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

1.1 Product identifier

Material Name

Kendall™ Hydrogel Breast Feeding Pads

Synonyms

9403, 9403B

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 gel discs

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]

None needed according to classification criteria

2.2 Label elements

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

None needed according to classification criteria

Signal word

None needed according to classification criteria

Hazard statements

None needed according to classification criteria

Precautionary statements

Prevention

None needed according to classification criteria

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 (%)
25322-68-3 500-038-2 Not available	Polyethylene glycol	Note(s): No classification	5-20
57-55-6 200-338-0 Not available	Propylene glycol	Note(s): No classification	5-20
Proprietary Proprietary Not available	Urethane Polymer	Note(s): No classification	10-30
65605-36-9 613-824-6 Not available	Polyoxyalkyleneamine	Note(s): No classification	0.20-2

SECTION 4: First aid measures

4.1 Description of 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.

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

Fumes from heating may cause irritation.

Combustion

Oxides of carbon, oxides of nitrogen

5.3 Advice for firefighters

Slight 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

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. Protect from sunlight.

Incompatible Materials

None known.

7.3 Specific end use(s)

Wound dressings gel discs

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Component Exposure Limits

Propylene glycol	57-55-6
Ireland:	150 ppm TWA total vapor and particulates; 470 mg/m ³ TWA total vapor and particulates; 10 mg/m ³ TWA particulate
	450 ppm STEL (calculated) total vapor and particulates; 1410 mg/m ³ STEL (calculated) total vapor and particulates; 30 mg/m ³ STEL (calculated) particulate
United Kingdom:	150 ppm TWA total particulates and vapour; 474 mg/m ³ TWA total particulates and vapour; 10 mg/m ³ TWA particulates
	450 ppm STEL (calculated) total particulate and vapor; 1422 mg/m ³ STEL (calculated) total particulate and vapor; 30 mg/m ³ STEL (calculated) particulate

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	Impregnated materials translucent gel	Physical State	Solid
Odor	Slight alcohol	Color	Colorless
Odor Threshold	Not available	pH	Not available
Melting Point	Not available	Boiling Point	Not available
Freezing point	Not available	Evaporation Rate	Not available
Boiling Point Range	Not available	Flammability (solid, gas)	Not available
Autoignition	Not available	Flash Point	Not available
Lower Explosive Limit	Not applicable	Decomposition	Not available
Upper Explosive	Not applicable	Vapor Pressure	Not

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

9.2 Other information

No additional information available.

SECTION 10: Stability and reactivity

10.1 Reactivity

Not known to occur.

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, oxides of nitrogen

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Component Analysis - LD50/LC50

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

Polyethylene glycol (25322-68-3)

Oral LD50 Rat 22 g/kg

Dermal LD50 Rabbit >20 mL/kg

Propylene glycol (57-55-6)

Oral LD50 Rat 20 g/kg

Dermal LD50 Rabbit 20800 mg/kg

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

Avoid release to the environment.

Component Analysis - Aquatic Toxicity

Propylene glycol	57-55-6
Fish:	LC50 96 h Oncorhynchus mykiss 51600 mg/L [static]; LC50 96 h Oncorhynchus mykiss 41 - 47 mL/L [static]; LC50 96 h Pimephales promelas 51400 mg/L [static]; LC50 96 h Pimephales promelas 710 mg/L
Algae:	EC50 96 h Pseudokirchneriella subcapitata 19000 mg/L IUCLID
Invertebrate:	EC50 48 h Daphnia magna >1000 mg/L [static] EPA

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 additional 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
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
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International Bulk Chemical Code

This material contains one or more of the following chemicals required by the IBC Code to be identified as dangerous chemicals in bulk.

Polyethylene glycol	25322-68-3
IBC Code:	Category Z
Propylene glycol	57-55-6
IBC Code:	Category Z

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.

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

Propylene glycol	57-55-6
	Present

Germany Regulations

Germany Water Classification

Polyethylene glycol (25322-68-3)

ID Number 279 , hazard class 1 - low hazard to waters (footnote 11, >=4 EO)

Propylene glycol (57-55-6)

ID Number 280 , hazard class 1 - low hazard to waters

Polyoxyalkyleneamine (65605-36-9)

ID Number 2878 , hazard class 1 - low hazard to waters

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: April 30, 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)

None needed according to classification criteria

16.6 Training advice

Read the Safety Data Sheet before handling product.

16.7 Further Information

Disclaimer:

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