



## MATERIAL SAFETY DATA SHEET

Synvisc® (Hylan G-F 20)

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Synvisc® (Hylan G-F 20)

**Synonym(s):** Hylan polymer solution; Cross-linked hylan polymer

**Product Use:** Synvisc® is an elastoviscous fluid containing hylan polymers in buffered physiological sodium chloride solution. Hylan polymers are hydrogels formed by cross-linking hyaluronan (hyaluronic acid; HA) obtained from chicken combs. (Hyaluronan is a natural, complex sugar from the glycosaminoglycan family, composed of repeating disaccharide units of 1,4-D-glucuronic acid and 1,3-N-acetyl-D-glucosamine.) Synvisc® is a viscosupplementation product, administered by intra-articular injection, to treat osteoarthritis in joints.

**Corporate Headquarters**

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**Manufacturer**

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**Emergency Telephone Numbers**

Genzyme Corporation: 617-562-4555  
CHEMTREC: 800-424-9300

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

Component	CAS #	Percent
Hylan A	Not Applicable	0.16 %wt
Hylan B	Not Applicable	0.64 %wt
Sodium chloride	7647-14-5	0.85 %wt
Sodium phosphate dibasic	7558-79-4	0.016 %wt
Sodium phosphate monobasic	7558-80-7	0.004 %wt
Sterile water	7732-18-5	98.33 %wt

This preparation is NOT considered hazardous under the criteria of the OSHA Hazard Communication Standard (29 CFR 1910.1200).

**MIXTURE INFO:** This preparation is a cross-linked glycosaminoglycan polymer mixture containing hylan A (hyaluronic acid slightly cross-linked with formaldehyde) and hylan B (hyaluronic acid slightly cross-linked with divinyl sulfone).

**SUGGESTED AIRBORNE EXPOSURE LIMITS:** -OSHA Permissible Exposure Limit (PEL): 15 mg/m<sup>3</sup> total dust, 5 mg/m<sup>3</sup> respirable fraction for nuisance dusts. -ACGIH Threshold Limit Value (TLV): 10 mg/m<sup>3</sup> total dust containing no asbestos and <1% crystalline silica for Particulates Not Otherwise Classified (PNOC).

### 3. HAZARDS IDENTIFICATION

**Emergency Overview:**

Based upon the concentration of the components in this preparation and the package size, this preparation is considered very unlikely to produce toxicity through the normal routes of occupational exposure.

The chemical, physical and toxicological properties of this substance, pertaining directly to occupational exposures, have not been thoroughly characterized.

**Precautionary Statements:**

Preparation is a colorless, odorless liquid.  
Avoid breathing dust, avoid contact with eyes, skin and clothing. Do not ingest.



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#### Potential Health Effects

<b>Inhalation:</b>	Inhalation is not expected to produce adverse health effects, but if irritation of the respiratory system occurs, symptoms could include coughing, sore throat, and pain and inflammation of the nasal passages.
<b>Eyes:</b>	Eye exposure may cause irritation, with symptoms such as redness, tearing, and burning.
<b>Skin:</b>	Skin contact is not expected to be a health hazard, but if irritation occurs, symptoms could include redness and rash.
<b>Ingestion:</b>	Ingestion is not expected to be harmful and is an unlikely route for occupational exposure.
<b>Chronic:</b>	Chronic effects are not expected based on the concentration of components in this preparation.
<b>Medical Conditions Aggravated By Exposure:</b>	Although hylan polymers constitute only 0.80% of this preparation, because they are derived from chickens, individuals with allergies to avian proteins, feathers, and egg products should avoid physical contact with Synvisc®.

#### 4. FIRST AID MEASURES

**Inhalation:**

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

**Eye Contact:**

In case of eye contact, remove contact lenses if worn. Immediately flush eyes with plenty of tepid water while separating eyelids with fingers. Continue to flush for at least 15 minutes. Obtain medical attention if needed or if symptoms, such as redness or irritation, persist.

**Skin Contact:**

In case of contact, flush skin with water, while removing contaminated clothing. Wash material from skin with soap and water and rinse thoroughly with clean water. Obtain medical attention if needed or if irritation or other symptoms develop.

**Ingestion:**

In case of ingestion, drink several glasses of water to dilute. If large amounts are ingested, get medical attention.

#### 5. FIRE FIGHTING MEASURES

**Fire Fighting Equipment/Instructions:**

As in any fire, firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

**Suitable Extinguishing Media:**

Water spray, carbon dioxide, or dry powder.

**Specific Hazards:**

Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

**Hazardous Combustion Products:**

Irritating and highly toxic gases may be generated by combustion, including carbon monoxide, carbon dioxide, nitrogen oxides and sulfur oxides.



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### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions:

Based on the concentration of the components in this preparation and the package size, this preparation is considered to be very unlikely to produce toxicity through the normal routes of occupational exposure. Wear Personal Protective Equipment (PPE) as indicated in Section 8.

#### Environmental Precautions:

US EPA Regulations require the reporting of spills and releases of CERCLA Hazardous Substances to soil, water and air in excess of established reportable quantities (RQ). To report a release or spill, contact the federal government's National Response Center at 1-800-424-8802. The NRC is staffed 24-hours a day with U.S. Coast Guard personnel who will facilitate a federal emergency response action if necessary.

#### Methods For Cleaning Up:

Individuals trained in chemical spill response should handle significant/large material spills. Placed contaminated towels or spilled material in an appropriate waste container. Dispose of spilled material and contaminated waste in accordance with all applicable Local, State, Federal, and Provincial Environmental Regulations, per Section 13.

### 7. HANDLING AND STORAGE

#### Handling:

Follow Good Laboratory/Industrial Hygiene Practices when handling this material. Wear proper Personal Protective Equipment (PPE) and employ exposure controls as indicated in Section 8. Avoid physical contact with material. Wash thoroughly after handling.

#### Storage:

Refer to product literature for specific storage conditions. Store in original packaging at room temperature below 86 degrees F (30 degrees C). Do not freeze. Protect from light.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Engineering Measures To Reduce Exposure:

A dilution ventilation system is a suitable health hazard control for this mixture. If conditions of use become uncomfortable, a local exhaust system is advisable. Facilities storing or utilizing this preparation should be equipped with an eyewash fountain and a safety shower.

#### Personal Protective Equipment

##### Respiratory:

A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z99.2 requirements must be followed whenever exposure limits are exceeded and engineering controls are not feasible, or if insufficient ventilation or workplace conditions warrant a respirator's use. In such cases a NIOSH-approved respirator is recommended to avoid breathing particulates or mist.

In 1998 new NIOSH Regulations (42 CFR 84) for Negative Pressure, Air-Purifying Respirators with Particulate Filters took effect. The new classification scheme for particulate filters is based on whether a filter is able to stop oil-based aerosols or not, the useful life of the filter, and the efficiency with which it takes particulates out of the air. The 3 categories of particulate filters are N (for Not Oil-Proof), R (for Oil-Resistant), and P (for Oil Proof). N series filters have to be changed each shift if the environment is dirty and R series filters have to be changed each shift if oil is present. N series filters in clean environments, R series filters in the absence of oil aerosols and P series filters can be used until they become dirty, damaged, lose their shape, or are difficult to breathe through. For each category, there are 3 possible efficiencies - 95%, 99%, and 99.97%. The 99.97% is referred to as 100%. So, the classes are N95, N100, R95, R99, R100, P95, P99, P100.

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<b>Eyes/Face:</b>	Wear appropriate protective safety glasses or goggles as described in OSHA's eye and face protection regulations 29 CFR 1910.134.
<b>Skin:</b>	Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over your clothes, to minimize contact and contamination of clothing.
<b>Gloves:</b>	Prevent skin exposure by wearing protective gloves impermeable to this material.
<b>General:</b>	Consult your company's safety manager/industrial hygienist or your safety equipment manufacturer/supplier for assistance with your selection of appropriate PPE.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Color: Clear, colorless  
Viscosity: 23 - 27 Pa

## 10. CHEMICAL STABILITY AND REACTIVITY INFORMATION

Stable under ordinary conditions of use and storage; (see handling and storage information in Section 7).

This preparation is optimized when protected from light. Do not freeze.

Unknown.

**Will not occur.**

Unknown

## 11. TOXICOLOGICAL INFORMATION

Based on the concentration of the components in this preparation and the package size, this preparation is considered very unlikely to produce toxicity through the normal routes of occupational exposure.

The chemical, physical and toxicological properties of this preparation, pertaining directly to occupational exposures, have not been thoroughly characterized.

## NIOSH - Selected LD50s and LC50s

Sodium chloride	7647-14-5	Inhalation LC50 Rat: >42 gm/m <sup>3</sup> /1H; Oral LD50 Rat: 3 gm/kg; Oral LD50 Mouse: 4 gm/kg; Dermal LD50 Rabbit: >10 gm/kg
Sodium phosphate dibasic	7558-79-4	Oral LD50 Rat: 17 gm/kg
Sodium phosphate monobasic	7558-80-7	Oral LD50 Rat: 8290 mg/kg

Components not listed by NTP, IARC or OSHA.



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### 12. ECOLOGICAL INFORMATION

**Environmental Effects:**

Adverse environmental effects are not expected under normal conditions of use and appropriate waste disposal.

**Ecological Information:**

No data is available on the product itself.

### 13. DISPOSAL CONSIDERATIONS

**Methods of Disposal:**

Dispose of unused product in accordance with all applicable Federal, State, Local and Provincial environmental regulations.

**Packaging:**

Containers of this material may retain product residues. Handle contaminated packaging in the same way as the substance itself, by disposing in accordance with all applicable Federal, State, Local, and Provincial environmental regulations. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.

**Waste Classification:**

Chemical waste generators must determine whether a used chemical is classified as hazardous waste and consult appropriate hazardous waste regulations to ensure complete and accurate classification. U.S. EPA guidelines for the classification determination are listed in 40 CFR 261.

### 14. TRANSPORTATION INFORMATION

**Regulations:**

Not classified as dangerous in the meaning of sea and air transport regulations.

**U.S. DOT - Appendix A Table 1 - Hazardous Substances**

Sodium phosphate dibasic      7558-79-4      RQ = 5000 pounds (2270 kg)

### 15. REGULATORY INFORMATION

**US Federal Regulations:**

**Inventory - United States TSCA - Sect. 8(b) Inventory**

Sodium phosphate monobasic	7558-80-7	XU
Sodium chloride	7647-14-5	XU
Sodium phosphate dibasic	7558-79-4	XU
Sterile water	7732-18-5	XU

**US State Regulations:**

**Massachusetts - Right To Know List**

Sodium phosphate dibasic	7558-79-4	[present]
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**Massachusetts - Toxics Use Reduction Act**

Sodium phosphate dibasic	7558-79-4	CERCLA Only chemical
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**New Jersey - Department of Health RTK List**

Sodium phosphate dibasic	7558-79-4	sn 1723
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**Pennsylvania - Right to Know List**

Sodium phosphate dibasic	7558-79-4	environmental hazard
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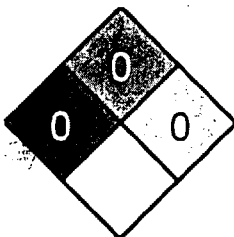
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### HMIS RATINGS

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0
PERSONAL PROTECTION	C

### NFPA RATINGS



### 16. OTHER INFORMATION

SDS Origination Date: 11/25/02

Revision #: 01

Revision Date: 11/26/02

#### Disclaimer:

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