



SECTION 1: Identification of the substance or mixture and of the company

1.1. Product identifier

Product Description: Fluorescent additive.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified Use Professional use: Additive for self-curing orthodontic resin, for spray-on or doughing techniques.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.

I – 50019 Sesto Fiorentino – Firenze - Via P. a Quaracchi, 50

e-mail: research@leone.it – <http://www.leone.it>

Tel. +39 055.30.44.1 – Fax +39 055 374808.

1.4. Emergency telephone number

+39 055.30.44.1. An answering machine is on during closing time.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

According to Regulation (EC) no. 1272/2008 [CLP].

This product does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) no. 1272/2008 on classification, labelling and packaging of substances and mixtures.

Upon a correct use, according to our experience no significant hazards to man or environment are reasonably foreseen.

2.2. Label elements

Not applicable.

2.3. Other hazards

Not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

Zinc sulfide.

According to Regulation (EC) No. 1272/2008 [CLP], the product does not meet the criteria for classification in any hazard class.

No hazardous components are listed.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation IF INHALED: ensure the supply of fresh air.

Skin contact IF ON SKIN (or hair): Wash affected skin with water, soap or mild detergents.

Eye contact IF IN EYES: flush eyes for several minutes with plenty of water with eyelids wide open. Eventually consult a doctor.

Ingestion Rinse the mouth and consult a doctor.

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

Not applicable.

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

None necessary.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media Water spray, foam, dry powder, CO₂.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition: sulfur oxides fumes.

5.3. Advice for firefighters

In case of fire, a self-breathing apparatus is recommended.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

6.2. Environmental precautions

Do not empty into drains, do not contaminate surface water and groundwater.

6.3. Methods and material for containment and cleaning up

Collect and reuse.



6.4. Reference to other sections

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with acid elements.

7.2. Conditions for safe storage, including any incompatibilities

Store in a dry place.

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Not applicable

8.2. Exposure controls

Appropriate engineering controls

Do not eat, drink or smoke at the work place. The following information is given as general guidance.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection	Safety glasses.
Respiratory protection	Dust respirator with filter type P3.
Skin protection	Use slightly permeable to dust clothes.
Hand protection	Wear protective gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Dust.
Colour	Yellow-green.
Odour	Characteristic.
pH	11 at 20°C watery extract.
Melting point	>1500°C.
Solubility (Water)	Insoluble.
Density	4.1 g/ml.

9.2. Other information

None.

SECTION 10: Stability and reactivity

10.1. Reactivity

Non-reactive material, under normal environmental condition.

10.2. Chemical stability

Stable under normal storage and handling conditions.

10.3. Possibility of hazardous reactions

If in contact with acid elements, development of sulfuric acid.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

Avoid acid elements.

10.6. Hazardous decomposition product(s)

Thermal decomposition: will not verify if correctly used and handled.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute Toxicity

Potential Acute Health Effects	Acute oral toxicity LD50 _{rat} >5000 mg/kg. Skin irritation (rabbit): no. Ocular irritation (rabbit): no.
Signs and Symptoms of Exposure	Not applicable.
Medical Conditions Generally Aggravated by Exposure	None known.
Carcinogenic or Potential Carcinogenic Effects	No ingredient listed as a carcinogen.
Other Potential Health Effects	Not known.
Potential Chronic Health Effects	Not known.



SECTION 12: Ecological information

Product water-insoluble separable by sedimentation. Avoid contamination of sewerage, water and soil.

12.1. Toxicity

Not applicable.

12.2. Persistence and degradability

Not applicable.

12.3. Bioaccumulative potential

Not applicable.

12.4. Mobility in soil

Not applicable.

12.5. Results of PBT and vPvB assessment

Not applicable.

12.6. Other adverse effects

Not known.

SECTION 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.

13.1. Waste treatment methods

Do not empty into drains, do not contaminate surface water and groundwater.

SECTION 14: Transport information

Not dangerous according to current transportation regulations.

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Avoid elevated temperatures and high intensity light.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: Regulatory information

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

Regulation (EC) no. 1272/2008 (Classification, labeling and packaging of substances and mixtures) and subsequent amendments, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) no. 1907/2006.

Directive 2009/161/EU (third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC).

This product is CE marked in accordance with the essential safety and performance requirements of Annex I of the European regulation on medical devices.

15.2. Chemical safety assessment

Not applicable.

SECTION 16: Other information

This Safety data sheet was prepared in accordance with the Commission Regulation (EU) no. 453/2010 and Commission Regulation (EU) no. 2015/830.

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

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 relates only to specific product designated 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 does not imply any liberty to break patent rights.

Previous safety data sheet no. R04/6E dated 29/05/2009 is to be considered obsolete. 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.

Legend

IBC Code: International Bulk Chemicals Code.

LD50, Lethal Dose 50: the dose required to kill half the members of a tested population after a specified test duration.

PBT: Persistent, Bioaccumulative And Toxic Substances.

vPvB: Very Persistent And Very Bioaccumulative Substances.