according to 190//2006/EC, Article

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

· 1.1 Product identifier

· Trade name: AH 26 Resin

- · 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: Research and Development

• 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 GB CLP regulation. Hazard pictograms



GHS07 GHS09

· Signal word Warning

· Hazard-determining components of labelling:

2.2-Bis-[4-(2.3-epoxy-propoxy)-phenyl]-propan

· 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.

• Additional information:

As this product is a medical device in the meaning of Directive 93/42/EEC and regulation (EC) 2017/745 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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- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
- Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

Dungerous compone	1663 •	
CAS: 1675-54-3	2.2-Bis-[4-(2.3-epoxy-propoxy)-phenyl]-propan	50-100%
EINECS: 216-823-5	Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin	
	Sens. 1, H317	
	Specific concentration limits: Eye Irrit. 2; H319: $C \ge 5 \%$	
	Skin Irrit. 2; H315: C ≥ 5 %	
4 1 11 4 1 4 0		

• 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
- *After inhalation Supply fresh air and to be sure call for a doctor.*
- After skin contact Immediately wash with water and soap and rinse thoroughly.
- · After eye contact
- Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- *After swallowing If symptoms persist consult doctor.*
- · Information for doctor No further relevant information available.
- 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.

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 clothing.
- · 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). 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.

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SECTION 7: Handling and storage

• 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace. Observe normal care for working with chemicals.

- Information about fire and explosion protection: No special measures required.
- · Handling Product is intended for dental use only.
- 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: Store away from oxidising agents.
- · Further information about storage conditions:
- Store in cool, dry conditions in well sealed receptacles.
- Protect from heat and direct sunlight.

· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see item 7.
- · Individual protection measures, such as 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.
- · Hand protection



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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

· Material of gloves

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

Penetration time of glove material

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

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· Eye/face protection



Tightly sealed goggles.

· Body protection: Protective work clothing.

· Self-reactive substances and mixtures

SECTION 9: Physical and chemical properties • 9.1 Information on basic physical and chemical properties · General Information · Physical state Fluid · Colour: Light yellow · Odour: Characteristic · Odour threshold: Not determined. • Melting point/freezing point: undetermined · Boiling point or initial boiling point and boiling range $> 200 \ ^{\circ}C$ · Flammability Not applicable. · Lower and upper explosion limit · Lower: Not determined. · Upper: Not determined. · Flash point: > 93 °C · Ignition temperature: *Not applicable* • Decomposition temperature: Not determined. · pH at 20 °C 8 · Viscosity: · Kinematic viscosity Not determined. · dynamic: Not determined. · Solubility · Water: Not miscible or difficult to mix · Partition coefficient n-octanol/water (log value) Not determined. · Vapour pressure at 20 °C: 23 hPa · Density and/or relative density • Density at 20 °C: 1.17 g/cm³ · Relative density Not determined. · Vapour density Not determined. • 9.2 Other information · Appearance: · Form: Fluid · Important information on protection of health and environment, and on safety. • Auto-ignition temperature: Product is not selfigniting. Product does not present an explosion hazard. · Explosive properties: · Change in condition · Evaporation rate Not determined. · Information with regard to physical hazard classes Void · Explosives · Flammable gases Void · Aerosols Void · Oxidising gases Void · Gases under pressure Void · Flammable liquids Void · Flammable solids Void

Void

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· Pyrophoric liquids	Void	
· Pyrophoric solids	Void	
Self-heating substances and mixtures	Void	
· Substances and mixtures, which emit flamma	ble	
gases in contact with water	Void	
· Oxidising liquids	Void	
· Oxidising solids	Void	
· Organic peroxides	Void	
· Corrosive to metals	Void	
Desensitised explosives	Void	

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 oxidants

strong acids

• 10.6 Hazardous decomposition products: No dangerous decomposition products known

SECTION 11: Toxicological information

· 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

· Skin corrosion/irritation Causes skin irritation.

- Serious eye damage/irritation Causes serious eye irritation.
- *Respiratory or skin sensitisation* May cause an allergic skin reaction.

• 11.2 Information on other hazards

• Endocrine disrupting properties

CAS: 1675-54-3 2.2-Bis-[4-(2.3-epoxy-propoxy)-phenyl]-propan

List II

SECTION 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.
- 12.5 Results of PBT and vPvB assessment
- *PBT:* Not applicable.
- · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties For information on endocrine disrupting properties see section 11.
- · 12.7 Other adverse effects
- · Remark: Toxic for fish
- Additional ecological information:
- · General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Also poisonous for fish and plankton in water bodies.

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Toxic for aquatic organisms

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.

• Uncleaned packaging:

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

14.1 UN number or ID number	
· ADR, IMDG, IATA	UN3082
· 14.2 UN proper shipping name	
· ADR	3082 ENVIRONMENTALLY HAZARDOU
	SUBSTANCE, LIQUID, N.O.S. (2.2-Bis-[4-(2.3-epoxy propoxy)-phenyl]-propane)
·IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANCE
	LIQUID, N.O.S. (2.2-Bis-[4-(2.3-epoxy-propoxy)
	phenyl]-propane), MARINE POLLUTANT
· IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCI
	LIQUID, N.O.S. (2.2-Bis-[4-(2.3-epoxy-propoxy) phenyl]-propane)
· 14.3 Transport hazard class(es)	r, J. r. v p)
· ADR	
ADR	
· Class	9 (M6) Miscellaneous dangerous substances an articles.
· Label	9
· IMDG, IATA	
· Class	9 Miscellaneous dangerous substances and articles.
· Label	9
· 14.4 Packing group	
· ADR, IMDĞ, IATA	III
14.5 Environmental hazards:	
• Marine pollutant:	Symbol (fish and tree)
· Special marking (ADR):	Symbol (fish and tree)

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14.6 Special precautions for user	Warning: Miscellaneous dangerous substances and articles.
Hazard identification number (Kemler code):	90
EMS Number:	F-A,S-F
Stowage Category	A
14.7 Maritime transport in bulk according to IM	10
instruments	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
Transport category	3
Tunnel restriction code	(-)
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 pe 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 ar complied with.
IMDG	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: El
	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
UN "Model Regulation":	UN 3082 ENVIRONMENTALLY HAZARDOU
~	SUBSTANCE, LIQUID, N.O.S. (2.2-BIS-[4-(2.3
	EPOXY-PROPOXY)-PHENYL]-PROPANE), 9, III

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t
- 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.

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[·] Directive 2012/18/EU

[·] Named dangerous substances - ANNEX I None of the ingredients is listed.

[·] Seveso category E2 Hazardous to the Aquatic Environment

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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:	
ADDR: Accord relatif au transport international des marchandises dangereuses par route (European Agre	amont Concarning t
International Carriage of Dangerous Goods by Road)	emeni Concerning i
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)	
PBT: Persistent, Bioaccumulative and Toxic	
vPvB: very Persistent and very Bioaccumulative	
Skin Irrit. 2: Skin corrosion/irritation – Category 2	
<i>Eye Irrit. 2: Serious eye damage/eye irritation – Category 2</i>	
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.	