

1. IDENTIFICATION

1.1. Product identifier "CORECEM"

Product Identification Numbers: 1410120, 1410125

1.2. Recommended use and restrictions on use

Recommended use: Dental product, dental composite

Restrictions on use: For use only by dental professionals

1.3. Supplier's details

Name: R.T.D : Recherches Techniques Dentaires

Address: 3 Rue Louis Neel. Espace Gavanière
38120 St-Egrève. France

Telephone: +33 4 76 56 56 66

Fax: +33 4 76 56 11 77

1.4. Emergency telephone number

Emergency Call USA Canada-Infotrac: 1-800-535-5053

Emergency Chemtrec USA: 1-800-424-9300

Emergency Chemtrec outside the U.S: 1-703-527-3887

2. HAZARD IDENTIFICATION

2.1. Hazard classification

Classification (GHS-US):

HDDMA		
Skin irritant	H315	2
Eye irritant	H319	2
UDMA		
Skin sensitizer	H317	1

2.2. Label elements

Signal word

Irritant, Sensitizer

Hazard pictograms



GHS07

GHS08

SAFETY DATA SHEET
acc. to OSHA HCS, to EU No. 453/2010

Issue: 08/07/2016

Version: 1.0

Precautionary statements

Wear protective gloves, mask, safety glasses.

Additional information

Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

2.3. Hazards not otherwise classified

Results of PBT and vPvB assessment

PBT: Not applicable

vPvB: Not applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: mixtures

CAS number	Ingredient	% by weight
66402-68-4	Ceramic fillers	40-50*
6606-59-3	HDDMA	10-20*
72869-86-4	UDMA	10-20*
13760-80-0	Ytterbium fluoride	10-20*
68611-44-9	SiO ₂	1-5*
10373-78-1	Camphorquinone	<0.1*

*The specific chemical identity and/or exact percentage is a trade secret. This is allowed under GHS as Confidential Business Information (CBI).

4. FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation: Supply fresh air and to be sure call a POISON CENTER or doctor/physician.

Skin contact: Wash immediately with mild soap and water. Rinse thoroughly. Remove immediately all contaminated clothing.

Eye contact: Rinse immediately with plenty of water. If symptoms persist, consult doctor.

If swallowed: Rinse mouth. Do NOT induce vomiting. Seek medical attention.

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

No further relevant information available.

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

No further relevant information available

5. FIRE FIGHTING MEASURES

5.1. Extinguish media:

CO₂, extinguish powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use firefighting measures that suit the environment. Do not use a heavy water stream.

5.2. Specific hazards arising from the substance or mixture:

No additional information available.

5.3. Special protective actions for fire-fighters:

Firefighting instructions : Use water spray or fog for cooling exposed containers.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures:

Evacuate unnecessary personnel. Equip cleanup crew with proper protection. Ventilate area.

6.2. Environment precautions:

Do not allow product to reach sewage system or any water course.

6.3. Methods and material for containment and cleaning up:

On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections:

See section 7 for information of safe handling

See section 8 for information on personal protection equipment.

See section 13 for disposal information on personal protection equipment.

7. HANDLING & STORAGE

7.1. Precautions for safe handling

For use in dentistry only. Observe instructions for use.

Wash hands and other exposed areas with mild soap and water before eating, drinking, smoking.

Provide good ventilation in process area to prevent formation of vapor. Avoid breathing mist, vapors.

7.2 Conditions for safe storage including any incompatibilities

Requirements to be met by storerooms and receptacles: Store only in the original receptacle, in a cool and well ventilated place. Keep container closed when not in use.

Information about storage in one common storage facility: Store away from foodstuffs.

Specific end use(s): No further relevant information available

Incompatible products: Strong bases. strong acids.

Incompatible conditions: Sources of ignition. Direct sunlight.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

Components with limit values that require monitoring at the workplace:

13760-80-0 ytterbium trifluoride

PEL	Long-term value: 2.5 mg/m ³ as F
REL	Long-term value : 2.5 mg/m ³ as F
TLV	Long-term value : 2.5 mg/m ³ as F, BEI

Ingredients with biological limit values:

13760-80-0 ytterbium trifluoride

BEI	2mg/L Medium: urine Time: prior to shift Parameter: Fluoride (background, no specific)
	3mg/L Medium: urine Time: end of shift Parameter: Fluoride (background, nonspecific)

Additional information: The lists that were valid during the creation were used as basis.

8.2. Exposure controls

Skin/ hand protective measure

Protective gloves, suitable protective clothing

Eye protective measures

Safety glasses

Other

Surgical mask and/or suction equipment when cutting.

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. As the product is a preparation of several substances, the resistance of the glove material cannot 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.

9. PHYSICAL & CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- Physical state:	Solid
- Appearance:	Pasty
- Colour:	Ivory white
- Odour:	slight acrylic odour
- Odour threshold:	no data available
- pH:	no data available
- Relative evaporation rate:	no data available
- Flash point:	no data available
- Melting point:	no data available
- Freezing point:	no data available
- Boiling point:	no data available
- Auto-ignition temperature:	no data available
- Decomposition temperature:	no data available
- Flammability:	no data available
- Vapour pressure:	no data available
- Relative vapour density at 20°C:	no data available
- Relative density:	no data available
- Solubility:	insoluble
- Log pow:	no data available
- Viscosity, kinematic:	no data available
- Viscosity, dynamic:	no data available
- Explosive properties:	no data available
- Oxidising properties:	no data available
- Explosive limits:	no data available

9.2 Other information

No additional information available

10. STABILITY & REACTIVITY

10.1. Reactivity: No additional information available

10.2. Chemical stability: No additional information available

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

10.4. Conditions to avoid: Open flame, direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials: Strong acids, strong bases.

10.6. Hazardous decomposition products: Carbon monoxide, carbon dioxide.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects:

Acute toxicity: not classified.
Primary irritant effect:
On the skin: not classified.
On the eye: cause serious eye irritation.
Sensitization: may cause allergy or asthma symptoms.
Additional toxicological information:

Carcinogenic categories

IARC (International Agency for Research on Cancer)		
13760-80-0	Ytterbium trifluoride	3

NTP (National Toxicology Program)	
Ceramic fillers	

OSHA-Ca (Occupational Safety & Health Administration)	
None of the ingredients is listed	

12. ECOLOGICAL INFORMATION

Possible impact to the environment/ ecotoxicity:

Toxicity
Aquatic toxicity: No further relevant information available.
Persistence and degradability: No further relevant information available.

Behavior in environment systems:
Bioaccumulative potential: No further relevant information available.
Mobility in soil: No further relevant information available.

Additional ecological information:
General notes: No further relevant information available.

Results of PBT and vPvB assessment
PBT: Not applicable
vPvB: Not applicable
Other adverse effects: Avoid release to the environment.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods:

Recommendation: Dispose in a safe manner in accordance with local/national regulations.

Uncleaned packagings:

Recommendation: Disposal must be made according to local/national regulations.

14. TRANSPORT INFORMATION

UN- number DOT, ADR, ADN, IMDG, IATA	Void
UN proper shipping name DOT, ADR, ADN, IMDG, IATA	Void
Transport hazard class(es) DOT, ADR, ADN, IMDG, IATA Class	Void
Packing group DOT, ADR, IMDG, IATA	Void
Environmental hazards Marine pollutant	No
Special precautions for user	Not applicable
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable
Transport/Additional information	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA)
UN "Model Regulation"	-

15. REGULATORY INFORMATION

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

SARA (Superfund Amendments and Reauthorization Act):

Section 313 (specific toxic chemical listings)

None of the ingredients is listed

Carcinogenic categories

EPA (Environment Protection Agency)

None of the ingredients is listed

TLV (Threshold Limit Value established by ACGIH)

13760-80-0	Ytterbium trifluoride	A4
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NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed

EU Regulations

REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)

Not contain substances with Annex XVII restrictions.

Not contain substance on the REACH candidate list.

Not contains substances on REACH Annex XIV.

Other regulations:

The product is a medical device according to the Directive 93/42/EEC.

The product has been classified as a medical device under US and Canadian regulations.

Chemical safety Assessment:

A Chemical safety Assessment has not been carried out.

16. OTHER INFORMATION

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

Date of preparation: 08/07/2016

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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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

*** This version replaces all previous versions.**