

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

Product description: Etching Gel.

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

Identified Use Professional use: Product utilized to enhance direct bonding technique on fixed orthodontic appliances.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.

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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].

Skin corrosion 1B

H314

For full text of H phrases see Section 16

2.2. Label elements

Signal word

Danger

Hazard statements

H314

Causes severe skin burns and eye damage.

Precautionary statements

P280

Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses if present and easy to do. Continue rinsing.

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

Phosphoric acid based aqueous solution (concentration approx. 33%)

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)
Phosphoric acid	33	231-633-2	7664-38-2	Skin Corrosion 1B Metallic Corrosion 1 Eye Damage 1 STOT SE 3	H314 H290 H318 H335

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): Rinse with water. Prolonged contact may destroy tissue. Seek medical attention in case of serious irritation or burns.

Eye contact IF IN EYES: Immediately rinse with copious amounts of water. Seek medical attention as soon as



possible.
Ingestion Corrosive to mouth and throat - Do not induce vomiting. Serve milk if available or solution of sodium bicarbonate (baking soda).

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

Causes skin irritation and burns. Prolonged contact may destroy tissue.

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 None.

5.2. Special hazards arising from the substance or mixture

None in quantities as packaged.

5.3. Advice for firefighters

Not required.

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

Dispose in DOT approved waste containers.

6.3. Methods and material for containment and cleaning up

Dilute with large amounts of water and dispose.

6.4. Reference to other sections

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid proximity of reactive metals and alkaline substances.

7.2. Conditions for safe storage, including any incompatibilities

Store at temperatures not exceeding 30°C.

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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	Use latex gloves and protecting glasses.
Industrial Hygiene	Avoid prolonged contact with skin; wash with soap and water.
Respiratory protection	Not required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Gel.
Colour	Green.
Odour	Negligible.
pH:	Approximately 1.
Melting point:	Not applicable.
Boiling point	Approximately 100°C.
Flash point	Not applicable.
Flammability	No.
Vapour pressure	<101325 Pa (760 mm Hg) at 100°C.
Vapour Density (Air=1)	<1.
Auto ignition temperature	Not applicable.
Explosive limits in air	Not applicable.
Oxidizing properties	None.



IMDG EMS	F-A,S-B
IATA	3
ADR-Classification code	C1
ADR HIN	80
ADR-Transport category	3
Tunnel Restriction Code	E
RID (Transport category)	3
AND (Transport category)	3

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

14.4. Packing group

III.

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. F02/7E dated 16/01/2017 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.

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

H290: May be corrosive to metals.

H318: Causes serious eye damage.

H335: May cause respiratory irritation.

Legend

ADR HIN: European Agreement concerning the International Carriage of Dangerous Goods by Road-Hazard Identification Number.

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.

CAS No.: Chemical Abstract Service Registry number.

CDG: Carriage Of Dangerous Good.

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



IATA: International Air Transport Association.

IBC Code: International Bulk Chemicals Code.

IMDG EMS: International Maritime Dangerous Goods-Emergency Response Procedures for Ships Carrying Dangerous Goods.

IMDG: International Maritime Dangerous Goods.

PBT: Persistent, Bioaccumulative And Toxic Substances.

RID: Regulations concerning the International rail trasport of goods Dangerous.

STOT SE: Specific Target Organ Toxicity-Single Exposure.

vPvB: Very Persistent And Very Bioaccumulative Substances.