according to Regulation (EC) 1907/2006



Date of issue: 19. October 2010 print date: 19 October 2010

1. Identification of the substance/preparation and of the company

Identification of the product:

Product name: 2-Seal Paste A

Use of the substance/preparation: Root canal filling material

Manufacturer/supplier identification:

Company: VDW GmbH

Bayerwaldstr.15, D-81737 München, Germany Tel: ++49 89 62734-0

e-mail: info@vdw-dental.com

Contact for information: Quality Management

Telephone: ++49 89 62734-0 • Telefax: ++49 89 62734-340

Emergency Call: Giftnotruf: Klinikum Rechts der Isar München Telephone: ++49 89-19240

2. Hazard Identification

Seal Paste A is a medical product according Directive 93/42/EC and no hazardous substance or preparation according Regulation 1272/2008 EC.

3. Composition / information on ingredients

Preparation

Components:

Name according Regulation EG:	CAS-No.	EG-No.	Risk symbols	R-Phrases	Content
Bisphenol-A Diglycidylether	25068-38-6	216-823-5	Xi, N	36/38, 43, 51/53	25-50%
Bis-[4-(-2,3-epoxy- propoxy)phenyl]-methan	9003-36-5	500-006-8	Xi, N	36/38, 43, 51/53	10-25%

4. First aid measures

After inhalation: fresh air. If feeling unwell contact doctor

After skin contact: wash off with plenty of water

After eye contact: rinse out 15 min. with plenty of water with the eyelid held wide open. Consult

doctor.

After swallowing: if victim is still conscious, make him drink plenty of water,

Consult doctor if feeling unwell.

5. Fire-fighting measures

Suitable extinguishing media: CO₂, water, foam, powder

Special risks: In event of fire formation of hazardous combustion gases or vapours possible

2-Seal Paste A Page 1 of 4

according to Regulation (EC) 1907/2006

Date of issue: 19. October 2010 print date: 19 October 2010



Accidental release measures

Procedures for cleaning / absorption:

Take up carefully mechanical. Forward for disposal. Clean up affected area

7. Handling and storage

Handling: Avoid contact with eyes, skin and clothes **Storage:** Tightly closed at a dark and dry place. $(15-25^{\circ})$

8. Exposure controls / personal protection

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier

Respiratory protection: not necessary
Eye protection: required (EN 166)

Hand protection: in full contact: Glove material: latex or butyl rubber

Layer thickness: 0,4 mm
Breakthrough time: > 480 min

Additional reference:

The data are based on own examinations, literature data and information from glove manufacturers or are derived by analogy reasoning from similar materials.

It is to be noted that the daily life of a chemical protection glove can be clearly shorter in practice because of the many factors of influence (e.g. temperature, stretch etc.) than the permeation time determined after EN 374.

Industrial hygiene:

Change contaminated clothing. Wash hands and face after working with substance.

Under no circumstances eat or drink at workplace

Physical and chemical properties

Form: pasty Colour: pasty yellow

Odour: characteristic

Flash point: not available

Ignition temperature: not available

Vapour pressure: (20℃) not available

Density: (20℃) not available

Solubility in water (20℃) slightly soluble

pH-value not available

2-Seal Paste A Page 2 of 4

according to Regulation (EC) 1907/2006

Date of issue: 19. October 2010 print date: 19 October 2010



10. Stability and reactivity

Hazardous decomposition products:

no information available

Hazardous reactions:

No dangerous reactions known

Conditions to be avoided: Strong heating

Substances to be avoided no information available

Hazardous decomposition products: no information available

11. Toxicological information

Acute toxicity:

No toxicological data available

Further toxicologic information

After eye contact: irritation

After skin contact: irritation to skin and mucosa
Sensitization: sensitization by skin contact

Further data:

The product should be handled with the care usual when dealing with chemicals

12. Ecological information

Ecotoxic effects:

Quantitative data on the ecological effect of this product are not available

Further ecologic data:

No ecological problems are to be expected when the product is handled and used with due care and attention

13. Disposal considerations

Contact a licensed professional waste disposal service to dispose of this material. Observe all federal, state and local environmental regulations

14. Transport information

Not subject to transport regulations

The transport regulations are cited according to international regulations and in form applicable in Germany. Possible national deviations in other countries are not considered

2-Seal Paste A Page 3 of 4

according to Regulation (EC) 1907/2006

Date of issue: 19. October 2010 print date: 19 October 2010



15. Regulatory information

Labelling according to EC Directives:

Seal Paste A is a medical product according Directive 90/385 EC and 93/42/EC and no hazardous substance or preparation according Regulation 1907/2006 EC

Symbol: -

R-phrases:

S-phrases:

16. Other information

Revised version

R-phrases listed under point 3: R 36/38 Irritating to eyes and skin

R 43 May cause sensitization by skin contact

R 51/53 Toxic to aquatic organisms, may cause long-term adverse

effects in the aquatic environment.

This Safety Data sheet is corresponding to the GHS (Globally Harmonized System of Classification and Labelling of chemicals)

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide.

VDW GmbH shall not be held liable for any damage resulting from handling or from contact with the above product

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions.

It does not represent a guarantee of the properties of the product.

2-Seal Paste A Page 4 of 4

according to Regulation (EC) 1907/2006

Date of issue: 19 October 2010 print date: 19 October 2010



1. Identification of the substance/preparation and of the company

Identification of the product:

Product name: 2-Seal Paste B

Use of the substance/preparation: Root canal filling material

Manufacturer/supplier identification:

Company: VDW GmbH

Bayerwaldstr.15, D-81737 München, Germany Tel: ++49 89 62734-0

e-mail: info@vdw-dental.com

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Emergency Call: Giftnotruf: Klinikum Rechts der Isar München Telephone: ++49 89-19240

2. Hazard Identification

Seal Paste B is a medical product according Directive 93/42/EC and no hazardous substance or preparation according Regulation 1272/2008 EC.

3. Composition / information on ingredients

Preparation

Components:

Name according Regulation EC:	CAS-No.	EG-No.	Risk symbols	R-Phrases	Content
N,N'-Dibenzyl-5- oxanonandiamine-1,9	113506-22-2		Xn	22, 36/37/38	2,5-10%
1-Aminoadamantane	768-94-5	212-201-2	Xn	22, 36/37/38	2.5-10%

4. First aid measures

After inhalation: fresh air. If feeling unwell contact doctor

After skin contact: wash off with plenty of water

After eye contact: rinse out 15 min. with plenty of water with the eyelid held wide open. Consult

doctor.

After swallowing: if victim is still conscious, make him drink plenty of water,

Consult doctor if feeling unwell.

5. Fire-fighting measures

Suitable extinguishing media: CO₂, water, foam, powder

Special risks: In event of fire formation of hazardous combustion gases or vapours possible

6. Accidental release measures

Procedures for cleaning / absorption:

Take up carefully mechanical. Forward for disposal. Clean up affected area

2-Seal Paste B Page 1 of 4

according to Regulation (EC) 1907/2006

Date of issue: 19 October 2010 print date: 19 October 2010



7. Handling and storage

Handling: Avoid contact with eyes, skin and clothes. Do not inhale dusts.

Storage: Tightly closed at a dark and dry place. (15-25℃)

8. Exposure controls / personal protection

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier

Respiratory protection: not necessary
Eye protection: required (EN 166)

Hand protection: in full contact: Glove material: latex or butyl rubber

Layer thickness: 0,4 mm
Breakthrough time: > 480 min

Additional reference:

The data are based on own examinations, literature data and information from glove manufacturers or are derived by analogy reasoning from similar materials.

It is to be noted that the daily life of a chemical protection glove can be clearly shorter in practice because of the many factors of influence (e.g. temperature, stretch etc.) than the permeation time determined after EN 374.

Industrial hygiene:

Change contaminated clothing. Wash hands and face after working with substance.

Under no circumstances eat or drink at workplace

9. Physical and chemical properties

Form: pasty Colour: white

Odour: characteristic

Flash point: not available

Ignition temperature: not available

Vapour pressure: (20°) not available Density: (20°) not available

Solubility in water (20°C) slightly soluble

pH-value not available

10. Stability and reactivity

Hazardous decomposition products:

no information available

Hazardous reactions:

No dangerous reactions known

Conditions to be avoided: Strong heating

Substances to be avoided no information available

Hazardous decomposition products: no information available

2-Seal Paste B Page 2 of 4

according to Regulation (EC) 1907/2006

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11. Toxicological information

Acute toxicity:

1-Aminoadamantane: N,N'-Dibenzyl-5-oxanonandiamine-1,9: LD_{50} (oral, rat) 900 mg/kg LD_{50} (oral, rat) 458 mg/kg

LD₅₀ (oral, mouse) 500 mg/kg

Further toxicologic information

After eye contact: irritation
After skin contact: irritation to skin

Sensitization: sensitization by skin contact possible

Further data:

The product should be handled with the care usual when dealing with chemicals

12. Ecological information

Ecotoxic effects:

Quantitative data on the ecological effect of this product are not available

Further ecologic data:

No ecological problems are to be expected when the product is handled and used with due care and attention

13. Disposal considerations

Contact a licensed professional waste disposal service to dispose of this material. Observe all federal, state and local environmental regulations

14. Transport information

Not subject to transport regulations

The transport regulations are cited according to international regulations and in form applicable in Germany. Possible national deviations in other countries are not considered

15. Regulatory information

Labelling according to EC Directives:

Seal Paste B is a medical product according Directive 90/385 EC and 93/42/EC and no hazardous substance or preparation according Regulation 1907/2006 EC

Symbol: -

R-phrases:

S-phrases: -

2-Seal Paste B Page 3 of 4

according to Regulation (EC) 1907/2006

Date of issue: 19 October 2010 print date: 19 October 2010



16. Other information

Revised version

R-phrases listed under point 3: R 22 Harmful if swallowed

R 36/37/38 Irritating to eyes, respiratory system and skin

This Safety Data sheet is corresponding to the GHS (Globally Harmonized System of Classification and Labelling of chemicals)

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide.

VDW GmbH shall not be held liable for any damage resulting from handling or from contact with the above product

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions.

It does not represent a guarantee of the properties of the product.

2-Seal Paste B Page 4 of 4