

Safety Data Sheet



Section 1: Identification

Product identifier

- Product Name** • **Ruconest® C1 esterase inhibitor (recombinant)**
- Product Code** • NDC 68012-350-02

Relevant identified uses of the substance or mixture and uses advised against

- Recommended use** • Finished Pharmaceutical Product; An injectable medicine that is used to treat acute angioedema attacks in adult and adolescent patients with Hereditary Angioedema (HAE).
- Restrictions on use** • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

- Manufacturer** • Salix Pharmaceuticals, Inc., a wholly owned subsidiary of Valeant Pharmaceuticals International, Inc.

Bridgewater, NJ 08807
United States
salix.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

- Manufacturer** • 1-800-535-5053 - US - Infotrac
- Manufacturer** • +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

- UN GHS** • Insufficient data to classify

Label elements

UN GHS

Other hazards

- UN GHS** • No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
C1 esterase inhibitor (rhC11NH)	NDA	N/A	UN GHS: NDA
Sucrose	CAS:57-50-1 EINECS:200-334-9	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Sodium citrate, dihydrate	CAS:6132-04-3	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Citric acid	CAS:77-92-9 EINECS:201-069-1	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5

N/A - Designates that the chemical percentage of composition is not available as it is considered a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell.

Skin

- IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

Eye

- 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.

Ingestion

- Call a physician or poison control center immediately.

Most important symptoms and effects, both acute and delayed

- Signs and symptoms of allergic hypersensitivity reactions, such as hives, urticaria, tightness of the chest, wheezing, etc. should be treated immediately.

Indication of any immediate medical attention and special treatment needed

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known - product is not flammable or combustible.

Hazardous Combustion • No data available

Products**Advice for firefighters**

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures**Personal precautions, protective equipment and emergency procedures****Personal Precautions**

- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Refer to Section 8.

Emergency Procedures

- No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available

Methods and material for containment and cleaning up**Containment/Clean-up Measures**

- Avoid generating dust. Moisten material first to prevent dust and sweep spilled substances into containers.

Section 7 - Handling and Storage**Precautions for safe handling****Handling**

- Minimize dust generation and accumulation. Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities**Storage**

- Keep tightly closed. Store between 2-25°C (36-77°F), to maintain product integrity. use before expiration date marked on carton and/or container. Store in original packaging to protect from light.

Section 8 - Exposure Controls/Personal Protection**Control parameters****Exposure Limits/Guidelines**

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Sucrose (57-50-1)	TWAs	10 mg/m3 TWA	10 mg/m3 TWA EV	10 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable dust)	15 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable fraction)

Exposure Control Notations**ACGIH**

- Sucrose (57-50-1): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen)

Exposure controls**Engineering****Measures/Controls**

- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory

- No respiratory protection required during normal handling.

Eye/Face

- Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands

- Wear appropriate gloves.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene Considerations

- Handle in accordance with good industrial hygiene and safety practice.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Solid	Appearance/Description	white to off-white lyophilized cake.
Color	White to off-white.	Odor	Not relevant
Odor Threshold	Not relevant		
General Properties			
Boiling Point	Not relevant	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	approximately 7.0 in water after reconstitution
Specific Gravity/Relative Density	No data available	Water Solubility	Soluble
Viscosity	Not relevant		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reactions known.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze. Store in original packaging to protect from light.

Incompatible materials

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information

Information on toxicological effects

Other Material Information

- Avoid exposure to Ruconest if you have an allergy to rabbits since this can put you at high risk of a serious allergic reaction. These allergy symptoms could include runny nose, itchy nose, sneezing, coughing, wheezing, difficulty breathing or watery eyes when you are near rabbits.

GHS Properties	Classification
Respiratory sensitization	UN GHS • Data lacking
Serious eye damage/Irritation	UN GHS • Classification criteria not met
Acute toxicity	UN GHS • Data lacking
Aspiration Hazard	UN GHS • Data lacking
Carcinogenicity	UN GHS • Data lacking
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Data lacking
STOT-RE	UN GHS • Data lacking
STOT-SE	UN GHS • Data lacking
Toxicity for Reproduction	UN GHS • Data lacking
Germ Cell Mutagenicity	UN GHS • Data lacking

Potential Health Effects

Inhalation

- Acute (Immediate)**
 - Exposure to dust may cause irritation.
- Chronic (Delayed)**
 - No data available.

Skin

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Eye

- Acute (Immediate)**
 - May cause mild eye irritation with direct contact to eye.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)**
 - May be harmful if swallowed.
- Chronic (Delayed)**
 - No data available.

Reproductive Effects

- Pregnancy category B. Studies performed in rats and rabbits at Ruconest doses up to 12.5 times the human dose of 50 U/kg could not exclude an effect on embryofetal development. There are, however, no adequate and well-controlled studies in pregnant women.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects**Section 13 - Disposal Considerations****Waste treatment methods****Product waste**

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user

- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

Section 15 - Regulatory Information**Safety, health and environmental regulations/legislation specific for the substance or mixture****SARA Hazard Classifications**

- No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Citric acid	77-92-9	Yes	Yes	Yes
Sodium citrate, dihydrate	6132-04-3	No	No	No
Sucrose	57-50-1	Yes	Yes	Yes

Canada

Labor**Canada - WHMIS - Classifications of Substances**

• Sodium citrate, dihydrate	6132-04-3	Uncontrolled product according to WHMIS classification criteria
• Sucrose	57-50-1	Uncontrolled product according to WHMIS classification criteria
• Citric acid	77-92-9	E (including 40%)

Canada - WHMIS - Ingredient Disclosure List

• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	1 %

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Sodium citrate, dihydrate	6132-04-3	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed

Section 16 - Other Information

Revision Date • 11/August/2015

Last Revision Date • 11/August/2015

Preparation Date • 11/August/2015

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