

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

Product description: Primer for ceramic crowns.

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

Identified Use Professional use: For conditioning of ceramics of bridges and crowns to bond orthodontic brackets and accessories in metal, plastic and ceramics.

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

Flammable liquid 3	H224
Eye irritation 2	H319
STOT SE 3	H336

2.2. Label elements

Signal word	Danger	
Hazard statements:	H224 H319 H336	Extremely flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness.
Precautionary statements	P102 P233 P210 P262 P305+P352+P313	Keep out of reach of children. Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not get in eyes, on skin, or on clothing. IF IN EYES: Wash with plenty of water. Get medical advice/attention.

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

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)
Isopropanol	-	200-661-7	67-63-0	Flammable liquid, cat. 3 STOT SE 3 Eye irritation, cat. 2	H224 H336 H319



SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation IF INHALED: No harm anticipated from materials in quantities as packaged.
Skin contact IF ON SKIN (or hair): Wash with copious amounts of water.
Eye contact IF IN EYES: Flush immediately with copious amounts of water.
Ingestion Induce vomiting, preferably by mechanical measures.

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

Not applicable.

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

None necessary.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media In case of fire, water contact acceptable.
Unsuitable extinguishing Media Not applicable.

5.2. Special hazards arising from the substance or mixture

None in quantities as packaged.

5.3. Advice for firefighters

None.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact of skin or eyes. Wash hands with soap and water if skin contact occurs.

6.2. Environmental precautions

Dilute with water before disposing.

6.3. Methods and material for containment and cleaning up

Dilute with water before disposing.

6.4. Reference to other sections

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Keep away from flames and sparks, oxidizing agents, alkalis, and isocyanates.

7.2. Conditions for safe storage, including any incompatibilities

Store at temperatures not exceeding 24°C (75°F).

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OSHA exposure limits: Not applicable.

8.2. Exposure controls

Appropriate engineering controls

Do not eat, drink or smoke at the work place. The following information is given as general guidance.

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

Protective Equipment	Not required under normal handling.
Respiratory protection	Not required under normal handling.
Industrial Hygiene	Avoid prolonged contact with skin; wash with soap and water.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid.
Colour	Clear.
Odour	Characteristic for alcohol.
Odour threshold	Not established.
pH:	Approximately 1.
Melting point:	Not applicable.
Boiling point	Approximately 27.9°C.
Flash point	11.7°C.
Flammability	Flammable.



Upper/Lower flammability or explosive limits	Lower 2% Upper 12%.
Evaporating rate	Not established.
Vapour pressure	96 mmHg at 37.8 °C.
Vapour Density (Air=1)	>1.
Auto ignition temperature	350°C.
Explosive limits in air	Not applicable.
Decomposition temperature	Not established.
Relative density	Approximately 0.8.
Solubility in Water	Soluble.
Partition coefficient: n-octanol/water:	Not established.
Viscosity	Not established.

9.2. Other information

None.

SECTION 10: Stability and reactivity

10.1. Reactivity

Isocyanates, strong oxidizing agents, alkali metals.

10.2. Chemical stability

Generally stable.

10.3. Possibility of hazardous reactions

Hazardous Polymerization: Not applicable.

10.4. Conditions to avoid

Avoid heat, open flame and sparks.

10.5. Incompatible materials

Isocyanates, strong oxidizing agents, alkali metals.

10.6. Hazardous decomposition product(s)

None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Potential Acute Health Effects

Eye irritation upon contact. Skin irritation upon prolonged exposure.

Signs and Symptoms of Exposure

Skin/eye irritation.

Medical Conditions Generally Aggravated by Exposure

None known.

Carcinogenic or Potential Carcinogenic Effects

No ingredient listed as a carcinogen.

Other Potential Health Effects

None known.

Potential Chronic Health Effects

Possibility of severe skin/eye damage upon prolonged or repeated exposure.

SECTION 12: Ecological information

No ecological damage or impact anticipated upon exposure to the environment in quantities as packaged.

12.1. Toxicity

Not applicable.

12.2. Persistence and degradability

Not applicable.

12.3. Bioaccumulative potential

Not applicable.

12.4. Mobility in soil

Not applicable.

12.5. Results of PBT and vPvB assessment

Not applicable.

12.6. Other adverse effects

Not applicable.

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

Do not dispose into sink. Dispose of in accordance with all federal, state, and local regulations.



SECTION 14: Transport information

14.1. UN-number

UN1219.

14.2. UN proper shipping name

Isopropanol.

14.3. Transport hazard class(es)

Class: 3, Flammable Liquid.

Leone current shipping mode (ADR): combination packaging total exemption.

14.4. Packing group

II.

14.5. Environmental hazards

Not classified as a Marine pollutant.

14.6. Special precautions for user

No special requirements.

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/not indicated.

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. F14/2E 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.

Legend

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

CAS No.: Chemical Abstract Service Registry number.

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

IBC Code: International Bulk Chemicals Code.

OSHA: Occupational Safety and Health Administration.

PBT: Persistent, Bioaccumulative And Toxic Substances.

STOT SE: Specific Target Organ Toxicity-Single Exposure.

vPvB: Very Persistent And Very Bioaccumulative Substances.