

SAFETY DATA SHEET FOR OPERATORS
(Information sheet)
HYAMIX 5
Sterile Solution with Hyaluronic Acid for odontoiatric use


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

- 1.1. **Supplier identification:** **Product Code:** ITD 022 I C1
- 1.2. **Relevant identified uses of the substance or mixture and uses advised against** Sterile solution with Hyaluronic Acid 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
In Italy: Centro Antiveleni Niguarda Milano - tel. 02-66101029

Sez. 2. HAZARDS IDENTIFICATION

- 2.1 **Classification of the mixture** :
Solution Sodium Hyaluronate
CAS n. 9067-32-7
Potassium dihydrogen phosphate
CAS n. 7778-77-0
Sodium phosphate dibasic,
CAS n. 7782-85-6
Deionized water
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: 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.

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

Solution

Sodium Hyaluronate

CAS n. 9067-32-7

Potassium dihydrogen phosphate

CAS n. 7778-77-0

Sodium phosphate dibasic,.

CAS n. 7782-85-6

Deionized water

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 RELEASE 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

6.3.3 **Other information:**

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

6.4. **Reference to other sections**

No further information available.

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 without odor characteristic
Colour:	No colour
Odore:	No odor
Specific weight:	1,005
PH	6,4-6,7
Viscosity:	40-120 cps

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

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: 31.03.2019

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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