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

- **1.1 Product identifier**
- **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
- **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.
  - Hazard pictograms
    - GHS07
    - GHS09
- **Signal word Warning**
- **Hazard-determining components of labelling:**
  - Bisphenol A Diglycidylether
  - Formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol
- **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.
- **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.

(Contd. on page 2)
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.

- **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.

<table>
<thead>
<tr>
<th>Dangerous components:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 25068-38-6</td>
</tr>
<tr>
<td>NLP: 500-033-5</td>
</tr>
<tr>
<td>Bisphenol A Diglycidylether</td>
</tr>
<tr>
<td>Aquatic Chronic 2, H411; Skin Irrit. 2, H313; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
</tr>
<tr>
<td>25-50%</td>
</tr>
<tr>
<td>CAS: 9003-36-5</td>
</tr>
<tr>
<td>formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxy propane and phenol</td>
</tr>
<tr>
<td>Aquatic Chronic 2, H411; Skin Irrit. 2, H313; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
</tr>
<tr>
<td>2.5-&lt;10%</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** 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.

- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

- **Information for doctor** 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 respirator protective device.

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: AH Plus Paste A

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 (Contd. on page 4)
application.
Nitrile rubber, NBR
Permeation: Level ≥3
Recommended thickness of the material: ≥ 0.38 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 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:** Pasty
    - **Colour:** Yellow
    - **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.
  - **Explosion temperature:** 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 %
Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 10.11.2017
Version number 10
Revision: 10.11.2017

Trade name: AH Plus Paste A

(Contd. of page 4)

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.

ATE (Acute Toxicity Estimate)

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

CAS: 25068-38-6 Bisphenol A Diglycidylether

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
<th>LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>&gt;2,000 mg/kg (rat)</td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>&gt;2,000 mg/kg (rabbit)</td>
<td></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</th>
<th>LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>&gt;5,000 mg/kg (rat)</td>
<td></td>
</tr>
</tbody>
</table>

11.2 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 (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:

CAS: 25068-38-6 Bisphenol A Diglycidylether

<table>
<thead>
<tr>
<th>Test</th>
<th>LC50/96h</th>
<th>EC50/24h</th>
<th>EC50/72h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish acute toxicity study</td>
<td>1.5 mg/l</td>
<td>3.6 mg/L (daphnia magna)</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>LC50/96h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish acute toxicity study</td>
<td>2 mg/l</td>
</tr>
</tbody>
</table>

(Contd. on page 6)
Trade name: AH Plus Paste A

EC50/24h 2 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.
- Ecotoxic effects:
  - Remark: 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.

  - European waste catalogue

    | 18 01 06* | chemicals consisting of or containing hazardous substances |
    | HP 4     | Irritant - skin irritation and eye damage |
    | HP 13    | Sensitising |
    | HP 14    | Ecotoxic |

  - 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
Trade name: AH Plus Paste A

(Contd. of page 6)

- **14.3 Transport hazard class(es)**
  - **ADR**
  - **Class**
  - **Label**
    - 9 (M0) Miscellaneous dangerous substances and articles.
  - **IMDG, IATA**
  - **Class**
  - **Label**
    - 9 Miscellaneous dangerous substances and articles.

- **14.4 Packing group**
  - **ADR, IMDG, IATA**
  - **Class**
  - **Label**
    - 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):**
    - **Special marking (IATA):**
      - Symbol (fish and tree)

- **14.6 Special precautions for user**
  - **Danger code (Kemler):**
  - **EMS Number:**
    - F-A,S-F
  - **Stowage Category**
    - A

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

- **Transport/Additional information:**
  - **ADR**
    - **Limited quantities (LQ)**
    - **Excepted quantities (EQ)**
      - 5L
      - Maximum net quantity per inner packaging: 30 ml
      - Maximum net quantity per outer packaging: 1000 ml
      - **Transport category**
      - **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)**
    - **Excepted quantities (EQ)**
      - 5L
      - Maximum net quantity per inner packaging: 30 ml
      - Maximum net quantity per outer packaging: 1000 ml

  - **UN "Model Regulation":**
    - UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (REACTION PRODUCT: BISPHENOL-A-(EPICHLOORHYDRIN) EPOXY RESIN (NUMBER AVERAGE MOLECULAR WEIGHT = 700),

(Contd. on page 8)
Trade name: AH Plus Paste A

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

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.

(Contd. on page 2)
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: AH Plus Paste B

· vPoB: 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: 113506-22-2</th>
<th>N,N'-Dibenzyl-5-oxanonandiamin-1,9</th>
<th>10-25%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 768-94-5</th>
<th>amantadine</th>
<th>2.5-&lt;10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 212-201-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 68889-71-4</th>
<th>Octahydro-4,7-methano-1H-indendimethylamin</th>
<th>0.1-&lt;1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonium salicylate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Tox. 3, H311; Skin Corr. 1B, H314; Acute Tox. 4, H302; Skin Sens. 1, H317</td>
<td></td>
<td></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.
- **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**
      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.
**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:** 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*{SECTION 11: Toxicological information}

- 11.1 Information on toxicological effects
  - Acute toxicity Based on available data, the classification criteria are not met.
  
  \begin{table}[h]
  \begin{tabular}{|l|l|}
  \hline
  ATE (Acute Toxicity Estimate) & \\
  \hline
  Oral LD$_{50}$ & 3.381 mg/kg (rat) \\
  Dermal LD$_{50}$ & 66,667-83,333 mg/kg (rat) \\
  \hline
  \end{tabular}
  \end{table}

- LD/LC$_{50}$ values relevant for classification:
  - 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*{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.
5.1.3 · 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 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
  - Class 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

(Contd. on page 7)
Trade name: AH Plus Paste B

...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.