



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.

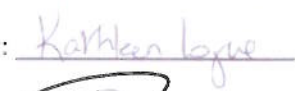

Lot No. and Expiry Date:

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:		Authorized By:	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

<i>BURNSHIELD DRESSINGS</i>	MSDS NO:	01c
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	REVISION NO:	05
	EFFECTIVE DATE:	19/09/2011

SECTION 1 – PRODUCT AND COMPANY

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

TOXIC INFORMATION:

RESPONSIBLE:	M. DI DOMENICO
EMERGENCY PHONE:	+27 82 881 2074

SECTION 2 - COMPOSITION**GEL FORMULA:**

TEA TREE OIL
PRESERVATIVES
GELLING AGENTS
PURIFIED WATER
BURNSHIELD GEL DOES NOT CONTAIN MARLOPHEN.

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

GENERAL	NONE
INHALATION	NONE – MOVE AWAY FROM SOURCE
SKIN CONTACT	IF SLIGHT IRRITATION OCCURS, RINSE WITH WATER AND STOP USE
INGESTION	NONE
INFORMATION TO HEALTH PERSONEL	THE LD50 HAS BEEN ESTABLISHED TO BE IN EXCESS OF 10G/KG BODY WEIGHT, THUS POSING A VERY LOW POTENTIAL RISK
MORE INFORMATION	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).

SECTION 5 – FIRE FIGHTING MEASURES

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



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. SPECIAL 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

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

SECTION 10 – STABILITY AND REACTIVITY

STABILITY	BURNSHIELD GEL IS VERY STABLE THROUGH A WIDE RANGE OF TEMPERATURES AND HUMIDITY
REACTIVITY	WILL NOT REACT WITH OTHER SUBSTANCES. WILL DISSOLVE OTHER WATER SOLUBLE CHEMICALS WHEN IN CONTACT.
HAZARDOUS DECOMPOSITION PRODUCTS	NONE
OTHER INFORMATION	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.

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SECTION 11 – TOXICOLOGICAL INFORMATION

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

SECTION 12 – ECOLOGICAL INFORMATION

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



MANUFACTURERS OF BURNSHIELD EMERGENCY BURNCARE PRODUCTS

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SECTION 13 - DISPOSAL

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

SECTION 14 – TRANSPORT INFORMATION

ROAD	NO SPECIAL PRECAUTIONS
RAILWAY	NO SPECIAL PRECAUTIONS
SEA	NO SPECIAL PRECAUTIONS
AIRPLANE	NO SPECIAL PRECAUTIONS

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:	M. DI DOMENICO (+27) 82 881 2074
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