



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**

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### IDENTIFICATION

#### SUPPLIER:

Company: Ardes Medical & Manufacturing  
Address: 5775 Wayzata Blvd. Suite 700  
PMB 200-009  
St. Louis Park, MN 55416  
  
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#### 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	
<b>Gel Tubes/Sachets/Bottles</b>	
- 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

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## **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

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## **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

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**OTHER INFORMATION****ENVIRONMENTAL PROTECTION**

Generally considered non-hazardous to the environment.

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**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.