

Halozyme Safety Data Sheet

Hylenex recombinant	SDS005	Revision: 0
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1. IDENTIFICATION

1.1. Product Identifiers:

Product Name: Hylenex recombinant

Product Codes: NDC 18657-117-01
NDC 18657-117-02
NDC 18657-117-04

Synonyms: Hyaluronidase Human Injection

1.2. Recommended Uses of Substance and Restrictions on Use

Product Use: Pharmaceutical

Chemical Family: Enzyme

1.3. Details of Supplier:

Company: Halozyme Therapeutics, Inc.
11388 Sorrento Valley Road
San Diego, CA 92121

Telephone: (858) 794-8889

1.4. Emergency Telephone:

Emergency Telephone Number: 800-424-9300

2. HAZARDS IDENTIFICATION

2.1. Classification of the Substance:

Not a hazardous substance or mixture as defined in 29 CFR 1910.1200.

2.2. Signal Word, Hazard Statement(s), Symbols, and Precautionary Statement(s):

None.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS	Concentration
Hyaluronidase, Human Recombinant	757971-58-7	0 – 0.1%
Dibasic Sodium Phosphate	7558-79-4	0.14%
Sodium Hydroxide	1310-73-2	0 – 0.1%
Albumin, human	70024-90-7	0 – 0.1%
Sodium Chloride	7647-14-5	0.85 %
L-Methionine	63-68-3	0 – 0.2 %
Polysorbate 80	9005-65-6	0 – 0.1%
Water	7732-18-5	> 98 %

4. FIRST AID MEASURES

4.1. Description of First-Aid Measures:

Routes of Exposure:

Skin and eye contact.

Skin Contact:

Wash contaminated skin with soap and water. Get medical attention if irritation develops.

Eye Contact:

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

4.2. Most Important Symptoms/Effects, Acute and Delayed:

No data available.

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5. FIRE FIGHTING MEASURES

5.1. Suitable Extinguishing Media:

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2. Special Hazards Arising from Substance:

No data available.

5.3. Advice for Firefighters:

Wear self contained breathing apparatus for firefighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions Protective Equipment and Emergency Procedures:

Avoid contact with skin and mucous membranes. No special protective equipment required. As a best practice gloves, safety glasses, and coveralls should be worn during clean up.

6.2. Environmental Precautions:

No information available.

6.3. Methods for Cleaning Up:

For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal. Vial breakage: Carefully sweep up glass shards. Wash area with water; rinse.

7. HANDLING AND STORAGE

7.1. Precautions for Safe Handling:

Technical measures/precautions: Wash thoroughly after handling.

7.2. Conditions for Safe Storage:

Keep containers tightly closed in a dry, cool and well-ventilated place. Store between 2-8°C (35.6 to 46.4°F). Do not freeze.

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7.3. Incompatible Products:

No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters:

Component	CAS	Value	Basis
Sodium Hydroxide	1310-73-2	2 mg/m ³ (C)(TWA)	USA. OSHA – Table Z-1 Limits for Air Contaminants USA. ACGIH Threshold Limit Values

8.2. Appropriate Engineering Controls:

Dilution ventilation is a satisfactory health hazard control. If conditions of use create discomfort to the worker, a local exhaust system should be considered.

8.3. Personal Protective Equipment:

Eye Protection:

Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

Skin and Body Protection:

Not required.

Respiratory Protection:

Not required.

Hand Protections:

Not required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Odor:	Odorless
Odor Threshold:	No data available

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pH:	6.8 – 7.2
Melting Point/Range:	No data available
Boiling Point/Range:	No data available
Flash Point:	No data available
Color:	Clear
Evaporation Rate:	No data available
Flammability:	No data available
Upper/Lower Flammability or Explosive Limits:	No data available
Vapor Pressure:	No data available
Vapor Density:	No data available
Relative Density:	No data available
Solubility:	No data available
Partition Coefficient (1-Octanol/Water):	No data available
Auto Ignition Temperature:	No data available
Decomposition Temperature:	No data available
Viscosity:	No data available

10. STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Stability:

Stable under recommended storage conditions.

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10.3. Possibility of Hazardous Reactions:

No data available.

10.4. Hazardous Decomposition Products:

No data available.

10.5. Conditions to Avoid

No data available.

10.6. Incompatible Materials

No data available.

10.7. Hazardous Decomposition Products

No data available.

11. TOXICOLOGY INFORMATION

11.1. Likely Routes of Exposure:

Ingestion, eye or skin contact.

11.2. Symptoms Related to Exposure:

No data available.

11.3. Delayed and Immediate Effects:

There are no acute toxicity studies to assess ingestion, eye or skin contact.

11.4. Numerical Measures of Toxicity:

Component	LD50s and LC50s
Hyaluronidase 9001-54-1	None
Dibasic Sodium Phosphate 7558-79-4	Oral LD50 Rat = 17 g/kg

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Sodium Hydroxide
1310-73-2 No data available

Albumin, human
70024-90-7 None

Sodium Chloride
7647-14-5 Inhalation LC50 Rat > 42 g/m³/1 H Oral LD50 Rat = 3
g/kg Oral LD50 Mouse = 4 g/kg Dermal LD50 Rabbit >
10 g/kg

Water
7732-18-5 Oral LD 50 Rat: > 50000 mg/kg

11.5. Carcinogenic Effects:

Not classified or listed by IARC, NTP, OSHA, EU and ACGIH.

11.6. Mutagenic Effects:

No data available

11.7. Reproductive Effects:

Subcutaneous embryo-fetal toxicity studies in mice at high doses showed reduced fetal body weights and increase in fetal resorptions. At 3 mg/kg/day, no adverse findings have been noted.

12. ECOLOGICAL INFORMATION

Not provided.

13. DISPOSAL CONSIDERATIONS

Not provided.

14. TRANSPORTATION INFORMATION

Not provided.

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15. REGULATORY INFORMATION

Not provided.

16. OTHER INFORMATION

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Prepared by: Halozyme Therapeutics, Inc.

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End of Safety Data Sheet