

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

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

Flammable liquids 2	H225
Eye irritation 2	H319
STOT SE 3	H336

2.2. Label elements



GHS07

GHS02

Signal word

Danger

Hazard statements:

H225
H319
H336

Highly 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

According to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1 %.

The product does not contain substances with endocrine-disrupting properties in a concentration ≥ 0.1 %.

SECTION 3: Composition/information on ingredients

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 ingredients	Product identifier	%W/W	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Isopropanol	CAS-No.: 67-63-0 EC-No.: 200-661-7	-	Flammable liquids, Hazard Category 2, H225 Serious eye damage/eye irritation, Hazard Category 2, H319 STOT SE 3, H336

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**8.2.1. Appropriate engineering controls**

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

8.2.2. Individual protection measures, such as personal protective equipment

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**

Physical state	Liquid.
Colour	Clear.
Odour	Characteristic for alcohol.
Odour threshold	Not established.
Melting point/freezing point	Not applicable.
Boiling point or initial boiling point and boiling range	82.3°C.
Flammability	Flammable.
Lower and upper explosion limit	Lower 2% Upper 12%.
Flash point	11,7°C.
Auto-ignition temperature	350°C.
Decomposition temperature	Not established.
pH	Not applicable.

Kinematic viscosity	Not established.
Solubility	Soluble
Partition coefficient n-octanol/water (log value)	Not established.
Vapour pressure	96 mmHg at 37.8 °C.
Density and/or relative density	Approximately 0.8.
Relative vapour density	>1.
Particle characteristics	/

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 products

None.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Acute toxicity	Eye irritation upon contact. Skin irritation upon prolonged exposure
Skin corrosion/irritation	Skin irritation.
Serious eye damage/irritation	Eye irritation.
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	Possibility of severe skin/eye damage upon prolonged or repeated exposure.
Aspiration hazard	None known

11.2 Information on other hazards

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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

According to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1 %.

12.6. Endocrine disrupting properties

Not applicable.

12.7 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 including those of Decree-Law No. 153 of 17 October 2024.

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 or ID 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. Maritime transport in bulk according to IMO instruments

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 has been 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. F14-4E 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

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

CAS No.: numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.

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

EC-Number: EINECS and ELINCS Number (see also EINECS and ELINCS).

GHS: Globally Harmonized System of Classification and Labelling of Chemicals.

IMO: International Maritime Organization.

OSHA: Occupational Safety and Health Administration.

PBT: Persistent, Bioaccumulative And Toxic Substances.

STOT SE 3: Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation.

vPvB: Very Persistent And Very Bioaccumulative Substances.