

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 08.05.2013

Version number 6

Revision: 25.02.2013

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**
No further relevant information available.
- **Application of the substance / the preparation** root canal filling material
- **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@dentsply.com
- **Further information obtainable from:**
 - Departement Analytical Research / Research & Development for technical information
 - Departement Marketing & Sales for distribution of the safety data sheets
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

2 Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Xi; Irritant
R36/38: Irritating to eyes and skin.
Xi; Sensitising
R43: May cause sensitisation by skin contact.
N; Dangerous for the environment
R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- **Information concerning particular hazards for human and environment:**
The product has 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 is according to the latest editions of the EU-lists, and extended by company and literature data.
- **2.2 Label elements**
- **Labelling according to EU guidelines:**
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials
- **Code letter and hazard designation of product:**

Xi Irritant

N Dangerous for the environment
- **Hazard-determining components of labelling:**
Bisphenol A Diglycidylether
Bis-[4-(-2,3-epoxypropoxy)phenyl]-methane
- **Risk phrases:**
36/38 Irritating to eyes and skin.

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43 May cause sensitisation by skin contact.

51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).

24 Avoid contact with skin.

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

28 After contact with skin, wash immediately with plenty of water.

37/39 Wear suitable gloves and eye/face protection.

57 Use appropriate container to avoid environmental contamination.

Special labelling of certain preparations:

Contains epoxy constituents. See information supplied by the manufacturer.

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

3 Composition/information on ingredients

3.2 Chemical characterization: Mixtures**Description:** Mixture of substances listed below with nonhazardous additions.**Dangerous components:**

CAS: 25068-38-6 NLP: 500-033-5	Bisphenol A Diglycidylether Xi R36/38; Xi R43; N R51/53 Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	25-50%
CAS: 9003-36-5	Bis-[4-(-2,3-epoxypropoxy)phenyl]-methane Xi R36/38; Xi R43; N R51/53 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 risk phrases refer to section 16.

4 First aid measures

4.1 Description of first aid measures**After inhalation**

In case of unconsciousness place patient stably in side position for transportation.

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.**4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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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.
- **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.

6 Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **6.2 Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

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.

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.

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· 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

The usual precautionary measures are to be adhered to when handling chemicals.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· **Respiratory protection:** Not necessary if room is well-ventilated.

· Protection of hands:



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

Nitrile rubber, NBR

Recommended thickness of the material: $\geq 0.38 \text{ mm}$

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

Value for the permeation: Level ≤ 3

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

· Eye protection:

Safety glasses



Tightly sealed goggles.

· Body protection: Protective work clothing.

9 Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Pasty

Colour: Yellow

· Odour: Characteristic

· Odour threshold: Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: undetermined

Boiling point/Boiling range: undetermined

· Flash point: Not applicable

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· Flammability (solid, gaseous)	Not applicable.
· Ignition temperature:	
· Decomposition temperature:	Not determined.
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	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 %
· 9.2 Other information	No further relevant information available.

10 Stability and reactivity

- 10.1 Reactivity
- 10.2 Chemical stability
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: Void

11 Toxicological information

- 11.1 Information on toxicological effects
- **Acute toxicity:**

· LD/LC50 values relevant for classification:		
25068-38-6 Bisphenol A Diglycidylether		
Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)
9003-36-5 Bis-[4-(-2,3-epoxypropoxy)phenyl]-methane		
Oral	LD50	> 5000 mg/kg (rat)

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

12 Ecological information

12.1 Toxicity

Aquatic toxicity:

25068-38-6 Bisphenol A Diglycidylether

EC50/24h 3.6 mg/L (daphnia)

LC50/96h 1.5 mg/l (fish)

9003-36-5 Bis-[4-(-2,3-epoxypropoxy)phenyl]-methane

EC50/24h 2 mg/L (daphnia)

LC50/96h 2 mg/l (fish)

- **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 water fleas
Toxic for fish
- **Additional ecological information:**
- **General notes:**
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Also poisonous for fish and plankton in water bodies.
Toxic for aquatic organisms
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

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 dangerous substances

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

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), Bis-[4-(-2,3-epoxypropoxy)phenyl]-methane)

· IMDG

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight = 700), Bis-[4-(-2,3-epoxypropoxy)phenyl]-methane), MARINE POLLUTANT

· IATA

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight = 700), Bis-[4-(-2,3-epoxypropoxy)phenyl]-methane)

· 14.3 Transport hazard class(es)

· ADR



· Class

9 (M6) Miscellaneous dangerous substances and articles.

· Label

9

· IMDG, IATA



· Class

9 Miscellaneous dangerous substances and articles.

· Label

9

· 14.4 Packing group

· ADR, IMDG, IATA

III

· 14.5 Environmental hazards:

Product contains environmentally hazardous substances: reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight = 700)

· Marine pollutant:

Yes

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):

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- | | |
|--|-----------------|
| · EMS Number: | F-A,S-F |
| · 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | |
| · ADR | |
| · Limited quantities (LQ) | 5L |
| · Transport category | 3 |
| · Tunnel restriction code | E |

15 Regulatory information

- **15.2 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**

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.

R36/38 Irritating to eyes and skin.

R43 May cause sensitisation by skin contact.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- **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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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**
No further relevant information available.
- **Application of the substance / the preparation** *root canal filling material*
- **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@dentsply.com
- **Further information obtainable from:**
 - Departement Analytical Research / Research & Development for technical information
 - Departement Marketing & Sales for distribution of the safety data sheets
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

2 Hazards identification

- **2.1 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 is according to the latest editions of the EU-lists, and extended by company and literature data.
- **2.2 Label elements**
- **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).
- **Special labelling of certain preparations:**
Contains TCD-diamin. May produce an allergic reaction.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

3 Composition/information on ingredients

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

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Trade name: AH Plus Paste B

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CAS: 113506-22-2	N,N'-Dibenzyl-5-oxanonandiamin-1,9 ■ Xn R22; ■ Xi R36/37/38 ⚠ 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 ■ Xn R22; ■ Xi R36/37/38 ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-10%

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

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.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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.
- **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.

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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 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.

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7 Handling and storage

- **7.1 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 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.

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.

Respiratory protection: 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

Body protection: Protective work clothing.

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form: Pasty

Colour: White

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· Odour:	Characteristic
· Odour threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· Flash point:	Not applicable
· Flammability (solid, gaseous)	Not applicable.
· Ignition temperature:	
Decomposition temperature:	Not determined.
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	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.

10 Stability and reactivity

- **10.1 Reactivity**
- **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:** Irritant gases/vapours

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Trade name: **AH Plus Paste B**

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11 Toxicological information

11.1 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 by prolonged exposure.

Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

12.1 Toxicity

• **Aquatic toxicity:** No further relevant information available.

• **12.2 Persistence and degradability** No further relevant information available.

• **12.3 Bioaccumulative potential** No further relevant information available.

• **12.4 Mobility in soil** No further relevant information available.

Additional ecological information:

General notes:

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.

• **12.6 Other adverse effects** No further relevant information available.

13 Disposal considerations

13.1 Waste treatment methods

• **Recommendation** Smaller quantities can be disposed of with household waste.

European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

Uncleaned packaging:

• **Recommendation:** Disposal must be made according to official regulations.

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

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- | | |
|---|-----------------|
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | Not applicable. |

15 Regulatory information

- 15.2 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.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

R22 Harmful if swallowed.

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

- 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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