

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078064253

N/A



# MATERIAL SAFETY DATA SHEET

Revision date: 07-Dec-2006

Version: 1.2

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

Pfizer Animal Health  
Pfizer Inc  
235 East 42nd Street  
New York, NY 10017  
Poison Control Center Phone: 1-866-531-8896  
Technical Services Phone: 1-800-366-5288

Pfizer Ltd,  
Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Sodium Hyaluronate Injection**

**Trade Name:** Hylartil Vet; Hylartin V  
**Synonyms:** Sodium Hyaluronate Sterile Solution  
**Chemical Family:** Mixture  
**Intended Use:** Veterinary product for the treatment of osteoarthritis

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Sodium Hyaluronate	9067-32-7	Not listed	1
Hydrochloric Acid	7647-01-0	231-595-7	*
Sodium hydroxide	1310-73-2	215-185-5	*

Ingredient	CAS Number	EU EINECS List	%
Disodium Hydrogen Phosphate, Dihydrate	Not Available	Not listed	*
Sodium dihydrogen phosphate dihydrate	13472-35-0	Not listed	*
Water for injection	7732-18-5	231-791-2	*
Sodium chloride	7647-14-5	231-598-3	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Solution

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

### Additional Hazard Information:

**Short Term:** May cause eye and skin irritation, Not acutely toxic (based on components). Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include skin rash and gastrointestinal disturbances.

**EU Indication of danger:** Not classified

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**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 4. FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

**General Handling:** Prevent inhalation, contact with eye, skin and clothing. Use with adequate ventilation. When handling, use proper personal protective equipment as specified in Section 8. Wash thoroughly after handling.

**Storage Conditions:** Protect from light. Store in a refrigerated area.

**Storage Temperature:** 2 - 8°C

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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### Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	= 2 ppm Ceiling
Australia PEAK	= 5 ppm Peak
	= 7.5 mg/m <sup>3</sup> Peak

### Sodium hydroxide

OSHA - Final PELs - TWAs:	2 mg/m <sup>3</sup>
ACGIH Ceiling Threshold Limit:	= 2 mg/m <sup>3</sup> Ceiling
Australia PEAK	= 2 mg/m <sup>3</sup> Peak

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

### Sodium Hyaluronate

Pfizer Occupational Exposure Band (OEB): OEB2 (control exposure to the range of >100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

Analytical Method: Not available

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

### Personal Protective Equipment:

Hands:	Wear impervious gloves if skin contact is possible.
Eyes:	Safety glasses or goggles
Skin:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection:	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

## 9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Solution	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

## 10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Conditions to Avoid:	Exposure to light
Incompatible Materials:	Not applicable

## 11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

### Acute Toxicity: (Species, Route, End Point, Dose)

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### Sodium Hyaluronate

Rat Oral LD 50 >800 mg/kg  
Mouse Oral LD 50 >2400 mg/kg  
Rat Intraperitoneal LD 50 1770 mg/kg  
Mouse Intraperitoneal LD 50 1500 mg/kg  
Rat Subcutaneous LD 50 >4 g/kg

### Sodium hydroxide

Mouse IP LD50 40 mg/kg

### Sodium chloride

Rat Oral LD50 3000 mg/kg  
Mouse Oral LD 50 4000 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

### Irritation / Sensitization: (Study Type, Species, Severity)

#### Sodium hydroxide

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

#### Hydrochloric Acid

Skin Irritation Severe  
Eye Irritation Severe

#### Sodium chloride

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### Sodium Hyaluronate

4 Week(s) Rat Intraperitoneal 1680 mg/kg LOAEL Blood

#### Sodium chloride

10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Sodium Hyaluronate

Fertility and Embryonic Development	Rat	Subcutaneous	60 mg/kg	NOAEL	Negative
Fertility and Embryonic Development	Rabbit	Intraperitoneal	60 mg/kg	NOAEL	Negative
Fertility and Embryonic Development	Rat	Intraperitoneal	64 mg/kg	NOAEL	Not Teratogenic
Fertility and Embryonic Development	Rat	Subcutaneous	50 mg/kg/day	NOAEL	Not Teratogenic
Prenatal & Postnatal Development	Rat	Subcutaneous	50 mg/kg/day	NOAEL	Not Teratogenic

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

#### Hydrochloric Acid

**IARC:** Group 3

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### 12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

### 13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

### 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

EU Indication of danger: Not classified

#### OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

#### Sodium Hyaluronate

Australia (AICS):

Present

#### Hydrochloric Acid

CERCLA/SARA 313 Emission reporting

= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size

CERCLA/SARA Hazardous Substances and their Reportable Quantities:

= 2270 kg final RQ

CERCLA/SARA - Section 302 Extremely Hazardous TPQs

= 5000 lb final RQ

= 500 lb TPQ gas only

CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

= 5000 lb EPCRA RQ gas only

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

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Australia (AICS):

Present

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Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS List	Schedule 5 Schedule 6 231-595-7
Sodium dihydrogen phosphate dihydrate Australia (AICS):	Present
Water for injection Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List	Present Present 231-791-2
Sodium hydroxide CERCLA/SARA Hazardous Substances and their Reportable Quantities: Inventory - United States TSCA - Sect. 8(b) Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS List	= 1000 lb final RQ = 454 kg final RQ Present Present Schedule 5 Schedule 6 215-185-5
Sodium chloride Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List	Present Present 231-598-3

### 16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet