

Name: Medi-MTA.Sealer/Art.N0.:10027 SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name :Medi-MTA-Sealer

Art.Nr:10027

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

For dental application by professional use only.

1.3. Details of the supplier of the safety data sheet

Registered company name: Swiss MediTec

Address: Gfellen, Postfach 513.6162 Finsterwald. Switzerland.

Telephone: +41 79 482 32 98 info@swiss-meditec.ch http://www.Swiss-meditec.ch

1.4. Emergency telephone number: +41 79 482 32 98

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site. This mixture does not present a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Skin irritation (Xi, R 38).

Eye irritation (Xi, R 36).

Irritant for the respiratory tract (Xi, R 37).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site. This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments. No labelling requirements for this mixture.

2.3. Other hazards

The mixture does not contain any substances classified as'Substances of Very High Concern' (SVHC) by the European Chemicals Agency (ECHA) under article 57 of REACH: http://echa.europa.eu/fr/candidate-list-tableThe mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

No substances fulfil the criteria set forth in annexe II section A of the REACH regulation (EC) n° 1907/2006.

Chemical components	CAS Number	Weight
3CaO.SiO2 Tricalcium silicate	12168-85-3	45-65%
2CaO.SiO2 Dicalcium silicate	10034-77-2	5-12%
3CaO.Al2O3 Tricalcium aluminate	12042-78-3	5-13%
4CaO.Al2O3.Fe2O3 Tetracalcium aluminoferrite	12068-35-8	1-6%
CaO Caocium oxide	1305-78-8	0-6%
Bi2O3 Bismuth oxide	1304-76-3	15-35%

SECTION 4: FIRST AID MEASURES

In case of doubt or if symptoms persist, always call a doctor.

Do NOT induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of exposure by inhalation:

In the event of massive inhalation, remove the person exposed to fresh air and seek medical attention.

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.

In the event of splashes or contact with eyes:

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Wash thoroughly with soft, clean water for 15 minutes holding the eyelids open.

In the event of splashes or contact with skin:

Wash the skin thoroughly with soap and fresh water.

In the event of an allergic reaction, seek medical attention.

In the event of swallowing:

Do NOT induce vomiting.

Rinse the mouth with water and then drink a lot of water. Seek medical attention.

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

No data available.

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

No data available.

SECTION 5: FIREFIGHTING MEASURES

Non-flammable

5.1. Extinguishing media

Suitable methods of extinction

The product is not combustible itself.

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

Wear self-contained breathing apparatus.

SECTION 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 generating dusts.

Avoid any contact with the skin and eyes.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

Avoid generating dusts.

Avoid any contact with the skin and eyes.

6.2. Environmental precautions

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Retrieve the product by mechanical means (sweeping/vacuuming): do not generate dust.

6.4. Reference to other sections

No data available.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Always wash hands after handling.

Avoid any contact with skin and eyes.

Fire prevention:

Prevent access by unauthorised personnel.

Recommended equipment and procedures:

For personal protection, see section 8.

7.2. Conditions for safe storage, including any incompatibilities

Keep in the original container, respect the storage temperatures mentioned on the container, the leaflet and the box.

Keep the container tightly closed and away from dampness

Keep away from direct light.

Storage

Follow the instructions mentioned on the packaging or in the instructions for use.

7.3. Specific end use(s)

Consult instructions for use enclosed.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No data available.

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

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





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Avoid contact with eyes.

Hand protection

Wear gloves according to the hygienic rules in force in dental surgeries.

Body protection

After contact with the product, all parts of the body that have been soiled must be washed.

Respiratory protection

Avoid breathing dust.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information:

Physical state: Colour: Grey pH: Not relevant. Boiling point/boiling range: Not relevant. Flash point interval: Not relevant. Vapour pressure (25°C): Not relevant. Density 3.3 gm/Cm3 Water solubility: Partially soluble. Melting point/melting range: Not relevant. Self-ignition temperature : Not relevant. Decomposition point/decomposition range: Not relevant.

SECTION 10: STABILITY AND REACTIVITY

No data available. 10.1. Reactivity

10.2. Chemical stability

9.2. Other information

This mixture is stable under the recommended handling and storage conditions in section 7.

Do not use if the expiry date is exceeded.

10.3. Possibility of hazardous reactions

No data available.

No data available.

10.4. Conditions to avoid

Avoid:

formation of dusts exposure to light

humidity

10.5. Incompatible materials

Keep away from : Acids

10.6. Hazardous decomposition products

The thermal decomposition may release/form:

carbon monoxide (CO) carbon dioxide (CO2)

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

No data available.

11.1.1. Substances

No toxicological data available for the substances.

11.1.2. Mixture

No toxicological data available for the mixture.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

No data available.

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.

SECTION 13: DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

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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.

SECTION 14: TRANSPORT INFORMATION

Exempt from transport classification and labelling.

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2013 - IMDG 2012 - ICAO/IATA 2014).

SECTION 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:

Directive 67/548/EEC and its adaptations

Directive 1999/45/EC and its adaptations

Regulation EC 1272/2008 modified by regulation EC 618/2012

EU Regulation No. 1272/2008 amended by EU Regulation No. 758/2013.

Container information:

The mixture is contained in packaging that does not exceed 125 ml.

Particular provisions:

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=0 Inflammability=1 Instability/Reactivity=1 Specific Risk=none



15.2. Chemical safety assessment

No data available.

SECTION 16: OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations. The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations. The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Hazard symbols:



Irritant

Risk phrase:

R 36/37/38 Irritating to eyes, respiratory system and skin.

S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 37 Wear suitable gloves.

S 60 This material and its container must be disposed of as hazardous waste.

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