aquatic life with long lasting effects.

2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008
  The product is classified and labelled according to the CLP regulation.

2.2.1 Hazard pictograms

- GHS07
- GHS09

2.2.2 Signal word Warning

2.2.3 Hazard-determining components of labelling:
- Bisphenol A Diglycidylether
- Formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol

2.2.4 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.

2.2.5 Precautionary statements
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P273 Avoid release to the environment.
- 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.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
Trade name: AH Plus Paste A

- 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 1272/2008.
  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.

| CAS: 25068-38-6 Bisphenol A Diglycidylether | 25-50% |
| NLP: 500-033-5 Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 |

| CAS: 9003-36-5 formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol | 2.5-<10% |
| NLP: 500-033-5 Aquatic Chronic 2, H411; 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
  - General information Immediately remove any clothing soiled by the product.
  - 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 If symptoms persist consult doctor. Rinse out mouth and then drink plenty of water.

- 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.
  - For safety reasons unsuitable extinguishing agents Water with full jet.
  - Special hazards arising from the substance or mixture Formation of toxic gases is possible during heating or in case of fire.

- 5.3 Advice for firefighters
  - Protective equipment: Self-contained respirator protective device.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective clothing
6.2 Environmental precautions:
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.

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.

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: 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: 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
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
Trade name: AH Plus Paste A

(Contd. of page 3)

- **Penetration time of glove material**
  - The exact breakthrough 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

<table>
<thead>
<tr>
<th>General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance:</strong></td>
</tr>
<tr>
<td>Form: Pasty</td>
</tr>
<tr>
<td>Colour: Yellow</td>
</tr>
<tr>
<td>Odour: Characteristic</td>
</tr>
<tr>
<td>Odour threshold: Not determined</td>
</tr>
<tr>
<td>pH-value: Not determined</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Change in condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting point/freezing point: Undetermined</td>
</tr>
<tr>
<td>Initial boiling point and boiling range: Undetermined</td>
</tr>
</tbody>
</table>

| Flammability (solid, gaseous) |
| Flash point: Not applicable |
| Ignition temperature: Not applicable |
| Decomposition temperature: Not determined |
| 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: |
| Flash point: Not determined |
| Auto-ignition temperature: Not applicable |

| Density: |
| 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 % |

(Contd. on page 5)
Safety data sheet
guided by 1907/2006/EC, Article 31

Printing date 10.11.2017
Version number 10
Revision: 10.11.2017

Trade name: AH Plus Paste A

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
No dangerous decomposition products known

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:

ATE (Acute Toxicity Estimate)

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50/LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>&gt;7,692 mg/kg (rat)</td>
</tr>
<tr>
<td>Dermal</td>
<td>&gt;7,692 mg/kg (rabbit)</td>
</tr>
</tbody>
</table>

CAS: 25068-38-6 Bisphenol A Diglycidylether

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50/LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>&gt;2,000 mg/kg (rat)</td>
</tr>
<tr>
<td>Dermal</td>
<td>&gt;2,000 mg/kg (rabbit)</td>
</tr>
</tbody>
</table>

CAS: 9003-36-5 formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50/LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>&gt;5,000 mg/kg (rat)</td>
</tr>
</tbody>
</table>

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.

CMR effects (carcinogenity, 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:

CAS: 25068-38-6 Bisphenol A Diglycidylether

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50/96h</td>
<td>1.5 mg/l (Fish acute toxicity study)</td>
</tr>
<tr>
<td>EC50/24h</td>
<td>3.6 mg/l (daphnia magna)</td>
</tr>
<tr>
<td>EC50/72h</td>
<td>9.4 mg/l (Alg)</td>
</tr>
</tbody>
</table>

CAS: 9003-36-5 formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50/96h</td>
<td>2 mg/l (Fish acute toxicity study)</td>
</tr>
</tbody>
</table>
SECTION 13: Disposal considerations

- 13.1 Waste treatment methods
  - Recommendation

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

- European waste catalogue

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 01 06*</td>
<td>chemicals consisting of or containing hazardous substances</td>
</tr>
<tr>
<td>HP 4</td>
<td>Irritant - skin irritation and eye damage</td>
</tr>
<tr>
<td>HP 13</td>
<td>Sensitising</td>
</tr>
<tr>
<td>HP 14</td>
<td>Ecotoxic</td>
</tr>
</tbody>
</table>

- 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. (reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight = 700), formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol) 
  - IMDG ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight = 700), formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol), MARINE POLLUTANT 
  - IATA ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight = 700), formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol)
Trade name: AH Plus Paste A

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

- **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:**
    - **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
  - **Stowage Category** A

- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**
  - **Transport/Additional information:** Not applicable.

- **Transport/Additional information:**
  - **ADR**
    - **Limited quantities (LQ):** 5L
      - Code: E1
      - Maximum net quantity per inner packaging: 30 ml
      - Maximum net quantity per outer packaging: 1000 ml
    - **Excepted quantities (EQ):**
      - **Transport category** 3
      - **Remarks:** Exemption according to ADR special provision 375:
        - This substance is not subject to the other provisions of the ADR if packed in net quantities of 5L or 5kg per individual or inner packaging, provided that sub-sections 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8 are complied with.
  - **IMDG**
    - **Limited quantities (LQ):** 5L
      - Code: E1
      - Maximum net quantity per inner packaging: 30 ml
      - Maximum net quantity per outer packaging: 1000 ml
    - **Excepted quantities (EQ):**

- **UN "Model Regulation":**
  - **UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (REACTION PRODUCT: BISPHENOL-A-(EPICHLORHYDRIN) EPOXY RESIN (NUMBER AVERAGE MOLECULAR WEIGHT = 700),**
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 E2 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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 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
  - 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
  - Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

* Data compared to the previous version altered.
* **SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- **1.1 Product identifier**
  - **Trade name:** AH Plus Paste B

- **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
    - 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**
    - **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**
    - GHS07

  - **Signal word:** Warning
  - **Hazard statements**
    - H315 Causes skin irritation.
    - H319 Causes serious eye irritation.
  - **Precautionary statements**
    - P264 Wash thoroughly after handling.
    - P280 Wear protective gloves / eye protection / face protection.
    - P302+P352 IF ON SKIN: Wash with plenty of water.
    - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
    - P332+P313 If skin irritation occurs: Get medical advice/attention.
    - P337+P313 If eye irritation persists: Get medical advice/attention.

  - **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 1272/2008.
    - Contains Octahydro-4,7-methano-1H-indendimethylamin. May produce an allergic reaction.

- **2.3 Other hazards**
  - **Results of PBT and vPvB assessment**
    - **PBT:** Not applicable.
SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

- Dangerous components:

<table>
<thead>
<tr>
<th>CAS:</th>
<th>Chemical Name</th>
<th>Amount</th>
<th>Dangerous Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>113506-22-2</td>
<td>N,N'-Dibenzyl-5-oxanondiamin-1,9</td>
<td>10-25%</td>
<td>Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</td>
</tr>
<tr>
<td>768-94-5</td>
<td>amantadine</td>
<td>2.5-&lt;10%</td>
<td>Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</td>
</tr>
<tr>
<td>68889-71-4</td>
<td>Octahydro-4,7-methano-1H-indendimethylamin</td>
<td>0.1-&lt;1%</td>
<td>Acute Tox. 3, H311; Skin Corr. 1B, H314; Acute Tox. 4, H302; Skin Sens. 1, H317</td>
</tr>
</tbody>
</table>

- 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: No special measures required.

- 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.
- After swallowing: Rinse out mouth and then drink plenty of water.
  Seek medical treatment.

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.

For safety reasons unsuitable extinguishing agents: Water with full jet.

5.2 Special hazards arising from the substance or mixture: Formation of toxic gases is possible during heating or in case of fire.

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.

6.2 Environmental precautions: Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

Ensure adequate ventilation.

6.4 Reference to other sections:

See Section 7 for information on safe handling.
SECTION 7: Handling and storage

7.1 Precautions for safe handling
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

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
  The usual precautionary measures are to be adhered to when handling chemicals.
  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.
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.
- Penetration time of glove material
  The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- Eye protection:
  Tightly sealed goggles.
5.1.3 · Body protection: Protective work clothing.

---

**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:**
    - Form: Pasty
    - Colour: White
  - Odour: Characteristic
  - Odour threshold: Not determined.
  - pH-value: Not determined.
- **Change in condition**
  - Melting point/freezing point: Undetermined
  - Initial boiling point and boiling range: Undetermined.
- **Flash point:** Not applicable
- **Flammability (solid, gaseous):** Not applicable.
- **Ignition temperature:** Not applicable
- **Decomposition temperature:** Not determined.
- **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:** 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 %
- **Solids content:** 89.7 %
- **9.2 Other information**
  - No further relevant information available.

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**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.
**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:**
    - **ATE (Acute Toxicity Estimate)**
      - Oral LD$_{50}$ 3,381 mg/kg (rat)
      - Dermal LD$_{50}$ 66,667-83,333 mg/kg (rat)
    - **CAS: 113506-22-2 N,N'-Dibenzyl-5-oxanonandiamin-1,9**
      - Oral LD$_{50}$ 458 mg/kg (rat)
    - **CAS: 768-94-5 amantadine**
      - Oral LD$_{50}$ 900 mg/kg (rat)
    - **CAS: 68889-71-4 Octahydro-4,7-methano-1H-indendimethylamin**
      - Oral LD$_{50}$ 502 mg/kg (rat)
      - Dermal LD$_{50}$ 400-500 mg/kg (rat)

- **Primary irritant effect:**
  - **Skin corrosion/irritation**
    - Causes skin irritation.
  - **Serious eye damage/irritation**
    - Causes serious eye irritation.
  - **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
  - **CMR effects (carcinogenity, 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:**
    - **CAS: 768-94-5 amantadine**
      - LC$_{50}$/96h 25 mg/L (Fish acute toxicity study)
      - EC$_{50}$/48h 22.1 mg/L (daphnia magna)
    - **CAS: 68889-71-4 Octahydro-4,7-methano-1H-indendimethylamin**
      - LC$_{50}$/96h 125 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.
  - **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.

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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 4 Irritant - skin irritation and eye damage

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

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 Void

14.4 Packing group
ADR, IMDG, IATA Void

14.5 Environmental hazards:
Not applicable.

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

Directive 2012/18/EU
Named dangerous substances - ANNEX I None of the ingredients is listed.
REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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

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of the product is given in the DFU.

Relevant phrases
- H302 Harmful if swallowed.
- H311 Toxic in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.

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
- Acute Tox. 4: Acute toxicity – Category 4
- Acute Tox. 3: Acute toxicity – Category 3
- Skin Corr. 1B: Skin corrosion/irritation – Category 1B
- 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
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.