Safety Data Sheet

Section 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product identifier
Product Name • Multidex® Gel Wound Dressing

1.2 Relevant identified uses of the substance or mixture and uses advised against
Relevant identified use(s) • A hydrophilic Maltodextrin NF wound dressing clinically proven to promote the growth of granulation tissue and epithelial proliferation.

1.3 Details of the supplier of the safety data sheet
Manufacturer • DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849
United States
www.deroyal.com
customerservice@deroyal.com

Telephone (General) • 800-251-9864

1.4 Emergency telephone number
• 800-524-3416

Section 2: Hazards Identification

EU/EEC
According to: EU Directive 67/548/EEC (DSD) or 1999/45/EC (DPD)

2.1 Classification of the substance or mixture
CLP • Not classified
DSD/DPD • Not classified

2.2 Label Elements
CLP

Hazard • No label element(s) required statements

DSD/DPD

Risk phrases • No label element(s) required

2.3 Other Hazards
CLP • According to Regulation (EC) No. 1272/2008 (CLP) this material is not considered hazardous.

DSD/DPD • According to European Directive 1999/45/EC this preparation is not considered dangerous.
UN GHS
According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
2.1 Classification of the substance or mixture
UN GHS • Eye Mild Irritation 2B

2.2 Label elements
UN GHS • WARNING

Hazard • Causes eye irritation

statements

Precautionary statements

Prevention • Wash thoroughly after handling.

Response • IF IN EYES: Rinse cautiously with water for fifteen minutes. If present, remove contact lenses and continue rinsing. If eye irritation persists, get medical advice/attention.

2.3 Other hazards
UN GHS • According to the Globally Harmonized System for Classification and Labeling (GHS), this product is considered hazardous.

United States (US)
According to: OSHA 29 CFR 1910.1200 HCS

2.1 Classification of the substance or mixture
OSHA HCS 2012 • Eye Mild Irritation 2B

2.2 Label elements
OSHA HCS 2012 • WARNING

Hazard • Causes eye irritation

statements

Precautionary statements

Prevention • Wash thoroughly after handling.

Response • IF IN EYES: Rinse cautiously with water for fifteen minutes. If present, remove contact lenses and continue rinsing. If eye irritation persists, get medical advice/attention.

2.3 Other hazards

Canada
According to: WHMIS

2.1 Classification of the substance or mixture
WHMIS • Not classified

2.2 Label elements
WHMIS • No label element(s) required.

2.3 Other hazards
WHMIS • In Canada, the product mentioned above is not considered hazardous under the Workplace Hazardous Materials Information System (WHMIS).
### Section 3 - Composition/Information on Ingredients

#### 3.1 Substances
- Material does not meet the criteria of a substance.

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Identifiers</th>
<th>%</th>
<th>LD50/LC50</th>
<th>Classifications According to Regulation/Directive</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maltodextrin</td>
<td>CAS:9050-36-6</td>
<td>&lt; 75%</td>
<td>NDA</td>
<td>UN GHS: Not Classified; EU DSD/DPD: Not Classified; EU CLP: Not Classified; OSHA HCS 2012: Not Classified</td>
<td>NDA</td>
</tr>
<tr>
<td></td>
<td>EC Number:232-940-4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycerin</td>
<td>CAS:56-81-5</td>
<td>0% TO 10%</td>
<td>Ingestion/Oral-Rat LD50 • 12600 mg/kg</td>
<td>UN GHS: Eye Irrit. 2; EU DSD/DPD: Not classified; EU CLP: Not classified; OSHA HCS 2012: Eye Irrit. 2</td>
<td>NDA</td>
</tr>
<tr>
<td></td>
<td>EC Number:200-289-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>L-Ascorbic acid</td>
<td>CAS:50-81-7</td>
<td>1%</td>
<td>Ingestion/Oral-Rat LD50 • 11900 mg/kg</td>
<td>UN GHS: Not Classified; EU DSD/DPD: Not classified; EU CLP: Not classified; OSHA HCS 2012: Not Classified</td>
<td>NDA</td>
</tr>
<tr>
<td></td>
<td>EINECS:200-066-2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Section 4 - First Aid Measures

#### 4.1 Description of first aid measures
- **Inhalation**: Move victim to fresh air. Get medical attention if symptoms occur.
- **Skin**: First-aid is not expected to be necessary under normal conditions of use.
- **Eye**: If direct eye contact occurs, flush with gently flowing fresh water thoroughly. Get medical attention if symptoms occur.
- **Ingestion**: Rinse mouth with water. Get medical attention if symptoms occur.

#### 4.2 Most important symptoms and effects, both acute and delayed
- Refer to Section 11 - Toxicological Information.

#### 4.3 Indication of any immediate medical attention and special treatment needed

- No specific actions or treatments recommended related to exposure to this material.

### Section 5 - Firefighting Measures

#### 5.1 Extinguishing media
- **Suitable Extinguishing Media**: Water, Carbon Dioxide, or Dry Chemical
- **Unsuitable Extinguishing Media**: No data available

#### 5.2 Special hazards arising from the substance or mixture
- **Unusual Fire and Explosion Hazards**: None
- **Hazardous Combustion Products**: No data available

#### 5.3 Advice for firefighters
- Wear positive pressure self-contained breathing apparatus (SCBA). Structural firefighters’ protective clothing will only provide limited protection.
Section 6 - Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions  • It is unlikely that this product, when spilled, will cause a problem; packaged as individual packets. Do not walk through spilled material. Use appropriate Personal Protective Equipment (PPE).

Emergency Procedures  • No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended.

6.2 Environmental precautions  
• None expected to be necessary under normal conditions of use.

6.3 Methods and material for containment and cleaning up

Containment/Clean-up Measures  • Wipe or mop up.

6.4 Reference to other sections  
• Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage

7.1 Precautions for safe handling

Handling  • Good housekeeping and sanitary procedures. Do not get in eyes. Wash thoroughly with soap and water after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage  • Store away from heat sources.

7.3 Specific end use(s)

• Refer to Section 1.2 - Relevant identified uses.

Section 8 - Exposure Controls/Personal Protection

8.1 Control parameters

Exposure Limits/Guidelines  • No data available

8.2 Exposure controls

Engineering Measures/Controls  • No special engineering measures/controls expected to be necessary under normal conditions of use.

Personal Protective Equipment

Respiratory  • None required under normal conditions of use.

Eye/Face  • Wear appropriate eye protection.

Skin/Body  • Wear appropriate gloves.

Environmental Exposure Controls  • Follow best practice for site management and disposal of waste.
Section 9 - Physical and Chemical Properties

9.1 Information on Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Material Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Form</td>
</tr>
<tr>
<td>Appearance/Description</td>
</tr>
<tr>
<td>Color</td>
</tr>
<tr>
<td>Odor Threshold</td>
</tr>
<tr>
<td>Odor</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
</tr>
<tr>
<td>Specific Gravity/Relative Density</td>
</tr>
<tr>
<td>Melting Point</td>
</tr>
<tr>
<td>pH</td>
</tr>
<tr>
<td>Water Solubility</td>
</tr>
<tr>
<td>Viscosity</td>
</tr>
<tr>
<td>Explosive Properties</td>
</tr>
<tr>
<td>Odor Threshold</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Volatility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vapor Pressure</td>
</tr>
<tr>
<td>Evaporation Rate</td>
</tr>
<tr>
<td>Vapor Density</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flammability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash Point</td>
</tr>
<tr>
<td>UEL</td>
</tr>
<tr>
<td>LEL</td>
</tr>
<tr>
<td>Autoignition</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Environmental</th>
</tr>
</thead>
<tbody>
<tr>
<td>Octanol/Water Partition coefficient</td>
</tr>
</tbody>
</table>

9.2 Other Information

No additional physical and chemical parameters noted.

Section 10: Stability and Reactivity

10.1 Reactivity
- No dangerous reaction known under normal conditions of use.

10.2 Chemical stability
- Stable

10.3 Possibility of hazardous reactions
- Hazardous polymerization will not occur.

10.4 Conditions to avoid
- None

10.5 Incompatible materials
- Strong oxidizing agents

10.6 Hazardous decomposition products
- Oxides of carbon
Section 11 - Toxicological Information

11.1 Information on toxicological effects

<table>
<thead>
<tr>
<th>GHS Properties</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>EU/CLP: No data available</td>
</tr>
<tr>
<td></td>
<td>OSHA HCS 2012: No data available</td>
</tr>
<tr>
<td></td>
<td>UN GHS: No data available</td>
</tr>
<tr>
<td>Aspiration Hazard</td>
<td>EU/CLP: No data available</td>
</tr>
<tr>
<td></td>
<td>OSHA HCS 2012: No data available</td>
</tr>
<tr>
<td></td>
<td>UN GHS: No data available</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>EU/CLP: No data available</td>
</tr>
<tr>
<td></td>
<td>OSHA HCS 2012: No data available</td>
</tr>
<tr>
<td></td>
<td>UN GHS: No data available</td>
</tr>
<tr>
<td>Germ Cell Mutagenicity</td>
<td>EU/CLP: No data available</td>
</tr>
<tr>
<td></td>
<td>OSHA HCS 2012: No data available</td>
</tr>
<tr>
<td></td>
<td>UN GHS: No data available</td>
</tr>
<tr>
<td>Skin corrosion/Irritation</td>
<td>EU/CLP: No data available</td>
</tr>
<tr>
<td></td>
<td>OSHA HCS 2012: No data available</td>
</tr>
<tr>
<td></td>
<td>UN GHS: No data available</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>EU/CLP: No data available</td>
</tr>
<tr>
<td></td>
<td>OSHA HCS 2012: No data available</td>
</tr>
<tr>
<td></td>
<td>UN GHS: No data available</td>
</tr>
<tr>
<td>STOT-RE</td>
<td>EU/CLP: No data available</td>
</tr>
<tr>
<td></td>
<td>OSHA HCS 2012: No data available</td>
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<td></td>
<td>UN GHS: No data available</td>
</tr>
<tr>
<td>STOT-SE</td>
<td>EU/CLP: No data available</td>
</tr>
<tr>
<td></td>
<td>OSHA HCS 2012: No data available</td>
</tr>
<tr>
<td></td>
<td>UN GHS: No data available</td>
</tr>
<tr>
<td>Toxicity for Reproduction</td>
<td>EU/CLP: No data available</td>
</tr>
<tr>
<td></td>
<td>OSHA HCS 2012: No data available</td>
</tr>
<tr>
<td></td>
<td>UN GHS: No data available</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>EU/CLP: No data available</td>
</tr>
<tr>
<td></td>
<td>OSHA HCS 2012: No data available</td>
</tr>
<tr>
<td></td>
<td>UN GHS: No data available</td>
</tr>
<tr>
<td>Serious eye damage/Irritation</td>
<td>EU/CLP: No data available</td>
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<tr>
<td></td>
<td>OSHA HCS 2012: Eye Mild Irritation 2B</td>
</tr>
<tr>
<td></td>
<td>UN GHS: Eye Mild Irritation 2B</td>
</tr>
</tbody>
</table>

Potential Health Effects

Inhalation

Acute (Immediate) • Under normal conditions of use, no health effects are expected.

Chronic (Delayed) • No data available

Skin

Acute (Immediate) • Under normal conditions of use, no health effects are expected.

Chronic (Delayed) • No data available

Eye

Acute (Immediate) • Under normal conditions of use, no health effects are expected.
Chronic (Delayed) • No data available

Ingestion

Acute (Immediate) • Under normal conditions of use, no health effects are expected.
Chronic (Delayed) • No data available

## Section 12 - Ecological Information

12.1 Toxicity
• No data available

12.2 Persistence and degradability
• No data available

12.3 Bioaccumulative potential
• No data available

12.4 Mobility in Soil
• No data available

12.5 Results of PBT and vPvB assessment
• No PBT and vPvB assessment has been conducted.

12.6 Other adverse effects
• No studies have been found.

## Section 13 - Disposal Considerations

13.1 Waste treatment methods

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

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

## Section 14 - Transport Information

<table>
<thead>
<tr>
<th>DOT</th>
<th>14.1 UN number</th>
<th>14.2 UN proper shipping name</th>
<th>14.3 Transport hazard class(es)</th>
<th>14.4 Packing group</th>
<th>14.5 Environmental hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
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<tr>
<td>TDG</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>IMO/IMDG</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>IATA/ICAO</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
</tbody>
</table>

14.6 Special precautions for user • None specified

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available
Section 15 - Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications  •  None

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS</th>
<th>Canada DSL</th>
<th>Canada NDSL</th>
<th>EU EINECS</th>
<th>EU ELNICS</th>
<th>TSCA</th>
<th>Korea KECL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>L-Ascorbic acid</td>
<td>50-81-7</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Maltodextrin</td>
<td>9050-36-6</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Canada

Labor

Canada - WHMIS - Classifications of Substances

• L-Ascorbic acid  50-81-7  Not Listed
  • Maltodextrin  9050-36-6  Not Listed
  • Glycerin  56-81-5  Not Listed

Canada - WHMIS - Ingredient Disclosure List

• L-Ascorbic acid  50-81-7  Not Listed
  • Maltodextrin  9050-36-6  Not Listed
  • Glycerin  56-81-5  Not Listed

Environment

Canada - CEPA - Priority Substances List

• L-Ascorbic acid  50-81-7  Not Listed
  • Maltodextrin  9050-36-6  Not Listed
  • Glycerin  56-81-5  Not Listed

Korea

Labor

Korea - ISHA - Harmful Substances Prohibited for Manufacturing, Importing, Transferring, or Supplying

• L-Ascorbic acid  50-81-7  Not Listed
  • Maltodextrin  9050-36-6  Not Listed
  • Glycerin  56-81-5  Not Listed

Korea - ISHA - Harmful Substances Requiring Permission

• L-Ascorbic acid  50-81-7  Not Listed
  • Maltodextrin  9050-36-6  Not Listed
  • Glycerin  56-81-5  Not Listed

Korea - ISHA - Name, Toxicity and Protective Measures of New Chemical Substances

• L-Ascorbic acid  50-81-7  Not Listed
  • Maltodextrin  9050-36-6  Not Listed
  • Glycerin  56-81-5  Not Listed

Environment

Korea - MOE - Toxic Chemicals Control Act (TCCA) - Observational Chemicals

• L-Ascorbic acid  50-81-7  Not Listed
  • Maltodextrin  9050-36-6  Not Listed
  • Glycerin  56-81-5  Not Listed
United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

- L-Ascorbic acid 50-81-7 Not Listed
- Maltodextrin 9050-36-6 Not Listed
- Glycerin 56-81-5 Not Listed

U.S. - OSHA - Specifically Regulated Chemicals

- L-Ascorbic acid 50-81-7 Not Listed
- Maltodextrin 9050-36-6 Not Listed
- Glycerin 56-81-5 Not Listed

Environment

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

- L-Ascorbic acid 50-81-7 Not Listed
- Maltodextrin 9050-36-6 Not Listed
- Glycerin 56-81-5 Not Listed

U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities

- L-Ascorbic acid 50-81-7 Not Listed
- Maltodextrin 9050-36-6 Not Listed
- Glycerin 56-81-5 Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

- L-Ascorbic acid 50-81-7 Not Listed
- Maltodextrin 9050-36-6 Not Listed
- Glycerin 56-81-5 Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

- L-Ascorbic acid 50-81-7 Not Listed
- Maltodextrin 9050-36-6 Not Listed
- Glycerin 56-81-5 Not Listed

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

- L-Ascorbic acid 50-81-7 Not Listed
- Maltodextrin 9050-36-6 Not Listed
- Glycerin 56-81-5 Not Listed

U.S. - CERCLA/SARA - Section 313 - PBT Chemical Listing

- L-Ascorbic acid 50-81-7 Not Listed
- Maltodextrin 9050-36-6 Not Listed
- Glycerin 56-81-5 Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

- L-Ascorbic acid 50-81-7 Not Listed
- Maltodextrin 9050-36-6 Not Listed
- Glycerin 56-81-5 Not Listed

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

- L-Ascorbic acid 50-81-7 Not Listed
- Maltodextrin 9050-36-6 Not Listed
- Glycerin 56-81-5 Not Listed

U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)

- L-Ascorbic acid 50-81-7 Not Listed
- Maltodextrin 9050-36-6 Not Listed
- Glycerin 56-81-5 Not Listed

U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)

- L-Ascorbic acid 50-81-7 Not Listed
15.2 Chemical Safety Assessment

- No Chemical Safety Assessment has been carried out.

Section 16 - Other Information

<table>
<thead>
<tr>
<th>Last Revision Date</th>
<th>12/March/2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation Date</td>
<td>12/March/2015</td>
</tr>
<tr>
<td>Disclaimer/Statement of Liability</td>
<td>The information presented herein is based on data considered to be accurate as of the date of preparation of this Safety Data Sheet. However, no warranty or representation, express or implied is made as to the accuracy or completeness of the foregoing data and safety information, nor is any authorization given or implied to practice any patented invention without a license. In addition, no responsibility can be assumed by vendor for any damage or injury resulting from abnormal use, from any failure to adhere to recommended practices, or from any hazards inherent in the nature of the product.</td>
</tr>
</tbody>
</table>

Key to abbreviations

NDA = No data available