



1. Identification of the preparation and of the company

1.1 Identification of the preparation

Fibreglass brackets and tubes.

1.2 Use of the preparation

Aesthetic brackets for direct bonding technique used with fixed orthodontic prosthesis.

1.3 Company identification

Leone s.p.a.

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Tel. ++39 (0)55.30.44.1 – Fax ++39 (0)55 374808.

1.4 Emergency telephone

++39 (0)55.30.44.1. An answering machine is on during closing time.

2. Hazards identification

The products generally are not considered as hazardous in the form they are supplied, nevertheless ingestion or inhalation of pieces or fragments may occur during use.

3. Composition/information on ingredients

Information on ingredients:

Polycarbonate based on bisphenol A 80%, glass-fibre reinforced 20% with very small amount of anticombustion agents.

4. First aid measures

In case of ingestion or inhalation of pieces or fragments seek for medical advice. Products are not radiopaque.

In case of fire due, to the melted material, medical advice is necessary.

5. Fire-fighting measures

Suitable extinguishing media: sprayed water jet, extinguishing powder, foam, CO₂, dry chemical.

Wear breathing apparatus in fire-fighting operations.

6. Accidental release measures

Pick up with mechanical means.

7. Handling and storage

No special handling/storage conditions required.

8. Exposure controls/personal protection

No special precautions/equipment are necessary.

9. Physical and chemical properties

9.1. General information

Appearance: solid
Colour: clear or according to colouration
Odour: odourless.

9.2. Health, safety and environmental information

Solubility in water: insoluble
pH: not applicable
Flash point: > 450°C
Autoignition temperature: > 450°C
Explosive limit: not applicable
Viscosity: not applicable
Softening point: 150-160°C
Density: approx. 1.35 g/cm³ at 20°C
Vapour pressure: not applicable.

10. Stability and reactivity

Thermal decomposition: decomposition occurs starting from 380°C. In case of thermal decomposition, which can happen during a fire or for overheating, harmful gases and vapours can be generated.

Hazardous decomposition products: in case of burning with insufficient oxygen or incomplete burning, toxic mixture of gases containing CO and CO₂ can be generated. Aromatic and aliphatic hydrocarbons, aldehydes, acids, phenols and their derivatives can also form. Practically it can be neglected the presence of fraction of halogen generating acids and halogenated hydrocarbons which are formed by the presence of small quantity of fire retardant.

Hazardous reactions: no hazardous reactions have been observed.



11. Toxicological information

According to our experience, if properly used, the product is not hazardous to health.

12. Ecological information

The product is practically insoluble in water. In view of its consistency and insolubility in water, no ecological problems are to be expected if the product is properly handled. The product is not readily biodegradable.

13. Disposal considerations

Dispose of in accordance with local and national regulations. In Italy dispose of according to Legislative Decree of April 3 2006 no. 152 "Regulations on environmental subject", application of European Directives on environmental protection, and subsequent modifications and integrations.

14. Transport information

None. The product is not hazardous within the meaning of transport regulations

15. Regulatory information

- Health, safety and environmental information shown on the label according to European Directives on hazardous materials and substances

None.

- Information related to further dispositions

This product is CE marked in accordance with the essential requirements of Directive 93/42/EC, Annex I, on medical devices.

16. Other information

The safety data sheet has been written according to relevant European provisions, on the basis of information received by the supplier of preparation.

The product is intended for orthodontic and odontological use only.

The use of the product has to be restricted to skilled and licensed professionals.

The information drawn herein is based on our knowledge at the date of the issue.

The information is exclusively provided related to the product herewith specified and is not intended as a warranty of quality.

Leone disclaims any responsibility arising out of the use of the information here furnished, or of the handling, the application or the manufacture of the product here described. The final user is called to verify the application and completeness of the information herein in relationship to the specific use and reliability of the rules and local applicable dispositions.

The present information doesn't imply any liberty to break patent rights.

Previous safety data sheet n. F08/3E of 17/05/2001 has to be considered cancelled. In comparison to the preceding revision, meaningful changes have not been effected but only adjustments to the European provisions which regulate the compilation of safety data sheet.

This safety data sheet is subject to revision.

Visit our web site www.leone.it for an updated version of the present sheet.