
SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

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

Substance Registration Number(s)

REACH obligation for the substances in this product is under review.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses

Wound dressings

Uses advised against

For use under medical supervision only.

1.3 Details of the supplier of the safety data sheet

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

1.4 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

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazardous to the Aquatic Environment - Chronic - Category 3

2.2 Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard symbols

None needed according to classification criteria

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

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

Signal word

None needed according to classification criteria

Hazard statements

H412 Harmful to aquatic life with long lasting effects

Precautionary statements

Prevention

P273 Avoid release to the environment

Response

None needed according to classification criteria

Storage

None needed according to classification criteria

Disposal

P501 Dispose of contents/container in accordance with local/regional/national/international regulations

Labeling according to Directive 67/548/EEC and/or 1999/45/EC

None needed according to classification criteria.

2.3 Other hazards

No additional information available.

SECTION 3: Composition / information on ingredients

CAS EC No Registration No	Component Name Synonyms	1272/2008 (CLP)	Percent (%)
27083-27-8 608-042-7 Not available	Poly(Hexamethylenebiguanide)hydrochloride	Acute Tox. (Oral) 4 - H302 Eye Dam. 1 - H318 Skin Sens. 1B - H317 Carc. 2 - H351 STOT RE 1 - H372 Aquatic Acute 1 - H400 Aquatic Chronic 1 - H410	0.2

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation

It is unlikely that first aid will be required.

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

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

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.

4.2 Most Important Symptoms/Effects

Acute

May cause mild eye irritation.

Delayed

None known.

4.3 Indication of Immediate Medical Attention and Special Treatment

Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

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

Unsuitable Extinguishing Media

None known.

5.2 Special hazards arising from the substance or mixture

None known.

Combustion

Oxides of carbon, hydrogen chloride

5.3 Advice for firefighters

Negligible fire hazard.

Fire Fighting Measures

Avoid inhalation of material or combustion by-products.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear personal protective clothing and equipment.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and Materials for Containment and Cleaning Up

Clear up spills immediately and dispose of waste safely.

6.4 Reference to other sections

Safe handling: see section 7. Personal protection equipment: see section 8. Disposal: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

7.2 Conditions for safe storage, including any incompatibilities

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

Incompatible Materials

None known.

7.3 Specific end use(s)

Wound dressings

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Component Exposure Limits

EU, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Netherlands, Portugal, Spain, Sweden and United Kingdom 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.

Derived No Effect Levels (DNELs)

No DNELs available.

Predicted No Effect Concentrations (PNECs)

No PNECs available.

8.2 Exposure Controls

Engineering controls

Based on available information, additional ventilation is not required.

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

9.1 Information on basic 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
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		

9.2 Other information

No additional information is available.

SECTION 10: Stability and reactivity

10.1 Reactivity

Not known to occur.

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

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

10.2 Chemical stability

Stable under normal conditions of use.

10.3 Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4 Conditions to avoid

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

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Oxides of carbon, hydrogen chloride

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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)

Irritation/Corrosivity Data

May cause mild eye irritation.

Respiratory Sensitization

No data available.

Dermal Sensitization

No data available.

Germ Cell Mutagenicity

No data available.

Component Carcinogenicity

None of this product's components are listed by IARC or DFG.

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.

SECTION 12: Ecological information

12.1 Toxicity

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

12.2 Persistence and degradability

No information available for the product.

12.3 Bioaccumulative potential

No information available for the product.

12.4 Mobility in soil

No information available for the product.

12.5 Results of PBT and vPvB assessment

EU - Interim Strategy for Management of PBT and vPvB Substances

No components of this material are listed.

12.6 Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

Component Marine Pollutants (IMDG)

Not regulated as dangerous goods.

		ADR	RID	ICAO	IATA	ADN	IMDG
14.1	UN Number	Not regulated	Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

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

14.2	UN Proper Shipping Name	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3	Transport Hazard Class(es)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4	Packing Group	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5	Environmental Hazards	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.6	Special Precautions For User	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.7	Transport in Bulk According to Annex II or MARPOL 73/78 and the IBC Code	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.8	Additional information	No additional information available	No additional information available	No additional information available	Consult current IATA regulations prior to shipping by air	No additional information available	No additional information available

International Bulk Chemical Code

This material does not contain any chemicals required by the IBC Code to be identified as dangerous chemicals in bulk.

SECTION 15: Regulatory information

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

EU - REACH (1907/2006) - Annex XIV List of Substances Subject to Authorization

No components of this material are listed.

EU - REACH (1907/2006) - Article 59(1) Candidate List of Substances Subject to Authorization

No components of this material are listed.

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

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

EU - REACH (1907/2006) - Annex XVII Restrictions of Certain Dangerous Substances, Mixtures and Articles

No components of this material are listed.

EU - Biocides (1451/2007) - Existing Active Substance

No components of this material are listed.

Germany Regulations

Germany Water Classification

No components of this material are listed.

Denmark Regulations

No components of this material are listed.

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out for the substance/mixture.

SECTION 16: Other information

16.1 Indication of changes

New SDS: May 1, 2015

16.2 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

16.3 Key literature references and sources for data

Available upon request.

16.4 Methods Used for Classification of Mixture According to Regulation (EC) No 1272/2008

Available upon request.

16.5 Relevant R-, H- and EUH-phrases (Number and full text)

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

H302 Harmful if swallowed

H351 Suspected of causing cancer

H318 Causes serious eye damage

H372 Causes damage to organs through prolonged or repeated exposure

H317 May cause allergic skin reaction

16.6 Training advice

Read the Safety Data Sheet before handling product.

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

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

16.7 Further Information

Disclaimer:

The information and recommendations in this safety data sheet are based on sources believed to be accurate as of the date of issue. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. Covidien LP makes NO WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED and usage of this safety data sheet shall not establish a legal, contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose. Covidien LP assumes no responsibility for injury to vendee or third party person proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Furthermore, Covidien LP assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed. Users should ensure that any use or disposal of the material is in accordance with applicable national, country, federal, state, and local laws, directives, orders and regulations.