

MATERIAL SAFETY DATA SHEET

1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product Name: BioActive 3D (Bio Ceramic Root Canal Sealer with strontium Glass)

Other Names: n/a

Recommended Use:

Company name: Safe Endo Dental India Pvt. Ltd.

Address: A/6/2, Kamdhenu Industrial Estate, Gorwa, Vadodara-390016, Gujarat, India

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E-Mail: director.safeendo@gmail.com

Website: www.safeendo.org

2 - HAZARDS IDENTIFICATION

Hazard Classification: not applicable

Information concerning to particular hazards to man and environment

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Classification system

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

3 - COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	Contents (%)	CAS
Calcium Silicates	<60 %	1344-95-2
Calcium Hydroxide	<10 %	1305-62-0
Zirconium Oxide	<50 %	1314-23-4
Strontium Silicate Glass	1 – 10%	12712-63-9

4 - FIRST AID MEASURES

General information: No special measures required.

After inhalation: Supply with fresh air; consult doctor in case of complaints.

After skin contact: Generally, the product does not irritate the skin.

After eye contact: Rinse with water for several minutes under running water.

After swallowing: If symptoms persist, consult doctor.

Most important acute and delayed symptoms and effects: See Safety phrases.

Indication of any immediate medical attention and special treatment needed:

5 - FIRE-FIGHTING MEASURES

Suitable extinguishing agents: CO₂, powder or water spray.

Fight larger fires with water spray or alcohol resistant foam.

6 - ACCIDENTAL RELEASE MEASURES

Person-related safety precautions : Not required.

Measures for environmental protection : Do not allow to enter sewers/ surface or ground water.

Measures for cleaning/collecting : Pick up mechanically.

Additional information : No dangerous substances are released.

7 – HANDLING AND STORAGE

Handling Product is intended for dental use only.

Information for safe handling:

No special measures required.

Observe normal care for working with chemicals.

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

Storage Requirements to be met by storerooms and receptacles: No special requirements.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: Store in dry conditions.

8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protective equipment

General protective and hygienic measures

The usual precautionary measures are to be adhered to when handling chemicals. Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work.

Respiratory protection: Not required.

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation **Material of gloves**

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 can not be calculated in advance and has therefore to be checked prior to the application. **Penetration time of glove material** The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed. Eye protection: Safety glasses Body protection: Protective work clothing.

9 - PHYSICAL AND CHEMICAL PROPERTIES

General Information Form: Solid Powder in Glass vial and Liquid in Dropper bottle

Colour: White

Odour: undistinguishable ·

Change in condition Melting point/Melting range: undetermined

Boiling point/Boiling range: undetermined ·

Flash point: Not applicable ·

Self-igniting: Product is not selfigniting. ·

Danger of explosion: Product does not present an explosion hazard. ·

Density: Not determined ·**Solubility in / Miscibility with Water:** Insoluble ·**Solids content:** 100 % SECTION**10 - STABILITY AND REACTIVITY****Thermal decomposition / conditions to be avoided :** No decomposition if used according to specifications.**Dangerous reactionsNo :** dangerous reactions known**Dangerous decomposition products :** No dangerous decomposition products known**11 - TOXICOLOGICAL INFORMATION****Acute toxicity:****Primary irritant effect:** On the skin : may cause skin irritation**On the eye :** Irritating effect.**Sensitization :** No sensitizing effects known.**Additional toxicological Information :** The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.**12 - ECOLOGICAL INFORMATION**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13 - DISPOSAL CONSIDERATIONS**Waste treatment methods:**

Unusable waste of the product be disposed of as hazardous waste. Contaminated packages must be burnt in an incineration plant or handled by a company authorised for dangerous waste disposal.

14 TRANSPORT INFORMATION

DOT shipping name	Not-regulated
DOT hazard class	Not-regulated
UN number	N/A
Sea transport IMDG/GGV sea class	N/A
UN number	N/A
MFGA number	N/A
EmS number	N/A
Air transport ICAO-Ti and	N/A
IAT A-DGR class	Not-regulated
UN number	N/A

15 - REGULATORY INFORMATION

Labelling according to EU guidelines: Observe the general safety regulations when handling chemicals. The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

National regulations Waterhazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

16 - OTHER INFORMATION

The above information applies to customer packages unless stated otherwise, and fully expresses our current knowledge and experience. The product is assumed for use at worksites corresponding to its designation, and the instructions on the enclosed instruction sheet as well as the standard labour safety regulations for the handling of chemical products are assumed to be adhered to.