

MATERIAL SAFETY DATA SHEET

Date Issue 01.01.2023

Version Number 1

Review date 01.01.2023

SECTION 1 : PRODUCT AND COMPANY IDENTIFICATION

Product Name: ActaCal Sealer
Intended use: Root Canal Filling Material
Company Name: Engineered Endodontics
Address: 4965 N. Campbell Dr. Menomonee Falls, WI 53051
Tel: 262-501-0075
Fax No: 262-781-2272
Email: orders@engineeredendo.com
Web: www.engineeredendo.com

SECTION 2 : HAZARD IDENTIFICATION

- Label elements

Labeling according to Regulation (EC) No 1272/2008

GHS label elements including precautionary statements

Health Hazard	Hazard Class	Hazard Statement
	Skin irritation	H315 Causes skin irritation
	Eye irritation	H319 Causes serious eye irritation

Precautionary Statements		
	P264	Wash hands thoroughly after handling.
	P280	Wear protective gloves, protective clothing, eye protection and face protection.
	P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
	P321	Specific treatment: Wash skin thoroughly with cool water and pH-neutral soap or a mild detergent intended for use on skin.
	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.

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	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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SECTION 3 : COMPOSITION /INFORMATION ON INGREDIENTS

3.1 Chemical characterization :

COMPONENTS*	C.A.S.	% by Wt
MTA powder	65997-15-1	35-40%
Radiopacifier*	-	10-15% (trade secret*)
Filler *	-	Trade secret*

*SDS Indicates the ingredient name and/or exact percentage is being withheld as a trade secret.

SECTION 4: FIRST AID 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.

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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

SECTION 5 : FIRE FIGHTING MEASURES

Conditions of Flammability	Not flammable or combustible.
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.
Specific Hazards Arising From the Product	None known.
Special Protective Actions Equipment and Precautions for Fire-Fighters	<ul style="list-style-type: none"> • Wear self-contained breathing apparatus and protective gloves for firefighting. • Equipment should be thoroughly decontaminated after use. • Prevent spillage from entering drains or water courses.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

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Personal Precautions, Protective Equipment and Emergency Procedures	<ul style="list-style-type: none"> • Wear appropriate personal protective equipment to prevent contamination of skin, eyes and personal clothing (see Section 8). • Avoid contact with the product: <ul style="list-style-type: none"> ◦ Avoid contact to the product, freshly cured product or prolonged wet skin exposure to the product. ◦ Avoid actions that cause dried product to become airborne. ◦ Avoid inhalation of dried product dust. • Use a scoop or moist paper towel(s) to clean up spilled product.
Environmental Precautions	<ul style="list-style-type: none"> • Prevent further spillage. • Keep product away from drains, surface and ground water.
Methods and Materials for Containment and Cleaning Up	<ul style="list-style-type: none"> • Use a scoop or moist paper towel(s) to clean up spilled product. Dispose of in a suitable sealed container. • Dispose of waste product according to local state and federal regulations. • Cover drains. • Wash spilled area with large amounts of water and dry thoroughly.

SECTION 7 : HANDLING AND STORAGE

Precautions for Safe Handling	<ul style="list-style-type: none"> • 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. • Remove contaminated clothing and personal protective equipment. Wash before reuse. • Avoid contact with ammonia, ammonia nitrate, chlorine or chlorine containing items.
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Conditions for Safe Storage	<ul style="list-style-type: none"> • Air and moisture sensitive. • Store at room temperature in a dry area. • Store tightly closed in the original packaging. Keep dry until used. • Protect from excessive heat and cold. • Protect packaging against physical damage. • Store away from incompatible materials, and from foodstuffs and beverages. • Do not store near ammonia, ammonia nitrate, chlorine or chlorine containing items.
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SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION




Control Parameters	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.	
Appropriate Engineering Controls	Use and store in a well-ventilated area.	
Individual Protections Measures, Such as Personal Protective Equipment (PPE)	Eye / Face Protection  	<ul style="list-style-type: none"> • Safety glasses with side shields. • Tightly sealed safety goggles. • Face shields. • Contact lenses should not be worn.

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Skin Protection  	<ul style="list-style-type: none"> Glove material has to be impermeable and resistant to the product: <ul style="list-style-type: none"> Exam gloves: nitrile rubber or latex. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practice. Wash and dry hands after handling product.
	<ul style="list-style-type: none"> Lightweight impermeable protective work clothing (labcoat), as appropriate, to prevent skin contact. Remove contaminated clothing and personal protective equipment before entering eating areas. Remove contaminated clothing and personal protective equipment. Wash before reuse.
Respiratory Protection 	<ul style="list-style-type: none"> Surgical face mask Handle product in a well-ventilated area.
Thermal Hazards	Not applicable
Hygiene Measures	<ul style="list-style-type: none"> Handle in accordance with good industrial hygiene and safety practice. Keep away from foodstuffs and beverages. Wash hands before breaks and at the end of work.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

· 9.1 Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	flowable paste
Colour:	white paste
· Odour:	Characteristic
· Odour threshold:	Not determined.
· pH-value: Not applicable.	

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· Change in condition Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not determined.
· Decomposition temperature:	Not determined.
· Self-igniting:	Product is not self igniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits: Lower:	Not determined.
Upper:	Not determined.
· Density:	Not determined.
· Relative density :	Not determined.
· Vapour density :	Not applicable.
· Evaporation rate :	Not applicable.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity: Dynamic:	Not applicable.
Kinematic:	Not applicable.

SECTION 10 : STABILITY AND REACTIVITY

Reactivity	Contact with water will result in hydration of the product and produces (caustic) calcium hydroxide.
Chemical Stability	<ul style="list-style-type: none"> Stable under recommended storage conditions. Keep dry.
Possibility of Hazardous Reactions	Not available
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.
Incompatible Materials	Incompatible with acids, ammonia, ammonia nitrate, ammonium salts, aluminum metal and chlorine.
Hazardous Decomposition Products	<ul style="list-style-type: none"> Decomposition will not spontaneously occur. Contact with water will result in hydration of the product and produces (caustic) calcium hydroxide.

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SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

This product is a white paste and is not likely to cause serious harm.

Substances

No toxicological data available for the substances.

- Mixture

No toxicological data available for the mixture.

SECTION 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.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Results of PBT and vPvB assessment

No data available.

Other adverse effects

No data available.

SECTION 13: DISPOSAL INFORMATION

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Disposal Methods	<ul style="list-style-type: none"> • For the safe handling of disposing of this product, wear appropriate personal protective equipment to prevent contamination of skin, eyes and personal clothing (see Section 8). • Dispose of waste product or contaminated product in a suitable sealed container. • Dispose of product according to local state and federal regulations.
Physical / Chemical Properties Affecting Disposal Options	No known precautions.
Discourage Sewage Disposal	Do not dispose of product down drains or from entering sewage systems.
Special Precautions for Incineration or Landfill	No known precautions.

SECTION 14 : TRANSPORT INFORMATION

14.1. UN Number

N/A

UN proper shipping name

N/A

Transport hazard class(es)

N/A

Packing Group

N/A

Environmental hazards

N/A

Special precautions for user

- ADR - road : N/A
- RID - rail : N/A
- IMDG - sea : N/A
- IATA - air : N/A

SECTION 15 : REGULATORY INFORMATION

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

- Classification and labeling information included in section 2:

No data available.

SECTION 16 : OTHER INFORMATION *

*Changes in content as per regulations – GHS classification

Full text of Classification abbreviations used in Section 2 and 3:

R22	Harmful if swallowed.
R36/38	Irritating to eyes and skin
R38	Irritating to skin.
R43	May cause sensitization by skin contact.
Acute Tox 4	Acute Toxicity Category 4
Eye Irrit. 2	Eye Irritation Category 2
Skin Irrit. 2	Skin Irritation Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labeling of Chemicals

- **Department issuing MSDS:** Regulatory affairs
- **SDS revision date:** 01.01.2023
- **Contact:** orders@engineeredendo.com

* Data compared to the previous version altered.

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