



Safety Data Sheet

In compliance with the Regulation 1907/2006/EC paragraph 31

Revision n°01 of 05.04.2016

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product Identifier

GELSYN- 3 – 16.8 mg/ml, 2 ml, 1 pre-filled syringe

1.2. Relevant identified uses of the substance or mixture and uses advised against

Only for treatment in osteoarthritis. Used as Medical Device under strict Medical Control.

1.3. Details of the supplier of the safety data sheet

IBSA Farmaceutici Italia
Via Martiri di Cefalonia,2
26900 Lodi -LO
Tel: +39 0371 6171
e-mail: info@ibsa.it

Fax: +39 0371 617144
web: www.ibsa.it

1.4. Emergency telephone number

Centro antiveleni Ospedale Niguarda: +39 02 64447053
CHEMTREC: +1-703-527-3887 (international)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

Classification according to OSHA HCS

This product is not hazardous by the OSHA Hazard Communication Standard (HCS) (29 CFR 1910.1200).

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

2.2. Label elements

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

2.3. Other hazards

Not determined

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SECTION 3: Composition/information on ingredients

3.1. Substance

Not Applicable

3.2. Mixture

Chemical Name	Percent	EINECS/ELINCS Number	CAS Number	EU - GHS Substance Classification	REACH No.
Sodium Hyaluronate	< 1%	618-620-0	9067-32-7	Not Hazardous*	No data available
Sodium Chloride	*	231-598-3	7647-14-5	Not Hazardous*	No data available
Sodium Phosphate dibasic anhydrous	*	231-448-7	7558-79-4	Not Hazardous*	01-2119489797-11-0003
Sodium Phosphate monobasic dihydrate	*	231-449-2	13472-35-0	Not Hazardous*	01-2119489796-13-0003

* Concentration in formula less than 1%

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: Unlikely route of administration

Eye contact: rinse with plenty of water

Ingestion: rinse mouth thoroughly with water. Call a doctor in case of any sickness

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

If correctly used the product does not have adverse reactions.

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

In case of ingestion treat symptomatically. Call a doctor.

SECTION 5: Firefighting measures

5.1. Extinguishing Media

NA

5.2. Special hazards arising from the substance or mixture

Not combustible

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5.3. Advice for firefighters

NA

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For personal protection see section 8

6.2. Environmental precautions

The product is packaged in syringe, protected by a sealed blister and a carton box.

In the event of accidental release the product is not harmful for environment.

6.3. Methods and material for containment and cleaning up

Dry the product with a suitable cloth.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling of product in the original packaging is not dangerous. Avoid ingestion of the syringe content.

7.2. Conditions for safe storage, including any incompatibilities

Store at room temperature, <25 °C (77°F), in the original packaging. Do not freeze. Protect contents from light. Store out of reach of children.

7.3. Specific end use(s)

Used as Medical Device under strict Medical Control .

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Chemical Name	Employee Exposure Limit (on workplace)
Sodium Hyaluronate	Not required.
Sodium Chloride	Not required.
Sodium Phosphate dibasic anhydrous	Not required.
Sodium Phosphate monobasic dihydrate	Not required.

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8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: Respiratory protection is not needed during normal product use.

Eyes: Eye protection not needed during typical product use conditions.

Gloves: use rubber nitrile gloves.

Other PPE Data: wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

(For product inside the syringe)

Appearance:

Pre-filled syringes containing transparent gel colorless and clear

Odor: N/A.

Odor Threshold: N/A

pH: 6.5-7.5

Boiling Pt. @ 760 mm Hg : $\geq 100^{\circ}\text{C}$ (212°F)

Melting/Freezing Point : $\leq 0^{\circ}\text{C}$ (32°F)

Flash Point (°C): N/A.

Evaporation Rate at 20°C: N/A.

Flammability : Not Flammable

Lower Explosive Limit: N/A.

Upper Explosive Limit: N/A.

Vapor Pressure (mm Hg): N/A.

Vapor Density (Air = 1): N/A.

Specific Gravity: N/A.

Solubility(ies): N/A.

Partition coefficient: n-octanol/water: N/A.

Autoignition Temp. (°C): N/A

Decomposition temperature (°C): N/A.

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Viscosity (mPascal): ≥ 50**Explosion Severity:** N/A.**Oxidizer Properties:** N/A.**9.2. Other information**

N/A.

SECTION 10: Stability and reactivity**10.1. Reactivity**

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Not determined.

10.4. Conditions to avoid

Not determined.

10.5. Incompatible materials

Not determined

10.6. Hazardous decomposition products

Not determined

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

In absence of experimental toxicological data on the product itself, the possible health hazards of the product were evaluated based on the properties of substances according to the criteria prescribed by OSHA Hazard Communication Standard (HCS) (29 CFR 1910.1200).

Toxicological properties:**Acute toxicity:****Sodium Hyaluronate***Oral:* LD₅₀ (rat) > 800 mg/kg*Dermal:* Data not available*Inhalation:* Data not available.*Other Toxicology Data:* PDE: 0.02 mg/die

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Corrosion/Irritation:

Dermal: Data not available.
Eye contact: Not irritation if correctly used.

Sensitization:

Dermal: Not sensitizing
Respiratory: Data not available.

Specific Target organ toxicity – Single exposure:

Data not available.

Specific Target organ toxicity – Repeated exposure:

Data not available

CMR effects:

Germinal cell mutagenicity: Data not available.
Carcinogenicity: **Sodium Hyaluronate**
IARC (International Agency for Research on Cancer): Not listed
NTP (National Toxicology Program): Not listed
OSHA carcinogenic classification: Not listed
Reproductive toxicity: Data not available.
Pregnancy/ nursing mothers/
children Data not available.

Aspiration hazard: The aspiration hazard is not expected, taking into account the use of the mixture.

SECTION 12: Ecological information**12.1. Toxicity**

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined.

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

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Not determined.

12.6. Other adverse effects

Do not allow large quantities of material to reach groundwater, bodies of water or sewer system.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste.

SECTION 14: Transport information**14.1. UN Number:** --**14.2. Proper shipping name:** Not applicable**14.3. Hazard class:** Not applicable**14.4. Packing group:** Not applicable**14.5. Environmental hazard:** Not applicable**14.6. Special Provisions:** Not applicable**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** --

Note 1: Not dangerous goods according to the transport regulations ADR/RID/ICAO/IMDG

Note 2: To prevent damage of the product if shipped by plane should be stored in pressurized room

SECTION 15: Regulatory Information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU Indication of danger:** Not classified**EU Safety Phrases:**

Not needed.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

SECTION 16: Other information**Document Authored By:** IBSA Safety Service**Issued:** April-05-2016**Supersedes the SDS dated:** --

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Classification and procedure used to derive the classification for mixtures according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) :

Classification:	Classification procedure
Not classified	-

GENERAL BIBLIOGRAPHY

NA

Disclaimer:

To the best of our knowledge, the information contained herein is accurate. The intended use of the product is as "MEDICAL DEVICE UNDER MEDICAL CONTROL" and must be used according to the instructions inside the packaging. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for an use different from the "intended use". For different use final determination of suitability of the product is the sole responsibility of the user. All products may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.