



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, 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

It does not have to be labeled according to the Regulation (EC) no. 1272/2008 [CLP].

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

Information given by this safety data sheet refers to the raw material used to manufacture all or part of Leone products; for this reason some instructions concern the personnel involved in the manufacturing process and not the final user.

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

Solid made of coated aluminium-foil. Substances in the product which may present a health or environmental hazard, or which have been assigned occupational exposure limits, are detailed below.

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

Hazardous ingredient(s)	%W/W	EC no.	CAS no.	Hazard class and category code(s)	Hazard statement Code (s)
Aluminium	95.8-97.2%	231-072-3	7429-90-5	Water Reaction 2 Flammable Solid 1;	H261 H228
Polyurethane coating	2.8%	-		Not classified as hazardous.	-
Color pigments					-
Red 122	depends to article, between 0-1.4 %	213-561-3	980-26-7	Not considered hazardous.	-
Yellow 83		226-939-8	5567-15-7	Not considered hazardous.	-
Blue 15		205-685-1	147-14-8	Not considered hazardous.	-
Green 7		215-524-7	1328-53-6	Not considered hazardous.	-
Red 88 (Maroon)		238-222-7	14295-43-3	Not considered hazardous.	-
Black 7		215-609-9	1333-86-4	Not considered hazardous.	-
Violet 23		228-767-9	6358-30-1	Not considered hazardous.	-

SECTION 4: First aid measures

4.1. Description of first aid measures

If damages to health occur contact a physician.

Inhalation IF INHALED: Remove person to fresh air.

Skin contact IF ON SKIN (or hair): Clean skin with water and soap.

Eye contact IF IN EYES: Remove particle carefully from the affected eye. If needed, remove contact lens. Rinse eye with plenty of water and consult a physician.

Ingestion Consult a physician after swallowing large quantities.

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

Dust particles may irritate skin and mucous membranes, eyes and respiratory tracts.

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

Decontamination and symptomatic treatments are in most cases sufficient.



SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media In case of fire, use drier sand, fire extinguisher class D.
Unsuitable extinguishing Media Water, extinguishing foam, carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Risk of dust explosion (through Aluminium powder).

5.3. Advice for firefighters

An independent respiratory device (isolation device) should be used.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Do not inhale any dust. Keep sources of ignition away from the dust.

6.2. Environmental precautions

Waste water must be mechanically cleaned from rest products prior to emptying into the sewer 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

-.

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.

Joint storage May not be stored together with products of storage class 1-3 (oxidizing substances), 4.1A (flammable solid materials) and 6.2 (infectious substances). Particular regulations will apply for the joint storage of storage classes 3B, 4.1B, 10, 11 and 12.

Additional details regarding storage Collocated storage with aqueous solutions should be avoided.
Storage class contact LGK 4.3 (Materials liberating flammable gases in with water).

7.3 Specific end use(s)

-.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The applicable limits which are to be complied with and monitored, particularly during mechanical processing with a risk of dust.

Parameter	Type of limit	Value	Comment
General dust limit, breathable fraction (E = breathable dust)	Limit at work (AGW) according to the TRGS 900 Regulation	10 mg/m ³ E.	2 times exceeding within 15 min, 4 times per shift with an interval of 1 hour is permitted.
	Measuring procedure:	For example: according to the BIA workbook: Measurement of dangerous substances.	
General dust limit, alveolar fraction (A = alveolar dust)	Limit at work (AGW) according to the TRGS 900 Regulation.	3 mg/m ³ A.	2 times exceeding within 15 min, 4 times per shift with an interval of 1 hour is permitted.
	Measuring procedure:	For example: according to the BIA workbook: Measurement of dangerous substances.	
Aluminium in Urine	biological limit (BGW) according to TRGS 903	200 µg/l.	sampling is done at the end of shift.
	Measuring procedure:	Atom Absorption Spectrometry (AAS).	

8.2. Exposure controls

Appropriate engineering controls

Do not inhale dust. Avoid contact with eyes, skin and clothes. Do not eat, drink, smoke or snuff during work. Wash hands prior to breaks and after finishing work. Change soiled clothes. Protect skin by using e. g. skin lotions and creams. An on-site extraction system is required in the event of gathered dust and thermal pollution from the product.



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

Eye/face protection	Side-shielded safety goggles (EN 166) are required when carrying out mechanical processing with exposure to dust.
Hand protection	Protective gloves are generally not required. However, for constant skin contact it is necessary to use gloves of low mechanical and special material demands, e.g. Material: Butyl rubber Mat. Thickness: min. 0.4 mm min. Penetration time: 30 min. acc. to EN 374.
Respiratory protection	Use respiratory protection in the event of dust exposure, e.g. a P1 dust mask that conforms to EN 143 or a half mask with particle filter FFP1 or PP2 conforms to EN 141. Caution! Limited wearing period.
Body protection	Generally, normal working clothes are sufficient.

Environmental exposure controls

There are no known properties of the product, that pose dangers to the environment. General operational measures are sufficient to protect the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Solid glitter particles in either rectangular, hexagonal or square shapes.
Colour	Various (refer to table regarding colour proportions).
Odour	Odourless.
pH	Not applicable.
Heat resistance	232 °C.
Melting point	659 °C.
Boiling point	2447 °C.
Flash point	Not applicable.
Explosive properties	None.
Vapour Tension	Negligible.
Solubility (Water)	Insoluble in water.
Evaporation speed	Not applicable.
Viscosity	Not-applicable.
Auto ignition temperature	Not self-igniting.
Risk of explosion	Possible dust- or decomposition gas explosion.
Partition coefficient n-Octanol/ water	Not applicable.
Specific weight	2.70 kg/dm ³ .
Bulk density	Between 0.60 and 1.0 kg/dm ³ - depending on particle size.

9.2. Other information

There are no further details required regarding safety-relevant parameters.

SECTION 10: Stability and reactivity

It is recommended to carry out a trial run prior to processing the product.

10.1. Reactivity

-.

10.2. Chemical stability

-.

10.3. Possibility of hazardous reactions

Dangerous reactions will not occur if the product is used as intended.

10.4. Conditions to avoid

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

10.5. Incompatible materials

Potent acids, bases and oxidation agents.

10.6. Hazardous decomposition product(s)

When heated: Aldehyde, carbon monoxide, carbon dioxide, hydrocarbons.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

There is no toxicological data available.

According to our knowledge, the product does not cause any health defects, if properly handled and the product has been applied as intended.

The contact with the melted product can cause burn wounds.

The inhalation of dust and decomposition gases can cause health defects.



SECTION 12: Ecological information

According to our knowledge, the product does not cause any damages to the environment, if properly handled and the product has been applied as intended.

12.1. Toxicity

Not available.

12.2. Persistence and degradability

Not available.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessment

Not available.

12.6. Other adverse effects

Not available.

SECTION 13: Disposal considerations

No waste is produced from the product, that would require special supervision according to EU-directive 2008/98/EC.

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

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

Not applicable.

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. R17/4E dated 16/01/2017 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.

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

Hazard statement:

H228: Flammable solid.

H261: In contact with water releases flammable gases.

Legend

AGW: (Arbeitsplatzgrenzwerte), see IOELV.

BGW (Biologische Grenzwerte): biological limit values.

BIA (Berufsgenossenschaftliches Institut für Arbeitsschutz: Institute for Occupational Safety and Health, Germany).

CAS No.: Chemical Abstract Service Registry number.

EC-No.: European Inventory of Existing Commercial Chemical Substances.

EN 141: Respiratory protective devices. Gas filters and combined filters. Requirements, testing, marking.

EN 143: Respiratory protective devices. Particle filters. Requirements, testing, marking.

EN 166: Personal eye-protection – Specifications”.

EN 374: Protective gloves against chemicals and micro-organisms.

IBC Code: International Bulk Chemicals Code Identification Number.

IOELV: Indicative Occupational Exposure Limit Value.

PBT: Persistent, Bioaccumulative And Toxic Substances.

vPvB: Very Persistent And Very Bioaccumulative Substances.