


SAFETY DATA SHEET

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SECTION I Identification of the substance/mixture and of the company/undertaking	
1.1. Product identifier	Sure-Seal Root
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	Sure Dent Corporation
Address	#809, 52, Sagimakgol-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea
Telephone / Fax	+82-31-737-4720 / +82-31-737-4724
E-mail	suredent@suredent.com
1.4. Emergency telephone number	+82-31-737-4720
SECTION II Hazards Identification	
2.1. Classification of the substance or mixture	
Classification according to Regulation (EC) No 1272/2008	
<i>Skin Irrit. 2</i>	<i>H315 Causes skin irritation.</i>
<i>Eye Irrit. 2</i>	<i>H319 Causes serious eye irritation.</i>
2.2. Label elements	
Labeling according to Regulation (EC) No 1272/2008	
<i>The product is classified and labeled according to the CLP regulation.</i>	
Hazard pictograms	
	
Signal word	Warning
Hazard-determining components of labeling	
<i>Zirconium oxide</i>	
<i>Calcium sodium phosphosilicate</i>	
Hazard Statements	
<i>H315 Causes skin irritation</i>	
<i>H319 Causes serious eye irritation</i>	
Precautionary statements	
<i>P280</i>	<i>Wear protective gloves/protective clothing/eye protection/face protection.</i>
<i>P305+P351+P338</i>	<i>If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses and immediately get medical attention.</i>
<i>P333+P313</i>	<i>If skin irritation or rash occurs: Get medical advice/attention.</i>

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P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information

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 of body contact, it is exempt from the labeling requirements according to regulation 1272/2008.

2.3. Other hazards

Result of PBT and vPvB assessments

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.

Dangerous components:		
CAS: 1314-23-4	Zirconium oxide Skin Irrit. 2, H315 ; Eye Irrit.2, H319	10-40%
CAS: 359684-27-8	Calcium sodium phosphosilicate Not applicable	1-10%

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

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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

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.

Additional information: The lists valid during the making were used as basis.

8.2. Exposure controls

Personal protective equipment

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

Respiratory protection: Not required.

Protection of hand: Protective gloves

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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

12.2

Melting point/freezing point

Undetermined

Initial boiling point and boiling range

Undetermined

Flash point

Not applicable

Evaporation rate

Not applicable

Flammability(solid, gas)

Not applicable

Upper/lower flammability or explosive limits

Not applicable

Vapor pressure

Not applicable

Vapor density

Not applicable

Relative density

2.0 g/cm³

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.

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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 : Not classified as a toxic substance.

Skin corrosion/irritation : May cause skin irritation.

Serious eye damage/irritation : May cause serious eye irritation.

Respiratory or skin sensitization : No allergic potential after uses and good tolerance by subcutaneous tissues.

Germ cell mutagenicity : No mutagenic effect.

Carcinogenicity : Ingredients not listed as carcinogens.

Reproductive toxicity : Not available.

STOT-single exposure : Not classified as a toxic substance.

STOT-repeated exposure : Not classified as a toxic substance.

Aspiration hazard : Not 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.

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SECTION XIV Transport information												
<p>14.1. UN number DOT, ADR, ADN, IMDG, IATA : Void</p> <p>14.2. UN proper shipping name DOT, ADR, ADN, IMDG, IATA : Void</p> <p>14.3. Transport hazard class(es) DOT, ADR, ADN, IMDG, IATA : Void</p> <p>14.4. Packing group DOT, ADR, IMDG, IATA : Void</p> <p>14.5. Environmental hazards Marine pollutant : No</p> <p>14.6. Special precautions for user Not applicable.</p> <p>14.7. Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable. UN "Model Regulation": Void</p>												
SECTION XV Regulatory information												
<p>15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture</p> <ul style="list-style-type: none">- SARA Section 355(extremely hazardous substances): None of the ingredients is listed.- SARA Section 313(specific toxic chemical listings): None of the ingredients is listed.- TSCA(Toxic Substances Control Act): Medical devices are exempted from TSCA.- The product is a medical device according to the Directive 93/42/EEC.- The product is classified as a medical device under US and Korea regulations and has been reviewed by the US Food and Drug Administration and Korea Food and Drug Administration. <p>15.2. Chemical safety assessment A Chemical safety assessment has not been carried out.</p>												
SECTION XVI Other information												
<p>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.</p> <p>Abbreviations and acronyms :</p> <table><tr><td>CAS : Chemical Abstract Service</td><td>CLP : EC Regulation 1272/2008</td></tr><tr><td>DOT : US Department of Transportation</td><td></td></tr><tr><td>ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road</td><td></td></tr><tr><td>ADN : European Agreement concerning the International Carriage of Dangerous Goods by Inland</td><td></td></tr><tr><td>IMDG : International Maritime Code for Dangerous Goods</td><td>IATA : International Air Transport Association</td></tr><tr><td>PBT : Persistent, Bioaccumulative and Toxic</td><td>vPvB : very Persistent and very Bioaccumulative</td></tr></table>	CAS : Chemical Abstract Service	CLP : EC Regulation 1272/2008	DOT : US Department of Transportation		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
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