



# A WORLD OF PROTECTION

Doc No. 68  
Doc Rev No: 1  
Spec Rev No: 4

## In House Specifications

**Specification No:** 130811B

**Customer:** St Johns Ambulance Supplies

**Customer Product Code:** F11508 ( Singles) 4000 wipes per outer carton  
: F11509 ( Pack of 10) 400 x 10 per outer carton  
: F11510 ( Pack of 100) 20 x 100 per outer carton

**Brief Description:** Sterile Saline Crepe Paper Wipe (0.9% w/v)

**Weight per 10 Sachets:** 25 g                      **Expiry Date:** 3 years

**Product Class:** IIa Medical Device                      **Product Code:** STRSAL01

**Sterilization Method:** Gamma Irradiation                      **Min Dose:** 25 kGy

### Solution Composition (Per 1000L Mixing Tank Solution)

% Conc.	Component
0.9% w/v (±5%)	Sodium Chloride BP Grade
99.1% w/v	Purified Water (>5MΩ/>15MΩ) UV Treated

### Sachet and Material Composition

Solution Amount	Tissue Type	Foil Type
2ml solution per sachet (±10%)	40g crepe paper	CCP50/PE 12/ALI6.35/ION23
	100mm x 105mm	75mm x 50.8mm

## Art Work for Printed Foil



### In House Specifications

#### **Packing Instructions:**

1. Each carton is poly-lined
2. Carton must be completely sealed with clear adhesive tape

#### **Labeling Details:**

1. The Product Code, Lot No., Quantity and Expiry Date will be printed on to a template sticker.
2. The A5 sized preprinted sticker is intended for the out side of the cardboard box  
(see attached sticker)

#### **Outer Label:**

1. The machine operator will check that the information on the outer sticker agrees with the batch to be packed.
2. The sticker is then placed on the end of the box.

#### **Palletisation:**

1. Each pallet must have a cardboard lining on the base.
2. Each pallet must contain 50 outer cartons
3. All four corners must be protected with pallet corners

4. Each pallet must be completely shrink wrapped to avoid damage in transit and sealed with security tape.

**Documentation:**

1. Each delivery will have a packing slip detailing how many sachets per batch
2. Certificate of Conformity
3. Certificate of Irradiation/Irradiation Number

**Foil size:**

The foil sachet should measure 75mm x 50.8mm.

**Foil Appearance:**

1. Single sachet.
2. The text on the foil should be clear and free from smudges.
3. The batch no. and Exp. Date should be clearly embossed in the area indicated by the Lot symbol and Exp Date symbol
4. There should be no stains on the foil.
5. All four seals should be intact, without leaks or bubbles.

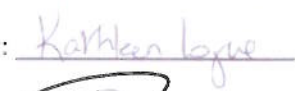

**Lot No. and Expiry Date:**

1. The Lot. No. is generated from the week and year of manufacture e.g. week 8 in 2011 is lot no. 0811
2. The expiry date is 3 years from date of manufacturing and is in the format YYYY-WW e.g. week 8 in 2011 exp date 2014-08

**Approved Inner/Outer Box Art Work (if any):**

No inner or outer box art work. Product is packed in clear grip lock bags

**Approved Labeling:** (See printed label attached)

Managing Director:		<b>Authorized By:</b>	Date: <u>9/2/2012</u>
Operations Director:			Date: <u>9/2/2012</u>
Customer:			Date: <u>10/02/2012</u>

## MATERIAL SAFETY DATA SHEET

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### SECTION 1 – PRODUCT AND COMPANY

<b>TRADE NAME:</b>	<b>BURNSHIELD</b>
<b>DOSAGE FORM:</b>	<b>DRESSINGS OF VARIOUS SIZES:</b>
	<b>100MMx100MM</b>
	<b>200MMx200mm</b>
	<b>600MMx400MM</b>
	<b>600MMx450MM FACE MASK</b>
	<b>200MMx450MM FACE MASK</b>
	<b>25MMx0,5M</b>
	<b>50MMx1,0M</b>
<b>APPLICATION:</b>	<b>EMERGENCY TREATMENT OF ALL TYPES OF BURNWOUNDS</b>
<b>DESCRIPTION:</b>	<b>POLYURETHANE DRESSING WETTED WITH BURNSHIELD GEL CONTAINED IN A MULTILAYERED ALUMINIUM POUCH</b>

### TOXIC INFORMATION:

<b>RESPONSIBLE:</b>	<b>M. DI DOMENICO</b>
<b>EMERGENCY PHONE:</b>	<b>+27 82 881 2074</b>

### SECTION 2 - COMPOSITION

#### GEL FORMULA:

<b>TEA TREE OIL</b>
<b>PRESERVATIVES</b>
<b>GELLING AGENTS</b>
<b>PURIFIED WATER</b>
<b>BURNSHIELD GEL DOES NOT CONTAIN MARLOPHEN.</b>

#### DRESSING:

**BURNSHIELD DRESSINGS ARE MADE FROM POLYURETHANE.**

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**SECTION 3 – HAZARDS IDENTIFICATION**

NO HAZARDS ARE IDENTIFIED FOR USE, STORAGE OR TRANSPORTATION OF BURNSHIELD DRESSINGS.

**SECTION 4 – FIRST AID MEASURES**

<b>GENERAL</b>	<b>NONE</b>
<b>INHALATION</b>	<b>NONE – MOVE AWAY FROM SOURCE</b>
<b>SKIN CONTACT</b>	<b>IF SLIGHT IRRITATION OCCURS, RINSE WITH WATER AND STOP USE</b>
<b>INGESTION</b>	<b>NONE</b>
<b>INFORMATION TO HEALTH PERSONEL</b>	<b>THE LD50 HAS BEEN ESTABLISHED TO BE IN EXCESS OF 10G/KG BODY WEIGHT, THUS POSING A VERY LOW POTENTIAL RISK</b>
<b>MORE INFORMATION</b>	<b>BURNSHIELD GEL IS COMPOSED MAINLY OF WATER AND IS VERY LOW HEALTH RISK. A SLIGHT SKIN IRRITATION(SKIN REDDENING TO BE OBSERVED IF PATIENT IS ALLERGIC TO THE GEL).</b>

**SECTION 5 – FIRE FIGHTING MEASURES**

<b>SUITABLE EXTINGUISHER</b>	<b>ALL TYPES SUITABLE</b>
<b>UNSUITABLE EXTINGUISH MEDIA</b>	<b>NONE</b>
<b>FIRE AND EXPLOSION HAZARDS</b>	<b>NONE</b>
<b>PERSONAL PROTECTION WHEN FIREFIGHTING</b>	<b>FIREFIGHTERS TO BE AWARE THAT BURNING POLYURETHANE RESULTS IN GAS TOXIC FUMES. MASKS TO BE WORN.</b>
<b>SPECIAL FIREFIGHTING PROCEDURES</b>	<b>NONE</b>



MANUFACTURERS OF BURNSHIELD EMERGENCY BURNCARE PRODUCTS

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## SECTION 6 – ACCIDENTAL SPILLAGE MEASURES

PERSONAL PRECAUTIONS	NONE
ENVIRONMENTAL PRECAUTIONS	NONE
CLEANING MEASURES	RINSE WITH WATER
GENERAL	BURNSHIELD GEL IS WATER SOLUBLE AND IS EASILY RINSED. DO NOT BURN THE POLYURETHANE FOAM AS THIS WILL RESULT IN TOXIC FUMES.

## SECTION 7 - HANDLING AND STORAGE

SPECIAL PRECAUTIONS	NONE
HANDLING	NO SPECIAL PRECAUTIONS
STORAGE	PROTECT FROM EXTREME TEMPERATURES.
OTHER INFORMATION	THE BURNSHIELD DRESSING ARE SUPPLIED IN A STERILE STATE. SPEACIAL PRECAUTIONS SHOULD BE OBSERVED TO ENSURE THAT THE PACKAGING IS NOT DAMAGED DURING STORAGE AND HANDLING.

## SECTION 8 – EXPOSURE CONTROL/PERSONAL PROTECTION

EXPOSURE	NONE
RESPIRATORY PROTECTION	NONE
EYE PROTECTION	NONE
HAND PROTECTION	NONE
SKIN PROTECTION	NONE

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**SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES**

<b>FORM</b>	<b>POLYURETHANE DRESSING WETTED WITH BURNSHIELD GEL</b>
<b>COLOUR OF GEL</b>	<b>WHITE TO COLOURLESS</b>
<b>ODOUR OF GEL</b>	<b>OF TEA TREE OIL</b>
<b>DENSITY</b>	<b>APPROX 1.000 AT 20°C</b>
<b>VISCOSITY</b>	<b>MINIMUM 5000cPs (BROOKFIELD – SINDLE 6,20rpm)</b>
<b>BOILING POINT</b>	<b>APPROX 105°C</b>
<b>PH</b>	<b>5.5 – 7.5</b>
<b>AUTO IGNITION TEMP</b>	<b>WILL NOT AUTO-IGNITE</b>
<b>SOLUBILITY IN WATER</b>	<b>100% SOLUBLE IN WATER</b>

**SECTION 10 – STABILITY AND REACTIVITY**

<b>STABILITY</b>	<b>BURNSHIELD GEL IS VERY STABLE THROUGH A WIDE RANGE OF TEMPERATURES AND HUMIDITY</b>
<b>REACTIVITY</b>	<b>WILL NOT REACT WITH OTHER SUBSTANCES. WILL DISSOLVE OTHER WATER SOLUBLE CHEMICALS WHEN IN CONTACT.</b>
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	<b>NONE</b>
<b>OTHER INFORMATION</b>	<b>BURNSHIELD GEL IS STABLE FOR MINIMUM 5 YEARS. NO HARMFUL DEGRADATION PRODUCTS HAVE BEEN ESTABLISHED. WATER SOLUBLE SUBSTANCES MAY DISSOLVE WHEN IN CONTACT WITH BURNSHIELD GEL. BURNSHIELD GEL IS COMPRISED MAINLY OF WATER AND WILL THUS CONDUCT ELECTRICITY.</b>

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**SECTION 11 – TOXICOLOGICAL INFORMATION**

<b>GENERAL</b>	<b>BURNSHIELD GEL HAS BEEN ESTABLISHED AS BEING NON-TOXIC</b>
<b>INHALATION</b>	<b>NON-TOXIC</b>
<b>SKIN CONTACT</b>	<b>NON-TOXIC</b>
<b>EYE CONTACT</b>	<b>NON-TOXIC</b>
<b>INGESTION</b>	<b>LOW RISK – LD50 MORE THAN 10G/KG BODY WEIGHT</b>
<b>CHRONIC EFFECTS</b>	<b>NONE</b>
<b>SENSITISATION</b>	<b>HYPERSENSITIVE SKINS MAY DEVELOP A SLIGHT SKIN REDDENING ON CONTACT</b>
<b>MUTOGENICITY</b>	<b>NONE</b>
<b>CANCER</b>	<b>NONE</b>
<b>REPRODUCTION</b>	<b>NO EFFECTS</b>
<b>OTHER TOXICOLOGICAL INFORMATION</b>	<b>NO OTHER TOXICOLOGICAL EFFECTS KNOWN</b>
<b>ORAL TOXICITY</b>	<b>LOW RISK – LD50 MORE THAN 10G/KG BODY WEIGHT</b>
<b>DERMAL TOXICITY</b>	<b>NONE</b>
<b>INHALATION TOXICITY</b>	<b>NONE</b>

**SECTION 12 – ECOLOGICAL INFORMATION**

<b>MOBILITY</b>	<b>NOT APPLICABLE</b>
<b>BIODEGRADABILITY</b>	<b>PRODUCT IS TOTALLY BIODEGRADABLE OR RECYCLABLE</b>
<b>ACCUMUALTION</b>	<b>NO EFFECTS</b>
<b>ECOTOXICITY</b>	<b>NONE</b>
<b>OTHER EFFECTS</b>	<b>NONE</b>





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## SECTION 13 - DISPOSAL

DECONTAMINATION/DISPOSAL	<b>NO SPECIAL PRECAUTIONS, CAN BE FLUSHED DOWN THE DRAIN</b>
DISPOSAL GROUP	<b>NOT APPLICABLE</b>
OTHER EFFECTS	<b>NONE</b>

## SECTION 14 – TRANSPORT INFORMATION

ROAD	<b>NO SPECIAL PRECAUTIONS</b>
RAILWAY	<b>NO SPECIAL PRECAUTIONS</b>
SEA	<b>NO SPECIAL PRECAUTIONS</b>
AIRPLANE	<b>NO SPECIAL PRECAUTIONS</b>

## SECTION 15 – REGULATORY INFORMATION

**BURNSHIELD DRESSINGS ARE PRODUCTS USED IN THE EMERGENCY TREATMENT OF ALL TYPE OF BURNS AND SCALDS. IT IS CLASSIFIED AS A MEDICAL DEVICE.**

## SECTION 16 – OTHER INFORMATION

FOR FURTHER INFORMATION CONTACT:	<b>M. DI DOMENICO (+27) 82 881 2074</b>
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