



Ardes Medical & Manufacturing
5775 Wayzata Blvd. Suite 700 PMB200-009
St. Louis Park, MN 55416
TEL: 1-844-802-1402
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SAFETY DATA SHEET

PRODUCT: BURN GEL 3.5g Sachets, Sterile Dressings, Gel Sprays, Squeeze Bottles, Tubes

IDENTIFICATION

SUPPLIER:

Company: Ardes Medical & Manufacturing
Address: 5775 Wayzata Blvd. Suite 700
PMB 200-009
St. Louis Park, MN 55416

Phone: 1-844-802-1402
Fax: 1-844-832-7826

STATEMENT OF HAZARDOUS NATURE:

Not classified as hazardous according to criteria of work safe China

Health Hazard: 0
Flammability: 0
Reactivity: 0
Body Contact: 1

Scale: min/nil=0 Low=1 Moderate=2 High=3 Extreme=4

Material Details:

CAS No.	None
NIOSH No.	None
UN No.	None
Dangerous G. Class	None
Packaging Group	None
IMO Class	None
Poison Schedule	None
HAZCHEM	None
Sub Risk	None
EPG	
IMDG Page	None

Label

Shipping Name
None

PHYSICAL PROPERTIES

Molecular Weight:	Not applicable
Boiling Range:	"
Melting Range:	"
Specific Gravity:	0.98 to 1.02
Water Solubility:	Miscible
Evaporation Rate:	Not available
State:	Gel
Vapor Pressure:	Not available
Volatile Component (%Vol):	"
Relative Vapor Density:	"
Flash Point:	Not applicable
Lower Explosive Limit (%):	"
Upper Explosive Limit (%):	"
Auto Ignition Temp@:	"
Decomposition Temp @:	Not available

APPEARANCE & INGREDIENTS

Ingredient/Component	Quantity
<i>Dressings</i>	
- An open cell polyester foam impregnated with white/off white to slightly clear hydrogel with a tea tree oil odour contained in a plastic/foil/plastic laminate pouch	
Gel Tubes/Sachets/Bottles	
- A white/off white to slightly clear hydrogel with a tea tree oil odor contained in a plastic/foil/plastic laminate sachet, tube or bottle.	

Single Use Dressing & Sachet Gel

- Melaleuca Oil	- 1.5 %
- Emulgator	- 1 %
- Propylene glycol	- 3 %
- Glycerin	- 3 %
- Carbomer	- 1.5 %
- Purified Water	- 90 %

Tubes & Bottles Gel

- Melaleuca Oil	- >4.5 %
- Thickeners	
- Emulsifiers Surfactant	

Sterility

STERILE R

Single Use Sachets and Dressings are sterilized by Gamma Irradiation – Minimum dosage of 25kygs

USAGE

A first aid burn gel for using on burns. cools and soothes, offers pain relief and helps prevent secondary infection. Available in tubes, dispensers and gel impregnated open cell foam dressings

SYNONYMS - None

HEALTH HAZARD

ACUTE HEALTH EFFECTS

SWALLOWED

Considered an unlikely route of entry. It is doubtful whether enough could be ingested to cause any irritation to the gastro-intestinal tract, or cause any pain or vomiting. Pure Melaleuca Oil is considered toxic. However formulation under 25% are considered non toxic. Oral Toxicity Testing indicated the LD50 to be greater than 10g/kg, indicating very low potential irritancy.

EYE

Considered a possible mild irritant to the eye and may cause some smarting and redness. Acute Eye Irritation Testing using the Draize procedure indicated a very mild eye irritant.

SKIN

Generally considered a non-irritant. Prolonged exposure may cause some mild irritation and redness in a very small number of people. In rare cases skin contact may cause some irritation during use. Acute Dermal Irritation and Skin Sensitisation Testing in accordance with Draize procedure indicated a non-irritant and non-sensitising.

INHALATION

No hazard as product is non-volatile.

CHRONIC

Prolonged contact may cause slight irritation or redness for a small number of people. Pure Melaleuca Oil is considered a mild irritant, however percentages under 10% are usually considered non-irritants.

FIRST AID

SWALLOWED

If swallowed, give a glass of water.

EYE

If in contact with the eyes, hold eye open and flush out the eye - especially under the eyelids with fresh water or saline solution. Seek medical attention if any irritation continues.

SKIN

If irritation occurs, discontinue use and wash off with fresh water.

INHALATION

Not applicable.

OTHER

Melaleuca Oil is generally considered a non-irritant in inert formula's below 10% concentration, and considered non toxic at levels of less than 25% concentration. Industry studies indicate allergic reaction to products containing less than 10% Melaleuca Oil is extremely rare, but when reported usually involves some redness and stinging of the skin.

Toxicity	LD50>10g/kg
Skin Sensitization	Non irritant
Skin Irritation	Non irritant
Eye Irritation	1 Draize Scale - very mild irritant

ADVICE TO HEALTHCARE PROFESSIONAL

Treat symptomatically. Refer to individual constituents

PRECAUTIONS FOR USE

EXPOSURE LIMITS

None known

OTHER EXPOSURE INFORMATION

None

ENGINEERING CONTROLS

None

PERSONAL PROTECTION

No special equipment required for normal handling

PROTECTIVE EQUIPMENT

None required

FLAMMABILITY

Non flammable

FIRE HAZARD

None

SAFE HANDLING INFORMATION

STORAGE AND TRANSPORT

Store in packaging provided in a cool place. Avoid extreme temperatures and sharp objects that may pierce the pack. Do not use if packaging is damaged. Can be refrigerated but do not freeze.

STORAGE PRECAUTIONS

As above

SHIPPING NAME (CSN)

None

SPILLS AND DISPOSAL

Wipe up or absorb with sponge. Place in waste disposal.

FIRE/EXPLOSION HAZARD

None

HAZARDOUS REACTION

None known

OTHER INFORMATION**ENVIRONMENTAL PROTECTION**

Generally considered non-hazardous to the environment.

DATE OF ISSUE

November 2012

DATE REVIEWED

June 2016

The information contained in this data sheet is accurate to the best of our knowledge as of the date issued. It is the user's obligation to assess that the product is suitable for the purpose chosen, and that it is used in accordance with the instructions.