1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier
Product name: Granulex V Spray

Intended Use of the Product
Use of the substance/mixture: Veterinary topical wound medication. Refer to product insert for usage instructions and product information.

Name, Address, and Telephone of the Responsible Party
Supplier: Mylan Institutional LLC
1718 Northrock Court
Rockford, IL 61103 USA
1-888-258-4199
www.mylan.com

Manufacturer: Mylan Institutional Inc.
12720 S Dairy Ashford Road
Sugar Land, TX 77478 USA

Emergency Telephone Number
Emergency number: +1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

Classification of the Substance or Mixture

Classification (GHS-US)
Flam. Aerosol 1 H222
Skin Sens. 1 H317

Label Elements
GHS-US labeling: Danger

Signal word (GHS-US): Danger
Hazard statements (GHS-US): H222 - Extremely flammable aerosol
H317 - May cause an allergic skin reaction

Precautionary statements (GHS-US):
P210 - Keep away from heat/sparks/open flames/hot surfaces - No smoking.
P211 - Do not spray on an open flame or other ignition source.
P251 - Pressurized container: Do not pierce or burn, even after use.
P261 - Avoid breathing mist, spray, vapors, gas.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear eye protection, protective clothing, protective gloves.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P410+P412 - Protect from sunlight. Do not expose to temperatures exceeding 50°C (122°F)
P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.
Other Hazards: Not available
Unknown acute toxicity (GHS-US): Not available

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Mixture</th>
<th>Name</th>
<th>Product identifier</th>
<th>% (w/w)</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Castor oil</td>
<td>(CAS No) 8001-79-4</td>
<td>50 - 60</td>
<td>Not classified</td>
</tr>
<tr>
<td></td>
<td>Propane</td>
<td>(CAS No) 74-98-6</td>
<td>20 - 30</td>
<td>Simple Asphy, H380 Flam. Gas 1, H220 Liquefied gas, H280</td>
</tr>
<tr>
<td></td>
<td>Isobutane</td>
<td>(CAS No) 75-28-5</td>
<td>10 - 30</td>
<td>Simple Asphy, H380 Flam. Gas 1, H220 Liquefied gas, H280</td>
</tr>
<tr>
<td></td>
<td>Balsams, Peru</td>
<td>(CAS No) 8007-00-9</td>
<td>5 - 10</td>
<td>Acute Tox. 4 (Oral), H302 Skin Sens. 1, H317 Aquatic Chronic 2, H411</td>
</tr>
</tbody>
</table>

Full text of H-phrases: see section 16

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**General**: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

**Inhalation**: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

**Skin Contact**: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

**Eye Contact**: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

**Ingestion**: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

**Most Important Symptoms and Effects Both Acute and Delayed**

**General**: Please refer to the package insert for more detailed information.

**Inhalation**: None expected under normal conditions of use. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

**Skin Contact**: Exposure may produce an allergic reaction.

**Eye Contact**: May cause eye irritation.

**Ingestion**: May be harmful if swallowed.

**Chronic symptoms**: May produce an allergic reaction.

**Indication of Any Immediate Medical Attention and Special Treatment Needed**

If exposed or concerned, get medical advice and attention.

### 5. FIREFIGHTING MEASURES

**Extinguishing Media**

**Suitable extinguishing media**: Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂).

**Unsuitable extinguishing media**: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

**Special Hazards Arising From the Substance or Mixture**

**Fire hazard**: Flammable aerosol.

**Explosion hazard**: Heat may build pressure, rupturing closed containers, spreading fire and increasing risk of burns and injuries.

**Reactivity**: Hazardous reactions will not occur under normal conditions.

**Advice for Firefighters**

**Precautionary measures fire**: Exercise caution when fighting any chemical fire.

**Firefighting instructions**: Use water spray or fog for cooling exposed containers.

**Protection during firefighting**: Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products**: Carbon oxides (CO, CO₂).

**Other information**: Refer to Section 9 for flammability properties.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**

**General measures**: Avoid all eye and skin contact and do not breathe vapor and mist. Keep away from open flames, hot surfaces and sources of ignition. No smoking.
For Non-Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective equipment: Equip cleanup crew with proper protection.

Environmental Precautions

Prevent entry to sewers and public waters.

Methods and Material for Containment and Cleaning Up

Methods for cleaning up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician’s directions.

Hygiene measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Conditions for Safe Storage, Including Any Incompatibilities

Storage conditions: Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight. Keep away from ignition sources (including static discharges).

Special rules on packaging: Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50°C (122°F). Do not pierce or burn, even after use.

Specific End Use(s)

Veterinary topical wound medication. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

<table>
<thead>
<tr>
<th>Isobutane (75-28-5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA ACGIH ACGIH STEL (ppm)</td>
</tr>
<tr>
<td>USA ACGIH ACGIH TW (mg/m³)</td>
</tr>
<tr>
<td>USA ACGIH ACGIH REL (mg/m³)</td>
</tr>
<tr>
<td>USA NIOSH NIOSH REL (mg/m³)</td>
</tr>
<tr>
<td>USA NIOSH NIOSH REL (ppm)</td>
</tr>
<tr>
<td>Manitoba OEL TW (ppm)</td>
</tr>
<tr>
<td>New Foundland &amp; Labrador OEL TW (ppm)</td>
</tr>
<tr>
<td>Nova Scotia OEL TW (ppm)</td>
</tr>
<tr>
<td>Ontario OEL TW (ppm)</td>
</tr>
<tr>
<td>Prince Edward Island OEL TW (ppm)</td>
</tr>
<tr>
<td>Québec VEMP (mg/m³)</td>
</tr>
<tr>
<td>Saskatchewan OEL STEL (ppm)</td>
</tr>
<tr>
<td>Saskatchewan OEL TW (ppm)</td>
</tr>
<tr>
<td>Prince Edward Island OEL STEL (ppm)</td>
</tr>
<tr>
<td>Saskatchewan OEL STEL (ppm)</td>
</tr>
<tr>
<td>Saskatchewan OEL TW (ppm)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Propane (74-98-6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA ACGIH ACGIH TW (ppm)</td>
</tr>
<tr>
<td>USA OSHA OSHA PEL (TWA) (mg/m³)</td>
</tr>
<tr>
<td>USA OSHA OSHA PEL (TWA) (ppm)</td>
</tr>
<tr>
<td>USA NIOSH NIOSH REL (TWA) (mg/m³)</td>
</tr>
<tr>
<td>USA NIOSH NIOSH REL (TWA) (ppm)</td>
</tr>
<tr>
<td>USA IDLH US IDLH (ppm)</td>
</tr>
<tr>
<td>Alberta OEL TW (ppm)</td>
</tr>
<tr>
<td>British Columbia OEL TW (ppm)</td>
</tr>
<tr>
<td>Manitoba OEL TW (ppm)</td>
</tr>
<tr>
<td>New Foundland &amp; Labrador OEL TW (ppm)</td>
</tr>
<tr>
<td>Nova Scotia OEL TW (ppm)</td>
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<tr>
<td>Prince Edward Island OEL TW (ppm)</td>
</tr>
<tr>
<td>Québec VEMP (mg/m³)</td>
</tr>
<tr>
<td>Saskatchewan OEL TW (ppm)</td>
</tr>
</tbody>
</table>
Exposure Controls
Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.


Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Information on Basic Physical and Chemical Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
</tr>
<tr>
<td>Appearance</td>
</tr>
<tr>
<td>Odor</td>
</tr>
<tr>
<td>Odor threshold</td>
</tr>
<tr>
<td>pH</td>
</tr>
<tr>
<td>Relative evaporation rate (butyl acetate=1)</td>
</tr>
<tr>
<td>Melting/Freezing point</td>
</tr>
<tr>
<td>Boiling point</td>
</tr>
<tr>
<td>Flash point</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
</tr>
<tr>
<td>Upper/Lower flammable limit</td>
</tr>
<tr>
<td>Vapor pressure</td>
</tr>
<tr>
<td>Relative vapor density at 20 °C</td>
</tr>
<tr>
<td>Relative density</td>
</tr>
<tr>
<td>Specific gravity</td>
</tr>
<tr>
<td>Solubility</td>
</tr>
<tr>
<td>Log Pow/Kow</td>
</tr>
<tr>
<td>Viscosity (kinematic, dynamic)</td>
</tr>
<tr>
<td>Explosion data - sensitivity to mechanical impact</td>
</tr>
<tr>
<td>Explosion data - sensitivity to static discharge</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Reactivity Hazardous reactions will not occur under normal conditions.

Chemical Stability Flammable aerosol.

Possibility of Hazardous Reactions Hazardous polymerization will not occur.

Conditions to Avoid Direct sunlight. Extremely high or low temperatures.


Hazardous Decomposition Products Carbon oxides (CO, CO₂).

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute toxicity: Not classified
LD50 and LC50 Data: Not available
Skin Corrosion/Irritation: Not classified (pH: 3 – 5)
Serious Eye Damage/Irritation: Not classified (pH: 3 – 5)
Respiratory or Skin Sensitization: May cause an allergic skin reaction.
Germ Cell Mutagenicity: Not classified
Teratogenicity: Not available
Carcinogenicity: Not classified
Specific Target Organ Toxicity (Repeated Exposure): Not classified
Reproductive Toxicity: Not classified
Specific Target Organ Toxicity (Single Exposure): Not classified
Aspiration Hazard: Not classified

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Toxicity</th>
<th>Persistence and Degradability</th>
<th>Bioaccumulative Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane (74-98-6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isobutane (75-28-5)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12. ECOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Persistence and Degradability</th>
<th>Bioaccumulative Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not available</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not available</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Propane (74-98-6)</th>
<th>Log Pow</th>
<th>2.3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isobutane (75-28-5)</td>
<td>BCF fish 1</td>
<td>1.57 - 1.97</td>
</tr>
<tr>
<td></td>
<td>Log Pow</td>
<td>2.88 (at 20 °C)</td>
</tr>
</tbody>
</table>

13. DISPOSAL CONSIDERATIONS

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.

14. TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG

<table>
<thead>
<tr>
<th>UN Number</th>
<th>UN-No.(DOT): 1950</th>
<th>DOT NA no.: UN1950</th>
</tr>
</thead>
</table>

UN Proper Shipping Name: Aerosols

Hazard labels (DOT): 2.1 - Flammable gas

15. REGULATORY INFORMATION

US Federal Regulations

Granulex V Spray

SARA Section 311/312 Hazard Classes

| Delayed (chronic) health hazard |
| Fire hazard |
| Sudden release of pressure hazard |

Castor oil (8001-79-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Propane (74-98-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Balsams, Peru (8007-00-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Isobutane (75-28-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

US State Regulations

Propane (74-98-6)

U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 1
U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 2
U.S. - Massachusetts - Oil & Hazardous Material List - Reportable Quantity
U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 1
U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 2
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Discharge Prevention - List of Hazardous Substances
U.S. - New Jersey - Environmental Hazardous Substances List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - New Jersey - Special Health Hazards Substances List
U.S. - New Jersey - TCPA - Extraordinarily Hazardous Substances (EHS)
U.S. - Pennsylvania - RTK (Right to Know) List

**Isobutane (75-28-5)**

- U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 1
- U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 2
- U.S. - Massachusetts - Oil & Hazardous Material List - Reportable Quantity
- U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 1
- U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 2
- U.S. - Massachusetts - Right To Know List
- U.S. - New Jersey - Discharge Prevention - List of Hazardous Substances
- U.S. - New Jersey - Environmental Hazardous Substances List
- U.S. - New Jersey - Right to Know Hazardous Substance List
- U.S. - New Jersey - Special Health Hazards Substances List
- U.S. - New Jersey - TCPA - Extraordinarily Hazardous Substances (EHS)
- U.S. - Pennsylvania - RTK (Right to Know) List

**Canadian Regulations**

**Granulex V Spray**

<table>
<thead>
<tr>
<th>WHMIS Classification</th>
<th>Class A - Compressed Gas</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Class B Division 1 - Flammable Gas</td>
</tr>
</tbody>
</table>

**Castor oil (8001-79-4)**

- Listed on the Canadian DSL (Domestic Substances List) inventory.
- Listed on the Canadian Ingredient Disclosure List

<table>
<thead>
<tr>
<th>WHMIS Classification</th>
<th>Uncontrolled product according to WHMIS classification criteria</th>
</tr>
</thead>
</table>

**Propane (74-98-6)**

- Listed on the Canadian DSL (Domestic Substances List) inventory.

<table>
<thead>
<tr>
<th>WHMIS Classification</th>
<th>Class A - Compressed Gas</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Class B Division 1 - Flammable Gas</td>
</tr>
</tbody>
</table>

**Balsams, Peru (8007-00-9)**

- Listed on the Canadian DSL (Domestic Substances List) inventory.

<table>
<thead>
<tr>
<th>WHMIS Classification</th>
<th>Class A - Compressed Gas</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Class B Division 1 - Flammable Gas</td>
</tr>
</tbody>
</table>

**Isobutane (75-28-5)**

- Listed on the Canadian DSL (Domestic Substances List) inventory.

<table>
<thead>
<tr>
<th>WHMIS Classification</th>
<th>Class A - Compressed Gas</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Class B Division 1 - Flammable Gas</td>
</tr>
</tbody>
</table>

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

16. **OTHER INFORMATION**

**Revision date** : 04/11/2014

**Data sources** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

**Other information** : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

**GHS Full Text Phrases**:

<table>
<thead>
<tr>
<th>Acute Tox. 4 (Oral)</th>
<th>Acute toxicity (oral) Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Chronic 2</td>
<td>Hazardous to the aquatic environment - Chronic Hazard Category 2</td>
</tr>
<tr>
<td>Eye Irrit. 2A</td>
<td>Serious eye damage/eye irritation Category 2A</td>
</tr>
<tr>
<td>Flam. Aerosol 1</td>
<td>Flammable aerosol Category 1</td>
</tr>
<tr>
<td>Flam. Gas 1</td>
<td>Flammable gases Category 1</td>
</tr>
<tr>
<td>Liquefied gas</td>
<td>Gases under pressure Liquefied gas</td>
</tr>
<tr>
<td>Simple Asphy</td>
<td>Simple Asphy xiant</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>Skin corrosion/irritation Category 2</td>
</tr>
</tbody>
</table>

04/11/2014 EN (English US) 6/7
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Sens. 1</td>
<td>Skin sensitization Category 1</td>
</tr>
<tr>
<td>H220</td>
<td>Extremely flammable gas</td>
</tr>
<tr>
<td>H222</td>
<td>Extremely flammable aerosol</td>
</tr>
<tr>
<td>H280</td>
<td>Contains gas under pressure; may explode if heated</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H411</td>
<td>Toxic to aquatic life with long lasting effects</td>
</tr>
</tbody>
</table>

**Party Responsible For The Preparation Of This Document:**
Mylan Global Environmental, Health, and Safety Department
Phone Number: 304-599-2595

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. 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 completeness of the information 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.

North America Mylan Pharmaceuticals