

2014-05-15 Hydrocolloid dressing

Section 1: Product and company identification

Product name: Pharmacoll ™ (hydrocolloid dressing)

Produced to: AlphraMedic AB Address: Kämpevägen 17 553 02 Jönköping

Sweden

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Product use:

Intended use: used as a wound with low to highly exuding severe wounds that have substantially and extensively breached the dermis, and where the healing process can only be by secondary intent

### Section 2: ingredients

# Hydrocolloid dressing composition:

Ingredient	C.A.S No	% by weight
Poly urethane film	N/A	5-10%
Sodium Carboxy methyl cellulose	9004-32-4	10-20%
butyl rubber	9000-69-5	40 - 60 %
tackifiying resin	unknown	20-40%
Silicon paper	Unknown	5-10%

#### Section 3: Hazards identification

#### 3.1 Emergency overview

Color: tan or yellowish, translucent hydrocolloid contained by paper liner

Odor: slight odor

General physical form: Solid

Immediate health, physical and environmental hazards: this product, when used under reasonable condition and in accordance with AlphraMedic AB directions for use, should not present a health hazard, however, use or processing of the product in a manner not in

accordance with the product's directions for use may affect the performance of the product and may present a potential health and safety hazards.

## 3.2 Potential health effects.

Eye contact: Not relevant Skin contact:

No health effects are expected

Inhalation: Not relevant

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Ingestion: Not relevant

#### Section 4: First aid measures

## 4.1 First aid procedures

the following first aid recommendations are based on an assumption that appropriate personal and industrial hygiene practices are followed

Eye contact: Not relevant

Skin contact: No need for first aid is anticipated

Inhalation: Not relevant IF Swallowed: Not relevant

Others: Show this Safety Data Sheet to a physician or emergency ward.

# Section 5: Firefighting measures

## 5.1 Flammable properties

Auto ignition temperature N/A
Flash point N/A
Flammable limits-LEL N/A
Flammable limits-UEL N/A

#### 5.2 Extinguishing media

Ordinary combustible material. Use fire extinguishers with class A extinguishing agent (water, foam.) use fire extinguishers with class B extinguishing agents (dry chemical, carbon dioxide..)

### 5.3 protections of fire fighters

Special firefighting procedures: wear full protective equipment (bunker gear) and a self –contained breathing apparatus (SCBA).

Unusual fire and explosion hazards: N/A

Section 6: Accidental release measures

Accidental release measures: N/A

Section 7: Handling and storage

#### 7.1 Handling

This product is considered to be an article which does not release or otherwise result in exposure to a hazardous chemical under normal use conditions. Please refer to instruction for use



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### 7.2 Storage

Store until use as supplied and at normal temperatures

### Section 8: Exposure controls/personal protection

8.1 Engineering controls

N/A

8.2 Personal protective equipment's

8.2.1 Eye/face protection

N/A

8.2.2 Skin protection

N/A

8.2.3 Respiratory protection

N/A

8.2.4 Prevention of swallowing

Don't ingest

# Section 9: Physical and Chemical properties

Odor, Color: tan or yellowish, translucent hydrocolloid contained by paper liner

General physical form: Solid Auto ignition Temp: N/A

Flash point: N/A

Flammable limits-LEL: N/A Flammable Limits- UEL: N/A

Boiling Point: N/A Density N/A

Vapor Density: N/A Specific gravity: N/A

PH: N/A

Melting point: No data available Solubility in water: Negligible

Evaporation rate: N/A

Volatile organic compounds: N/A

Percent volatile: N/A

VOC less H2O &exempt solvents: N/A

Viscosity: N/A

## Section 10: Stability and reactivity

Stability: Stable

Materials and conditions to avoid: None Known Hazardous polymerization: Will Not occur



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Hazardous decomposition: Hydrocarbons, Carbon monoxide, carbon dioxide

## Section 11: Toxicological information

- 11.1 Acute reactions: the product did not cause an acute reaction under the test conditions
- 11.2 Cytotoxicity Test: the product caused no toxicological/biological critical cell damages and growth inhibition (non-cytotoxic)

The product meets the requirements of DIN-ISO 10993

Section 12: Ecological information

Eco toxicological information: N/A Chemical Fate information: N/A

Section 13: Disposal considerations

Waste disposal method:

Dispose of in accordance with all applicable local and national regulations

Section14: Transport information

Wound dressing not a dangerous good,

Please apply the appropriate regulations to properly classify your shipment.

Section 15: Regulatory information

<u>United States:</u> This product is regulated under the Federal Food Drug and Cosmetic Act and do not require an MSDS for hazard communication as stated in 29 CFR 1910.1200.

This MSDS is supplied as an additional service.

<u>European Union:</u> This product is a medical device and is regulated under the Council Directive 93/42/EEC (commonly known as the Medical Device Directive). Medical devices do not require a safety data sheet for hazard communication.



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(	Section 16: Other information

Not applicable

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