
Safety Data Sheet dated 27/4/2015, version 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY

This Safety Data Sheet has been updated in accordance with the Global Harmonized System and 29 CFR 1910.1200 Appendix D

1.1. Product identifier

Trade name: Hyalgan® (sodium hyaluronate)

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

Product type and use Intra-articular Injection

1.3. Details of the manufacturer of the safety data sheet

Company Fidia Farmaceutici spa
Address Via Ponte della Fabbrica, 3/A
District and Country 35031 - Abano Terme (PD)
Italy
tel. +39 49 8232111
fax +39 49 8232299

e-mail address SDSinfo@fidiapharma.it

1.4. Emergency telephone number

References to emergency information **Fidia Farmaceutici spa tel. +39 49 8232111**
available Monday to Friday (except holidays) from 8:30 a.m. to 5:30 p.m. (local time)

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture.

Classification according to Regulation (EC) n. 1272/2008 [EU-GHS/CLP]

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Classification according to paragraph (d) of 29 CFR 1910.1200

Not a hazardous substance or mixture according to regulation.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC

Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

2.2. Label elements.

Labelling according to Regulation (EC) n. 1272/2008 [EU-GHS/CLP] or 29 CFR 1910.1200

Labelling not applicable. Not a hazardous substance or mixture according to both regulations .

Labelling according to Directive 67/548/EEC

Labelling not applicable.

2.3. Other hazards

Based on the available data of this product no hazardous properties are known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Composition

Chemical Name	Concentration	CAS No.	EC No.
Hyaluronic acid sodium salt (Hyalectin®)	1%	9067-32-7	-
Sodium chloride	0.8%	7647-14-5	231-598-3
Sodium phosphate dibasic dodecahydrate	0.06%	10039-32-4	231-448-7
Sodium dihydrogen phosphate dihydrate	0.01%	13472-35-0	231-449-2
Water for Injections BP	As needed	7732-18-5	231-791-2

3.2 Mixtures

Not a hazardous substance or mixture according to EC-directives 67/548/EEC, 1999/45/EC, Regulation (EC) No. 1272/2008 or 29 CFR 1910.1200.

4. FIRST AID MEASURES

4.1. Description of first aid measures

- Eye contact** Rinse cautiously with plenty of water for 15 minutes also raising the eyelids. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation, blurred vision or swelling occurs and persists, consult your doctor.
- Inhalation** In case of symptoms arising from inhalation of product fumes, mists or vapor: Remove patient to a quiet and well ventilated place if safe to do so. Seek medical assistance if breathing remains difficult.
- Skin contact** Wash the area with soap and water. Seek medical attention if skin irritation develops and persists.
- Ingestion** Thoroughly rinse the mouth out with water (only if the injured person is conscious). In case of a reaction, seek medical assistance

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

No adverse effects are expected.

4.3. Indication of immediate medical attention and special treatment needed

No data available

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Recommended

extinguishers:

Water, Foam, CO₂, Dry chemical powders, according to the materials involved in the fire.

Extinguishers not to be used:

None known.

5.2. Special hazards arising from the substance or mixture

Avoid inhaling the fumes in case of fire.

5.3. Advice for firefighter protective equipment:

Use protection for the respiratory tract.

Wear respirator, gloves, protective footwear.

CAUTION: it's recommended the use of breathing apparatus and full protection for firefighting, since the combustion may generate toxic fumes. If possible contain water used for firefighting and collect for later disposal.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Handle in accordance with good industrial hygiene and safety practice.

6.2. Environmental measures

No adverse effects are expected.

6.3. Methods and materials for containment and cleaning up

Immediate actions:

- Stop the liquid product from leaking, if possible and if this does not present a risk for people.
- Create a barrier to prevent the liquid product from reaching streams and sewers.

Cleaning actions:

- Gather up any pieces of glass with a broom and the liquid state with absorbent material while being careful to not cut yourself.
- Collect what has been spilled in a container, and then send it to waste disposal.
- Air out and thoroughly wash the area affected with water.

Special precautions:

- Dress in a proper manner in order to reduce the chance of contact with skin and eyes to a minimum.
- Use gloves to prevent being cut by slivers of glass that could result from breakage of the syringes.

6.4 Reference to other sections

See Section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. For personal protection, see section 8.

Recommended equipment and procedures: Observe precautions stated on label.

Prohibited equipment and procedures:

No smoking, eating or drinking in areas where the product is used.

Wear suitable protective clothing and gloves

7.2. Conditions for safe storage, including any incompatibilities

Store in a dry, ventilated place

Keep away from the light

Store at temperatures lower than 25°C, but not at freezing temperatures: even though nothing changes from the safety viewpoint, the product could degrade and lose its pharmacological characteristics

Do not store the product for periods longer than 36 months: even though nothing changes from the safety viewpoint, it could degrade and lose the pharmacological characteristics associated with it

Packaging: Always keep in original packaging.

Incompatible materials: None known

7.3. Specific end use(s)

No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure controls

Respiratory protection:

Handle in accordance with good industrial hygiene and safety practice.

Make sure there is adequate ventilation where product is used or stored

Protection for hands:

Cut-resistance gloves should be worn.
Wash hands after handling.

Eye protection: None in particular.

Protection for skin: None in particular.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Clear liquid
Color	Colorless
Odor	odorless
Odor threshold	Not applicable
pH	6.8 -7.5 [20°C]
Melting point/freezing point	Not determined
Boiling point & range	Not determined
Flashpoint	Not determined
Evaporation rate	Not determined
Flammability	Not determined
Explosive limits	No explosive properties
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Solubility	It is an aqueous solution
Partition coefficient: n-octanol/water	Not determined
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
Viscosity	1.0-1.5 m ³ /kg

9.2 Other information

No additional information.

10. STABILITY AND REACTIVITY

10.1. Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2. Chemical stability

This product is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

The product is stable under normal conditions of storage and use, hazardous reactions will not occur.

10.4. Conditions to avoid

Do not freeze the product

The product is sensitive to sunlight

Do not storage at temperatures higher the 77°F (25°C)

10.5. Incompatible materials

Avoid strong oxidizing agents

Do not use with quaternary ammonium salts. It may cause precipitation of HA.

10.6. Hazardous decomposition products

Carbon monoxide, carbon dioxide and nitrous oxides could be generated by decomposition of the liquid state

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

No known significant effects or critical hazards. Handle in accordance with good industrial hygiene and safety practice.

Sodium hyaluronate is a non-hazardous polysaccharide present in the extra cellular matrix of all tissues in all vertebrates.

11.2. Acute toxicity exposure

Based on available data, the classification criteria are not met.

11.3. Chronic exposure

The following information refers to the active ingredient of the liquid state

- Carcinogenic properties: Based on studies carried out up to today, one may deduce that the product has no carcinogenic properties.
- Teratogenic properties: Based on studies carried out up to today, the product has no teratogenic properties.
- Mutagenic properties: Based on studies carried out up to today, the product has no mutagenic properties.
- Risks for the Reproduction System: Based on studies carried out up to today, one may deduce that the product has no properties that present risks for the reproduction system.
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12. ECOLOGICAL INFORMATION

12.1. Toxicity

No further relevant information available. Given the nature of the liquid product, problems attributable to its hypothetical ecotoxicological properties are not foreseen if used correctly.

12.2. Persistence and degradability

No further relevant information available. Given the nature of the liquid product, negative impacts on the environment are not foreseen if used correctly.

12.3. Bioaccumulative potential

No further relevant information available.

12.4. Mobility in soil

No further relevant information available.

12.5. Other adverse effects

No further relevant information available.

13. DISPOSAL CONSIDERATION

13.1. Waste treatment methods

The liquid product is not classified as dangerous. It should however be kept in mind that it is a product of biological origin, so it is subject to organic deterioration phenomena up to decomposition.

Pursuant to the laws in force, it is necessary to precisely classify the single waste by chemical analysis, as is true for all other types of substances and products.

Remarks on disposal:

The waste disposal of this product must be carried out in accordance with local laws in force

It is recommended to incinerate the product after having contacted the authorities in charge or specialized and authorized companies that can provide information about how to destroy this waste.

14. TRANSPORT INFORMATION

14.1. The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

15. REGULATORY INFORMATION

15.1. There are no additional safety, health or environmental regulations specific to this product.

16. OTHER INFORMATION

Abbreviations and acronyms:

RID:	Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO:	International Civil Aviation Organization
ADR:	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG:	International Maritime Code for Dangerous Goods IATA:
	International Air Transport Association
GHS:	Globally Harmonized System of Classification and Labelling of Chemicals LC50:
	Lethal concentration, 50 percent

Main bibliographic sources:

1. Internal Report - Fidia Research Laboratories Report No 629150 (1983b)
2. The Merck Index. Ed. 10
3. Handling Chemical Safety
4. Registry of Toxic Effects of Chemical Substances
5. INRS - Fiche Toxicologique
6. Patty - Industrial Hygiene and Toxicology
7. N.I. Sax - Dangerous properties of Industrial Materials-7 Ed., 1989
8. 29 CF 1910.1200 (g) and Appendix D, Occupational Safety and Health Standards, Hazard communication, Safety Data Sheet
9. Directive 1999/45/EC and following amendments
10. Directive 67/548/EEC and following amendments and adjustments
11. Regulation (EC) 1907/2006 (REACH) of the European Parliament
12. Regulation (EC) 1272/2008 (CLP) of the European Parliament
13. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
14. Regulation (EC) 453/2010 of the European Parliament

DISCLAIMER OF LIABILITY

The information contained in this document are based on knowledge available at the time of completion, the requirements relating to proper use of the product.

This only refers to the product indicated and constitutes no guarantee, express or implied, regarding its correctness or accuracy. The user must verify the suitability and completeness of such information in relation to the specific use intended. In case of any uncertainty, please consult the supplier.

The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

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This sheet is the first editions.