

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

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, 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

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.

2.2. Label elements

Not applicable.

2.3. Other hazards

This substance/mixture does not contain any components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Polycarbonate based on Bisphenol A 80%, glass-fibre 20% reinforced with very small amount of anticomustion 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 In case of inhalation of pieces or fragments seek for medical advice. Products are not radiopaque.

Skin contact In case of fire due, to the melted material, medical advice is necessary.

Ingestion In case of ingestion of pieces or fragments 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

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6.2. Environmental precautions

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6.3. Methods and material for containment and cleaning up

Pick up with mechanical means.

6.4. Reference to other sections

Section 13.

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

No special handling/storage conditions required.

7.2. Conditions for safe storage, including any incompatibilities

No special storage precautions are required.

7.3 Specific end use(s)

No further relevant information available.

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

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8.2. Exposure controls**8.2.1. Appropriate engineering controls**

Do not eat, drink, smoke or sneeze at the workplace.

8.2.2. Individual protection measures, such as personal protective equipment

Eye/face protection	No special precautions/equipment are necessary.
Body protection	No special precautions/equipment are necessary.
Hand protection	No special precautions/equipment are necessary.
Respiratory protection	No special precautions/equipment are necessary.

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

Physical state	Solid at 20 °C at 1,013 hPa
Colour	Different, depending on the colouring given
Odour	Odourless
Odour threshold	Not determined
Melting point/freezing point	Not applicable.
Softening point	130-160°C.
Boiling point or initial boiling point and boiling range	Not determined
Flammability	Not determined
Lower and upper explosion limit	Not applicable
Flash point	Not determined
Auto-ignition temperature	Not applicable
Decomposition temperature	>= 380 °C
pH:	Not applicable.
Kinematic viscosity	Not determined
Dynamic viscosity	Not applicable
Solubility in water	Practically insoluble
Partition coefficient n-octanol/water (log value)	Not determined
Vapour pressure	Not applicable.
Density and/or relative density	Ca. 1.2-1.4 g/cm ³
Relative vapour density	Not determined
Particle characteristics	Not determined

9.2. Other information**9.2.1. Information with regard to physical hazard classes**

The indicated value does not necessarily correspond to the product specification. For specification data, please refer to the product information sheet or data sheet.

Explosive properties	Not determined
Dust explosion class	Not determined
Combustion class	Not determined
Oxidising properties	Not determined
Ignition temperature	>450 °C
Heat of combustion	Not determined

9.2.2. Other safety characteristics

Evaporation rate	Not determined
Bulk density	600 - 700 kg/m ³
Miscible with water	Not determined
Surface tension	Not determined

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)

Thermal decomposition: decomposition occurs starting from 380°C.

Hazardous decomposition products: in case of burning with insufficient oxygen or incomplete burning, toxic mixture of gases containing CO and CO₂ can be generated. Aromatic and aliphatic hydrocarbons, aldehydes, acids, phenols and their derivatives can also form. Practically it can be neglected the presence of fraction of halogen generating acids and halogenated hydrocarbons which are formed by the presence of small quantity of fire retardant.

Hazardous reactions: no hazardous reactions have been observed.

SECTION 11: Toxicological information

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

Acute toxicity	None.
Skin corrosion/irritation	None.
Serious eye damage/irritation	None.
Respiratory or skin sensitisation	None known.
Germ cell mutagenicity	None known.
Carcinogenicity	No ingredient listed as a carcinogen.
Reproductive toxicity	None known.
STOT-single exposure	None known.
STOT-repeated exposure	None known.
Aspiration hazard.	None known.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to Article 57(f) of REACH or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

11.2.2. Other information

Assuming correct use, according to our experience and information the product has no harmful effects on health.

SECTION 12: Ecological information

12.1. Toxicity

Not applicable.

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

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12.4. Mobility in soil

Data not available.

12.5. Results of PBT and vPvB assessment

This substance/mixture does not contain any components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

12.6. Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to Article 57(f) of REACH or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7. Other adverse effects

Data 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

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

SECTION 14: Transport information

Not dangerous according to current transportation regulations.

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

The product is not transported by us in bulk.

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 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. F11-6E 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

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

IMO: International Maritime Organisation

PBT: Persistent, Bioaccumulative And Toxic Substances.

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

vPvB: Very Persistent and Very Bioaccumulative Substances.