

SAFETY DATA SHEET

According to Regulation (EC) 1907/2006 and Regulation (EU) 2020/878

Version 2
Revision Date 22.07.2024

SECTION 1: Identification of the substance / mixture and of the company / undertaking

1.1. Product identifier

Trade name: Medcem MTA® Radio-opaque Portland Cement

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

- Application of the substance / the mixture: root canal filling material
- Uses advised against: No further relevant information available

1.3. Details of the supplier of the safety data sheet:

Address:

Medcem GmbH
Bahnhofstrasse 12
CH-8570 Weinfelden
Switzerland
Tel.: +41 71 620 04 21
Fax: +41 71 620 04 22
Email: info@medcem.ch

1.4. Emergency telephone number:

+41 71 620 04 21 8 :00 – 18 :00 (GMT + 1.00)

Switzerland : tox centre 145

or any toxicological centre

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to regulation (EC) Nr. 1272/2008

- Skin Irrit. 2 H315 Causes skin irritation
- Eye Dam. 1 H318 Causes serious eye damage
- Skin Sens. 1 H317 May cause an allergic skin reaction
- STOT SE 3 H335 May cause respiratory irritation

2.2. Label elements

- Labelling according to Regulation (EC) Nr. 1272/2008

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

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

- Hazard pictograms



GHS05



GHS07

- Signal word: Danger
- Hazard-determining components of labelling: Portland Cement (<1% Quarz)
- Hazard statements

H315 Causes skin irritation
 H318 Causes serious eye damage
 H317 May cause an allergic skin reaction
 H335 May cause respiratory irritation

- Precautionary statements

P261	Avoid breathing dust/fume/gas/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P333+P313	If skin irritation or rash occurs: get medical advice/attention.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3. Other hazards:

Results of PBT and vPvB assessment

PBT: Not applicable
 vPvB: Not applicable

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Dangerous components

CAS Nr.: 65997-15-1 Hydraulic silicate cement according to EN 197-1 75%
 (Carrier of sulphur, Gypsum: <4%)

EINECS Nr.: 266-043-4

Classification according to Regulation (EC) Nr. 1272/2008)



Eye Dam. 1 H318 Causes serious irritation
 Skin Irrit. H315 Causes skin irritation



Skin Sens. 1 H317 May cause an allergic skin reaction
 STOT SE 3 H335 May cause respiratory irritation

SECTION 4: First aid measures

4.1. Description of first aid measures

- after inhalation: Supply fresh air; consult doctor in case of complaints.
- after skin contact: Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.
- after eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- after swallowing: Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.

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

No further relevant information available.

Information for doctor: No further relevant information available.

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

No further relevant information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing agents:

- CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- For safety reasons unsuitable extinguishing agents: Water with full jet

5.2. Special hazards arising from the substance or mixture:

No further relevant information available.

5.3. Advice for firefighters

Protective equipment: No special measures required.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Wear protective equipment. Keep unprotected persons away.

6.2. Environmental precautions

Do not allow to enter sewers/surface or ground water.

6.3. Methods and material for containment and cleaning up

Pick up mechanically.

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 7: Handling and storage

7.1. Precautions for safe handling

Observe normal care for working with chemical.

Prevent formation of dust.

Handling: Product is intended for dental use only.

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

7.2. Conditions for safe storage, including any incompatibilities

Storage requirements to be met by storerooms and receptacles: Store only in the original receptacle.

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

Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.

7.3. Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ingredients with limit values that require monitoring at the workplace:

- 65997-15-1 Hydraulic silicate cement (Carrier of sulphur, Gypsum: <4%)
- WEL Long-term value: 10^{-4} mg/m³
**respirable dust *
inhalable dust

Additional information: the lists valid during the making 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.
 - Keep away from foodstuffs, beverages and feed.
 - Wash hands before breaks and at the end of the work..
- Respiratory protection: Not necessary if room is well-ventilated.
- 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 to the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

- Materials 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.
- Body protection: Protective work clothing.
- Eye protection:



Tightly sealed goggles.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

General information:

- Appearance:
 - Form: solid
 - Colour: white
- Odour: undistinguishable
- Odour threshold: not determined
- pH-value: 12-13
- Change in condition:
 - Melting point/Melting range: not determined
 - Boiling point/Boiling range: not determined
- Flash point: not applicable
- Flammability (solid, gaseous): not determined
- Ignition temperature: not applicable
- Decomposition temperature: not determined
- Self-igniting: Product is not selfigniting.
- Danger of explosion: Product does not present an explosion hazard.
- Explosion limits:
 - Lower: not determined
 - Uper: not determined
- Vapour pressure: not applicable
- Density: not determined
- Relative density at 20 °C: 4-4,5
- Vapour density: not applicable
- Evaporation rate: not applicable
- Solubility in /Miscibility with water: insoluble
- Partition coefficient (n-octanol/water): not determined
- Viscosity:
 - dynamic: not applicable
 - kinematic: not applicable
- Solvent content:
 - Organic solvents: 0,0%
- Solids content: 100%

9.2. Other information:

No further relevant information available.

SECTION 10: Stability and reactivity

10.1. Reactivity: No further relevant information available

10.2. Chemical stability

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.3. Possibility of hazardous reactions: No dangerous reactions known.

10.4. Conditions to avoid: No further relevant information available.

10.5. Incompatible materials: No further relevant information available.

10.6. Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

11.1. Informations on toxicological effects

Acute toxicity:

Primary irritant effect:

- on the skin: irritant to skin and mucous membranes
- on the eye: strong caustic effect
- Sensitisation: Sensitisation possible through skin contact

SECTION 12: Ecological information

12.1. Toxicity

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.

Additional ecological information :

General notes : Do not allow product to reach ground water, water course or sewage system.

12.5. Results of PBT and vPvB assessment:

- PBT: Not applicable
- vPvB: Not applicable

12.6. Other adverse effects: No further relevant information available.

13: Disposable considerations

13.1. Waste treatment methods

Recommendation:



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

European waste catalogue:

18 01 06* Chemicals consisting of or containing dangerous substances.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1. UN-Number

- ADR, IMDG, IATA void

14.2. UN proper shipping name

- ADR, IMDG, IATA void

14.3. Transport hazard class(es)

- ADR, IMDG, IATA
- Class void

14.4. Packing group

- ADR, IMDG, IATA void

14.5. Environmental hazards

- Marine pollutant: No

14.6. Special precautions for user: Not applicable

14.7. Transport in bulk according to Annex II of Marpol 73/78 and the IBC Code: Not applicable

UN „Model Regulation“: -

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific of the substance or mixture: No further relevant information available.

15.2. Chemical safety assessment: A chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage the product is given in the DFU.

Relevant phrases

- H315 Causes skin irritation
- H317 May cause an allergic skin reaction
- H318 Causes serious eye damage
- H335 May cause respiratory irritation

Department issuing MSDS: Safety officer development

Contact: Hotline for urgent technical support: +41 71 620 04 21

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 Harmonised System of Classification and Labelling of Chemicals
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- Skin Irrit. 2: Skin corrosion/irritation. Hazard Category 2
- Eye Dam. 1: Serious eye damage/eye irritation. Hazard Category 1
- Skin Sens. 1: Sensitisation – Skin, Hazard Category 1