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**Frost, Larry**

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**From:** Don Nuss [dnuss@hwsusa.com]  
**Sent:** Monday, September 20, 2010 11:10 AM  
**To:** Rayfield, Jason  
**Cc:** Frost, Larry  
**Subject:** Non-Haz pharmaceuticals  
**Attachments:** Recothrom - MSDS - ZymoGenetics - 2008-4-9.pdf

Jason,

I left you a voicemail regarding a waste stream of non-haz pharmaceuticals that we would like to incinerate at our Matthews facility. I am attaching the msds for your review. The amount to be processed is 1000 lbs. As we move forward, you and I should get together and develop a protocol for future approvals.

Thanks,

**Don Nuss**

Healthcare Waste Solutions  
Dir of Environmental Health  
and Safety Compliance  
513-475-3032 office  
513-543-7073 cell

 Please consider the environment before you print this E-mail.

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Thank you  
Healthcare Waste Solutions, Inc.

**1. PRODUCT NAME AND COMPANY IDENTIFICATION**



**Substance:** RECOTHROM™ Thrombin, Topical (Recombinant)

**Trade Names/Synonyms:**

Recombinant Thrombin (rThrombin) Drug Product: 5,000 IU (8 mL vial) and 20,000 IU (20 mL vial)

**Company:** ZymoGenetics, Inc.  
**Street Address:** 1201 Eastlake Avenue East  
**City, State, Zip:** Seattle, WA 98102  
**Central Phone:** 206-442-6600  
**Central Fax:** 206-442-6608  
**CHEMTREC (24-Hour Emergency Telephone):** 1-800-424-9300  
**International and Maritime CHEMTREC:** +1 (703) 527-3887

**2. COMPOSITION, INFORMATION OR INGREDIENTS**

Classification: Recombinant thrombin is a biological protein product produced by recombinant DNA technology in Chinese Hamster Ovary (CHO) cells that is used as a topical hemostat.

CHEMICAL NAME	CONTENT PER VIAL (5,000 IU, 8 mL VIAL)	CONTENT PER VIAL (20,000 IU, 20 mL VIAL)	CAS#	EINECS/ELINCS
rThrombin	1.7 mg	6.8 mg	Not assigned	Not assigned
L-histidine	1.3 mg	5.1 mg	71-00-1	200-745-3
Mannitol	68 mg	271 mg	87-78-5	201-770-2
Sucrose	51 mg	204 mg	57-50-1	200-334-9
Calcium Chloride	0.7 mg	3.0 mg	10043-52-4	233-140-8
Sodium Chloride	15 mg	59 mg	7647-14-5	231-598-3
Polyethylene Glycol	1.7 mg	6.8 mg	25322-68-3	Not Listed

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### 3. HAZARD IDENTIFICATION

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#### Emergency Overview

rThrombin must not be injected. Should this occur, seek immediate medical attention.

#### Potential Health Effects

All physical and functional measures of activity demonstrate rThrombin activity consistent with its intrinsic biologic activity as a protease associated with coagulation system activation. Thus, the primary health effects of concern are associated with stimulation of coagulation system activation following intravenous injection. Available toxicology testing demonstrates rapid inactivation of rThrombin by endogenous inhibitors in the blood stream. For this reason, topical application of rThrombin to an open wound does not result in systemic coagulation system activation. However, intravenous rThrombin injection could overwhelm the available inhibitors, leading to a systemic coagulation system activation.

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### 4. FIRST AID MEASURES

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- Inhalation: Remove to fresh air. If breathing difficulty or other adverse symptoms develop, seek medical attention.
- Eye Contact: While eye irritation is not expected from contact with rThrombin, immediately flush eyes with water as a general precaution. Obtain medical advice if irritation occurs.
- Skin Contact: While skin irritation is not expected from contact with rThrombin, wash exposed skin areas with soap and water as a general precaution. If irritation occurs, seek medical advice.
- Ingestion: Seek medical attention if significant amount is swallowed.

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### 5. FIRE-FIGHTING MEASURES

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Recombinant thrombin is a non-combustible product. Use suitable media based upon the source of the fire: water spray, carbon dioxide, dry chemical powder, or appropriate foam. As in any fire, use appropriate self-contained breathing apparatus and protective clothing.

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### 6. ACCIDENTAL RELEASE MEASURES

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Occupational Spill: Avoid breathing any aerosols. Prevent direct contact with skin, eyes and mucus membranes. Wipe up material carefully and thoroughly, wash the areas of the spill with soap and water.

Waste disposal: The material is non-hazardous and may be disposed of in accordance with local, state and federal regulations.

**7. HANDLING AND STORAGE**

Handling: Avoid contact with eyes, skin, and clothing.

Storage: rThrombin Drug Product should be stored at: 2 to 25 °C.

**8. EXPOSURE CONTROLS AND PERSONAL PROTECTION**

**Established Exposure Limits**

CHEMICAL NAME	OSHA PEL	NIOSH REL
rThrombin	Not Listed	Not Listed
L-histidine	Not Listed	Not Listed
Mannitol	Not Listed	Not Listed
Sucrose	15 mg/m3 total 5 mg/m3 respirable	10 mg/m3 total 5 mg/m3 respirable
Calcium Chloride	Not Listed	Not Listed
Sodium Chloride	Not Listed	Not Listed
Polyethylene Glycol	Not Listed	Not Listed

**Engineering Controls**

Good general ventilation is adequate for normal use of product. Utilize local exhaust ventilation as necessary to control exposures.

**Personal Protective Equipment**

- Inhalation: Wear approved respirator, as necessary, to limit inhalation exposure.
- Eye Protection: Wear protective safety glasses or chemical goggles as appropriate for potential exposure. Ensure the availability of an eyewash station in the event of accidental ocular exposure.
- Clothing: Wear appropriate protective clothing to guard against skin contact.
- Gloves: Where chemical resistant gloves.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

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**Physical State:** Lyophilized solid/powder  
**Appearance and Color:** White to off-white  
**Molecular Weight:** rThrombin has a MW of approximately 36 kilodaltons  
**Solubility in Water:** rThrombin is freely soluble in water  
**Boiling Point:** N/A  
**Percent Volatile:** Non-volatile  
**Evaporation:** Negligible

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**10. STABILITY AND REACTIVITY**

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rThrombin Drug Product is stable at normal temperatures and pressure.

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**11. TOXICOLOGY INFORMATION**

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As a recombinant protein, rThrombin is not caustic or corrosive.

**Cytotoxicity:** In vitro studies evaluating rThrombin demonstrate no direct toxicity to cells. Repeated SC injection to nonhuman primates or implantation on a surgical liver injury in nonhuman primates was not associated with tissue injury or irritation, and did not affect wound repair.

**Skin Contact:** No evidence of cytotoxicity, irritation or tissue injury was observed after topical application to normal or abraded skin of rabbits.

**Eye Contact:** Studies of rThrombin installation in the eyes of rabbits demonstrate no irritation.

**Mutagenicity and Genotoxicity:** rThrombin is not anticipated to have direct mutagenic or genotoxic potential.

**Reproduction:** Effects of topical rThrombin administration on reproduction have not been evaluated. However, because rThrombin does not circulate in the blood in an active form, no effect on reproduction is anticipated.

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**12. ECOLOGICAL INFORMATION**

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Information not available.

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**13. DISPOSAL CONSIDERATIONS**

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The material is considered a biological product derived from DNA technology and should be disposed of in accordance with local, state and federal regulations.

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**14. TRANSPORT INFORMATION**

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DOT:            Proper shipping name: Biological Product  
                  This substance is considered to be non hazardous for transport.

IATA:           Non-hazardous for air transport.

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**15. REGULATORY INFORMATION**

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rThrombin has been evaluated in multiple human clinical studies. A Biological License Application for rThrombin has been submitted to the US FDA (December 2006).

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**16. OTHER INFORMATION**

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The information herein is provided without any warranty, expressed or implied, except that it is accurate to the reasonable knowledge of ZymoGenetics, Inc. The provided information is not purported to be all-inclusive and shall be used only as a guide. ZymoGenetics assumes no legal responsibility, and shall not be held liable, for any damage resulting from handling of or contact with the product or from reliance on this information.