

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: Regulation (EC) No 1272/2008 (CLP)/REACH 1907/2006 [amended by 453/2010]

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 statements • No label element(s) required

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 statements • Causes eye irritation

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 statements • Causes eye irritation

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

OSHA HCS 2012 • Under United States Regulations (29 CFR 1910.1200 - Hazard Communication Standard), this product is considered hazardous.

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

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

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

- Notes to Physician** • 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

Material Description			
Physical Form	Liquid	Appearance/Description	Tan gel with little odor.
Color	Tan	Odor	Little odor
Odor Threshold	No data available		
General Properties			
Boiling Point	No data available	Melting Point	No data available
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	Soluble
Viscosity	No data available	Explosive Properties	No data available
Oxidizing Properties:	No data available		
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available	Volatiles (Wt.)	No data available
Flammability			
Flash Point	No data available	UEL	No data available
LEL	No data available	Autoignition	No data available
Flammability (solid, gas)	No data available		
Environmental			
Octanol/Water Partition coefficient	No data available		

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

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

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

	14.1 UN number	14.2 UN proper shipping name	14.3 Transport hazard class(es)	14.4 Packing group	14.5 Environmental hazards
DOT	Not Regulated	Not Regulated	NDA	NDA	NDA
TDG	Not Regulated	Not Regulated	NDA	NDA	NDA
IMO/IMDG	Not Regulated	Not Regulated	NDA	NDA	NDA
IATA/ICAO	Not Regulated	Not Regulated	NDA	NDA	NDA

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

Component	Inventory						
	CAS	Canada DSL	Canada NDSL	EU EINECS	EU ELNICS	TSCA	Korea KECL
Glycerin	56-81-5	Yes	No	Yes	No	Yes	Yes
L-Ascorbic acid	50-81-7	Yes	No	Yes	No	Yes	Yes
Maltodextrin	9050-36-6	Yes	No	Yes	No	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

•L-Ascorbic acid	50-81-7	Uncontrolled product according to WHMIS classification criteria
•Maltodextrin	9050-36-6	Not Listed
•Glycerin	56-81-5	Uncontrolled product according to WHMIS classification criteria

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. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants

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

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
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•Maltodextrin	9050-36-6	Not Listed
•Glycerin	56-81-5	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
•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 - Reproductive Toxicity - Male		
•L-Ascorbic acid	50-81-7	Not Listed
•Maltodextrin	9050-36-6	Not Listed
•Glycerin	56-81-5	Not Listed

15.2 Chemical Safety Assessment

- No Chemical Safety Assessment has been carried out.

Section 16 - Other Information

Last Revision Date	• 12/March/2015
Preparation Date	• 12/March/2015
Disclaimer/Statement of Liability	• 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.

Key to abbreviations

NDA = No data available