



1. Identification of the preparation and of the company

1.1 Identification of the preparation

Primer for ceramic crowns.

1.2 Use of the preparation

For conditioning of ceramics of bridges and crowns to bond orthodontic brackets and accessories in metal, fiber glass and ceramics.

1.3 Company identification

Leone s.p.a.

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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

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.

Hazards to man or environment:

- Physical/chemical hazards: highly flammable.
- Human health hazards: see section 11.
- Environment hazards: see section 12.

No other hazards to man or the environment other than those related to flammability of isopropanol are reasonably foreseen.

3. Composition/information on ingredients

Information on hazardous components¹

Chemical name	Number EC ²	CAS ³ Number	Hazard symbols ⁴	R ⁴ Phrases
Isopropanol	200-661-7	67-63-0	F, Xi	R 11-36-67

4. First aid measures

- Inhalation: vapours may cause drowsiness and dizziness, no harm anticipated from material in quantities as packaged.
- Skin contact: wash with water.
- Eye contact: flush thoroughly with water.
- Ingestion: induce vomiting, preferably by mechanical measures.

5. Fire-fighting measures

- Suitable extinguishing media: water contact acceptable.
- Extinguishing media which should not be used: not applicable.
- Special exposure hazards from combustion products: none in quantities as packaged.
- Special protective equipment for fire-fighters: none.

6. Accidental release measures

- Personal precautions: avoid contact of skin or eyes. Wash hands with water if contact occurs.
- Environmental precautions: dilute with water before disposing.
- Methods of cleaning up: dilute with water before disposing.

7. Handling and storage

7.1 Handling

During product handling keep away from flames and sparks, oxidizing agents, alkalis and isocyanates.

7.2 Storage

Store at temperature not exceeding 24°C.

Other restrictions or recommendations: none.

¹ Occupational exposure limit (OEL, occupational exposure limits), 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 Hazards related to the ingredients of the product are indicated in section 2, information to be shown on the label, if applicable, are indicated in section 15. Explanation of hazardous symbols and Risk phrases is indicated in section 15 and/or 16..



8. Exposure controls/personal protection

8.1. Exposure limit values⁵

USA. Isopropanol, occupational exposure limits (TWA): 980 mg/m³ (400ppm) [Occupational Safety and Health Administration (OSHA) Regulation 29 CFR 1910.1000, Table Z-1].

8.2. Exposure control

8.2.1. Occupational exposure control

Respiratory protection and ventilation are not required.

8.2.2. Protective clothing or equipment

Not required under normal handling.

8.2.3. Unusual work/hygienic practices

Avoid prolonged contact skin, wash with soap and water.

9. Physical and chemical properties

9.1. General information

Appearance: liquid, clear
Odour: characteristic for alcohol.

9.2. Health, safety and environmental information

Boiling point /range: 82.3°C
Melting point/range: not applicable
Flash point: 11.6°C (method: Open Cup)
Explosive limits, vol.% in Air: 2% (lower)
12% (upper)
Vapour pressure (mm Hg): 96 at 37.8°C
Specific gravity (H₂O=1): approx. 0.8
Solubility in water: soluble
pH: not applicable
Auto-ignition temperature: 350°C
Reactivity in water: not reactive
Flammability: flammable
Oxidizing properties: not applicable
Vapour density (air=1): > 1.

10. Stability and reactivity

- Stability: generally stable.
- Conditions of instability: avoid exposure to heat, open flames and sparks.
- Incompatibility with various substances: isocyanates, strong oxidizing agents, alkali metals.
- Hazardous decomposition products: none.
- Hazardous polymerization: not applicable.
- Conditions to avoid: avoid heat, open flames and sparks.

11. Toxicological information

Potential acute health effects: eye irritation upon contact. Skin irritation upon prolonged exposure.

Potential chronic health effects: possibility of skin sensitization or irritation upon prolonged or repeated 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.

12. Ecological information

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

13. Disposal considerations

Do not dispose into sink.

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.

⁵ 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.

14. Transport information⁶

Transport dispositions:	see dangerous goods regulation.
UN classification:	1219
Transport identification:	isopropanol
Leone current shipping mode (ADR):	combination packaging total exemption.

15. Regulatory information

- Health, safety and environmental information shown on the label according to European Directives on hazardous materials and substances

Hazard symbols:



Highly flammable



Irritant

Risk phrases:	R 11	Highly flammable
	R 36	Irritating to eyes
	R 67	Vapours may cause drowsiness and dizziness.
Safety phrases :	S 2	Keep out of the reach of children
	S 7	Keep container tightly closed
	S 16	Keep away from sources of ignition - No smoking
	S 24/25	Avoid contact with skin and eyes
	S 26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

- 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.

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. F14/1E dated 24/03/2009 has 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.

⁶ UN: United Nations (ONU). ADR: Accord Dangereuses par Route.