



## 1. Identification of the preparation and of the company

### 1.1 Identification of the preparation

Etching gel.

### 1.2 Use of the preparation

Substance utilized to enhance direct bonding technique on fixed orthodontic appliances.

### 1.3 Company identification

Leone s.p.a.

I – 50019 Sesto Fiorentino – Firenze - Via P. a Quaracchi, 50

e-mail: [research@leone.it](mailto:research@leone.it) – <http://www.leone.it>

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.*

No other significant hazards to man or environment are reasonably foreseen.

Hazardous data:

Hazardous data legend:

Health: 2

4 - Extreme

Flammability 0

3 - High

Reactivity: 2

2 – Moderate

1 – Slight

0 – Insignificant.

Potential acute health effects: irritating to eyes by contact; irritating to skin by prolonged exposure.

Potential chronic effects for the health: possibility of serious damages to skin and eyes from prolonged or repeated exposure.

Exposure signs and symptoms: irritating to eyes and skin.

Medical conditions generally increased by the exposure: none.

Carcinogenic or potentially carcinogenic effects: none of the listed ingredient is considered as carcinogenic.

Other possible effects for health: none.

## 3. Composition/information on ingredients

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

Information on hazardous ingredients and composition:

Chemical name	EC <sup>1</sup> Number	%	CAS <sup>2</sup> Number	Hazard symbols <sup>3</sup>	R <sup>3</sup> Phrases
Phosphoric acid	231-633-2	33	7664-38-2	C	R 34

## 4. First aid measures

Inhalation: no harm anticipated from materials in quantities as packaged.

Skin contact: rinse with water. Prolonged contact may destroy tissues; seek medical attention in case of serious irritation or burns.

Eye contact: 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).

## 5. Fire-fighting measures

Suitable extinguishing media: water contact acceptable.

Not suitable extinguishing media : none.

Special exposure hazards from combustion products: none in quantities as packaged.

Special protective equipment for fire fighters: none.

<sup>1</sup> 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."

<sup>2</sup> CAS Number (Chemical abstract service).

<sup>3</sup> Hazards related to the ingredients of the product are indicated in section 2, information to be shown on the label are indicated in section 15. Explanation of hazardous symbols and Risk phrases is indicated in section 15 and 16.



## 6. Accidental release measures

Personal precautions: avoid contact of skin or eyes. Wash hands with soap and water if skin contact occurs.  
Environmental precautions: dispose of in approved waste containers.  
Methods for cleaning up: dilute with plenty of water and dispose of waste.

## 7. Handling and storage

Handling precautions: avoid proximity of reactive metals and alkaline substances.  
Safe storage conditions: store at temperatures not exceeding 30°C.  
Other restrictions: none.

## 8. Exposure controls/personal protection

Respiratory protection and ventilation: not required.  
Protective clothing or equipment: use latex gloves and protecting glasses.  
Hygienic practices: avoid prolonged contact with skin; wash with soap and water.

## 9. Physical and chemical properties

### 9.1. General information

Appearance: green gel  
Odour: negligible.

### 9.2. Health, safety and environmental information

pH: approx. 1  
Boiling point: approx. 100°C  
Melting point: not applicable  
Flash point: not applicable  
Auto-ignition temperature: not applicable  
Flammability: no  
Explosive limits in air: not applicable  
Oxidizing properties: none  
Vapour pressure (mm Hg): < 760 mm Hg at 100°C  
Vapour density (air=1): < 1  
Specific gravity (H<sub>2</sub>O=1): approx. 1.2  
Solubility in water: soluble  
Reactivity in water: not reactive  
Other data: none.

## 10. Stability and reactivity

Stability: generally stable.  
Conditions of instability: none.  
Incompatibility with various substances: reactive metals, alkaline substances.  
Hazardous decomposition products: phosphoric acid vapours and phosphoric oxides, if exposed to extreme heat.  
Polymerization hazard: it doesn't occur.  
Conditions to avoid: avoid temperatures exceeding 30°C.

## 11. Toxicological information

Acute toxicity – oral: LD<sub>50</sub><sup>4</sup> (rat): >810 mg/kg  
Irritating effects to skin and eyes: corrosive.

## 12. Ecological information

No ecological hazard derived by exposure in quantity as packaged.

## 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.  
Do not empty into sink.

<sup>4</sup> LD<sub>50</sub> Lethal Dose, dose of substance which results to be lethal for 50% of organisms used in a toxicity test.

## 14. Transport information <sup>5</sup>

UN number: 1805

Land – road/railway (ADR/RID)  
Proper shipping name: phosphoric acid solution  
ADR/RID Class: 8  
Packaging group: III  
Leone current shipping mode  
(ADR): combination packaging total exemption.

See current hazardous goods regulations for transport by:

Inner water flows (ADNR)  
Sea (IMDG)  
Air (IATA-ICAO).

## 15. Regulatory information

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

Hazard symbols:



Corrosive

Risk phrases: R 34 Causes burns

Safety phrases: 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 Directive 93/42/EC, 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. F02/5E dated 14/11/2006 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](http://www.leone.it) for an updated version of the present sheet.

<sup>5</sup> UN: United Nations (ONU). ADR: Accord Dangereuses par Route. RID: Règlement concernant le transport international ferroviaire des marchandises dangereuses. ADNR: Accord pour le transport de matières dangereuses par bateau de navigation intérieure sur le Rhin. IMDG: International Maritime Dangerous Goods. IATA: International Air Transport Association. ICAO: International Civil Aviation Organization.