

- ADSEAL : KometSeal -

1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : Root Canal Sealer Brand name: ADSEAL : KometSeal

1.2. Relevant identified uses of the substance or mixture and uses advised against

Root canal sealing materials

1.3. Details of the supplier of the safety data sheet

Registered company name: METABIOMED CO., LTD.

Address: Head Office & Osong Factory) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu,

Cheongju-si, Chungcheongbuk-do, Korea

Telephone: (82-43) 216-0433, 0434 Fax: (82-43) 216-0438

e-mail: info@meta-biomed.com

Manufacturer : METABIOMED CO., LTD.

Distributor/Importer for USA and Canada: Komet US LLC

1.4. Emergency telephone number

(82-43) 216-0433, 0434



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2. Hazards identification

- Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Skin irritation, Category 2(Skin Irrit. 2, H315)

Eye irritation, Category 2(Eye Irrit. 2, H319)

Specific target organ toxicity(single exposure), Category 3(STOT SE 3, H335)

This mixture dose not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

- Label elements

Labelling according to Regulation (EC) No 1272/2008

- * GHS label elements including precautionary statements
 - Hazard Pictograms



GHS07

- Signal word : Warning

- Product identifiers : CAS 25036-25-3, Bisphenol A Diglycidyl Ether – Bisphenol A Copolymer

- Hazard statement(s) : H315 Causes skin irritation.

H319 Causes serious eye irritation. H335 May cause respiratory irritation.

- Precautionary Statement(s) : P261 Avoid breathing vapours.

Prevention P264 Wash hands thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves/protective clothing/eye protection/ face

protection.

- Response : P302+P352 IF ON SKIN: Wash with plenty of water.

P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in

apposition comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue

rinsing.

P312 Call a POISON CENTER/doctor/if you feel unwell.



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P332+P313 If skin irritation occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before reuse.

- Storage P403+P233 Store in a well-ventilated place. Keep container tightly closed.

- Disposal P501 Dispose of contents/container at a disposal facility in accordance

with local regulations.

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern'(SVHC) >=0.1% published by the European CHemical Agency(ECHA) under articl 57 of REACH: http://echa.europa.eu/fr/candidate-list-table

The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annex XIII of the REACH regulations EC1907/2006.

3. Composition/information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

				Classification	Classification
Chemical Name	CAS No.	EC No.	Wt.%	according to Directive	according to
Onemical Ivallic	OAO NO.	LO 140.	VVI. 70	67/548/EEC	Regulation(EC) No
				01/340/LLO	1272/2008[CLP]
Poly(1,4-	54667-43-				GHS07
butanediol)bis(4-	5	-	30~40	-	Warning
aminobenzoate)	5				H319
Bisphenol A					GHS07
diglycidyl ether –	25036-25-		20~30		
bisphenol A	3	-	20~30	-	Warning
copolymer					H315, H319, H335
2 Hydroxyothyd					GHS07
2-Hydroxyethyl	87-28-5	201-737-2	15~20	-	Warning
salicylate					H302
Triethanolamine	102-71-6	203-049-8	<10	Xi;R36/37/38	GHS07
THEMANOIANNIE	102-71-0	203-049-0	\10		Warning



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					H319
Calcium oxide	1305-78-8	215-138-9	<5	-	-
•					

4. First aids measures

4.1. Description of first aid measures

- Eyes : Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

- Skin : Remove contaminated clothing and wash the skin thoroughly with soap and water

or a recognised cleaner.

Watch out for any remaining product between skin and clothing, watches, shoes, etc. If the contaminated area is widespread and/or there is damage to the skin, a

doctor must be consulted or the patient transferred to hospital.

- Inhalation : In the event of massive inhalation, remove the person exposed to fresh air. Keep

warm and at rest. If the person is unconscious, place in recovery position. Notify a doctor in all events, to ascertain whether observation and supportive hospital

care will be necessary.

If breathing is irregular or has stopped, effect mouth-to-mouth resuscitation and call

a doctor.

- Ingestion : Do not give the patient anything orally.

In the event of swallowing, if the quantity is small (no more than one mouthful),

rinse the mouth with water and consult a doctor.

Seek medical attention immediately, showing the label.

4.2. Most important symptoms and effects, both acute and delayed

Eyes : N/A
 Skin : N/A
 Inhalation : N/A
 Ingestion : N/A

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

- N/A

5. Fire fighting measures

5.1. Extinguishing media

- Extinguishing media : In the event of a fire, use: water, carbon dioxide, dry chemical agents



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5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed :

- carbon monoxide (CO)
- carbon dioxide (CO2)

5.3. Advice for firefighters

Due to the toxicity of the gas emitted on thermal decomposition of the products, fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non first aid worker

Avoid inhaling the vapors.

Avoid any contact with the skin and eyes.

If a large quantity has been spilt, evacuate all personnel and only allow intervention by trained operators equipped with safety apparatus.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Clean preferably with a detergent, do not use solvents.

6.4. Reference to other sections

N/A

7. Handling and storage

7.1. Precautions for safe handling

Follow all prevention measures on the SDS/labels.

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Fire prevention:

Handle in well-ventilated areas.



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Prevent access by unauthorised personnel.

Recommended equipment and procedures:

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Avoid inhaling vapors.

Avoid inhaling vapors. Carry out any industrial operation which may give rise to this in a sealed apparatus.

Provide vapor extraction at the emission source and also general ventilation of the premises.

Also provide breathing apparatus for certain short tasks of an exceptional nature and for emergency interventions.

In all cases, recover emissions at source.

Avoid skin and eye contact with this mixture.

Prohibited equipment and procedures:

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available

Storage

Keep the container tightly closed in a dry, well-ventilated place.

Packaging

Always keep in packaging made of an identical material to the original..

7.3. Specific end use(s)

No data available.

8. Exposure controls and personal protection

8.1. Control parameters

Occupational exposure limits:

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010):

CAS TWA: STEL: Ceiling: Definition: Criteria: 102-71-6 5 mg/m3 - - - -

1305-78-8 2 mg/m3 - - - -

- Belgium (Order of 19/05/2009, 2010):

CAS TWA: STEL: Ceiling: Definition: Criteria:

102-71-6 5 mg/m3 - - - -

1305-78-8 2 mg/m3 - - -

- France (INRS - ED984:2012):

CAS VME-ppm: VME-mg/m3: VLE-ppm: VLE-mg/m3: Notes: TMP No:



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1305-78-8 - 2 - - - -

- Switzerland (SUVA 2009):

CAS VME-mg/m3: VME-ppm: VLE-mg/m3: VLE-ppm: Temps: RSB:

1305-78-8 2i - 2i - 15 min -

- UK / WEL (Workplace exposure limits, EH40/2005, 2007) :

CAS TWA: STEL: Ceiling: Definition: Criteria:

1305-78-8 2 mg/m3 - - - -

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :









Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

Eye / face protection : Avoid contact with eyes.

Use eye protectors designed to protect against liquid splashes

Before handling, wear safety goggles with protective sides accordance with

standard EN166.

In the event of high danger, protect the face with a face shield.

Prescription glasses are not considered as protection.

Individuals wearing contact lenses should wear prescription glasses during

work where they may be exposed to irritant vapours.

Provide eyewash stations in facilities where the product is handled constantly.

- Hand protection : Wear suitable protective gloves in the event of prolonged or repeated skin

contact.

Use suitable protective gloves that are resistant to chemical agents in

accordance with standard EN374.

Gloves must be selected according to the application and duration of use at

the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question: other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of



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dexterity required.

Recommended properties:

- Impervious gloves in accordance with standard EN374

- Body protection : Avoid skin contact.

Wear suitable protective clothing.

Suitable type of protective clothing:

In the event of substantial spatter, wear liquid-tight protective clothing against chemical risks (type 3) in accordance with EN14605 to prevent skin contact. In the event of a risk of splashing, wear protective clothing against chemical

risks (type 6) in accordance with EN13034 to prevent skin contact. $\label{eq:entropy}$

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must

be washed.

- Respiratory protection : Avoid breathing vapours.

If the ventilation is insufficient, wear appropriate breathing apparatus.

When workers are confronted with concentrations that are above occupational exposure limits, they must wear a suitable, approved, respiratory protection

device.

Anti-gas and vapour filter(s) (Combined filters) in accordance with standard

EN14387 : - A1 (Brown)

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties							
- Appearance	: Paste	Paste - Vapor pressure					
- Odor	: Odorless:	- Vapor density	: N/A				
- Color	: Yellowish	- Relative density	: N/A				
- pH	: N/A	- Solubility(ies)	: Insoluble				
- Melting/freezing point	: N/A	- Partition coefficient :	: N/A				
- Initial boiling point and	: N/A	n-octaol/water					
boiling range		- Auto-ignition temperature	: N/A				
- Flash point	: N/A	- Decomposition temperature					
- Evaporation rate	: N/A	- Viscosity	: N/A				
- Flammability(solid, gas)	: N/A	- Explosive properties	: N/A				
- Upper/lower flammability or	: N/A	- Oxidising properties	: N/A				
explosive limits							



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9.2. Other information

No data available.

10. Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

heat

10.5 Incompatible materials

No data available.

10.6. Hazardous decomposition products

Carbon monoxide(CO), carbon dioxide(CO2)

11. Toxicological information

11.1. Information on toxicological effects

May cause irreversible damage to the skin; namely inflammation of the skin or the formation of erythema and eschar or oedema following exposure up to four hours.

May have reversible effects on the eyes, such as eye irritation which is totally reversible by the end of observation at 21 days.

Respiratory tract irritation may occur, together with symptoms such as coughing, choking and breathing difficulties.

- Substances

No toxicological data available for the substances.

- Mixture

No toxicological data available for the mixture.

Monograph(s) from the IARC (International Agency for Research on Cancer):

CAS 102-71-6: IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.

12. Ecological information

12.1. Toxicity

- Mixture



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No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

- Substances

BISPHENOL A DIGLYCIDYL ETHER - BISPHENOL A COPOLYMER (CAS: 25036-25-3)

Biodegradability: no degradability data is available, the substance is considered as not degrading quickly.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

German regulations concerning the classification of hazards for water (WGK) :

WGK 2 (VwVwS vom 27/07/2005, KBws): Hazardous for water.

13. Disposal considerations

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste:

Waste management is carried out without endangering human health, without harming the environment and, in particular without r isk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging:

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

14. Transport information

4.1. UN Number

N/A

14.2. UN proper shipping name

N/A



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14.3. Transport hazard class(es)

N/A

14.4. Packing Group

N/A

14.5. Environmental hazards

N/A

14.6. Special precautions for user

- ADR - road : N/A

- RID - rail : N/A

- IMDG - sea : N/A

- IATA - air : N/A

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Transport in bulk: N/A

15. Regulatory information

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

- Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 487/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 758/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 944/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 605/2014.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 1297/2014.
- Container information:

No data available.

- Particular provisions :

No data available.

- German regulations concerning the classification of hazards for water (WGK) :

WGK 2 (AwSV 21 April 2017): Ordinance on facilities for the handling of substances hazardous to water

- Standardised American system for the identification of hazards presented by the product in view of emergency procedures (NFPA 704):

NFPA 704, Labelling: Health=2 Inflammability=1 Instability/Reactivity=1 Specific Risk=none



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15.2. Chemical safety assessment

No data available.

16. Other information

The information contained in the Safety data sheet is correct to the best of our knowledge at the date of issue. It is intended as a guide for the safe use, handling, disposal, storage and transportation and is not intended as warranty or as a specification. The information relates only to the product specified and may not be suitable for combinations with other materials or in processes other than those specifically described herein.

- Abbreviations :

ADR: European agreement concerning the international carriage of dangerous goods by Road.

IMDG: International Maritime Dangerous Goods.

IATA: International Air Transport Association.

ICAO: International Civil Aviation Organisation

RID: Regulations concerning the International carriage of Dangerous goods by rail.

WGK: Wassergefahrdungsklasse (Water Hazard Class).

GHS07: Exclamation mark

PBT: Persistent, bioaccumulable and toxic. vPvB: Very persistent, very bioaccumulable.

SVHC: Substances of very high concern.

HISTORY

- Date of creation : 03-08-2015

- Revision number and Revision date

* Revision number : 3

* Date of last revision : 13-07-2020

- Prepared by : METABIOMED CO., LTD.