

SAFETY DATA SHEET FOR OPERATORS
(Information sheet)
GELCIDE
Film Forming Solution for odontoiatric use

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

- 1.1. **Supplier identification:** **Product Code:** ITD004IVA2
- 1.2. **Relevant identified uses of the substance or mixture and uses advised against** Film forming solution for odontoiatric use
- 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

Sez. 2. HAZARDS IDENTIFICATION

- 2.1 **Classification of the mixture** :
- Powder Piperacillin Sodium
CAS n. 59703-84-3
Tazobactam Sodium
CAS n. 89785-84-2
- Solution Copolymer aminoalkyl methacrylate RS-JPE
Ammonium Methacrylate copolymer type A and B –
USP/NF
Ethyl alcohol 95% CAS n. 64-17-5
Deionized dwater CAS n. 7732-18-5

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

Pictograms:  GHS07
Hazard class and category codes Eye Irrit. 2
Hazards codes: R41- H319 – Eye Irrit

2.1.2 Classification as per Directive 1999/45/CEE:

Classification: Non dangerous
Nature of the specific risks attributed: Cruciate allergy with penicillins e

cephalosporins

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:



R41 - H319 – Eye Irrit.

Hazard codes:

Precautionary statements:

Reaction

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

Powder

Piperacillin Sodium

CAS n. 59703-84-3

Tazobactam Sodium

CAS n. 89785-84-2

Solution

Copolymer aminoalkyl methacrylate RS-JPE

Ammonium Methacrylate copolymer type A and B –USP/NF

Ethyl alcohol 95% CAS n. 64-17-5

Deionized dwater CAS n. 7732-18-5

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:

Solution:

Aspect:

Colorless clear solution of mild odor

Colour:	characteristic No colour
Odore:	characteristic
Specific weight:	0,845±0,025
Dry residue:	11,5 - 12,6%
Water:	18,0 - 20%

Powder:

Physical state	Crystalline solid, powder
Colour:	White
Density:	0,20 g/m°C
Fusion point:	183 – 185
PH sol. 10%	5,5 – 7,5

9.2. **Other information** No data available

Sez. 10. STABILITY AND REACTIVITY

10.1 Reactivity	No risk of reactivity
10.2 Stability:	Stable if stored as instructed
10.3 Possibility of dangerous reactions:	None in particular
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

Method of use: See the leaflet

16.2 Last revision: 31.05.2017

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.

ITALMED srl does not assume any responsibility deriving from the irresponsible, improper or illegal use of the product; therefore no request for damages can be presented.