

Issue: 18/07/2016 Version: 1.0

1. IDENTIFICATION

1.1. Product identifier

FIBER POST "MACRO-LOCK OVAL" (red, yellow, blue, green)

Product Identification Numbers: 4690-

1.2. Recommended use and restrictions on use

Recommended use: Dental product, dental fiber post **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

The product is not classified according to the Globally Harmonised System (GHS).

2.2. Label elements

GHS label elements: Void

Signal word: Void

Hazard pictograms: Void **Precautionary statements**

Avoid breathing dust.

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



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3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: mixtures

Description: Fiber reinforced composite dental root canal post

CAS number	Ingredient	% by weight
65997-17-3	Radio-opaque quartz fibres	75-85*
036425-15-7	Epoxy resin matrix	10-25*
None	Pigment	<0.2*

^{*}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:

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:

 CO_2 , 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:

No further relevant 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.



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6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures:

No special measures required.

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:

Pick up mechanically.

Dispose of the collected material according to regulations.

Minimize generation of dust.

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.

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

Information about protection against explosions and fires: No special measures required

7.2 Conditions for safe storage including any incompatibilities

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

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

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

No additional information available.

8.2. Exposure controls

Skin/ hand protective measure

Protective gloves

Eye protective measures

Safety glasses

Other

Surgical mask and/or suction equipment when cutting.



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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: small diameter (<3mm) cylinder
 Colour: red, yellow, blue or green

- Odour: odorless

- 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 undetermined - Boiling point: - Auto-ignition temperature: no data available - Decomposition temperature: no data available - Flammability: non flammable - 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



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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: no sensitizing effects known **Additional toxicological information:**

Carcinogenic categories

IARC (International Agency for Research on Cancer)

None of the ingredients is listed

NTP (National Toxicology Program)

None of the ingredients is listed

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed



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



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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

TSCA (Toxic Substances Control Act)

All ingredients are 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.

Chemical safety Assessment:

A Chemical safety Assessment has not been carried out.



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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.