



## 1. Identification of the preparation and of the company

### 1.1 Identification of the preparation

Fluorescent additive "x".

### 1.2 Use of the preparation

Additive for self-curing orthodontic resin, for spray-on or doughing techniques.

### 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 information contained herein is to be referred to the raw material which these products are manufactured with; for this purpose some instructions and indications are related to the personnel employed in the manufacturing processes and not to the final user.*

Substances considered hazardous for the health according to the Directive 67/548/EEC and further modifications or for which exposure limits exist: none

## 3. Composition/information on ingredients

Referring to European Directives on hazardous materials and compounds, the material is considered not dangerous

## 4. First aid measures

- Inhalation: if affected by inhalation of vapours at high temperatures, remove the affected person from exposure. Apply artificial respiration if breathing is interrupted, maintain to rest and seek for medical advice.
- Ingestion: seek medical advice immediately, showing this safety data sheet. It is possible to give activated carbon suspended in water or medicinal white mineral oil.
- Skin contact: wash with plenty of water and soap. For hot products, dip the contaminated area in cold water and seek medical advice
- Eye contact: flush immediately with water for at least 15 minutes.

## 5. Fire-fighting measures

- Suitable fire extinguishing methods: water, CO<sub>2</sub>, foam, chemical powders according to materials involved in fire.
- Unsuitable fire extinguishing methods: none.
- Physical exposure hazards: poor conditions of oxygen can release carbon monoxide and irritating fume. Protect the respiratory tract. Dispose of waste water in accordance with local regulations.
- Personal precautions: use protection for the respiratory tract.

## 6. Accidental release measures

- Personal precautions: wear suitable protective clothing and gloves
- Environmental precautions: contain leakage. Pick up the product leaked for recycling or disposal. If the product has flowed out in a water way or sewers and has contaminated the ground or the vegetation, inform the competent authorities.
- Cleaning methods: if the product is in liquid form, prevent it from entering the sewers. Absorb it with inert material, flush the contaminated area and materials with water.

## 7. Handling and storage

### 7.1 Handling

Handling precaution: see section 8. When using do not eat or drink.

### 7.2 Storage

Storage conditions: keep containers tightly closed.

Indications for locals: provide a good local ventilation.

## 8. Exposure controls/personal protection

### 8.1. Exposure limit values<sup>1</sup>

Exposure limits of the ingredients: none.

<sup>1</sup> The "occupational exposure limit", if not otherwise specified, is the average limit or serious concentration in the time of a chemical agent in the air inside the breathing area of a worker related to a specific period of time (Directive 98/24/EC on health and safety protection of the workers against the consequential risks from chemical agents during the job); the TWA (time weighted average) indicator is the serious average concentration in the time for a working day of 8 hours.



## 8.2. Professional exposure control

### 8.2.1. Respiratory protection

Not required during normal use

### 8.2.2 Hand protection

Not required during normal use.

### 8.2.3. Eye protection

Wear safety goggles.

### 8.2.4. Skin protection

Not required during normal use.

## 8.3 Environmental exposure control

Provide a good local ventilation of the place(s) where the product is stored and/or handled.

## 9. Physical and chemical properties

### 9.1. General information

Appearance: solid

Odour: none.

### 9.2. Health, safety and environmental information

pH: not applicable

Flammability point: not applicable

Flammability solids/gases: not determined

Explosive properties: not determined

Melt Flow Index: not determined.

## 10. Stability and reactivity

- Conditions to avoid: stable under normal conditions.

- Material to avoid: none.

- Decomposition products: hydrogen sulphide, sulphur oxide, zinc oxide.

## 11. Toxicological information

The concentration of the single substances shall be considered in order to evaluate the consequential toxicological effects from the exposure to the preparation.

In the granulated solid form the product is not usable for tests on animals. Harmful consequences have not actually been found in case of use according to the prescriptions.

Toxicological information concerning the principal substances contained in the preparation:

Toxicity acute– rat oral:  $LD_{50} \Rightarrow 5 \text{ g/kg}$  [Source: FHSA<sup>3</sup>].

Hazardous decomposition products: hydrogen sulphide, sulphur oxide, zinc oxide.

## 12. Ecological information

Use properly according to the regular working procedures and avoid to disperse the product in the environment.

## 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

The product is not hazardous within the meaning of transport regulations

## 15. Informazioni sulla regolamentazione

- 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 93/42EEC Directive, Annex I, on medical devices.

<sup>2</sup> LD<sub>50</sub> Lethal Dose, dose of substance which results to be lethal for 50% of organisms used in a toxicity test.

<sup>3</sup> FHSA, Federal Hazardous Substances Act, 15 U.S.C. §§1261–1278, USA.



## 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..

Safety phrases shown on sections 4 e 7,

Safety phrases:           S25                   Avoid contact with eyes  
                                  S 7                        Keep container tightly closed

are specific of some ingredients and are not shown on the label.

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 no. R04/5E 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](http://www.leone.it) for an updated version of the present sheet.