

SAFETY DATA SHEETS

This SDS packet was issued with item:

078740903

N/A



MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Aquaflo™ Hydrogel Wound Dressing,
Maternimates™ Gel Discs,
Mother Mates

Use/Size Wound Dressings, Gel Discs

Product Numbers 8884-476139, 8884-476154
17262, 17264
9403, 9403B, 9404

Manufacturer/Supplier Tyco Healthcare/ Kendall

Address 15 Hampshire Street
Mansfield, MA 02048

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

Chemtrec Number (800) 424-9300

Revision Date: April 1, 2010

MSDS Date: September 22, 1998

This MSDS has been compiled in accordance with - EC Directive 91/155/EC - OSHA's Hazcom Standard (29 CFR 1910.1200)

2. COMPOSITION/INFORMATION ON THE COMPONENTS

| Component Name | CAS#/Codes | Concentration | R Phrases | Classification |
|------------------------------|-------------------------|---------------|-----------|----------------|
| Polyoxyethylene Glycol | 25322-68-3 200-849-9 | 5.00 -20.00% | R-None | None |
| Propylene Glycol | 57-55-6 200-338-0 | 5.00 -20.00% | R-None | None |
| Water | 7732-18-5 231-791-2 | 20.00 -70.00% | R-None | None |
| Proprietary Urethane Polymer | N.A. No EC # | 10.00 -30.00% | R-None | None |
| Polyoxyalkyleneamine | 65605-36-9 | 0.20 -2.00% | R-None | None |

3. HAZARD IDENTIFICATION

EU Main Hazards

Not classified as hazardous.

Routes of Entry

- Eye contact - Skin contact

Carcinogenic Status

Not considered carcinogenic by NTP, IARC, and OSHA.

Target Organs

- Eye - Skin

Health Effects - Eyes

Contact may cause very slight irritation.

Health Effects - Skin

This product is non-irritating to the skin and skin absorption is not associated with any health effects.
Does not cause irritation or sensitization.

Health Effects - Ingestion

No adverse effects are expected.

Health Effects - Inhalation

No adverse effects are expected during normal conditions of use.

4. FIRST AID MEASURES

Eyes

Immediately flood the eye with plenty of water for at least 15 minutes, holding the eye open. Obtain medical attention if soreness or redness persists.

Skin

If skin irritation develops, or other symptoms occur, discontinue use. Seek medical attention if symptoms persist.

Ingestion

Do not induce vomiting. Have victim drink 1-3 glasses of water to dilute stomach contents. Never administer anything by mouth if a victim is losing consciousness, is unconscious or is convulsing. Obtain medical attention immediately.

Inhalation

If there is difficulty in breathing, give oxygen. Seek medical attention if symptoms persist.

Advice to Physicians

Treat symptomatically.

5. FIRE FIGHTING MEASURES

Extinguishing Media

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

Unusual Fire and Explosion Hazards

This product may give rise to hazardous fumes in a fire.

Protective Equipment for Fire-Fighting

Wear full protective clothing and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

This product, in final form, is a wound dressing, and is not expected to present a spill or release hazard. No specific measures necessary.

7. HANDLING AND STORAGE

Keep container tightly closed when not in use. Storage area should be: - cool - dry - well ventilated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Standards

Exposure limits are listed below, if they exist.

Polyoxyethylene Glycol

None assigned.

Propylene Glycol

None assigned.

Water

None assigned.

Proprietary Urethane Polymer

None assigned.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Polyoxyalkyleneamine

None assigned.

Engineering Control Measures

No specific measures necessary.

Respiratory Protection

Respiratory protection not normally required.

Hand Protection

Skin protection not normally required.

Eye Protection

Chemical goggles or safety glasses with side shields

Body Protection

Normal work wear.

9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|-----------------------------------|-------------------|
| Physical State | Gel |
| Color | Translucent |
| Odor | Slight polyol |
| pH | Slightly Alkaline |
| Boiling Range/Point (°C/F) | No data. |
| Flash Point (PMCC) (°C/F) | No data. |
| Explosion Limits (%) | No data. |
| Vapor Pressure | No data. |
| Density | No data. |
| Solubility in Water | No data. |
| Vapor Density (Air = 1) | No data. |
| Viscosity (cSt) | No data. |

10. STABILITY AND REACTIVITY

Stability

Stable under normal conditions.

Conditions to Avoid

- Heat - High temperatures - Pressure - Mechanical shock

Materials to Avoid

None known.

Hazardous Polymerization

Will not occur.

Hazardous Decomposition Products

- oxides of carbon - oxides of nitrogen

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Aquaflo™ Hydrogel Wound Dressing saline extract did not cause significant cytotoxicity.

Aquaflo™ Hydrogel Wound Dressing saline extract did not cause systemic toxicity by subcutaneous and intraperitoneal injections at 2, 24, 48 and 72 hours.

Aquaflo™ Hydrogel Wound Dressing did not cause erythema, edema or eschar formation from direct IM injections at 24, 48 and 72 hours.

Aquaflo™ Hydrogel Wound Dressing did not cause dermal sensitization, edema or erythema at 24 and 72 hours.

Aquaflo™ Hydrogel Wound Dressing caused significant encapsulation when injected intramuscularly into rodents. An inadvertent injection of this product does not pose a significant risk of harm based on negative systemic toxicity and the encapsulation by a tissue barrier preventing release of non-soluble components into the body.

There were no statistically different (95% confidence limit) product-related mortalities, clinical signs of toxicity, loss in body weight or microscopic tissue pathology observed in groups of 10 mice of each sex repeatedly injected with a saline extract of the product every day for 5 days over 4 weeks.

Chronic Toxicity/Carcinogenicity

This product is not expected to cause long-term adverse health effects.

Genotoxicity

Saline and DMSO extracts of Aquaflo™ Hydrogel Wound Dressing tested for genotoxicity using the Ames Mutagenic Assay system was negative.

Reproductive/Developmental Toxicity

This product is not expected to cause reproductive or developmental health effects.

12. ECOLOGICAL INFORMATION

Mobility

No relevant studies identified.

Persistence/Degradability

The product is readily biodegradable.

Bio-accumulation

Product is not expected to bioaccumulate.

Ecotoxicity

No relevant studies identified.

13. DISPOSAL

Dispose of in accordance with all applicable local and national regulations.

14. TRANSPORT INFORMATION

DOT CFR 172.101 Data

Not Regulated

14. TRANSPORT INFORMATION

| | |
|---|--|
| UN Proper Shipping Name | Not Regulated |
| UN Class | None. |
| UN Number | None. |
| UN Packaging Group | None. |
| Classification for AIR Transportation (IATA) | Consult current IATA Regulations prior to shipping by air. |

15. REGULATORY INFORMATION

EU Label Information

Classification and labelling have been performed according to EU directives 67/548/EEC and 99/45/EC including amendments.

EU Hazard Symbol and Indication of Danger

According to EC Commission Directive 67/548/EEC this product is not classified.

R phrases

None.

S phrases

None.

US REGULATIONS (Federal, State) and INTERNATIONAL CHEMICAL REGISTRATION LAWS**TSCA Listing**

This product contains ingredients that are listed on or exempt from listing on the EPA Toxic Substance Control Act Chemical Inventory.

EINECS Listing

All ingredients in this product are listed on the European Inventory of Existing Commercial Chemical Substances (EINECS) or are exempt from listing.

DSL/NDSL (Canadian) Listing

This product contains ingredients which are not listed on the Domestic Substance List (DSL) or the Non-Domestic Substance List (NDSL).

MA Right To Know Law

This product does not contain any chemicals listed on the Massachusetts Right To Know Substance List.

PA Right To Know Law

This product does not contain any chemicals on the Pennsylvania Hazardous Substance List. – Propylene glycol

NJ Right To Know Law

This product does not contain any chemicals on the New Jersey Workplace Hazardous Substance List.

California Proposition 65

This product does not contain materials which the State of California has found to cause cancer, birth defects or other reproductive harm.

SARA Title III Sect. 302 (EHS)

This product does not contain any chemicals subject to SARA Title III Section 302.

15. REGULATORY INFORMATION

SARA Title III Sect. 304

This product does not contain any chemicals subject to SARA Title III Section 304.

SARA Title III Sect. 311/312 Categorization

This product does not meet any of the SARA Title III Section 311/312 categorizations.

SARA Title III Sect. 313

This product does not contain a chemical that is listed in Section 313 at or above de minimis concentrations.

16. OTHER INFORMATION

NFPA Ratings

NFPA Code for Flammability - 0

NFPA Code for Health - 0

NFPA Code for Reactivity - 0

NFPA Code for Special Hazards - 0

HMIS Ratings

HMIS Code for Flammability - 0

HMIS Code for Health - 0

HMIS Code for Reactivity - 0

HMIS Code for Personal Protection - See Section 8

Abbreviations

N/A: Denotes no applicable information found or available

CAS#: Chemical Abstracts Service Number

ACGIH: American Conference of Governmental Industrial Hygienists

OSHA: Occupational Safety and Health Administration

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

STEL: Short Term Exposure Limit

NTP: National Toxicology Program

IARC: International Agency for Research on Cancer

EU: European Union

R: Risk

S: Safety

LC50: Lethal Concentration 50%

LD50: Lethal Dose 50%

BOD: Biological Oxygen Demand

KoC: Soil Organic Carbon Partition Coefficient

Prepared By: EnviroNet LLC.

The information and recommendations presented in this MSDS are based on sources believed to be accurate; therefore, The Kendall Company assumes no liability for the accuracy or completeness of this information. It is the user's responsibility to determine the suitability of the information for their particular purposes.