

SAFETY DATA SHEETS

This SDS packet was issued with item:

071181122

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

070506584 070506592 070507657 070507665

Material Safety Data Sheet

selon 1907/2006/CE, Article 31

Printing date 08/06/2013

Version number 6

Reviewed on 02/25/2013

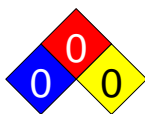
1 Identification

- **Product identifier**
- **Trade name:** *AH Plus Paste B*
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation** root canal filling material
- **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@dentsply.com
- Supplier for CANADA:
Dentsply Canada
161 Vinyl Court
Woodbridge, ON L4L4A3

Tel.: (905) 851 6060 or 1-800-263-1437
Fax: (905) 851-9809
- **Information department:**
 - Departement Analytical Research for technical information
 - Departement sales for distribution of the safety data sheets
- **Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

2 Hazard(s) identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** not applicable
- **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- **Label elements**
- **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals
The product is not subject to identification regulations according to directives on hazardous materials.
- **Special labeling of certain preparations:**
Contains TCD-diamin. May produce an allergic reaction.
- **Classification system**
- **NFPA ratings (scale 0-4)**



Health = 0
Fire = 0
Reactivity = 0

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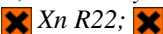

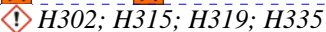
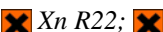

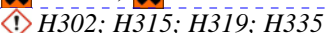
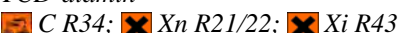


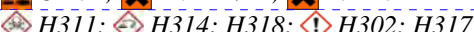
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- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

113506-22-2	N,N'-Dibenzyl-5-oxanonandiamin-1,9   	10-25%
768-94-5	amantadine   	2.5-10%
	TCD-diamin    	≤ 2.5%

- **Additional information** For the wording of the listed risk phrases refer to section 16.

4 First-aid measures

- **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.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
 No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents**
 CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture**
 Formation of toxic gases is possible during heating or in case of fire.
- **Advice for firefighters**
- **Protective equipment:** Self-contained respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
 Wear protective equipment. Keep unprotected persons away.

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- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Precautions for safe handling**
Observe normal care for working with chemicals.
Ensure good ventilation/exhaustion at the workplace.
- **Handling** Product is intended for dental use only.
- **Information about protection against explosions and fires:** No special measures required.
- **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.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components 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 that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not necessary if room is well-ventilated.
- **Protection of hands:**
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 break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses

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· **Body protection:** Protective work clothing.

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Pasty
Color:	White
Odor:	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.

· Auto igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapor 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 %

· Other information No further relevant information available.

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10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Irritant gases/vapors

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** The unpolymerized product may be irritant to the skin for susceptible persons.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitizing effect by skin contact is possible with prolonged exposure.
- **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations.
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

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14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT, TDG, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, TDG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, TDG, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, TDG, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Carcinogen categories**

· **TLV (Threshold Limit Value established by ACGIH)**

1314-23-4 zirconium dioxide

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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**

- 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.
 H318 Causes serious eye damage.
 H319 Causes serious eye irritation.

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H335 May cause respiratory irritation.

R21/22 Harmful in contact with skin and if swallowed.

R22 Harmful if swallowed.

R34 Causes burns.

R36/37/38 Irritating to eyes, respiratory system and skin.

R43 May cause sensitization by skin contact.

· **Department issuing MSDS:** Analytical Research

· **Contact:** HotLine for urgent technical support: +49-7531-583-333

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

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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 16.10.2018

Version number 11

Revision: 16.10.2018

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:**
 - 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.
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.

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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 (EC) 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.

Dangerous components:

CAS: 25068-38-6 NLP: 500-033-5	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	formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≥ 2.5 – < 10%

· **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

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.

· **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:** No special measures required.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.

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- **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**

Nitrile rubber, NBR
Permeation: Level ≥ 3

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*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***The exact break through 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:**

Form:	<i>Pasty</i>
Colour:	<i>Yellow</i>
· Odour:	<i>Characteristic</i>
· Odour threshold:	<i>Not determined.</i>

· pH-value: *Not determined.***· Change in condition**

Melting point/freezing point:	<i>undetermined</i>
Initial boiling point and boiling range:	<i>Undetermined.</i>

· 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:	<i>Not determined.</i>
Upper:	<i>Not determined.</i>

· 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:	<i>Not determined.</i>
kinematic:	<i>Not determined.</i>

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· 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:**
 - strong bases
 - strong acids
 - strong oxidants
- **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:**
- | | | |
|--|------|------------------------|
| CAS: 25068-38-6 Bisphenol A Diglycidylether | | |
| Oral | LD50 | > 2,000 mg/kg (rat) |
| Dermal | LD50 | > 2,000 mg/kg (rabbit) |
| CAS: 9003-36-5 formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol | | |
| Oral | LD50 | > 5,000 mg/kg (rat) |
- **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**

LC50/96h 1.5 mg/l (Fish acute toxicity study)

EC50/24h 3.6 mg/L (daphnia magna)

EC50/72h 9.4 mg/l (Alg)

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

LC50/96h 2 mg/l (Fish acute toxicity study)

EC50/24h 2 mg/L (daphnia magna)

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- **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.
- **Ecotoxicological 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

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· 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)

· 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:

Symbol (fish and tree)

· 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

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

3

· 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)

5L

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· Excepted quantities (EQ)	Code: E1 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-(EPICHLORHYDRIN) EPOXY RESIN (NUMBER AVERAGE MOLECULAR WEIGHT = 700), FORMALDEHYDE, OLIGOMERIC REACTION PRODUCTS WITH 1-CHLORO-2,3-EPOXYPROPANE AND PHENOL), 9, III

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.**

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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 Dam. 1 H318 Causes serious eye damage.
Repr. 2 H361 Suspected of damaging fertility or the unborn child.

- **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**



GHS05 GHS08

- **Signal word** *Danger*
- **Hazard-determining components of labelling:**
amantadine
- **Hazard statements**
H315 Causes skin irritation.
H318 Causes serious eye damage.
H361 Suspected of damaging fertility or the unborn child.
- **Precautionary statements**
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**
As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation (EC) 1272/2008.

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Contains octahydro-4,7-methano-1H-indenedimethylamine. 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: 113506-22-2	N,N'-Dibenzyl-5-oxanonandiamin-1,9 Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	10 – 25%
CAS: 768-94-5 EINECS: 212-201-2	amantadine Repr. 2, H361; Skin Corr. 1B, H314; Acute Tox. 4, H302; STOT SE 3, H335; Aquatic Chronic 3, H412	≥ 5 – < 10%
CAS: 68889-71-4	octahydro-4,7-methano-1H-indenedimethylamine Acute Tox. 3, H311; Skin Corr. 1B, H314; Acute Tox. 4, H302; Skin Sens. 1, H317	≥ 0.1 – < 1%

- **Additional information** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information** Immediately remove any clothing soiled by the product.
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **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** Use fire extinguishing methods suitable to surrounding conditions.
- **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.

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- **6.3 Methods and material for containment and cleaning up:**
Pick up mechanically.
Ensure adequate ventilation.
Dispose contaminated material as waste according to item 13.
- **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**
Open and handle receptacle with care.
Ensure good ventilation/exhaustion at the workplace.
Observe normal care for working with chemicals.
- **Handling** *Product is intended for dental use only.*
- **Information about fire - and explosion protection:** *Keep respiratory protective device available.*
- **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.
Store protective clothing separately.
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

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application.

· **Penetration time of glove material**

The exact break through 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:**

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:**

Solids content: 85.0 %

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· 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)**

Oral	LD50	3,381 mg/kg (rat)
Dermal	LD50	66,667 – 83,333 mg/kg (rat)

CAS: 113506-22-2 N,N'-Dibenzyl-5-oxanonandiamin-1,9

Oral	LD50	458 mg/kg (rat)
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CAS: 768-94-5 amantadine

Oral	LD50	900 mg/kg (rat)
------	------	-----------------

CAS: 68889-71-4 octahydro-4,7-methano-1H-indenedimethylamine

Oral	LD50	502 mg/kg (rat)
Dermal	LD50	400 – 500 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Other information (about experimental toxicology):**
Product is not classified as Skin Corr. 1B (H314), as a test according to OECD 435 had shown no corrosivity to the skin.
- **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**
Suspected of damaging fertility or the unborn child.
- **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.

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SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

CAS: 768-94-5 amantadine

LC50/96h 25 mg/l (Fish acute toxicity study)

EC50/48h 22.1 mg/L (daphnia magna)

CAS: 68889-71-4 octahydro-4,7-methano-1H-indenedimethylamine

LC50/96h 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 product to reach ground water, water course or sewage system.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

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 8 Corrosive

HP 10 Toxic for reproduction

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

Class Void

14.4 Packing group

ADR, IMDG, IATA Void

14.5 Environmental hazards:

Not applicable.

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- | | |
|--|-----------------|
| · 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
- **National regulations**
- **Information about limitation of use:**
 - Employment restrictions concerning women of child-bearing age must be observed.
 - Employment restrictions concerning juveniles must be observed.
- **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**
 - 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.
 - H361 Suspected of damaging fertility or the unborn child.
 - H412 Harmful 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
 - 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 Dam. 1: Serious eye damage/eye irritation – Category 1

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*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**Repr. 2: Reproductive toxicity – Category 2**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3***· * Data compared to the previous version altered.**

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