SECTION 1: Identification of the mixture and of the company

1.1. Product identifier

Product description: Natura® brackets and hooks in siliceous copolymer.

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

Identified Use: Professional use: Aesthetic brackets for direct bonding technique used with fixed orthodontic prosthesis.

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.
The products generally are not considered as hazardous in the form they are supplied, nevertheless ingestion or inhalation of pieces or fragments may occur during use.
The information contained herein is to be referred to the raw material which these products are manufactured with; for this purpose some instructions and indications are related to the personnel employed in the manufacturing processes and not to 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

Polycarbonate based on bisphenol A 80%, siliceous filler 20% with very small amount of anticombustion agents.
According to Regulation (EC) no. 1272/2008 [CLP], no dangerous ingredients.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: IF INHALED: Seek for medical advice. Products are not radiopaque.
Skin contact: IN CASE OF CONTACT WITH THE HOT MELT: Cool immediately with plenty of water . The crust formed by the product on the part of the affected skin should not be removed by force or with solvents. For skin cleansing and care for possible burns seek medical advice immediately.
Ingestion: Seek for medical advice. Products are not radiopaque.

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

Not available.

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

Not available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media: Water spray , extinguishing powder , Carbon dioxide (CO2) , Foam, Dry chemical.
Unsuitable extinguishing Media: None in particular.

5.2. Special hazards arising from the substance or mixture

Burnings releases monoxide and carbon monoxide, oxides of nitrogen and traces of hydrogen cyanide. In case of fire and/or explosion, do not breathe fumes.

5.3. Advice for firefighters

Wear breathing apparatus in fire-fighting operations. Do not allow contaminated extinguishing water to enter the soil, ground-water or surface waters.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

-.

6.2. Environmental precautions

Do not flush into surface water or sanitary sewer system.

6.3. Methods and material for containment and cleaning up

Use mechanical device, avoid dust formation.

6.4. Reference to other sections

Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Under recommended processing conditions they may be released small amounts of emissions , of monomer and solvent residues. Provide adequate ventilation and suction devices in the workplace to ensure compliance with the limit values specified in Section 8. During mechanical process, provide for dust extraction.

7.2. Conditions for safe storage, including any incompatibilities

Not specific measure required.

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

In the processing of this product, especially in the heating process, must observe the regulations for the substances listed below. In our experience, it is possible to comply with the tolerance limits quoted below, employing appropriate ventilation and suction devices placed on the emission points of the vapors may be generated.

Substance	EC no.	CAS no.	Base	Type	Value	Observation
Phenol	203-632-7	108-95-2	EU ELV	TWA	2 ppm 8mg/m^3	Indicative
Phenol	203-632-7	108-95-2	EU ELV			Possible dermal absorption
Phenol	203-632-7	108-95-2	EU ELV	STEL	4 ppm 16 mg/m^3	Indicative
Phenol	203-632-7	108-95-2	OEL IT	TWA	2 ppm 8mg/m^3	
Phenol	203-632-7	108-95-2	OEL IT			Possible dermal absorption
Phenol	203-632-7	108-95-2	OEL IT	STEL	4 ppm 16 mg/m^3	
Chlorobenzene	203-628-5	108-90-7	EU ELV	TWA	5 ppm 23 mg/m^3	Indicative
Chlorobenzene	203-628-5	108-90-7	EU ELV	STEL	15ppm 70 mg/m^3	Indicative
Chlorobenzene	203-628-5	108-90-7	OEL IT	TWA	5 ppm 23 mg/m^3	
Chlorobenzene	203-628-5	108-90-7	OEL IT	STEL	15ppm 70 mg/m^3	
4,4'-sopropylidenediphenol	201-245-8	80-05-7	EU ELV	TWA	10 mg/m^3	Indicative
4,4'-isopropylidenediphenol	201-245-8	80-05-7	OEL IT	TWA	10 mg/m^3	
General limit value for dust			OEL IT	TWA	10 mg/m^3	Inhalable fraction
General limit value for dust			OEL IT	TWA	3 mg/m^3	alveolar fraction dust

8.2. Exposure controls

Appropriate Engineering Controls

Do not eat, drink, smoke or sneeze at the workplace. It is required a proper suction/ventilation system.

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

Eye/face protection Protect eyes and face.

Body protection	Use protective gloves.
Hand protection	Appropriate material for protective gloves; EN 374: Polyvinyl chloride -PVC (>=0.5mm). Contaminated or damaged gloves must be changed.
Respiratory protection	In case of dust formation use respiratory equipment with filter type particle filter P1 according to EN 143.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Solid.
Colour	Various according to colouration.
Odour	Odourless.
pH:	Not applicable.
Melting point	130-160°C.
Upper flammable/explosive limit	Not applicable.
Vapour tension	Not applicable.
Density	Ca. 1.2-1.4 g/cm^3.
Bulk density	600-700 kg/m^3.
Water solubility	Practically insoluble.
Auto-ignition temperature	Not applicable.
Ignition temperature	>450°C.
decomposition temperature	>=380°C.
Dynamic viscosity	Not applicable.

9.2. Other information

No further details as regards the safety-relevant parameters are required.

SECTION 10: Stability and reactivity

10.1. Reactivity

Information not available.

10.2. Chemical stability

In case of thermal decomposition , which may arise in the event of fire or excessive heating , eg during an improperly processing, gases and vapors hazardous to health may occur.

10.3. Possibility of hazardous reactions

No dangerous reactions known.

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition product(s)

In the case of combustion in oxygen defect or incomplete combustion develop toxic gas mixtures consisting mainly of CO and CO_2.

Under recommended processing conditions they may be sold small amounts of emissions .

In the processing of this product , especially in the heating process must observe the regulations for the substances listed below.

Hazardous ingredient(s)	EC no.	CAS no.	Hazard class and category codes	Hazard statement code(s)
phenol	203-632-7	108-95-2	Mutagenicity. 2 Acute toxicity 3 (Inhalative) Acute toxicity 3 (Dermal) Acute toxicity 3 (Oral) Skin corrosion. 1B Eye damage 1 STOT RE 2 Aquatic chronic 2	H341 H331 H311 H301 H314 H318 H373 H411
Chlorobenzene	203-628-5	108-90-7	Flammable liquid 3 Acute toxicity (Inhalation) Eye irritation 2 Aquatic chronic 2	H226 H332 H315 H411
4-tert-butylphenol	202-679-0	98-54-4	Skin irritation 2 Ocular damage 1	H315 H318

			Reproduction 2 Aquatic chronic 1	H361f H410
4,4'-isopropylidenediphenol	201-245-8	80-05-7	Re production 2 STOT SE 3 Inalazione Eye damage 1 Skin Sensitization 1 Aquatic chronic 2	H361f H335 H318 H317 H411

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Data not available.

SECTION 12: Ecological information

Do not allow product to reach ground water, water course or sewage system.

12.1. Toxicity

Information not available.

12.2. Persistence and degradability

Information 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

The product is practically insoluble in water. Due to its consistency and insolubility in water, no ecological problems are to be expected if the product is properly handled. The product is not readily biodegradable.

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

After carefully removing the residues (liquid, solid and pasty), empty containers may be delivered to collection points set up by the chemical responsible for the respective types of packaging, so that must be processed for the recovery. Recovery must be made in accordance with national legislation and regulations on environmental protection.

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. F11/4E 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.

Hazard statements

H226: Flammable liquid and vapour.
H301: Toxic if swallowed.
H311: Toxic in contact with skin.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H331: Toxic if inhaled.
H332: Harmful if inhaled.
H335: May cause respiratory irritation.
H341: Suspected of causing genetic defects.
H361f: Suspected of damaging fertility.
H373: May cause damage to organs through prolonged or repeated exposure.
H410: Very toxic to aquatic life with long-lasting effects.
H411: Toxic to aquatic life with long-lasting effects.

Legend

ACGIH: American Conference of Governmental Industrial Hygienists.
CAS No.: Chemical Abstract Service Registry number.
EC No.: European Inventory of Existing Commercial Chemical Substances.
ELV: emission limit value.
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.
IOELV: Indicative Occupational Exposure Limit Value.
LTEL: Long Term Exposure Limit.
OEL: occupational exposure limit.
PBT: Persistent, Bioaccumulative And Toxic Substances.
STEL: Short Term Exposure Limit.
STOT RE: Specific Target Organ Toxicity-Repeated Exposure.
STOT SE: Specific Target Organ Toxicity-Single Exposure.
TLV: Threshold Limit Value.
TWA: Time Weighted Average.
vPvB: Very Persistent And Very Bioaccumulative Substances.