

1. IDENTIFICATION

1.1. Product identifier

QUARTZ SPLINT “MESH”

Product Identification Numbers: 5010081, 5010083

1.2. Recommended use and restrictions on use

Recommended use: Dental product, dental restoration materials

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

Skin sensitizer	May cause an allergic skin reaction	H317	1
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2.2. Label elements

GHS label elements:

Void

Signal word

Warning

Hazard pictograms



GHS07

Precautionary statements

Avoid breathing dust/fume/gas/mist/vapour/spray.

Wear protective gloves, mask, safety glasses.

Contaminated work clothing must not be allowed out of the workplace.

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

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

Description: Mixture of the substances listed below with nonhazardous additions.

CAS number	Ingredient	% by weight
65997-17-3	Quartz fibres	50-65*
1565-94-2	Bis-GMA	25-35*
77302-65-9	Tegdma	5-15*
10373-78-1	Camphorquinone	0.1-0.2*
68611-44-9	SiO ₂	<1*
	Red Pigment	<0.001*

*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 for a doctor.

Skin contact: Wash immediately with mild soap and water. Rinse thoroughly.

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

If swallowed: Rinse mouth. Seek medical attention.

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

Allergic reactions.

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.

5.2. Specific hazards arising from the substance or mixture:

Formation of toxic gases is possible during heating or in case of fire.

5.3. Special protective actions for fire-fighters:

Wear self-contained respiratory protective device. Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures:

Remove persons from danger area.
Avoid contact with the eyes and skin.
Wear protective clothing.

6.2. Environment precautions:

Do not allow product to reach sewage system or any water course.
Do not allow to penetrate the ground/soil.

6.3. Methods and material for containment and cleaning up:

Pick up mechanically.
Prevent formation of dust.
Dispose of the collected material according to regulations.

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.

Prevent formation of dust. Do not inhale dust/mist.

Avoid contact with the eyes and skin.

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

Information about protection against explosions and fires: Dust can combine with air to form an explosive mixture.

7.2 Conditions for safe storage including any incompatibilities

Requirements to be met by storerooms and receptacles: Store only in the unopened original receptacle.

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

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

8.2. Exposure controls

Skin/ hand protective measure

Protective gloves

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:	solid
- Colour:	Pink
- Odour:	slight acrylic odour
- Odour threshold:	no data available
- pH:	not applicable
- Relative evaporation rate:	no data available
- Flash point:	not applicable
- Melting point:	undetermined
- Freezing point:	no data available
- Boiling point:	undetermined
- Auto-ignition temperature:	no data available
- Decomposition temperature:	no data available
- Flammability:	not applicable
- Vapour pressure:	not applicable
- Relative vapour density at 20°C:	not applicable
- Relative density:	not determined
- 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 further relevant information available

10.2. Chemical stability: Stable under normal handling and storage conditions.

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: None under normal conditions of storage and use.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects:

Acute toxicity:

Primary irritant effect:

On the skin: no irritant effect

On the eye: no irritating effect

Sensitization: Sensitization possible through skin contact.

Additional toxicological information:

Carcinogenic categories

IARC (International Agency for Research on Cancer)

None of the ingredients is listed

NTP (National Toxicology Program)
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None of the ingredients is listed

OSHA-Ca (Occupational Safety & Health Administration)
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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: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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 355 (extremely hazardous substances)

None of the ingredients is listed

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)

None of the ingredients is listed

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 and has been reviewed by the US FDA and Health Canada.

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.

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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.**