

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

Printing date 09.03.2015


Version number 7

Revision: 09.03.2015

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

- **1.1 Product identifier**
- **Trade name: THERMASEAL PLUS RIBBON 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@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)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Regulation (EC) No 1272/2008**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
 - **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008**
As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.
The product is classified and labelled according to the CLP regulation.
 - **Hazard pictograms**
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GHS07
- **Signal word** Warning
 - **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
 - **Precautionary statements**

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P264	Wash thoroughly after handling.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321	Specific treatment (see on this label).
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
 - **Additional information:**
Contains Octahydro-4,7-methano-1H-indendimethylamin. May produce an allergic reaction.

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

· **Dangerous components:**

CAS: 113506-22-2	<i>N,N'</i> -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 ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	3-<10%
CAS: 68889-71-4	Octahydro-4,7-methano-1H-indendimethylamin ⚠ Acute Tox. 3, H311; ⚠ Skin Corr. 1B, H314; ⚠ Acute Tox. 4, H302; Skin Sens. 1, H317	0,3-<1%

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

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information** No special measures required.
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
Seek medical treatment.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Information for doctor** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

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

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SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures** Wash hands before breaks and at the end of work.
- **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

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· **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.
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· 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.
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· Ignition temperature:

· Decomposition temperature:	Not determined.
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· Self-igniting:	Product is not selfigniting.
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· Danger of explosion:	Product does not present an explosion hazard.
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· Explosion limits:

· Lower:	Not determined.
· Upper:	Not determined.

· Vapour pressure:	Not determined.
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· Density:	Not determined
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· Relative density	Not determined.
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· Vapour density	Not determined.
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· Evaporation rate	Not determined.
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· Solubility in / Miscibility with

· Water:	Not miscible or difficult to mix
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· Partition coefficient (n-octanol/water):	Not determined.
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· Viscosity:

· dynamic:	Not determined.
· kinematic:	Not determined.

· Solvent content:

· Organic solvents:	0,0 %
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· Solids content:	89,7 %
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· 9.2 Other information	No further relevant information available.
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SECTION 10: Stability and reactivity

· 10.1 Reactivity	No further relevant information available.
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- **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

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

LD/LC50 values relevant for classification:

AH Plus Paste B

Oral	LD50	3381 mg/kg (rat) (ATE)
Dermal	LD50	66667 mg/kg (rat) (ATE)

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

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

Oral	LD50	900 mg/kg (rat)
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68889-71-4 Octahydro-4,7-methano-1H-indendimethylamin

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

Primary irritant effect:

- **on the skin:** Irritant to skin and mucous membranes.

- **on the eye:** Irritating effect.

- **Sensitisation:** Sensitising effect by skin contact is possible by prolonged exposure.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

768-94-5 amantadine

EC50/48h	22,1 mg/L (daphnia magna)
LC50/96h	25 mg/l (Fish acute toxicity study)

68889-71-4 Octahydro-4,7-methano-1H-indendimethylamin

LC50/96h	125 mg/l (Fish acute toxicity study)
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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.

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.

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· **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.

· **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:**

· **Marine pollutant:** No

· **14.6 Special precautions for user** Not applicable.

· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

· **UN "Model Regulation":** -

SECTION 15: Regulatory information

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

No further relevant information available.

· **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.

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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.

· **Department issuing MSDS:** Analytical Research

· **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

Acute Tox. 4: Acute toxicity, Hazard Category 4

Acute Tox. 3: Acute toxicity, Hazard Category 3

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

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

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