

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

Printing date 10/11/2022

Version number 0

Revision: 10/11/2022

SECTION I Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Identifier	Brand Name	Reference Number
	BC Universal Sealer	08.650.00.013.XX

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

Recommended use: Permanent obturation of the root canal

Restriction on use: For use only dental professionals

1.3. Details of the supplier of the safety data sheet

Manufacturer Vericom Co., LTD.

Address 48, Toegyegongdan 1-gil, Chuncheon-Si, Gangwon-Do 200-944, Korea

Telephone / Fax 82-31-441-2881 / 82-31-441-2883

E-mail vericom@vericom.co.kr

1.4. Emergency telephone number

82-31-441-2881

SECTION II Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labeled according to the CLP regulation.

Hazard pictograms N/A

Signal word N/A

Hazard-determining components of labeling N/A

Hazard Statements N/A

Precautionary statements N/A

2.3. Other hazards

Result of PBT and vPvB

PBT: Not applicable.

vPvB: Not applicable.

SECTION III Composition/information on ingredients

3.2 Chemical characterization: Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

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Dangerous components:

CAS: 1314-23-4 EC No.:215-227-2	Zirconium oxide Not applicable	15 ~ 25
CAS: 10101-41-4 EC No.:231-900-3	Calcium sulfate dehydrate Not applicable	< 5
CAS: 65997-17-3 EC No.: 266-046-0	Calcium sodium phosphosilicate Not applicable	< 5
CAS: 57-55-6 EC No.: 200-338-0	Propylene glycol Not applicable	2 ~ 7
CAS: 13463-67-7 EC No.: 236-675-5	Titanium dioxide Not applicable	2 ~ 7

Additional information For the wording of the listed hazard phrases refer to section 16.

SECTION IV First aid measures**4.1. Description of first aid measures**

Eye Contact: Immediately rinse eye with a large amount of water, get medical attention.

Skin Contact: Wash immediately with soap and water.

Inhalation: Remove with fresh air. If not breathing, give artificial respiration or give oxygen by professional.

Ingestion: Give a large amount of water, do not induce vomiting and seek medical attention.

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

Skin Contact – Skin irritation, drying, cracking or fissuring of the skin.

Eye contact – Severe irritation and/or inflammation.

Inhalation – Irritation to the moist mucus membranes of the nose, throat and upper respiratory system.

Ingestion – Internal discomfort or irritation to the digestive tract.

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

No further relevant information available.

SECTION V Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media

There is no restriction on the type of extinguisher.

5.2. Special hazards arising from the substance or mixture

No further relevant information available.

5.3. Advice for firefighters

Protective equipment: Respiratory protective device.

SECTION VI Accidental release measures

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6.1. Personal precautions, protective equipment and emergency procedures

See section 8

6.2. Environmental precautions

No special measures required.

6.3. Methods and material for containment and cleaning up

Wash spilled area with large amounts of water and dry thoroughly.

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.

SECTION VII Handling and storage**7.1. Precautions for safe handling**

For dental use only.

Avoid contact with skin and eyes.

Information about fire and explosion protection: No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Avoid exposure to intense light and elevated heat, store in a cool place.

7.3. Specific end use(S)

No further relevant information available.

SECTION VIII 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.

Zirconium oxide (CAS No. 1314-234)	
TWA	5 mg/m ³
STEL	10 mg/m ³ zirconium compound

Calcium sulfate dehydrate (CAS No.10101-41-4)	
ACGIH(20050 TWA	10 mg/m ³ (I) (Nasal symptoms)

Calcium sodium phosphosilicate (CAS No. 65997-17-3)	
Alveolar fraction	3 mg/m ³
Respirable fraction	10 mg/m ³

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Propylene glycol (CAS No. 57-55-6)	
Ireland OELV TWA Particulate.	10 mg/m ³
UK WEL TWA Particulate.	10 mg/m ³
UK WEL TWA Total vapour and particulates.	474 mg/m ³ 150ppm
WEEL TWA Aerosol.	10 mg/m ³

Titanium dioxide(CAS No. 13463-67-7)	
WEL long-time exposure limit (8-hour TWA reference period)	10 mg/m ³ (total inhalable) 4 mg/m ³ (respirable)

Additional information: The lists that were valid during the creation of this SDS were used as basis.

8.2. Exposure controls

Personal protective equipment

General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection: Not required.

Protection of hand: Protective gloves

Material of glove

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 cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

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

Eye/face protection: Safety glasses with side shield.

Body protection: Protective work clothing

SECTION IX Physical and chemical properties

9.1. Information on basic and chemical properties

Appearance

Form	Paste
Color	White
Odor	Odorless
pH	>12
Melting point/freezing point	Undetermined
Initial boiling point and boiling range	Undetermined
Flash point	Not applicable

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Evaporation rate	Not applicable
Flammability(solid, gas)	Not applicable
Upper/lower flammability or explosive limits	Not applicable
Vapor density	Not applicable
Relative density	2.0 g/cm ³
Solubility in water	Soluble
Partition coefficient: n-octanol/water	Not applicable
Auto-ignition temperature	Not applicable
Decomposition temperature	Not applicable
Viscosity	Not applicable
Explosive properties	Not applicable
Oxidizing properties	Not applicable

9.2. Other information

No further relevant information available.

SECTION X Stability and reactivity**10.1. Reactivity**

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

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known.

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 (caustic) calcium hydroxide.

10.5. Incompatible materials

Incompatible with acids, ammonia, ammonia nitrate, ammonium salts, aluminum metal and chlorine.

10.6. Hazard decomposition products

Decomposition will not spontaneously occur.

Contact with water will result in hydration of the product and produces (caustic) calcium hydroxide

SECTION XI Toxicological information**11.1. Information on toxicological effects****Acute toxicity** : No Acute toxicity data available.

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Skin sensitization : No sensitization

Serious eye damage/irritation : Not irritating

Germ cell mutagenicity : No mutagenic effect data available.

Carcinogenicity : No Carcinogenic effects data available.

Reproductive toxicity : No Reproductive toxicity data available.

STOT-single exposure : No STOT-single exposure data available.

STOT-repeated exposure : Not STOT-repeated exposure data available.

Aspiration hazard : No Aspiration hazard data available.

Additional toxicological information : When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

SECTION XII Ecological information

12.1. 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. Result of PBT and vPvB assessments : Not applicable.

12.6. Other adverse effects : No further relevant information available

SECTION XIII Disposal consideration

13.1. Waste treatment methods

Dispose of contents/container to in accordance with local/regional/national/international regulations.

SECTION XIV 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 : Void

14.4. Packing group

ADR, IMDG, IATA : Void

14.5. Environmental hazards

Marine pollutant : No

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14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

UN "Model Regulation": Void

SECTION XV Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

- The product is a medical device according to the Directive 93/42/EEC.
- Regulation (EC) No 1907/2006 ANNEX XVII conditions of restriction: 3

15.2. Chemical safety assessment

A Chemical safety assessment has not been carried out.

SECTION XVI Other information

This MSDS is taken from raw material MSDS and manufacturer's knowledge and experience. It is intended to describe our products from the point of view of safety requirements and is not intended to guarantee any particular properties.

Relevant phrases: N/A**Abbreviations and acronyms :**

CAS : Chemical Abstract Service

CLP : EC Regulation 1272/2008

ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road

ADN : European Agreement concerning the International Carriage of Dangerous Goods by Inland

IMDG : International Maritime Code for Dangerous Goods

IATA : International Air Transport Association

PBT : Persistent, Bioaccumulative and Toxic

vPvB : very Persistent and very Bioaccumulative