

PRODUCT SPECIFICATION SHEET

1. PRODUCT: BURNSHIELD DRESSING 100 mm x 100 mm (4" x 4")

PRODUCT CODE	L901111
UDI CODE	6007645001380
TRADE NAME	Burnshield
DOSAGE FORM	DRESSING 100 mm x 100 mm (4" x 4") wetted with 40 g – 42 g of Burnshield Gel
APPLICATION DESCRIPTION	Emergency treatment of all types of wounds Polyurethane foam material wetted with Burnshield Gel contained in a multilayered aluminium pouch

2. PRODUCT DESCRIPTION

Burnshield Dressings are made from a Polyurethane foam material. The foam is placed in a multilayer aluminium pouch, wetted with 40 g – 42 g of Burnshield Gel, and sealed.

3. PRODUCT SPECIFICATIONS

PROPERTY	SPECIFICATION
Appearance of Gel	Soft gel of even consistency
Colour of Gel	White to off-white
Appearance of Polyurethane foam material	Soft foam
Colour of Polyurethane foam material	White to off-white
Weight of Dry Polyurethane foam	0.85 g – 0.95 g
Odour of Gel	Of Tea-Tree Oil
Dressing Dimensions	Length 100 mm – 110 mm
	Width 100 mm – 110 mm
	Thickness 3 mm – 4 mm
Gel fill weight	40 g – 42 g
Viscosity (Brookfield - Spindle 6, 20rpm, 25°C)	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)

Product Specification continued...

PROPERTY	SPECIFICATION
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%