

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****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](mailto: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](http://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].

Skin corrosion/irritation 1B

H314

For full text of H phrases see Section 16

**2.2. Label elements**

GHS05

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**According to the available data, the product does not contain PBT or vPvB substances in a proportion  $\geq 0.1$  %.The product does not contain substances with endocrine-disrupting properties in a concentration  $\geq 0.1$  %.**SECTION 3: Composition/information on ingredients****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)	Product identifier	%W/W	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Phosphoric acid	CAS-No.: 7664-38-2 EC-No.: 231-633-2	33	Skin corrosion/irritation 1B, H314 Corrosive to metals 1, H290 Serious eye damage/eye irritation 1, H318 STOT SE 3, 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****8.2.1. Appropriate engineering controls**

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

**8.2.2. Individual protection measures, such as personal protective equipment**

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**

Physical state	Gel.
Colour	Green.
Odour	Negligible.
Melting point/freezing point	Not applicable.
Boiling point or initial boiling point and boiling range	Approximately 100°C.
Flammability	No.
Lower and upper explosion limit	Not applicable.
Flash point	Not applicable.
Auto-ignition temperature	Not applicable.
Decomposition temperature	/
pH	Approximately 1
Kinematic viscosity	/
Water solubility	Soluble.
Partition coefficient n-octanol/water (log value)	/
Vapour pressure	<101325 Pa (760 mm Hg) at 100°C.
Density and/or relative density	/
Relative vapour density	<1.

Particle characteristics

/

## 9.2. Other information

None.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Reactive metals, alkaline substances.

### 10.2. Chemical stability

Generally stable.

### 10.3. Possibility of hazardous reactions

Polymerization hazard: will not occur.

### 10.4. Conditions to avoid

Avoid temperatures above 30°C.

### 10.5. Incompatible materials

Reactive metals, alkaline substances.

### 10.6. Hazardous decomposition products

Phosphoric acid vapors and phosphoric oxides, if exposed to extreme heat.

## 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  $\geq 0.1$  %.

### 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

UN1805.

**14.2. UN proper shipping name**

Phosphoric Acid, Solution.

**14.3. Transport hazard class(es)**

Class	8
IMDG-Class	8
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
ADN (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. 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. F02-8E 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](http://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

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

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

Identification Number.

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.

IATA : International Air Transport Association.

IMDG: International Maritime Dangerous Goods.

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

IMO: International Maritime Organization.

PBT: Persistent, Bioaccumulative And Toxic Substances.

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

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail.

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

vPvB: Very Persistent And Very Bioaccumulative Substances.