

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 g/cm ³ – 1.025 g/cm ³
pH (Metrohm 744 Combined Glass Electrode pH Meter)	Before Sterilisation 5.5 – 7.5
	After Sterilisation 5.0 – 7.5
Sterility	Sterile
Content of Melaleuca Oil	0.927 – 1.133% (1.03 ± 10%) (w / w)
Chromatographic Profile	<i>α-pinene</i> : 1% to 6% <i>sabinene</i> : maximum 3.5% <i>α-terpinene</i> : 5% to 13% <i>limonene</i> : 0.5% to 4% <i>cineole</i> : maximum 15% <i>γ-terpinene</i> : 10% to 28% <i>p-cymene</i> : 0.5% to 12% <i>terpinolene</i> : 1.5% to 5% <i>terpinen-4-ol</i> : minimum 30% <i>aromadendrene</i> : maximum 7% <i>α-terpineol</i> : 1.5% to 8%