

SECTION 1: Identification of the substance or mixture and of the company**1.1. Product identifier**

Product description: Silver, gold, multicolour, blue and red glitters.

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

Identified Use For Leocryl® powder coatings with spray-on or doughing techniques for orthodontic removable plates.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.

I – 50019 Sesto Fiorentino – Firenze - Via P. a Quaracchi, 48/50

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.

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

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture**

Not classified according to Regulation (EC) No 1272/2008 (CLP).

No obvious risk to human health or the environment. However, we have no knowledge of chronic effects or skin irritation in case of contact with the product.

The information contained in this sheet refers to the raw material from which these products are made; for this reason some warnings and indications are related to the processing personnel and not to the end user.

2.2. Label elements

Not subject to labelling according to Regulation (EG) No. 1272/2008 (CLP).

2.3. Other hazards

No risks from this product regarding human health or environment are apparent. We therefore have no knowledge of chronic or skin irritating effects when physical contacts has occurred.

SECTION 3: Composition/information on ingredients**3.2. Mixtures**

Coated aluminium particles.

SECTION 4: First aid measures**4.1. Description of first aid measures**

Contaminated clothing must be changed after contact with the melted product. In case of fainting, place and transport the person in the recovery position. In case of persistent malaise, contact a doctor.

Inhalation After inhaling dust particles and especially decomposition gases, move the injured person to fresh air, lie him down and protect him from hypothermia. In case of fainting and existing breathing, place the person in a stabilised lateral position. Contact a doctor for treatment.

Skin contact In case of contact with molten product, rinse affected skin areas with water for at least 15 minutes. Remove contaminated clothing, but do not remove product residues from the skin. Burns should be covered with sterile bandages. In case of burns, skin irritation or other symptoms, contact a doctor.

Eye contact Carefully remove the particle from the affected eye. If necessary, remove contact lenses. Rinse the eye 15 minutes with plenty of water. If necessary, consult a doctor.

Ingestion Rinse your mouth thoroughly and drink plenty of water. If you feel unwell, call a doctor.

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

No information available

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

The toxic effects of the product itself, with the exception of thermal decomposition and fire, are unknown. In case of complaints, treat symptomatically.

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

Suitable extinguishing Media The product itself is neither combustible nor explosive. Extinguishing agents must be coordinated with the surrounding fire.

Unsuitable extinguishing Media Water jet.

5.2. Special hazards arising from the substance or mixture

Carbon monoxide (CO) and other toxic and flammable gases may be released.

5.3. Advice for firefighters

In case of fire, the use of self-contained breathing apparatus is recommended.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Do not inhale dust. Keep dust away from heat sources.

6.2. Environmental precautions

Wastewater must be mechanically cleaned of product residues before entering the sewage system.

6.3. Methods and material for containment and cleaning up

Dry absorption and if possible re-utilisation of the material.

6.4. Reference to other sections

Personal protective equipment according to section 8.2, disposal according to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Safety advice

Avoid overheating through improper processing and dusting.

Technical protective measures

Local ventilation and airing guarantee, that all limits mentioned in section 8.1 are maintained.

Fire and explosion protection information

Keep away from sources of ignition.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage in rooms and containers

Store in tightly closed (original) containers. Store in dry place.

Additional details regarding storage

Protect against heat. Comply with the company's fire prevention regulations.

Storage class

Storage class according to TRGS 510: LGK 11 (flammable solids).

There are no incompatible products to mention.

7.3 Specific end use(s)

See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Dry mechanical processing of the product can generate a dust hazard: local dust concentration limits at the workplace must be considered.

Parameter	CAS No.	EINECS	Value	Type of limit
general limit for dust, respirable fraction (E = respirable dust)	----	----	10 mg/m ³ E	Threshold limit value according to TRGS 900
General limit for dust, alveolar fraction (A = alveolar dust)	----	----	1.25mg/m ³ A	Threshold limit value according to TRGS 900
Aluminium	7429-90-5	231-072-3	50 µg/g Creatinine	Biological limit value in accordance with TRGS 903

8.2. Exposure controls

8.2.1. Appropriate engineering controls

An on-site vacuum system is required in case of dust collection and thermal pollution from the product.

8.2.2. Individual protection measures, such as personal protective equipment

8.2.3. Environmental exposure controls

The environmentally hazardous properties of the product are not known, so general operational measures to protect the environment are sufficient.

Respiratory protection	Use respiratory protection in case of dust exposure, e.g. a P1 dust mask complying with EN 143 or a half mask with an FFP1 or PP2 particle filter complying with EN 141. with EN 143 or a half mask with an FFP1 or PP2 particle filter complying with EN 141.
Hand protection	Protective gloves are generally not required. In case of constant skin contact, gloves are sufficient for low mechanical and material stress, see also BGR 195, e.g.: Material: Butyl rubber Penetration time: 30 min. according to DIN EN 374 Material thickness: Butyl rubber min. 0.4 mm
Eye protection	Safety glasses with side protection in accordance with EN 166 are required when performing mechanical work with exposure to dust.
Body protection	Safety shoes and normal work clothes are sufficient.
General safety and industrial hygiene measures	Do not inhale dust. Avoid contact with the eyes. Do not eat, drink or smoke while working. Wash hands before breaks and at the end of work.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state

Solid

Colour	Various
Odour	Odourless.
Melting point/freezing point	659 °C
Boiling point or initial boiling point and boiling range	2447 °C
Heat resistance	230 °C
Flammability	Not self-ignorant
Lower and upper explosive limit	Possible explosion of dust or decomposition gases.
Flash point	Not self-flammable
pH	Not applicable
Kinematic viscosity	Not applicable
Water solubility	Insoluble in water
Partition coefficient n-octanol/water (log value)	Not applicable
Vapour pressure	To be disregarded.
Density and/or relative density	Between 0.20 and 1.00 kg/dm ³ - depending on particle size.
Relative vapour density	Not applicable
Particle characteristics	Specific weight: 2.70 kg/dm ³
Particle shape	Rectangular, hexagonal and square particles.

9.2. Other information

No further details are necessary with regard to safety-relevant parameters.

SECTION 10: Stability and reactivity

It is recommended to carry out an initial test before processing the product.

10.1. Reactivity

It is non-reactive under the indicated conditions of use and storage.

10.2. Chemical stability

Stable if stored and applied as directed.

10.3. Possibility of hazardous reactions

No chemical reaction if stored and applied according to instructions.

10.4. Conditions to avoid

Pyrolysis, hazardous decomposition products and dangerous reactions do not occur if the product is used as intended.

10.5. Incompatible materials

Strong acids, basic and oxidation agents. Protect from temperatures > 150 °C.

10.6. Hazardous decomposition products

Aldehyde, carbon monoxide, carbon dioxide, hydrocarbons.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity	No toxicological data are available.
Skin corrosion/irritation	Contact with the molten product may cause
Serious eye damage/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	No sensitizing effects on the skin or respiratory organs are known.
Germ cell mutagenicity	No mutagenic effects are known.
Carcinogenicity	No carcinogenic effects are known.
Reproductive toxicity	No reproductive toxicity effects are known.
STOT-single exposure	No organ toxicity effects are known.
STOT-repeated exposure	No organ toxicity effects are known.
Aspiration hazard	Inhalation of dust and decomposition gases may cause health problems.

11.2 Information on other hazards

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SECTION 12: Ecological information

12.1. Toxicity

No data available.

12.2. Persistence and degradability

The product is insoluble and the inorganic substances it contains are not bioavailable.

12.3. Bioaccumulative potential

The product is insoluble and the inorganic substances it contains are not bioavailable, so it is not bioaccumulative.

12.4. Mobility in soil

The product is insoluble and therefore not mobile.

12.5. Results of PBT and vPvB assessment

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

12.6. Endocrine disrupting properties

No endocrine disrupting properties are known.

12.7 Other adverse effects

No ecological and eco-toxicological data are available. No threat to the environment is expected if the product is handled and disposed of safely.

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 October 17, 2024.

13.1. Waste treatment methods

Re-use product remainders again if possible.

Recommendation: Packaging can be used again if not contaminated. Cleaning agent: water.

SECTION 14: Transport information

Non-hazardous for transportation purposes.

14.1. UN number or ID number

Not relevant

14.2. UN proper shipping name

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14.3. Transport hazard class(es)

Not relevant

14.4. Packing group

Not relevant

14.5. Environmental hazards

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14.6. Special precautions for user

See section 7.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous goods as defined by ADR/RID/ADN/GGVSEB, ICAO/IATA, IMDG.

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

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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. R17/5E 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

A: Honeycomb powder

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road transport of dangerous goods by road.

AGW: Occupational exposure limit according to TRGS 900

BGW: Biological limit value according to TRGS 903

CAS: Chemical Abstracts Service (division of the American Chemical Society)

CLP: Classification, labeling and packaging of substances and mixtures

E: Inhalable powder

EC No.: EINECS (European Inventory of Existing Commercial Chemical Substances) number.

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

IMDG: International Maritime Dangerous Goods Code

REACH: Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals. chemicals.

RID: Relating to the International Carriage of Dangerous Goods by Rail

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.

TRGS: Technical regulations for hazardous substances

WGK: Water hazard class

STOT: Specific target organ toxicity.

vPvB: very Persistent very Bioaccumulative.

PBT: Persistent, Bioaccumulative and Toxic: hazardous chemicals.

IMO: International Maritime Organization.