1. Identification of the preparation and of the company

1.1 Identification of the preparation

Silver, gold, multicolour, blue and red glitters.

1.2 Use of the preparation

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

1.3 Company identification

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 (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

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.
No relevant hazards to environment or human health. No chronic effects or skin irritations due to the contact with the product are known.

3. Composition/information on ingredients

Particles made of coated aluminium film.
Information on hazardous ingredients[1] and composition %

Chemical name	EC[2] Number	%	CAS[3] Number	CI[4] Number	Hazard symbols[5]	R[5] Phrases
Aluminium	231-072-3	90-92	7429-90-5	77000	F	R 10-15
Epoxy resin coating	-	8	-	-	-	-
Pigments		0-2			-	-
Pigment combination of different colours of the product:						
- Silver coloured pigments		*0*				
- Gold coloured pigments:		*≤2*				
Yellow 83	*226-939-8*		*5567-15-7*	*21108*		
Red 190	*229-187-9*		*6424-77-7*	*71140*		
Red 221	*275-639-3*		*71566-54-6*	*20065*		
- Red coloured pigments:		*≤2*				
Yellow 83	*226-939-8*		*5567-15-7*	*21108*		
Red 144	*226-106-9*		*5280-78-4*	*20735*		
Red 221	*275-639-3*		*71566-54-6*	*20065*		
- Blue coloured pigments:		*≤2*				
Blue 15	*205-685-1*		*147-14-8*	*74160*		
Red 144	*226-106-9*		*5280-78-4*	*20735*		
- Multicolour pigments:		*≤2*				
Yellow 83	*226-939-8*		*5567-15-7*	*21108*		
Red 190	*229-187-9*		*6424-77-7*	*71140*		
Red 221	*275-639-3*		*71566-54-6*	*20065*		
Red 144	*226-106-9*		*5280-78-4*	*20735*		
Blue 15	*205-685-1*		*147-14-8*	*74160*		
Red 88	*238-222-7*		*14295-43-3*	*73312*		

4. First aid measures

General advice: if damages to one's health occur, contact a physician.
- Inhalation: remove to fresh air.
- Skin contact: clean skin with water and soap.
- Eye contact: remove particle carefully from the affected eye. If necessary, remove contact lenses. Rinse eye with plenty of water and consult a physician.

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[1] The occupational exposure limits (OEL), if known, are listed in section 8.
[2] Number of European Catalogue. The EC number is made of a sequence of 7 figures, whose first group of 3 figures begins with 2 or 4 depending on which substance is included in the EINECS (European Inventory of Existing Commercial Chemical Substances) or in the ELINCS (European List of Notified Chemical Substances), or it begins with 5 if the substance is included in the list of "ex-polymers."
[3] CAS Number (Chemical abstract service).
[4] CI Number of color agents (Color Index).
[5] Hazards related to the ingredients of the preparation are indicated in section 2, information to be shown on the label are indicated in section 15. Explanation of hazardous symbols and Risk phrases is indicated in section 15 and 16.

- Ingestion: consult a physician after swallowing large quantities.
-Advise to the physician: dust particles may irritate skin, mucosa, eyes and respiratory tract. Decontamination and symptomatic treatments are in most cases sufficient.

5. Fire-fighting measures

- Suitable extinguishing agents: drier sand, fire extinguishers class D.
- Unsuitable extinguishing agents : water, extinguishing foam, carbon dioxide.
- Special hazards: risks of dust explosion (through aluminium powder).
- Special protective equipment: a self-breathing apparatus should be used.

6. Accidental release measures

- Personal protection: avoid the build up of dust. Do not inhale any dust. Keep sources of ignition away from the dust.
- Environmental measures: waste water must be mechanically cleaned from rest of product prior to emptying into the sewer system.
- Cleaning procedures and absorption: dry absorption and if possible re-utilisation of the material.

7. Handling and storage

7.1 Handling

Safety advice: avoid overheating through improper processing and dusting.
Technical protective measures: guarantee good local ventilation in order to maintain all limits mentioned on section 8.
Fire and explosion protection information: keep away from sources of ignition.

7.2 Storage

Requirements for storage in rooms and containers: store in tightly closed (original) containers. Store in dry place.
Joint storage: do not store together with oxidizing substances, flammable solid materials and infectious substances.
Additional details regarding storage: storage with aqueous solutions should be avoided. Flammable material releasing gases in contact with water.

8. Exposure controls/personal protection

8.1. Exposition limit values[6]

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)	TLV[7] according to TRGS 900[8]	10 mg/m³ 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 BGIA[9] workbook: “Measurement of dangerous substances”	
General dust limit, alveolar fraction (A = alveolar dust)	TLV according to TRGS 900	3 mg/m³ 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 BGIA workbook: “Measurement of dangerous substances”	
Aluminium in Urine	BLV[10] according to TRGS 903[11]	200 µg/l	Sampling is done at the end of shift
	Measuring procedure	AAS[12]	

8.2. Exposure control

8.2.1. Professional exposure control

An on-site extraction system is required in the event of gathered dust and thermal pollution from the product.

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[6] 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.

[7] TLV, Threshold Limit Value, represents the concentration below which the most part of workers can be exposed to, in relationship to a reference specific period, without negative effects for the health.

[8] TRGS (Technischen Regeln für Gefahrstoffe) n. 900 “Arbeitsplatzgrenzwerte“, January 2006 and further modifications, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), Germany.

[9] BGIA (Berufsgenossenschaftliches Institut für Arbeitsschutz), Institute for Occupational Safety and Health, Germany.

[10] BLV, Biological Limit Value, is the maximum concentration limit allowed for a substance and its metabolites within which any damage to the health of a worker should be avoided. It is generally calculated on the basis of a daily exposure of 8 hours for 40 weekly hours.

[11] TRGS (Technischen Regeln für Gefahrstoffe) n. 903 “Biologische Grenzwerte“, December 2006 and further modifications, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), Germany.

[12] AAS (Atomic absorption spectroscopy) in analytical chemistry, it is a technique for determining the concentration of a particular metal element in a sample.

8.2.1.1. Hand protection
Protective gloves are generally not required. However for constant skin contact it is necessary to use special purpose gloves (i.e according to EN 374[13]).

8.2.1.2. Eye protection
Side-shielded safety goggles conforming to EN 166[14] are required when carrying out mechanical processing with exposure to dust.

8.2.1.3. Respiratory protection
Use respiratory protection in the event of dust exposure, e.g. a P1 dust musk conforming to DIN 3181-3[15] or a half mask with particle filter FFP1 conforming to EN 140[16].

8.2.1.4. Body protection
Generally normal working clothes are sufficient.

8.2.1.5. General protection and hygiene measures
Do not inhale dust. Avoid contact with eyes, skin and clothes. Do not eat, drink or smoke during work. Wash hands prior to breaks and after finishing work. Change contaminated clothes. Protect skin by using skin lotions or creams.

8.2.2. Environmental exposure control
There are no known properties of the product causing dangers to the environment. General operational measures are sufficient to protect the environment.

9. Physical and chemical properties

9.1. General information

Appearance:	solid
Shape:	rectangular glitter particles 0.40mm x 0.20mm, thickness 19µm (±10%).
Odour:	odourless
Colour:	various, see section 3.

9.2. Health, safety and environmental information

pH:	not applicable
Heat resistance:	220°C
(Particles/Pigment/Coating)	
Melting point:	659°C
Boiling point:	2447°C
Flash point:	not applicable
Self-ignition point:	not self-igniting
Risk of explosion:	possible dust or decomposition gas explosion
Vapour pressure:	to be disregarded
Specific weight (H_2O=1)	2.70 kg/dm³
Apparent specific gravity:	between 0,20 and 1.0 kg/dm³
Water solubility:	insoluble
Viscosity:	not applicable
Vapour density:	not applicable
Evaporation speed:	not applicable.

10. Stability and reactivity
It is recommended to carry out a trial run prior to processing the product.
- Conditions to avoid: pyrolysis, dangerous decomposition products and dangerous reactions will not occur if the product is used as intended.
- Material to avoid: potent acids, bases and oxidation agents.
- Dangerous decomposition products when heated: aldehyde, carbon monoxide, carbon dioxide, hydrocarbons.

11. Toxicological information
There is no toxicological data available.
According to our knowledge, the product does not cause any health injuries, if proper handled and applied as intended.
The contact with the melted product can cause burn wounds. The inhalation of dust and decomposition gases can cause health injuries.

12. Ecological information
Ecological respectively ecotoxicological data is not available.

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[13] European Norm EN 374-1 “Protective gloves against chemicals and micro-organisms - Part 1: Terminology and performance requirements”.
[14] European Norm EN 166 “Personal eye-protection – Specifications”.
[15] German Norm DIN 3181-3 “Atemschutzgeräte; CO- und Reaktor-Filter; Einteilung, Kennzeichnung“ (Respiratory protective devices; CO and reactor filters; classification, marking).
[16] European Norm EN 140 “Respiratory protective devices - Half masks and quarter masks - Requirements, testing, marking”.

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

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.
Use product residuals again if possible.
Recommendation: packaging may be used again if not contaminated. Cleaning agent: water.

14. Transport information

None. The product is not hazardous within the meaning of transport regulations.

15. Regulatory information

- 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.

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.
Hazard symbols or risk phrases shown on section 3, and safety phrases:

Risk phrases:	R 10	Flammable
	R 15	Contact with water liberates extremely flammable gases
Safety phrases:	S 2	Keep out of the reach of children
	S 7/8	Keep container tightly closed and dry
	S 43	In case of fire use dry powder - Never use water

are specific for some ingredients and not shown on the product 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 n. R17/2E dated 17/05/2001 is 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 for an updated version of the present sheet.