MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION

Product Name: Cinryze™ Date: Jan/28/2009
NDC: 42227-081-05
Generic name: C1 esterase inhibitor
General Use: Treatment for Hereditary Angioedema (HAE)

ViroPharma Incorporated
730 Stockton Drive
Exton, PA 19341
(877) 707-8476 Toll Free Daytime
(610) 458-7300 Daytime
(610) 458-7380 Fax

Emergency Telephone Number: (866) 676-1615

After HOURS CHEMTREC: 1-800-424-9300

COMMENTS: To the best of our knowledge, this MSDS conforms to the requirements of USA OSHA 29 CFR 1910.1200.

2. COMPONENTS AND HAZARDOUS INGREDIENTS

Cinryze™ is a human plasma-derived C1-esterase inhibitor that has been purified and lyophilized into a dry powder cake. The drug is shipped in a vial and re-constituted with sterile water.

Ingredient Name	CAS No.	Percent	OSHA PEL	ACGIH TLV
C1-Esterase Inhibitor (human)	80295-38-1	100%	N/A	N/A

3. HAZARDS IDENTIFICATION (Effects of Over-Exposure)

Emergency Overview: Exposure outcome is primarily irritation.

Inhalation: Exposure may result in upper respiratory tract irritation.

Ingestion: No effects under normal handling conditions. May be harmful if swallowed.

Skin Contact: May cause skin irritation. May be harmful if absorbed through the skin.

Eye Contact: May cause eye irritation.

4. FIRST AID MEASURES

After skin contact: If product gets on skin, wash the skin with soap and copious amounts of water. Remove contaminated clothing and shoes.

After eye contact: If product gets into eyes, open eyelids with fingers and flush eyes with copious amounts of water for at least 15 minutes.

After ingestion: If swallowed and person is conscious, rinse mouth with water, consult a health care provider.

After inhalation: If product is inhaled, get to fresh air. If there is any difficulty in breathing, seek medical attention. If there is any irritation, consult a health care provider.

5. FIRE FIGHTING MEASURES

Flash Point: Not available.

Flammability: Not flammable.

Explosion Hazard: Not considered to be an explosion hazard.

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

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Wear the proper personal protective equipment (gloves, safety goggles and respiratory protection, as needed). Sweep and shovel into a suitable, properly labeled container for recovery or disposal according to local and regional requirements. Avoid creating dust. Wash spill area with 10% bleach solution. In case of spills, prevent entry into waterways, sewers, surface drainage systems or wildlife water supply.

7. HANDLING AND STORING

Handle drug in such a manner as to minimize the dispersion of the powder. Wear protective gloves when handling this product. Store in a tightly closed container at temperatures of 2°C – 25°C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory: Wear N-95 filtering face piece or half-mask respirators with mechanical filters if dust may be generated.

Gloves: Wear protective gloves when handling this product.

Eye Protection: Safety glasses or goggles may be required if dust is generated.

Special Clothing/Equipment: Laboratory coat.

Engineering Controls: Local exhaust ventilation (e.g., biological safety cabinet) should be used if powder is dispersed into the air.

Work/Hygienic Practices: Avoid dust generation and accumulation. Wash thoroughly after handling.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Lyophilized Powder
Appearance:	White
Odor:	None
pH:	N/A
Vapor Pressure:	N/A
Vapor Density:	N/A
Evaporation Rate:	N/A
Boiling Point:	N/A
Decomposition Temperature:	N/A
Solubility:	Soluble in water.
Specific Gravity/Density:	N/A
Molecular Weight:	Approximately 76,000 Daltons
Molecular Formula:	N/A

10. STABILITY AND REACTIVITY

Stability:	Stable under normal conditions of use and storage.
Conditions to Avoid:	Incompatibilities.
Incompatibilities Materials:	Strong oxidizing agents.
Hazardous Decomposition Products:	Thermal decomposition produces noxious odors.
Hazardous Polymerization:	Will not occur during normal storage and use conditions.

11. TOXICOLOGICAL INFORMATION

Acute Toxicology : Acute toxicity of CINRYZE was studied in a combined acute toxicity and 7-day repeat dose/ dose range finding (DRF) study in Sprague Dawley rats. Repeat dose toxicity was studied in a 7-day repeat dose follow up to the acute dose study. The acute and repeated dose toxicity study were performed with intravenous administration of CINRYZE at dose levels of 1, 7 and 28 times normal dose. No signs of toxicity were observed in the single dose study. In the repeated dose study, no signs of toxicity were observed in the two lower doses. Repeat dosing in the rat resulted in a robust neutralizing antibody response between days 1 and 14. Therefore, toxicity in animals dosed repeatedly is difficult to interpret. In vitro and in vivo thrombogenicity studies showed a potential for clot formation when CINRYZE was administered at doses 14 times the recommended clinical dose (greater than 200U/kg).

Irritancy: Upper respiratory system and mucous membrane irritation. May be harmful if inhaled. May cause eye and skin irritation.

Chronic Toxicology None Known.

Carcinogenicity: No animal studies have been completed to evaluate the effects of CINRYZE on carcinogenesis, mutagenesis, and impairment of fertility.

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California Prop 65: This product and its contents are not known to the state of California to cause cancer.

Mutagenicity: Not Evaluated.

Teratogenicity: Not Evaluated.

12. ECOLOGICAL INFORMATION

In case of spills, prevent entry into waterways, sewers, surface drainage systems or wildlife water supply.

Environmental Fate: Data not available.
Environmental Effect: Data not available.

13. WASTE DISPOSAL CONSIDERATIONS

Dispose of in a manner consistent with federal, state and local regulations. Waste may be considered special medical waste.

14. TRANSPORT INFORMATION

U.S. DOT: Shipping Name: Cinryze
Hazard Class: Not Regulated Material

IATA: N/A

15. REGULATORY INFORMATION

U.S. TSCA Inventory: No.
California Proposition 65: No.
SARA 311/312: No.

16. OTHER INFORMATION

NFPA Designation

Fire	0
Health	2
Reactivity	0
Special Hazard	None

The information contained herein is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. ViroPharma Incorporated shall not be held liable for any damage resulting from handling or contact with the above product, or for any matters arising out of the use of this document.