

Issuing Date: 20-Aug-2018

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**Product identifier**

SDS Number: BXU527783
Product Name: RECOTHROM™, Thrombin Topical (Recombinant)

Other means of identification

Product Code(s): 20011A, 20011B, 20012A, 07074100, 06064100
Synonyms: None

Recommended use of the chemical and restrictions on use

Product Use: Pharmaceutical.
Product Type: Regulated Prescription Drug
Uses advised against No information available

Details of the supplier of the safety data sheet

BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY
DEERFIELD, ILLINOIS 60015
US: (800) 933-0303
Canada: (855)-584-1368

Emergency telephone number

Verisk 3E Global Incident Response Hotline +1 760 476 3962; Access Code 335625

2. HAZARDS IDENTIFICATION**Classification****OSHA Regulatory Status**

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin Corrosion/Irritation	Category 2
Serious eye damage/eye irritation	Category 2B

Label Elements**Emergency Overview****Warning****Hazard Statements**

Causes skin irritation
Causes eye irritation

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling
Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements -

Response

Specific treatment (see supplemental first aid instructions on this label)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention

IF ON SKIN: Wash with plenty of soap and water

If skin irritation occurs: Get medical advice/attention

Take off contaminated clothing and wash before reuse

Hazards not otherwise classified (HNOC)**Other Information**

Unknown Acute Toxicity 1.27 % of the mixture consists of ingredient(s) of unknown toxicity

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	Weight-%
Recombinant Thrombin (rThrombin)	NONE	1.2
Histidine	71-00-1	1-3
Mannitol	69-65-8	<50
Sucrose	57-50-1	<35
Polyethylene Glycol	25322-68-3	1-3
Sodium Chloride	7647-14-5	<15
Calcium Chloride, Dihydrate	10035-04-8	<1

4. FIRST AID MEASURES**Description of first aid measures****General Advice**

Treat symptomatically and supportively.

Eye contact:

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

Skin contact:

In case of contact, immediately flush skin with plenty of water. Get medical attention.

Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms occur.

Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed

Irritating to eyes and skin.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. See patient package insert in shipping carton for complete information.

5. FIRE-FIGHTING MEASURES**Suitable extinguishing media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards arising from the chemical

No information available.

Special protective equipment for firefighters

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental precautions

See Section 12 for environmental precautions.

Methods and material for containment and cleaning up

Methods for Containment:

If emergency personnel are unavailable, contain spilled material.

Methods for cleaning up:

Shovel or sweep up. Place spilled material in an appropriate container for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical measures/precautions: Avoid skin contact. Avoid eye contact. Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions: Keep containers tightly closed in a cool, well-ventilated place. Store in original container. Store between 2-25°C (36-77°F). Do not freeze.

Incompatible materials: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Exposure Limits:

Chemical Name	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Recombinant Thrombin (rThrombin) NONE	None	None	None	None	None	None
Histidine 71-00-1	None	None	None	None	None	None
Mannitol 69-65-8	None	None	None	None	None	None
Sucrose 57-50-1	15 mg/m ³ 5 mg/m ³ 15 mg/m ³ (vacated) 5 mg/m ³ (vacated)	None	None	10 mg/m ³	None	None
Polyethylene Glycol 25322-68-3	None	None	None	None	None	None
Sodium Chloride 7647-14-5	None	None	None	None	None	None
Calcium Chloride, Dihydrate 10035-04-8	None	None	None	None	None	None

Appropriate engineering controls

Engineering Measures Provide general or local exhaust ventilation. Open handling must be limited.

Individual protection measures, such as 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.

Hand protection Use chemical resistant, impervious gloves.

Skin and body protection Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Respiratory protection No personal respiratory protective equipment normally required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Solid.
Appearance:	Lyophilized powder
Color:	White to off-white
Odor:	No information available
Odor Threshold:	No information available
pH:	No information available
Melting point / melting range:	No information available
Boiling point / boiling range:	No information available
Flash point:	No information available
Evaporation rate:	No information available
Flammability (solid, gas):	No information available
Flammable limits in air-upper (%):	No information available
Flammable limits in air-lower (%):	No information available
Vapor pressure:	No information available
Vapor density	No information available
Density:	No information available
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	No information available
Autoignition temperature:	No information available
Decomposition temperature	No information available
Viscosity:	No information available
Explosive Properties:	No information available
Oxidizing Properties:	No information available

Other information

10. STABILITY AND REACTIVITY

Reactivity

No data available

Chemical stability

Stable under recommended storage conditions

Possibility of hazardous reactions

None under normal use conditions

Conditions to Avoid

Do not freeze. Avoid excessive heat.

Incompatible materials

Strong oxidizing agents.

Hazardous decomposition products

Carbon oxides. Nitrogen oxides (nox). Hydrogen chloride.

11. TOXICOLOGICAL INFORMATION

Chemical Name	Inhalation LC50	Dermal LD50	Oral LD50
Recombinant Thrombin (rThrombin) NONE	-	-	-
Histidine 71-00-1	-	-	> 15 g/kg (Rat)
Mannitol 69-65-8	-	-	= 13500 mg/kg (Rat)
Sucrose 57-50-1	-	-	= 29700 mg/kg (Rat)
Polyethylene Glycol 25322-68-3	-	> 20 mL/kg (Rabbit)	= 22 g/kg (Rat) = 28 g/kg (Rat)
Sodium Chloride 7647-14-5	42 g/m³ 1 h (Rat)	> 10 g/kg (Rabbit)	= 3 g/kg (Rat)
Calcium Chloride, Dihydrate 10035-04-8	-	-	-

Information on likely routes of exposure

Inhalation:	Inhalation not likely under normal use conditions. May cause respiratory tract irritation.
Eye contact:	Causes eye irritation.
Skin contact:	Causes skin irritation
Ingestion:	May irritate digestive tract. Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Thromboembolic events.

Information on Toxicological Effects

Symptoms: No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation:	Irritating to eyes and skin.
Corrosivity:	Not classified.
Sensitization:	Not classified.
Mutagenic effects:	Not classified.
Carcinogenic effects:	Not classified.

Chemical Name	ACGIH	IARC	NTP	OSHA
Recombinant Thrombin (rThrombin) NONE	-	-	-	-

Histidine 71-00-1	-	-	-	-
Mannitol 69-65-8	-	-	-	-
Sucrose 57-50-1	-	-	-	-
Polyethylene Glycol 25322-68-3	-	-	-	-
Sodium Chloride 7647-14-5	-	-	-	-
Calcium Chloride, Dihydrate 10035-04-8	-	-	-	-

Reproductive toxicity: Not classified.

STOT - single exposure: Not classified.

STOT - repeated exposure: Not classified.

Aspiration Hazard: Not classified.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 1.27 % of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document.

ATEmix (oral) 11181 mg/kg

ATEmix (dermal) 78206 mg/kg

12. ECOLOGICAL INFORMATION

Chemical Name	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Recombinant Thrombin (rThrombin) NONE	None.	None.	None.	None.
Histidine 71-00-1	None.	None.	None.	None.
Mannitol 69-65-8	None.	None.	None.	None.
Sucrose 57-50-1	None.	None.	None.	None.
Polyethylene Glycol 25322-68-3	None.	5000 mg/L LC50 Carassius auratus 24 h	None.	100000mg/LEC50Ph otobacterium phosphoreum15min
Sodium Chloride 7647-14-5	1000 mg/L EC50 48 h 340.7 - 469.2 mg/L EC50 48 h	5560 - 6080 mg/L LC50 Lepomis macrochirus 96 h 12946 mg/L LC50 Lepomis macrochirus 96 h 6020 - 7070 mg/L LC50 Pimephales promelas 96 h 7050 mg/L LC50 Pimephales promelas 96 h 6420 - 6700 mg/L	None.	None.

		LC50 Pimephales promelas 96 h 4747 - 7824 mg/L LC50 Oncorhynchus mykiss 96 h		
Calcium Chloride, Dihydrate 10035-04-8	None.	None.	None.	None.

Ecotoxicity

No information available

87.82 % of the mixture consists of component(s) of unknown hazards to the aquatic environment

Persistence and degradability

No information available.

Bioaccumulative potential

Bioaccumulative potential

Mobility in soil

No information available

Other adverse effects

No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

**Waste from residues/unused
products**

In accordance with local and national regulations

Contaminated Packaging

In accordance with local and national regulations.

14. TRANSPORT INFORMATION

DOT

Not regulated

**Environmental hazard
Special Provisions**

Not applicable
None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List -

The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Chemical Name	Weight-%	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Recombinant Thrombin	1.2	Not Listed	Not Listed	Not Listed	Not Listed

(rThrombin) NONE					
Histidine 71-00-1	1-3	Not Listed	Not Listed	Not Listed	Not Listed
Mannitol 69-65-8	<50	Not Listed	Not Listed	Not Listed	Not Listed
Sucrose 57-50-1	<35	Not Listed	Not Listed	Not Listed	Not Listed
Polyethylene Glycol 25322-68-3	1-3	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride 7647-14-5	<15	Not Listed	Not Listed	Not Listed	Not Listed
Calcium Chloride, Dihydrate 10035-04-8	<1	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Chemical Name	California Prop. 65	Minnesota Right-To -Know:	Florida Right-to-Kno w Reporting List:	Rhode Island Right-to-Kno w List:	Massachusett s Right-to-Kno w List:	Pennsylvania Right-to-Kno w:	New Jersey Right-to-Kno w:
Recombinant Thrombin (rThrombin) NONE	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Histidine 71-00-1	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Mannitol 69-65-8	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sucrose 57-50-1	Not Listed	Present	Not Listed	Not Listed	Present	Present	Not Listed
Polyethylene Glycol 25322-68-3	Not Listed	Present	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride 7647-14-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Calcium Chloride, Dihydrate 10035-04-8	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:
Canada DSL Inventory List -

This product does not comply with DSL

16. OTHER INFORMATION
This data sheet contains changes from the previous version in section(s):

None

Additional information:

Not Available.

Prepared by:

Baxter Research & Development

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To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final

determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of Safety Data Sheet