

SAFETY DATA SHEET FOR OPERATORS
(Information sheet)
IMPLAPROTECT
Etching Gel

Sez. 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

- 1.1. **Supplier identification:** **Product Code:** ITD013IC1
- 1.2. **Relevant identified uses of the substance or mixture and uses advised against** Etching Gel
- 1.3. **Details of the supplier of the safety data sheet:** **Name:** Italmed srl
Address: viale Mazzini, 15 – 50132 Firenze
Phone: 055 5003124
- 1.4. **Emergency telephone number :** Nearest center poisons
In Italy: Centro Antiveleni Niguarda
Milano - tel. 02-66101029

Sez. 2. HAZARDS IDENTIFICATION

- 2.1 **Classification of the mixture :**
Orthophosphoric Acid
CAS n. 7664-38-2
Clhorexidine Digluconate
CAS n. 18472-51-0

2.1.1 **Classification as per Regulation (CE) N. 1272/2008:**

Pictograms:
Hazard class and category codes
Hazards codes:

 **GHS07** 
Eye Irrit. 2, Corrosive
R41- H319 – Eye Irrit; H314
corrosive, H290 corrosive to metals


2.1.2 **Classification as per Directive 1999/45/CEE:**

Classification: Corrosive
Nature of the specific risks attributed: Corrosive
The product if in contact with skin and eyes can be irritating

2.2. Label elements


Labels conforming to Regulation (CE) n. 1272/2008:

Pictograms, hazards code:

 GHS07 - Warnings

Hazard codes:

R41 - H319 – Eye Irrit., H314

corrosive 

Precautionary statements:

Reaction

P301, P330, P303, P305+P351+P338 - IN CASE OF CONTACT WITH EYES:

Rinse thoroughly for several minutes. Remove any contact lenses if it is easy to do.

Continue to rinse. P337+P313 - If eye irritation persists, consult a doctor.

For professional use only.

2.3. Other hazards

Cross-allergy with penicillins and cephalosporins

Sez. 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance:

3.2 Mixture

Orthophosphoric Acid

CAS n. 7664-38-2

Clhorexidine Digluconate

CAS n. 18472-51-0

Refer to item 16 for the full text of the risk phrases and hazard statements

Sez. 4. FIRST AID MEASURES

4.1. Description of first aid measures

After Inhalation:

Allow the subject to breathe fresh air. If the breathing is difficult, make oxygen inhale.

Consult a doctor

After Skin contact:

Immediately wash with water.

Contact with mucous membranes:

Rinse the part affected thoroughly with water for at least 15 minutes. Contact a doctor if irritation persists.

Eye contact:

Remove contact lenses if worn.

Rinse opened eye for at least 15 minutes under running water. Contact an ophthalmologist if the irritation persists.

After swallowing:

Consult a doctor.

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

No data available

4.3. Indication of any immediate medical attention and special treatment needed

If the irritation persists, contact a doctor

Sez. 5. FIRE-FIGHTING MEASURES

5.1 **Suitable extinguishing agents:** Water, suitable foams

5.2 **Special hazards arising from the substance or mixture**

No data available.

5.3 **Advice for firefighters**

Use respiratory protection.
Safety helmet and complete protective clothing.
Water spray can be used to protect people involved in extinction
It is also advisable to use self-contained breathing apparatus, above all, if operating in closed and poorly ventilated areas.

Sez. 6. ACCIDENTAL REALEASE MEASURES

6.1 **Personal precautions**

Protective equipment and emergency procedure:

Wear appropriate protective clothing.

6.2 **Protective equipment**

Absorb the material with sand or vermiculite and confine it in closed containers for subsequent disposal. Wash the contaminated area with plenty of water.

6.3. **Methods and material for containment and cleaning up:**

6.3.1 **For containment**

Collect the product for re-use, if possible, or for disposal. If necessary, absorb it with inert material.

Prevent it from entering the drainage system.

6.3.2 **For cleaning up**

After collection, wash the affected area and materials with water.

6.3.3 **Other information:**

No further information available.

6.4. **Reference to other sections**

Refer to steps 8 and 13 for more information

Sez. 7. HANDLING AND STORAGE

7.1 Preacutions for safe handlings

7.1.1 General advises

Wear suitable protective clothing.
Tender far from the reach of children. Do not smoke during handling and use

7.2 Conditions for safe storage, including any incompatibilities:

Store in its original packaging tightly closed, in a dry and cool place. Keep away from heat and away from light.

7.3 Specific end uses:

Store in a well ventilated place and away From heat sources.

Sez. 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

No data available.

8.2. Exposure controls

No specific controls required

Personal protective equipment:

Use the product in well-ventilated areas.

Use protective gloves

Use appropriate protective glasses

Use suitable protective clothing

Avoid contact with the mucous membranes

Sez. 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

Aspect:	Gel
Colour:	Blue
Odore:	No odor
PH	1,00-1,5
Viscosity:	-----

9.2. **Other information** No data available

Sez. 10. STABILITY AND REACTIVITY

10.1 **Reactivity** Corrosive to metals

10.2 **Stability:** Stable if stored as instructed

10.3 **Possibility of dangerous reactions:** Reactions with alkalis

10.4 **Conditions to avoid:** None in particular.

10.5 **Incompatible materials:** None in particular

10.6 **Decomposition products dangerous:** By thermal decomposition or in case of fire, gases and vapors potentially dangerous for health can be released

Sez. 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects: No data available

Toxicity data: No data available

Local effects:

After contact with the skin: contact may result in an irritant effect.

After contact with the eyes: causes irritation

Carcinogenic categories: Do not report evidence of this kind.

The toxicity of the product is partly attributable to that of its components
The product is a medical device and as such has been considered not dangerous or harmful both under normal conditions of use and for an improper use.

Sez. 12. ECOLOGICAL INFORMATION

12.1 **Toxicity:** Prevent soil contamination, subsoil and groundwater: do not eliminate the product using water courses, sewage systems or land of any nature

12.2 **Persistence and degradability:** No available data

12.3. **Bioaccumulative potential** No available data

12.4. **Mobility in soil** No available data.

12.5. **Results of the assesment** No available data

12.6. **Other adverse effects** No adverse effects found

Sez. 13. DISPOSAL CONSIDERATION

13.1 Waste treatment methods

Do not disperse in the environment, in the drains, in waterways.
The used packs must be eliminated according to local regulations in force.
To request information for this specific case, please contact an authorized waste disposal company.

Sez. 14. TRANSPORT INFORMATION

14.1. UN-number

Not included in the field of application of regulations on the transport of dangerous goods: by road (ADR); on rail (RID); by air (ICAO / IATA); by sea (IMDG)

14.2. UN shipping name

None.

14.3. Transport hazard classes

None.

14.4. Packing group

None.

14.5. Environmental hazards

None.

14.6. Special recommendation for users

No data available.

14.7. Transport in bulk according to the annex II of MARPOL 73/78 and the IBC code

It is not expected to transport bulk cargoes

For transport, applies the same to pharmaceutical products.

Sez. 15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (CE) n. 1907/2006 (REACH), Regulation (CE) n. 1272/2008 (CLP),

15.2. Evaluation of chemical safety

The supplier has carried out a chemical safety assessment

The product can cause cross-allergy with penicillins and cephalosporins

Sez. 16. OTHER INFORMATION

16.1. Other information

Description of the risk phrases set out in point 3

R41 = Risk of serious damage to eyes

Description of the hazard statements set out in point 3

H319 = Causes serious eye damage

H314 = Corrosive

Method of use: See the leaflet

16.2 **Last revision:** 31.12.2017

Notice to users:

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

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