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Recombinant Human Tropoelastin Protein Material Safety Data Sheet

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**PRODUCT NAME: Recombinant Human Tropoelastin Protein****1. CHEMICAL PRODUCT AND COMPANY INFORMATION****Manufactured By:**

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 Australian Technology Park
 National Innovation Centre, 4 Cornwallis St
 Eveleigh, New South Wales, 2015
 Australia

Manufactured For:

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Product Name

Recombinant Human Tropoelastin

Synonyms

N/A

2. HAZARD INFORMATION**Emergency Overview**

Recombinant human tropoelastin is a recombinant version of the human protein tropoelastin. Tropoelastin is a naturally occurring monomeric protein precursor which polymerizes and assembles to form the extracellular matrix protein elastin. Elastin is a key component of tissues in the body which require the ability to stretch and recoil, including the skin, lungs, arteries and elastic ligaments. In clinical use, recombinant human tropoelastin is intended for use in biomaterial implants for the treatment of dermatological conditions including the symptoms of skin aging, sun damage and scarring. In the workplace, this product should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the skin.

Occupational Exposure Potential

Information on the absorption of this product via inhalation or skin contact is not available.

Signs and Symptoms

Avoid the generation of dusty environments.
 None known from occupational exposure. Inadvertent contact of this product with eyes may produce mechanical irritation. In general, inhalation of dusts may produce coughing and shortness of breath.

Medical Conditions Aggravated by Exposure

Pre-existing pulmonary ailments.

Carcinogen Lists:

IARC: Not listed

NTP: Not listed

OSHA: Not listed

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Recombinant Human Tropoelastin

Chemical Formula NA

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Recombinant Human Tropoelastin	100	NA	NA

**PRODUCT NAME: Recombinant Human Tropoelastin Protein****4. FIRST AID MEASURES**

Eye Contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin Contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability	None anticipated for this product.
Fire & Explosion Hazard	None anticipated for this product.
Extinguishing Media	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the material with an inert absorbent material (e.g. absorbent pad). Clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.
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7. HANDLING AND STORAGE

Handling	No special handling required under conditions of normal product use. Protect from light until contents are to be used.
Storage	Store at <-10°C for long term storage. Can be stored at 2-8°C for up to 4 weeks. Protect from light and moisture exposure.
Special Precautions	No special precautions are required for hazard control.



PRODUCT NAME: Recombinant Human Tropoelastin Protein

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure limits			
	ACGIH-TLV	AIHA WEEL	Elastagen OEL	Other Limits
rh Tropoelastin	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes:

ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.

AIHA WEEL : Workplace Environmental Exposure Level

OEL: Occupational Exposure Limit.

TWA: Time Weighted Average.

Respiratory Protection

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets EU EN529 requirements (or equivalent) must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin Protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye Protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	White to off-white powder
Odour	NA
Odour Threshold	NA
pH	Between 6 and 7 when reconstituted with WFI
Melting point/Freezing point	NA
Initial Boiling Point/Boiling Point Range	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapour Pressure	NA
Vapour Density (Air =1)	NA
Evaporation Rate	NA
Specific Gravity	NA
Solubility	NA
Partition coefficient: n-octanol/water	NA
Auto-ignition temperature	NA
Decomposition temperature	NA



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10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to avoid	High temperature; ionizing radiation
Incompatibilities	Avoid contact with strong oxidizing agents
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapours and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).
Hazardous Polymerization	Not anticipated to occur with this product

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
rh Tropoelastin	100	LD50	NA	NA	NA	NA

LD 50: Dosage that produces 50% mortality.

Aspiration Hazard	None anticipated from normal handling of this product. No systemic toxicity is anticipated following ingestion of this product.
Dermal Irritation/Corrosion	None anticipated from normal handling of this product. Formulations of tropoelastin, both cross-linked and uncross-linked have shown minimally to no irritating when injected intra-cutaneously in animals. However, some evidence of a mild inflammatory response was noted in these studies as assessed by histopathology.
Ocular Irritation/Corrosion	None anticipated from normal handling of this product. However, some product may produce mechanical irritation. Inadvertent contact of this product with eyes may produce redness and irritation.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. Not anticipated to be sensitizing in clinical use. Recombinant human tropoelastin is classified as a weak sensitizer in the Local Lymph Node Assay.
Reproductive Effects	None anticipated from normal handling of this product. However, the potential for adverse reproductive effects from formulations of tropoelastin, both cross-linked and uncross-linked have not been fully investigated in studies in animals.
Mutagenicity	Recombinant human tropoelastin was negative for mutagenicity in the Ames test (with and without metabolic activation) and in an <i>in vivo</i> mouse micronucleus assay.
Carcinogenicity	The carcinogenic potential of formulations of tropoelastin, both cross-linked and uncross-linked has not been evaluated.
Target Organ Effects	Based on clinical use, possible target organs include the skin, nervous system, lungs, cardiovascular system, and blood.

**PRODUCT NAME: Recombinant Human Tropoelastin Protein****12. ECOLOGICAL INFORMATION**

Aquatic Toxicity	Not determined for product.
Persistence/Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

Notes:

1. LC50: Concentration in water that produces 50% mortality in fish.
2. EC50: Concentration in water that produces 50% inhibition of growth in algae.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

PRODUCT NAME: Recombinant Human Tropoelastin Protein**15. REGULATORY INFORMATION****GHS Classification**

Hazard Class	Acute Oral Toxicity	Eye Irritation
Hazard Category	Unclassified	2B
Symbol	NA	NA
Signal Word	NA	Warning
Hazard Statement	NA	Causes eye irritation

Prevention: Keep container tightly closed

Wear protective gloves and eye/face protection

Response: 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 attention.

Wash hands after handling.

EU Classification

Classification(s) Irritant

Symbol



Indication of Danger Xi

Risk Phrases R36/37 - Irritating to eyes and respiratory system

Safety Phrases S22: Do not breathe dust

S23: Do not breathe vapour/spray

S25: Avoid contact with eyes

S37/39 Wear suitable gloves and eye/face protection.

**PRODUCT NAME: Recombinant Human Tropoelastin Protein****16. OTHER INFORMATION**

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
DOT	US Department of Transportation Regulations
OEL	Occupational Exposure Limit
IATA	International Air Transport Association
LD ₅₀	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
STEL	15-minute Short Term Exposure Limit
TWA	8-hour Time Weighted Average

MSDS Coordinator: Orsola Regaglia

Date Prepared: 19 July 2011

Disclaimer:

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17. VERSION HISTORY

Version No.	Date	Change Request
1	28/09/2010	1
2	19/07/2011	30
2.1	24/02/2012	55