

Safety Data Sheet

Material Name: KERLIX® AMD Super Sponges; KERLIX® AMD Rolls ; Excilon® AMD Sponges; TELFA AMD Sponges; CURITY® AMD Packing Strips; CURITY® AMD Gauze Sponges

SDS ID: COV-007

Section 1 - PRODUCT AND COMPANY IDENTIFICATION

Material Name

KERLIX® AMD Super Sponges; KERLIX® AMD Rolls ; Excilon® AMD Sponges; TELFA AMD Sponges; CURITY® AMD Packing Strips; CURITY® AMD Gauze Sponges

Synonyms

6662, 6665, 6660, 3331, 3332, 7088, 7089, 7662, 7663, 7665, 7666, 7667, 7668, 7831AMD, 7832AMD, 7833AMD, 2506, 2533, 2539

Product Use

Wound dressings

Restrictions on Use

For use under medical supervision only.

Manufacturer Information

Covidien, LP

15 Hampshire Street

Mansfield, MA 02048

USA

Phone: +1-(508) 261-8000 (Monday - Friday 8:00 am to 5:00 pm)

Email: customerservice@medtronic.com

Emergency Telephone Number:

CHEMTREC (800) 424-9300 (for US and Canada)

1(703) 527-3887 (Outside US and Canada)

Collect calls accepted

Section 2 - HAZARDS IDENTIFICATION

Classification in accordance with paragraph (d) of 29 CFR 1910.1200.

None needed according to classification criteria

GHS Label Elements

Symbol(s)

None needed according to classification criteria

Signal Word

None needed according to classification criteria

Hazard Statement(s)

None needed according to classification criteria

Precautionary Statement(s)

Prevention

None needed according to classification criteria

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Response

None needed according to classification criteria

Storage

None needed according to classification criteria

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations

Other Hazards

No additional information available.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

CAS	Component Name	Percent (%)
27083-27-8	Poly(Hexamethylenebiguanide)hydrochloride	0.2

Section 4 - FIRST AID MEASURES

Inhalation

It is unlikely that first aid will be required.

Skin

It is unlikely that first aid will be required. Get medical attention if irritation develops.

Eyes

Rinse cautiously with water for several minutes. If eye irritation persists, get medical advice/attention.

Ingestion

If swallowed, get medical attention.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

Most Important Symptoms/Effects

Acute

May cause mild eye irritation.

Delayed

None known.

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Section 5 - FIRE FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media

Use carbon dioxide, regular dry chemical, regular foam or water.

Unsuitable Extinguishing Media

None known.

Special Hazards Arising from the Chemical

None known.

Hazardous Combustion Products

Oxides of carbon, hydrogen chloride

Fire Fighting Measures

Avoid inhalation of material or combustion by-products.

Section 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Wear personal protective clothing and equipment.

Methods and Materials for Containment and Cleaning Up

Clear up spills immediately and dispose of waste safely.

Environmental Precautions

Avoid release to the environment.

Section 7 - HANDLING AND STORAGE

Precautions for Safe Handling

Wear personal protective clothing and equipment. Observe good hygiene and safety practices when handling this product.

Conditions for Safe Storage, Including any Incompatibilities

Store in a cool, dry place. Store in a well-ventilated place.

Incompatible Materials

None known.

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Component Exposure Limits

ACGIH, NIOSH, EU, OSHA (US) and Mexico have not developed exposure limits for any of this product's components

Biological limit value

There are no biological limit values for any of this product's components.

Engineering Controls

Based on available information, additional ventilation is not required.

Individual Protection Measures, such as Personal Protective Equipment

Eye/face protection

Eye protection not required under normal conditions. Safety glasses or goggles are recommended when there is a potential for eye contact.

Skin Protection

Not required.

Respiratory Protection

No respirator is required under normal conditions of use.

Glove Recommendations

Not required.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Colorless to pale yellow fabric	Physical State	Solid
Odor	Odorless	Color	Colorless to pale yellow
Odor Threshold	Not available	pH	5 - 5.5 , conc: 10% w/w in water
Melting Point	Not available	Boiling Point	215.6 °F (102 °C)
Freezing point	Not available	Evaporation Rate	Not available
Boiling Point Range	Not available	Flammability (solid, gas)	Not available
Autoignition	Not available	Flash Point	Not flammable
Lower Explosive Limit	Not available	Decomposition	Not available

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Upper Explosive Limit	Not available	Vapor Pressure	Not available
Vapor Density (air=1)	Not available	Specific Gravity (water=1)	~1.04
Water Solubility	Soluble	Partition coefficient: n-octanol/water	Not available
Viscosity	Not available	Solubility (Other)	Not available
Density	Not available		

Other Information

No additional information is available.

Section 10 - STABILITY AND REACTIVITY

Reactivity

Not known to occur.

Chemical Stability

Stable under normal conditions of use.

Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

Conditions to Avoid

Avoid heat, flames, sparks and other sources of ignition.

Incompatible Materials

None known.

Hazardous decomposition products

Oxides of carbon, hydrogen chloride

Section 11 - TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure

Inhalation

None known.

Skin Contact

Repeated or prolonged exposure may cause allergic sensitization.

Eye Contact

May cause mild eye irritation.

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Ingestion

If large amounts are swallowed, nausea and vomiting may occur. May cause gastrointestinal irritation with diarrhea.

Acute and Chronic Toxicity

The amount of PHMB released while in use is only 1.3% of the total concentration present in the wound dressing. Therefore, this product is not considered a carcinogen.

Component Analysis - LD50/LC50

The components of this material have been reviewed in various sources and the following selected endpoints are published:

Poly(Hexamethylenebiguanide)hydrochloride (27083-27-8)

Oral LD50 Rat >2000 mg/kg (Safety Data Sheet)

Dermal LD50 Rat >2000 mg/kg (Safety Data Sheet)

Immediate Effects

May cause mild eye irritation.

Delayed Effects

No information on significant adverse effects.

Irritation/Corrosivity Data

May cause mild eye irritation.

Respiratory Sensitization

No data available.

Dermal Sensitization

No data available.

Component Carcinogenicity

None of this product's components are listed by ACGIH, IARC, NTP, DFG or OSHA

Germ Cell Mutagenicity

No data available.

Reproductive Toxicity

No data available.

Specific Target Organ Toxicity - Single Exposure

No data available.

Specific Target Organ Toxicity - Repeated Exposure

No data available.

Aspiration hazard

No hazard expected.

Medical Conditions Aggravated by Exposure

No data available.

Additional Data

No additional information available.

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Section 12 - ECOLOGICAL INFORMATION

Ecotoxicity

Harmful to aquatic life with long lasting effects. Avoid release to the environment.

Component Analysis - Aquatic Toxicity

No LOLI ecotoxicity data are available for this product's components

Persistence and Degradability

No information available for the product.

Bioaccumulative Potential

No information available for the product.

Mobility

No information available for the product.

Other Toxicity

No information available.

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Methods

Dispose in accordance with all applicable regulations.

Section 14 - TRANSPORT INFORMATION

US DOT Information:

Shipping Name: Not applicable

Hazard Class: Not applicable

UN/NA #: Not regulated

Packing Group: Not applicable

Required Label(s): Not applicable

IATA Information:

Shipping Name: Not applicable

Hazard Class: Not applicable

UN#: Not regulated

Packing Group: Not applicable

Required Label(s): Not applicable

IMDG Information:

Shipping Name: Not applicable

Hazard Class: Not applicable

UN#: Not regulated

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Required Label(s): Not applicable

TDG Information:

Shipping Name: Not applicable
Hazard Class: Not applicable
UN#: Not regulated
Packing Group: Not applicable
Required Label(s): Not applicable

Section 15 - REGULATORY INFORMATION

U.S. Federal Regulations

None of this products components are listed under SARA Sections 302/304 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), CERCLA (40 CFR 302.4), TSCA 12(b).

Not listed under California Proposition 65

Canadian WHMIS Ingredient Disclosure List (IDL)

The components of this product are either not listed on the IDL or are present below the threshold limit listed on the IDL.

Section 16 - OTHER INFORMATION

Summary of Changes

New SDS: May 1, 2015

Key / Legend

ACGIH - American Conference of Governmental Industrial Hygienists; ADR - European Road Transport; AU - Australia; BOD - Biochemical Oxygen Demand; C - Celsius; CA - Canada; CAS - Chemical Abstracts Service; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CLP - Classification, Labelling, and Packaging; CN - China; CPR - Controlled Products Regulations; DFG - Deutsche Forschungsgemeinschaft; DOT - Department of Transportation; DSD - Dangerous Substance Directive; DSL - Domestic Substances List; EEC - European Economic Community; EINECS - European Inventory of Existing Commercial Chemical Substances; EPA - Environmental Protection Agency; EU - European Union; F - Fahrenheit; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; ICAO - International Civil Aviation Organization; IDL - Ingredient Disclosure List; IDLH - Immediately Dangerous to Life and Health; IMDG - International Maritime Dangerous Goods; JP - Japan; Kow - Octanol/water partition coefficient; KR - Korea; LEL - Lower Explosive Limit; LLV - Level Limit Value; LOLI - List Of Lists™ - ChemADVISOR's Regulatory Database; MAK - Maximum Concentration Value in the Workplace; MEL - Maximum Exposure Limits; NFPA - National Fire Protection Agency; NIOSH - National Institute for Occupational Safety and Health; NJTSR - New Jersey Trade Secret Registry; NTP - National Toxicology Program; NZ - New Zealand; OSHA - Occupational Safety and Health Administration; PH - Philippines; RCRA - Resource Conservation and Recovery Act; REACH - Registration, Evaluation, Authorisation, and restriction of Chemicals; RID - European Rail Transport; SARA - Superfund Amendments and Reauthorization Act; STEL - Short-term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; UEL - Upper Explosive Limit; US - United States; WHMIS - Workplace Hazardous Materials Information System

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Other Information

Disclaimer:

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