



Material Safety Data Sheet

- CeraSeal -

METABIOMED CO., LTD.

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

1.1. Product identifier

Product name : CeraSeal

Product code : D1CSL00

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

Cheongju Factory) 136, Mochung-ro, Seowon-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.

1.4. Emergency telephone number

(82-43) 216-0433, 0434

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)

This product reacts chemically with water or moisture, and specific intermediate products of this reaction can produce a strong alkaline material than that of the dry paste..

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



Material Safety Data Sheet

- CeraSeal -

METABIOMED CO., LTD.

- Signal word : Warning
- Hazard statement(s) : H315 Causes skin irritation.
H319 Causes serious eye irritation.
- Precautionary Statement(s) : P264 Wash hands thoroughly after handling.
Prevention P280 Wear protective gloves/protective clothing/eye protection/ face protection.
- Response : P302+P352 IF ON SKIN: Wash with plenty of water.
P321 Specific treatment: Wash skin thoroughly with cool water and pH-neutral soap or a mild detergent intended for use on skin.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
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 P402+P404 Store in a dry place. Store in a closed container.
- Disposal P501 Dispose of contents/container at a disposal facility in accordance with local regulations.

2.3. Other hazards

- Health : 2
- Flammability : 0
- Reactivity : 0

3. Composition/information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS No.	EC No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008[CLP]
Zirconium dioxide	1314-23-4	215-227-2	45~50	Xi Irritant R41, R43	H315, H319, H335
Tricalcium silicate	12168-85-3	235-336-9	20~30	Xi Irritant R36, R38	H315, H319
Dicalcium silicate	10034-77-2	215-710-8	1~10		
Tricalcium aluminate	12042-78-3	234-931-0	1~10		



Material Safety Data Sheet

- CeraSeal -

METABIOMED CO., LTD.

Thickening agent

- None are classified as hazardous to the health or environment and do not contribute to the classification of the product.
- The specific chemical identity and the exact concentration of the fillers in the product have been withheld as per Confidential Business Information.

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 recognized 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, expose 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



Material Safety Data Sheet

- CeraSeal -

METABIOMED CO., LTD.

5. Fire fighting measures

5.1. Extinguishing media

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

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.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Avoid contact with skin and eyes.

Avoid inhalation of dried product.

Wear personal protective equipment.

Remove contaminated clothing and personal protective equipment before entering eating areas.

Wash hands after handling product.

7.2. Conditions for safe storage, including any incompatibilities

No data available

Storage

Air and moisture sensitive.

Keep the container tightly closed in a dry

Store at room temperature in a dry area.

Protect from excessive heat and cold

Protect packaging against physical damage.

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

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

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

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





Material Safety Data Sheet

- CeraSeal -

METABIOMED CO., LTD.

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 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.

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.



Material Safety Data Sheet

- CeraSeal -

METABIOMED CO., LTD.

- Respiratory protection : Surgical face mask.
Handle product in a well-ventilated area.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Appearance	: Paste	- Vapor pressure	: N/A
- Odor	: Odorless:	- Vapor density	: N/A
- Color	: White	- Relative density	: N/A
- pH	: >12	- Solubility(ies)	: Slightly soluble
- Melting/freezing point	: N/A	- Partition coefficient :	: N/A
- Initial boiling point and boiling range	: N/A	n-octanol/water	
- Flash point	: N/A	- Auto-ignition temperature	: N/A
- Evaporation rate	: N/A	- Decomposition temperature	
- Flammability(solid, gas)	: N/A	- Viscosity	: N/A
- Upper/lower flammability or explosive limits	: N/A	- Explosive properties	: N/A
		- Oxidising properties	: N/A

9.2. Other information

No data available.

10. Stability and reactivity

10.1. Reactivity

Contact with water will result in hydration of the product and produces calcium hydroxide.

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

Avoid unintentional contact with water to prevent premature setting/curing; contact will result in hydration of the product and produces calcium hydroxide.

10.5 Incompatible materials

No data available.

10.6. Hazardous decomposition products

Decomposition will not spontaneously occur.



Material Safety Data Sheet

- CeraSeal -

METABIOMED CO., LTD.

11. Toxicological information

11.1. Information on toxicological effects

This product is a white paste that poses little immediate hazard. A single-term exposure to the paste is not likely to cause serious harm. However, exposure of sufficient amount and duration (either single or multiple) to the moist product can cause serious irritation to the skin and eyes in the form of chemical (caustic) burns. Similar tissue damage can occur if wet or moist areas of the body are exposed for sufficient duration to the product.

- 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) :

N/A

12. Ecological information

12.1. Toxicity

- Mixture

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

- Substances

No aquatic toxicity data available for the mixture.

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) :

No data available.

13. Disposal considerations

13.1. Waste treatment methods

Do not pour into drains or waterways.



Material Safety Data Sheet

- CeraSeal -

METABIOMED CO., LTD.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk 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

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 :

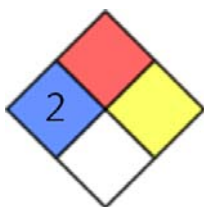
No data available.

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

No data available.

- 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=0 Instability/Reactivity=0 Specific Risk=0



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 : Wassergefährdungsklasse (Water Hazard Class).

GHS07 : Exclamation mark

PBT: Persistent, bioaccumulable and toxic.



Material Safety Data Sheet

- CeraSeal -

METABIOMED CO., LTD.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.

HISTORY

- **Date of creation** : 07-27-2018
- **Revision number and Revision date**
 - * Revision number : 0
 - * Date of last revision : 07-27-2018
- **Prepared by** : METABIOMED CO., LTD.