

Material Safety Data Sheet

1 SUBSTANCE IDENTIFICATION/MIXTURE AND COMPANY/FIRM

1.1. Product identifier

Product name and related code:
OverCEM SA Universal - ROCUN
OverCEM SA Opaque - ROCOP
OverCEM SA Translucent – ROCTR

1.2. Relevant identified uses of the substance or mixture

Product for dental use, exclusively for professional use (dentistry).

1.3 Details of the supplier of the safety data sheet

Overfibers S.r.l.
Via Malatesta,7 40026 - Imola - Italy
www.overfibers.com
Phone + 39 0542 52153 Fax +39 0542 1900078

1.4. Emergency Phone number

Poisoning Control Centers Niguarda Ca' Granda – Milan +39 02 661 010 29

This product is a kit or product consisting of multiple components. The safety data sheet applicable to each of the components is attached with the document numbers shown below. Kit components:

Endocanal post; Reaming drill.

2 RISKS IDENTIFICATION

2.1 Classification according to regulation (EC) n. 1272/2008

Skin Irrit. 2 H315 Causes skin irritation
Skin Sens. 1 H317 May cause an allergic skin reaction.
Eye Irrit. 2 H319 Causes serious eye irritation.
STOT SE 3 H335 May cause respiratory irritation.

2.2 Label elements

Labeling according to regulation (EC) n. 1272/2008

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

Hazard pictograms: Nessuno.

Hazardous components:

urethane dimethacrylate
ytterbium trifluoride
triethylene glycol dimethacrylate
2- hydroxyethyl methacrylate
dibenzoyl peroxide
Titanium dioxide
Butylated Hydroxy Toluene

Hazard statements

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.

Precautionary statements

P280 Wear protective gloves/goggles/face protection.
P302+P352 IN CASE OF SKIN CONTACT: Wash with plenty of water.
P305+P351+P338 IN CASE OF EYES CONTACT: rinse thoroughly for several minutes. Remove any contact lenses if it is easy to do so. Continue to rinse.
P333+P313 In case of skin irritation or rash: consult a doctor.
P337+P313 If eye irritation persists, consult a doctor.
P501 Dispose of contents/container in accordance with local/regional regulations/national/international.

Further data:

Medical devices, as defined in Directive 93/42 / EC intended for the end user and of an invasive type or used in direct contact with the human body, are exempted from the labeling obligation provided for in Regulation (EC) 1272/2008 (CLP/GHS).

2.3 Other hazards

- Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.

3 Composition/information on ingredients

3.1 Chemical characteristics

Urethane dimethacrylate

CAS: 72869-86-4

H317, H412

Concentration: 5-15 %

ytterbium trifluoride

CAS: 13760-80-0

H302, 312, H332, H315, H319, H335

Concentration: 0-10 %

triethylene glycol dimethacrylate

CAS: 109-16-0

H317

Concentration: 5-15%

2- hydroxyethyl methacrylate

CAS: 868-77-9

H315, H319, H317

Concentration: 0-10%

dibenzoyl peroxide

CAS: 94-36-0

H242, H319, H317, H400, H410

Concentration: 0-10%

Titanium dioxide

CAS: 13463-67-7

H351

Concentration: 0-5%

Butylated Hydroxy Toluene

CAS: 128-37-0

H410

Concentration: 0-10%

3.2 Other ingredients:

Bismuth Oxychloride

4-methacryloxyethyl trimellitic anhydride

10-methacryloyl-oxydecyl-dihydrogenphosphate

Bisphenol-A Glycidyl dimethacrylate

Ytterbium fluoride

Nanosilica

UV stabilizer

Co-initiators and initiators

Activators

Pigments

Silanized and ionomeric glass filler

4 First aid measures

4.1 Description of first aid measures

General indications:

Avoid contact with eyes.

Avoid contact with skin.

Inhalation:

Take the person to a very well ventilated area and consult a doctor for safety.

If the subject is unconscious, keep him in a stable position on his side during transport.

Skin contact:

Wash immediately with soap and water and rinse thoroughly.

In case of persistent skin irritation consult the doctor.

Eye contact:

Wash with running water for several minutes keeping the eyelids wide open. If the pain persists, consult the doctor.

Ingestion: If pain persists, consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed: No further information available.

4.3 Indication of any immediate medical attention and special treatment needed: No further information available.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: use extinguishing agents suitable for normally flammable materials, such as water and foam to extinguish.

5.2 Special hazards arising from the substance or mixture: No further information available.

5.3 Recommendations for firefighters: There are no special protective actions for firefighters.

6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See chapter 8

6.2. Environmental precautions

Do not disperse in the environment.

6.3. Methods and materials for containment and cleaning up

Collect as much of the spilled material as possible. Place in container with closure. Clean the residue. Seal the container. Dispose of the collected material as soon as possible.

7 Handling and storage

7.1 Precautions for safe handling

In case of contact with the skin, wash the skin with soap and water. Acrylates can penetrate in commonly used gloves. If the product comes into contact with the gloves, remove and discard them, wash your hands immediately with soap and water, then put on a new pair of gloves. In case of contact with eyes, rinse thoroughly with water and consult a doctor. Do not allow the substance to come into contact with eyes, skin or clothing. Do not eat, drink or smoke while using this product. Avoid release to the environment. Wash the contaminated garments before reusing them.

In case of prolonged contact with soft oral tissues, rinse with plenty of water and, if possible, with sodium bicarbonate in aqueous solution. If an allergic reaction occurs, remove the product from the oral cavity as soon as possible and consult a doctor.

Indications in case of fire and explosion: No special measures are required.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements for warehouses and containers: OverCEM SA must be stored between 2°C/36°F and 25°C/77°F.

Notes on mixed storage:

Do not store in contact with oxidants.

Do not store in contact with reducing agents.

Further information on storage conditions:

Keep containers tightly closed.

Keep in a cold and dry place.

Protect from heat and direct sunlight.

7.3 Specific end uses: After the first use, for better maintenance of the performance of OverCEM SA, it is recommended storage from 2°C/36°F to 8°C/46°F. For best results, do not use OverCEM SA cements after the expiration date.

8 Exposure controls/personal protection

8.1 control parameters

Components whose limit values must be monitored in the workplace:

ytterbium trifluoride
CAS: 13760-80-0
Italian limit values
TWA(8 ore) 2.5 mg/m³

Titanium dioxide
CAS: 13463-67-7
Italian limit values
TWA(8 ore): 10 mg/m³

8.2 Exposure controls

General protective and hygiene standards:

Wash your hands before intervention and after work is finished.

Avoid contact with eyes and skin.

Personal protective equipment:

Safety goggles.

Protective neoprene or latex gloves. The glove material has to be impermeable and stable against the product/the substance/the formulation

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Pasty

Color:

Universal: yellow;

Translucent: clear;

Opaque: white;

Odor: Odorless

Odor threshold: not defined

PH values: not defined

Melting point / freezing point: not determined

Initial boiling point and boiling range: not defined

Flash point: not determined

Flammability (solid, gas): not determined

Ignition temperature: not defined

Decomposition temperature: not determined

Explosive properties: Non-explosive product.

Flammability limits: Lower: not defined; Upper: not defined

Oxidizing properties: not defined

Vapor pressure: not determined

Density: Base: 1.9-2.1 g/cm³

Catalyst: 1.7-1.85 g/cm³

Relative density: not defined

Vapor density: not determined
Evaporation rate: not defined
Solubility in/Miscibility with water: Insoluble.
Viscosity: not defined
Dynamics: not defined
Kinematics: not defined

10 Stability and reactivity

10.1 Reactivity: No information available

10.2 Chemical stability

Thermal decomposition/conditions to avoid:

Do not use OverCEM SA on substrates contaminated with temporary cements containing phenols (e.g. eugenol) because they could inhibit polymerization.

Do not use hydrogen peroxide (H₂O₂) because free oxygen has a negative effect on both the adhesion and the polymerization of OverCEM SA.

The product does not decompose if handled and stored according to the rules and within the expiry date.

10.3 Possibility of hazardous reactions: Avoid using the product on patients with known allergies to acrylates and peroxides

10.4 Conditions to avoid: see 10.2

10.5 Incompatible materials: see 10.2

10.6 Hazardous decomposition products:

In case of fire: Carbon oxides, nitrogen oxides.

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity: MD does not come into direct contact with living material. If it came into contact with it in its final polymerized form, however, it would be neutral and non-reactive.

Skin corrosion/irritation: It is not corrosive. It can cause skin irritation and allergic reactions for patients with known allergies to acrylates and peroxides.

Serious eye damage/serious eye irritation: Causes eye irritation.

Respiratory or skin sensitization: The product is not sensitizing, but can cause skin irritation and allergic reactions for patients with known allergies to acrylates and peroxides.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

Specific target organ toxicity (STOT) - single exposure: Based on available data, the classification criteria are not met.

Specific target organ toxicity (STOT) - repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

12 Ecological information

12.1 Aquatic toxicity: No further information is available.

12.2 Persistence and degradability: No further information is available.

12.3 Bioaccumulative potential: No further information is available.

12.4 Mobility in soil: No further information is available.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects: No further information available.

13 Disposal considerations

13.1 Waste treatment methods: Do not dispose of the product together with domestic waste. Do not enter into drains.

Uncleaned packaging: Disposal in accordance with administrative regulations.

14 Transport information

14.1 Number UN, ADR, ADN, IMDG, IATA: Not applicable

14.2 Shipping name of UN, ADR, ADN, IMDG, IATA: Not applicable

14.3 Transport hazard classes ADR, ADN, IMDG, IATA: Class not applicable

14.4 Packing group ADR, IMDG, IATA: Not applicable

14.5 Environmental hazards: No

14.6 Special precautions for user: Not applicable

14.7 Transport in bulk according to Annex II of MARPOL and the IBC code: Not applicable.

14.8 UN "Model Regulation": Not applicable.

15 Regulatory information

15.1 Health and safety and environmental laws and regulations specific for the substance or mixture:

This safety data sheet complies with the provisions of Regulation (EC) No. 1907/2006

15.2 Chemical safety assessment commercial use of this material is regulated by the CE marking.

16 Other information

The data are reported on the basis of our current knowledge, however they do not represent any guarantee of the characteristics of the product and do not motivate any contractual legal relationship.

16.1 H phrases and P advices:

H242 Risk of fire due to heating.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

H400 Very toxic for aquatic organisms.

H410 Very toxic for aquatic organisms with long lasting effects.

H412 Harmful for aquatic organisms with long lasting effects.

P280 Wear protective gloves/goggles/face protection.

P302 + P352 IN CASE OF CONTACT WITH SKIN: Wash with plenty of water.

P305 + P351 + P338 IN CASE OF EYE CONTACT: rinse thoroughly for several

minutes. Remove any contact lenses if it is easy to do so. Continue to rinse.

P333 + P313 In case of skin irritation or rash: consult a doctor.

P337 + P313 If eye irritation persists, consult a doctor.

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

16.2 Intended user

The device is used only by medical-dental personnel. The MD implantation must be carried out by dentist. The use of the MD does not require special training as the procedure is part of the operator's cultural background.

Precautions for use:

Avoid exposure of OverCEM SA to light or humidity during the application of the same in order not to decrease setting times.

Storage and expiration:

OverCEM SA must be stored between 2°C/36°F and 25°C/77°F. After the first use, for better maintenance of OverCEM SA performance, conservation is recommended from 2°C/36°F to 8°C/46°F. For best results, do not use OverCEM SA cements after the expiration date.

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