MATERIAL SAFETY DATA SHEET

PRODUCT NAME: Recombinant Human Tropoelastin Protein

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufactured By: Elastagen Pty Ltd
Australian Technology Park
National Innovation Centre, 4 Cornwallis St
Eveleigh, New South Wales, 2015
Australia

Manufactured For: Elastagen Pty Ltd
Australian Technology Park
National Innovation Centre, 4 Cornwallis St
Eveleigh, New South Wales, 2015
Australia

Emergency Telephone
Elastagen Pty Ltd
+61 (0)2 9209 4054 Monday – Friday, 09:00– 17:00
Poisons Information Centre 13 1126

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.

Avoid the generation of dusty environments.

Signs and Symptoms
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

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recombinant Human Tropoelastin</td>
<td>100</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>
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.

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**

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ACGIH-TLV</td>
</tr>
<tr>
<td>rh Tropoelastin</td>
<td>8-hr TWA: Not Established</td>
</tr>
</tbody>
</table>

**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

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

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>rh Tropoelastin</td>
<td>100</td>
<td>LD50</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

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 in vivo 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**

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Acute Oral Toxicity</th>
<th>Eye Irritation</th>
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</thead>
<tbody>
<tr>
<td>Hazard Category</td>
<td>Unclassified</td>
<td>2B</td>
</tr>
<tr>
<td>Symbol</td>
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<td>NA</td>
</tr>
<tr>
<td>Signal Word</td>
<td>NA</td>
<td>Warning</td>
</tr>
</tbody>
</table>

**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**

![Symbol](image)

**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.
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
LD₅₀ 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

<table>
<thead>
<tr>
<th>Version No.</th>
<th>Date</th>
<th>Change Request</th>
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<tr>
<td>1</td>
<td>28/09/2010</td>
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</tr>
<tr>
<td>2</td>
<td>19/07/2011</td>
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</tr>
<tr>
<td>2.1</td>
<td>24/02/2012</td>
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