

SECTION 1: Identification of the substance/mixture and of the company/undertaking**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.

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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.

www.leone.it/emergency (EU and international telephone numbers).

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

According to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1 %.

The product does not contain substances with endocrine-disrupting properties in a concentration ≥ 0.1 %.

SECTION 3: Composition/information on ingredients**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 Move the person to fresh air. If breathing is difficult, call for medical help immediately.

Skin contact Take off contaminated clothing. Wash immediately and thoroughly with water. If irritation persists, seek medical attention. Wash contaminated clothing before reuse.

Eye contact Remove any contact lenses. Wash immediately and thoroughly with water for at least 15 minutes, opening your eyelids wide. Consult a doctor if the problem persists.

Ingestion Consult a doctor immediately. Induce vomiting only if instructed to do so by a doctor. Do not give anything by mouth if the person is unconscious and unless instructed to do so by a doctor.

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

Information not available.

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

Information not available.

SECTION 5: Firefighting measures**5.1. Extinguishing media**

Suitable extinguishing Media The extinguishing agents are traditional: carbon dioxide, foam, powder and water mist.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

HAZARDS DUE TO EXPOSURE IN CASE OF FIRE

Avoid breathing combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION

Cool containers with water jets to prevent product decomposition and the development of substances that are potentially hazardous to health. Always wear full fire protection equipment. Collect extinguishing water, which must not be discharged into drains. Dispose of contaminated water used for extinguishing and fire residues in accordance with current regulations.

EQUIPMENT

Normal firefighting clothing, such as an open-circuit compressed air breathing apparatus (EN 137), full flame-resistant suit (EN469), flame-resistant gloves (EN 659) and firefighting boots (HO A29 or A30).

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Stop the leak if there is no danger.

Wear appropriate protective equipment (including personal protective equipment according to section 8 of the safety data sheet) to prevent contamination of skin, eyes and personal clothing. These instructions apply to both workers and emergency responders.

6.2. Environmental precautions

Prevent the product from entering sewers, surface water and groundwater.

6.3. Methods and material for containment and cleaning up

Vacuum the spilled product into a suitable container. Assess the compatibility of the container to be used with the product, checking section 10. Absorb the remainder with inert absorbent material.

Ensure sufficient ventilation of the place affected by the leak. Dispose of contaminated material in accordance with section 13.

6.4. Reference to other sections

Information on personal protection and disposal can be found in sections 8 and 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Handle the product after consulting all other sections of this safety data sheet. Avoid dispersing the product in the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, check section 10.

7.3. Specific end use(s)

Information not available.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

Information not available.

8.2. Exposure controls**8.2.2. Individual protection measures, such as personal protective equipment**

Eye protection The use of protective goggles is recommended.

Respiratory protection In short exposures use a mask, in case of more intensive exposures and during exposure wear self-contained breathing apparatus.

Skin protection Wear clothing or normal protective overalls resistant to dust contamination.

Hand protection Wear protective gloves.

8.2.3. Environmental exposure controls

Emissions from production processes, including those from ventilation equipment, should be controlled in order to comply with environmental protection regulations.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	Dust.
Colour	Green, yellow.
Odour	Odourless.
Melting point/freezing point	>1500°C.
Boiling point or initial boiling point and boiling range	Not applicable.
Flammability	Not available.
Lower and upper explosion limit	Not available.
Flash point	Not applicable.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
pH	11.
Kinematic viscosity	Not available.
Solubility	Negligible in water.
Partition coefficient n-octanol/water (log value)	Not available.
Vapour pressure	Not available.
Density and/or relative density	4,1 kg/l
Relative vapour density	Not available.

Particle characteristics

Not available.

9.2. Other information

Information not available.

SECTION 10: Stability and reactivity**10.1. Reactivity**

There are no particular hazards of reaction with other substances under normal conditions of use.

10.2. Chemical stability

The product is stable under normal conditions of use and storage.

10.3. Possibility of hazardous reactions

Dusts are potentially explosive when mixed with air.

10.4. Conditions to avoid

Avoid dust accumulation in the environment.

10.5. Incompatible materials

Information not available.

10.6. Hazardous decomposition products

Information not available.

SECTION 11: Toxicological information

There are no known cases of damage to health due to exposure to the product. In any case, it is recommended to work in accordance with good industrial hygiene practices.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008Metabolism, kinetics, mechanism of action

Information not available

Information on likely routes of exposure

Information not available

Immediate, delayed and chronic effects resulting from short-term and long-term exposure

Information not available

Interactive effects

Information not available

ATE (Inhalation) of the mixture

Not classified (no relevant components)

ATE (oral) of the mixture

Not classified (no relevant components)

ATE (Dermal) of the mixture

Not classified (no relevant components)

Skin corrosion/irritation

Does not meet the classification criteria for this hazard class.

Serious eye damage/irritation

Does not meet the classification criteria for this hazard class.

Respiratory or skin sensitisation

Does not meet the classification criteria for this hazard class.

Germ cell mutagenicity

Does not meet the classification criteria for this hazard class.

Carcinogenicity

Does not meet the classification criteria for this hazard class.

Reproductive toxicity

Does not meet the classification criteria for this hazard class.

STOT-single exposure

Does not meet the classification criteria for this hazard class.

STOT-repeated exposure

Does not meet the classification criteria for this hazard class.

Aspiration hazard

Does not meet the classification criteria for this hazard class.

11.2 Information on other hazards**11.2.1. Endocrine disrupting properties**

Based on available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with effects on human health that are currently being evaluated.

SECTION 12: Ecological information

Use in accordance with good working practices, avoiding dispersal of the product into the environment. Notify the competent authorities if the product has reached watercourses or if it has contaminated the soil or vegetation.

12.1. Toxicity

Information not available.

12.2. Persistence and degradability

Information not available.

12.3. Bioaccumulative potential

Information not available.

12.4. Mobility in soil

Information not available.

12.5. Results of PBT and vPvB assessmentAccording to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1 %.**12.6. Endocrine disrupting properties**

Based on available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with effects on the environment under assessment.

12.7. Other adverse effects

Information not available.

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 including those of Decree-Law No. 153 of 17 October 2024.

13.1. Waste treatment methods

Reuse if possible. Product residues as such are to be considered non-hazardous special waste.

Disposal must be entrusted to a company authorised to manage waste, in compliance with national and, where applicable, local regulations.

For solid residues, consider disposal in an authorised landfill.

CONTAMINATED PACKAGING

Contaminated packaging must be sent for recovery or disposal in accordance with national waste management regulations.

SECTION 14: Transport information

The product is not considered dangerous according to current regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

14.1. UN number or ID 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

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

Information 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

No chemical safety assessment has been carried out for the mixture/substance indicated in section 3.

SECTION 16: Other information

This safety data sheet has been prepared in accordance with REACH Regulation (EC) 1907/2006 as amended by Regulation (EU) 2020/878.

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. R04-8E dated 31/01/2023 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 sheets.

Certain subsections of some sections are omitted because, as permitted by Annex II, Part B of Regulation (EU) 2020/878, they are not applicable.

This safety data sheet is subject to revision. Visit our web site www.leone.it for an updated version of the present sheet.

Legend

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

ATE: Acute Toxicity Estimate.

CLP: Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008.

EN: European Standard.

EN137: Respiratory protective devices - Self-contained open-circuit compressed air breathing apparatus with full face mask - Requirements, testing, marking.

EN469: Protective clothing for firefighters - Performance requirements for protective clothing for firefighting activities.

EN659: Protective gloves for firefighters.

HO A29/ A30: Technical specifications for firefighting boots.

IATA : International Air Transport Association.

IMDG Code: International Maritime Dangerous Goods.

IMO: International Maritime Organization.

PBT: Persistent, Bioaccumulative And Toxic Substances.

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail.

SVHC: Substances of Very High Concern.

vPvB: Very Persistent And Very Bioaccumulative Substances.