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l Identification of the substan	ce/mixture and of the company/und	ertaking
· 1.1 Product identifier		
No further relevant information av	substance or mixture and uses advised aga ailable. preparation root canal filling material	uinst
 1.3 Details of the supplier of the set 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@det 		
- Departement Marketing & Sales	om: h / Research & Development for technical in for distribution of the safety data sheets : +49-(0)7531-583-0 8:00 - 17:00 (GMT	·
		
2 Hazards identification		
• 2.1 Classification of the substance		
• Classification according to Direct Xi; Irritant R36/38: Irritating to eyes and sk	ive 67/548/EEC or Directive 1999/45/EC	
Xi; Sensitising		
R43: May cause sensitisation N; Dangerous for the environment		
• Information concerning particula The product has to be labelled d	sms, may cause long-term adverse effects in r hazards for human and environment: ue to the calculation procedure of the "Ge	-
preparations of the EU" in the late • Classification system:		
• 2.2 Label elements	he latest editions of the EU-lists, and extend	ed by company and literature date
· Labelling according to EU guidel	ines: and marked in accordance with EU Dire	ectives / Ordinance on Hazardor
\cdot Code letter and hazard designation	n of product:	
Xi Irritant N Dangerou	s for the environment	
• Hazard-determining components Bisphenol A Diglycidylether Bis-[4-(-2,3-epoxypropoxy)phenyl		
• Risk phrases: 36/38 Irritating to eyes and skin.		
		(Contd. on page

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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 compo	onents:	
CAS: 25068-38-6 NLP: 500-033-5	Bisphenol A Diglycidylether Xi R36/38; Xi R43; N R51/53 Aquatic Chronic 2, H411; OSkin 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; 2 N R51/53 Aquatic Chronic 2, H411; () Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. I, 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
- \cdot Suitable extinguishing agents
- CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- \cdot 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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· Flash point:

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	(Contd. of page 3)
· 8.2 Exposure controls	
· Personal protective equipment	
• General protective and hygienic me	
Keep away from foodstuffs, beverage	
Immediately remove all soiled and co	
	re to be adhered to when handling chemicals.
Wash hands before breaks and at the	
Avoid contact with the eyes and skin.	
· Respiratory protection: Not necessar	ry if room is well-ventilated.
· Protection of hands:	
MA	
Protective clover	
Protective gloves.	
The glove material has to be imperm	eable and resistant to the product/ the substance/ the preparation.
	nsideration of the penetration times, rates of diffusion and the degradation
• Material of gloves	nsideration of the penetration times, rates of affusion and the degradation
Nitrile rubber, NBR	
Recommended thickness of the mater	rial > 0.38 mm
	loes not only depend on the material, but also on further marks of quality and
	acturer. As the product is a preparation of several substances, the resistance
	ulated in advance and has therefore to be checked prior to the application.
• Penetration time of glove material	
Value for the permeation: Level ≤ 3	
	b be found out by the manufacturer of the protective gloves and has to be
observed.	
· Eye protection:	
Safety glasses	
Tishda anglad ang dar	
Tightly sealed goggles.	
· Body protection: Protective work clo	nthing
bouj protection. Trotective work etc	
9 Physical and chemical proper	ties
• 9.1 Information on basic physical a	nd 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
- string point, Donning runger	

Not applicable

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		(Contd. of page 4)
· 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/wa	ter): 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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Trade name: AH Plus Paste A

· 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.
- · Ecotoxical 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.

14.1 UN-Number	
ADR, IMDG, IATA	UN3082
14.2 UN proper shipping name ADR	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCI LIQUID, N.O.S. (reaction product: bisphenol-A
IMDG	(epichlorhydrin) epoxy resin (number average molecula weight = 700), Bis-[4-(-2,3-epoxypropoxy)phenyl]-methane) ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUII N.O.S. (reaction product: bisphenol-A-(epichlorhydrin) epox resin (number average molecular weight = 700), Bis-[4-(-2, epoxypropoxy)phenyl]-methane), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUII
	<i>N.O.S.</i> (reaction product: bisphenol-A-(epichlorhydrin) epox resin (number average molecular weight = 700), Bis-[4-(-2,3 epoxypropoxy)phenyl]-methane)
14.3 Transport hazard class(es)	
ADR	
Class Label	9 (M6) Miscellaneous dangerous substances and articles. 9
IMDG, IATA	
Class Label	9 Miscellaneous dangerous substances and articles. 9
14.4 Packing group ADR, IMDG, IATA	III
14.5 Environmental hazards:	Product contains environmentally hazardous substances reaction product: bisphenol-A-(epichlorhydrin) epoxy rest (number average molecular weight = 700)
Marine pollutant:	Yes Symbol (fish and tree)
Special marking (ADR): Special marking (IATA):	Symbol (fish and tree) Symbol (fish and tree)
14.6 Special precautions for user Danger code (Kemler):	<i>Warning: Miscellaneous dangerous substances and articles.</i> 90

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Safety data sheet according to 1907/2006/EC, Article 31

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· EMS Number:	F-A,S-F	
· 14.7 Transport in bulk according to Ann		
MARPOL73/78 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
- \cdot * 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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		(Contd. of page 1)
CAS: 113506-22-2	N,N'-Dibenzyl-5-oxanonandiamin-1,9	10-25%
	🗙 Xn R22; 🗙 Xi R36/37/38	
CAS: 768-94-5	amantadine	2.5-10%
EINECS: 212-201-2	🗙 Xn R22; 🗙 Xi R36/37/38	
	① Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

• 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
- $\cdot \textit{Protective equipment: Self-contained respiratory protective device.}$

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 trough 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:PastyColour:White

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		(Contd. of page 2
· 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/wa	ter): 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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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 succeptible 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.

· 14.1 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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		(Contd. of page 5)
· 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 Anno MARPOL73/78 and the IBC Code	e x II of 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

• Kelevan	t phrases
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
R22	Harmful if swallowed.
R36/37/3	38 Irritating to eyes, respiratory system and skin.
· Departm	nent issuing MSDS: Analytical Research
· Contact:	HotLine for urgent technical support: +49-7531-583-333
$\cdot * Data c$	ompared to the previous version altered.