

Tel: +27 (0) 11 827 4140 Fax: +27 (0) 11 827 9009 Email: contact@burnshield.com Website: www.burnshield.com

Co. Reg No.: 1997/008394/07

SAFETY DATA SHEET

SDS No: 04c	BURNSHIELD SACHETS &	PAGES 1 of 5
	CARTRIDGES	

SECTION 1 – IDENTIFICATION

TRADE NAME:	BURNSHIELD	
PRODUCT	BURNSHIELD STERILE BURNBLOTTS	
DESCRIPTION	BURN SACHETS	
DOSAGE FORM:	SACHETS OF VARIOUS SIZES	
SIZES	IDENTIFIER	BARCODE
0.9G SACHETS	550021	6007645006057
3.5G SACHETS	550004	6007645000215
1.2kg CARTRIDGES	550022	6007645007078
150g CARTRIDGES	550023	6007645007153
APPLICATION:	EMERGENCY TREATMENT OF ALL TYPES OF BURN WOUNDS AND SCALDS	
PRODUCT	SACHETS CONTAINING BURNSHIELD GEL IN A MULTILAYERED ALUMINIUM	
DESCRIPTION:	POUCH.	

MANUFACTURER CONTACT: BURNSHIELD (PTY) LTD

MEDOPARK BLOCK 3

NO 1 MANCHESTER ROAD

WADEVILLE SOUTH AFRICA

TEL: +27 11 827 4140

 $MONDAY-THURSDAY\colon 8AM-4PM$

FRIDAY: 8AM - 1PM

EMAIL: max@burnshield.com

SECTION 2 – HAZARD IDENTIFICATION

NO HEALTH OR PHYSICAL HAZARDS ARE IDENTIFIED FOR USE, STORAGE OR TRANSPORTATION OF BURNSHIELD BLANKETS **WARNINGS:**

(i) DO NOT USE IF PACKAGING IS DAMAGED



(ii) SAFE FOR USE ON CHILDREN AND FACIAL BURNS **PHYSICAL HAZARDS**:

(i) PROTECT FROM EXTREME TEMPERATURES (-10°C TO +40°C)



PROPERTY OF GELLING MIXTURE:

(i) NON TOXIC



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SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

ALL INGREDIENTS ARE OF PHARMACUTICAL QUALITY.

PROPRIETARY: YES

NAME	IDENTIFIER NUMBER/ CAS #	WEIGHT PERCENT CONTENT
TEA-TREE OIL	7732-18-5	1%
GELLING MIXTURE	PROPRIETARY	
PURIFIED WATER (AQUA)		ad 100%

SECTION 4 FIRST AID MEASURES

GENERAL	NONE
INHALATION	NONE – MOVE AWAY FROM SOURCE
SKIN CONTACT	IF SLIGHT IRRITATION OCCURS, RINSE WITH WATER AND
	DISCONTINUE USE
EYE CONTACT	FLUSH WITH WATER FOR A MINIMUM OF 5 MINUTES. IF
	IRRITATION PRESISTS, SEEK MEDICAL ATTENTION.
INGESTION	NONE
INFORMATION TO HEALTH	THE LD50 HAS BEEN ESTABLISHED TO BE IN EXCESS OF 10G/KG
PERSONEL	BODY WEIGHT, THUS POSING A VERY LOW POTENTIAL RISK
MORE INFORMATION	BURNSHIELD GEL IS COMPOSED MAINLY OF WATER AND IS A
	VERY LOW HEALTH RISK. A SLIGHT SKIN IRRITATION (SKIN
	REDDENING MAY BE OBSERVED IF PATIENT IS ALLERGIC TO THE
	BURNSHIELD GEL).

SECTION 5 FIRE FIGHTING MEASURES

SUITABLE EXTINGUISHER	WATER, FOAM AND DRY CHEMICAL
UNSUITABLE EXTINGUISH MEDIA	NONE
FIRE AND EXPLOSION HAZARDS	NONE
PERSONAL PROTECTION WHEN FIREFIGHTING	NONE
SPECIAL FIREFIGHTING PROCEDURES	NONE

SECTION 6 ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS	NO PROTECTIVE GEAR REQUIRED
ENVIRONMENTAL PRECAUTIONS	NONE
CLEANING MEASURES	RINSE WITH WATER
GENERAL	BURNSHIELD GEL IS WATER SOLUBLE AND IS EASILY
	RINSED.



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SECTION 7 HANDLING AND STORAGE

SPECIAL PRECAUTIONS	KEEP OUT OF REACH OF CHILDREN.
HANDLING	NO SPECIAL PRECAUTIONS
STORAGE	STORE AT ROOM TEMPERATURE. PROTECT FROM EXTREME
	TEMPERATURES FOR PROLONGED PERIODS OF TIME.
OTHER INFORMATION	THE BURNSHIELD SACHET IS 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 CONTROLS/PERSONAL PROTECTION

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

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

COLOUR OF GEL	WHITE TO COLOURLESS
ODOUR OF GEL	OF TEA TREE OIL (MEDICAL SCENT)
DENSITY	APPROX 1.000g/cm³ AT 20°C
VISCOSITY	MINIMUM 5000cPs
	(BROOKFIELD – SPINDLE 6:20rpm)
BOILING POINT	APPROX 106°C/228°F
PH	5.5 – 7.5
AUTO IGNITION TEMP	WILL NOT AUTO-IGNITE
SOLUBILITY IN WATER	100% SOLUBLE IN WATER
CECCETON 40 CEL DIT TEST AND DEL CESTION	

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
HAZARDOUS DECOMPOSITION	BURNSHIELD GEL CONTAINS 1,0% TEA TREE OIL. THEREFORE
PRODUCTS	NON HAZARDOUS.
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
GENERAL	
	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	THE ENVIROMENTAL EFFECTS OF THIS	
	PRODUCT HAS NOT BEEN FULLY	
	INVESTIGATED	
OTHER EFFECTS	NONE	
SECTION 13 DISPOSAL CONSIDERATIONS		

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

SECTION 14 TRANSPORT INFORMATION

DOT CLASSIFICATION	NOT REGULATED FOR DOMESTIC TRANSPORT
IATA CLASSIFICATION	NOT REGULATED FOR INTERNATIONAL
	TRANSPORT
IMDG CLASSIFICATION	NOT REGULATED FOR INTERNATIONAL
	WATER TRANSPORT



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SECTION 15 REGULATORY INFORMATION

BURNSHIELD SACHETS & CARTRIDGES ARE PRODUCTS USED IN THE EMERGENCY TREATMENT OF ALL TYPE OF BURNS AND SCALDS. BURNSHIELD PRODUCTS ARE CLASSIFIED AS MEDICAL DEVICES.

SECTION 16 OTHER INFORMATION

REFERENCE: GLOBALLY HARMONIZED SYSTEM OF

CLASSIFICATION AND LABELLING OF

CHEMICALS (GHS)

ORIGINAL DATE: OCTOBER 1999 REVISION DATE: 14 JUNE 2021

REVISION VERSION: 13

FURTHER INFORMATION CONTACT: M. DI DOMENICO

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SUMMARY AND CONCLUSION

BURNSHIELD SACHETS & CARTRIDGES CONTAINS NO DANGEROUS SUBSTANCES AND DO NOT POSE ANY RISKS DURING HANDLING, TRANSPORTATION AND USE. AS SUCH, BURNSHIELD SACHETS & CARTRIDGES CAN BE REGARDED AS SAFE REQUIRING NO SPECIAL HANDLING OR PRECAUTIONS.

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PRODUCT SPECIFICATION SHEET

1. PRODUCT: BURNSHIELD BURN SACHET 3.5 ml (1/8 oz)

PRODUCT CODE

L550004

UDI CODE

6007645000215

TRADE NAME

Burnshield

DOSAGE FORM

BURNSHIELD BURN SACHET 3.5 ml (1/8 oz)

contains 3.5 g - 3.7 g of Burnshield Gel

APPLICATION

Emergency treatment of all types of wounds

DESCRIPTION

Burnshield Gel contained in a multilayered aluminium pouch

2. PRODUCT DESCRIPTION

BURNSHIELD BURN SACHET 3.5 ml (1/8 oz) is composed 3.5 g – 3.7 g of Burnshield Gel, contained in a multilayered aluminium pouch and sealed. Each sealed Aluminium Pouch is encoded with a Lot Number and Expiry Date.

3. PRODUCT SPECIFICATIONS

PROPERTY	SPECIFICATION
Appearance of Gel	Soft gel of even consistency
Colour of Gel	White to off-white
Odour of Gel	Of Tea-Tree Oil
Gel fill weight	3.5 g – 3.7 g
Viscosity (Brookfield - Spindle 6, 20rpm)	Before Sterilisation minimum 25 000 cPs
	After Sterilisation minimum 7 000 cPs
Density (Anton Paar, 20 °C)	$0.975 \text{ g/cm}^3 - 1.025 \text{ g/cm}^3$
pH (Metrohm 744 Combined Glass Electrode pH	Before Sterilisation 5.5 – 7.5
Meter)	After Sterilisation 5.0 – 7.5
Sterility	Sterile
Content of Melaleuca Oil	$0.927 - 1.133\% (1.03 \pm 10\%) (w/w)$
Chromatographic Profile	α-pinene: 1% to 6% sabinene: maximum 3.5% α-terpinene: 5% to 13% limonene: 0.5% to 4% cineole: maximum 15% γ-terpinene: 10% to 28% ρ-cymene: 0.5% to 12% terpinolene: 1.5% to 5% terpinen-4-ol: minimum 30% αromadendrene: maximum 7% α-terpineol: 1.5% to 8%

Rev.0

Date: 29.11.2021

Prepared By: (Quality Assurance Manager)

Approved By: (Regulatory Affairs Pharmacist)