



*BSN medical Inc.*  
100 Beiersdorf Drive, Rutherford College, NC 28671

# SAFETY DATA SHEET

## PART I - FRONT PAGE FOR BSN MEDICAL USE ONLY

**DATA SHEET REFERENCE NO:** ...SDS220.....

**PRODUCT NAME:** Gelocast Unna's Boot

PRODUCT CODES:			
01052-00001-00	01053-00001-00		

**COMPILED BY:** Leslie Lockee

**DATE:** 14 August 2014

**CURRENT REVISION:** NEW

**REVIEW DATE:** New Issue

### AUTHORISED BY:

Position	Signature	Date
Global Regulatory Affairs		

**CIRCULATION:** Original held with Technical File



**BSN medical Inc.**  
100 Beiersdorf Drive, Rutherford College, NC 28671

**1. PRODUCT NAME(S): Gelocast Unna's Boot**

**PRODUCT CODES:**

01052-00001-00	01053-00001-00		
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**USE OF SUBSTANCE / PREPARATION**

A medicated bandage impregnated with zinc oxide and calamine to soothe irritated skin. Provides semi-rigid cast for immobilization of strains and sprains.

**2. COMPANY CONTACT DETAILS:**

**Company:** BSN medical Inc., 100 Beiersdorf Drive, Rutherford College, NC 28671  
**Responsible Department:** Regulatory Affairs  
**Telephone No.:** (828) 879-5100 ext. 4300

**3. COMPOSITION / INFORMATION ON INGREDIENTS:**

<u>Ingredients:</u>	<u>%</u>	<u>CAS No.:</u>	<u>Risk Phrases*:</u>
Zinc Oxide	<5% wt/wt	1324-13-2	N/A
Mg / Al silicates	<3% wt/wt	12199-37-0	N/A

Chemical Composition: Proprietary

\* see other information for key to Risk Phrases

**4. HAZARDS IDENTIFICATION:**

Hazard classification from 67/548/EEC or 1999/45/EC:

No hazardous components over 1.0%.

No carcinogenic components over 0.1%.

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**5. FIRST AID MEASURES:**

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<b>Inhalation</b>	Not hazardous. Silicates and metal oxides are bound within a colloidal matrix and are not a respiratory hazard unless desiccated.
<b>Contact with skin</b>	Not hazardous.
<b>Contact with eyes</b>	Irrigate promptly with flowing water immediately and continuously for 15 minutes. Seek medical advice.
<b>Ingestion</b>	For external use only. If ingested, seek medical advice.
<b>Advice for doctor</b>	Treatment on basis of judgment of physician in response to reactions of patient.

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**6. FIREFIGHTING MEASURES:**

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<b>Fire extinguishing agents</b>	Class B & C
<b>Restrictions</b>	N/A
<b>Fire / Explosion hazards</b>	None
<b>Main combustion gas</b>	N/A
<b>Personal Protection</b>	N/A

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**7. ACCIDENTAL RELEASE MEASURES:**

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<b>Personal Protection</b>	No Personal Protective Equipment (PPE) is necessary when using this product.
<b>Environmental Protection</b>	No environmental controls are necessary for this single use packaged product.
<b>Spillage Procedure</b>	If spilled, clean up according to local, state, and federal guidelines.
<b>Additional Information</b>	None

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**8. HANDLING and STORAGE**

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<b>Occupational hygiene</b>	N/A
<b>Storage facility</b>	Cool and dry. Do not exceed 86° F or store below 32° F.
<b>Fire precautions</b>	N/A
<b>Storage Conditions</b>	Cool and dry. Do not exceed 86° F or store below 32° F
<b>Segregation</b>	Not required

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**9. EXPOSURE CONTROLS / PERSONAL PROTECTION:**

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<b>Respiratory protection</b>	No personal protective equipment is necessary when using this product.
<b>Hand protection</b>	Product NOT intended or recommended for use in contact with open wounds.
<b>Eye protection</b>	Avoid getting product in eyes.
<b>Skin protection</b>	Product NOT intended or recommended for use in contact with open wounds.

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**10. PHYSICAL & CHEMICAL PROPERTIES:**

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Include the following information where applicable on the substance or product:-

<b>Appearance</b>	Light pink / salmon; 100% cotton gauze coated with a smooth, easily spread gelatinous ointment.
<b>Odor</b>	N/A
<b>pH</b>	6.25 – 7.50
<b>Boiling point / range</b>	N/A
<b>Melting point / range</b>	N/A
<b>Flash point</b>	N/A > 50% water
<b>Flammability (solid, gas)</b>	N/A
<b>Auto flammability</b>	N/A
<b>Explosive properties</b>	None
<b>Oxidizing properties</b>	None
<b>Vapor pressure</b>	N/A
<b>Relative density</b>	N/A
<b>Solubility</b>	a) Water: N/A b) Fat: N/A
<b>Other data</b>	
<b>Partition coefficient (for ingredients):</b>	N/A
<b>Viscosity</b>	N/A
<b>Specific Gravity H<sub>2</sub>O = 1</b>	1.1100 – 1.1600

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**11. STABILITY & REACTIVITY:**

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<b>Conditions to avoid</b>	Extreme heat
<b>Materials to avoid</b>	None known
<b>Hazardous Decomposition</b>	None known
<b>Products</b>	N/A
<b>Other data</b>	Product is stable

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**12. TOXICOLOGICAL INFORMATION:**

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<b>Acute toxicity</b>	N/A
<b>Irritant to eyes</b>	Avoid getting product in eyes.

<b>Irritant to skin</b>	Product NOT intended or recommended for use in contact with open wounds.
<b>Respiratory / dermal sensitizer</b>	Silicates and metal oxides are bound within a colloidal matrix and are not a respiratory hazard unless desiccated.
<b>Chronic toxicity / carcinogenicity</b>	There are no known significant health hazards, either acute or chronic, from exposure to this product.
<b>Genotoxicity</b>	No links evident
<b>Reproductive toxicity</b>	No links evident
<b>Other data</b>	

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**13. ECOLOGICAL INFORMATION:**

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**Eco toxicity : short & long term effects on:-**

Aquatic organisms:	No impact
Soil organisms:	No impact
Plants & terrestrial animals:	No impact

**Mobility in soil** No impact

**Persistence and Degradability** N/A

**Bioaccumulation Potential** N/A

**Other known adverse effects on the Environment**

Ozone depletion potential (CO <sub>2</sub> generation)	Minimal
Photochemical ozone creation (CO <sub>2</sub> generation)	Minimal
Global warming potential (CO <sub>2</sub> generation)	Minimal

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**14. DISPOSAL CONSIDERATIONS:**

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<b>Product</b>	Observing local regulations and safety the product is to be disposed of as household waste.
<b>Contaminated packaging</b>	Observing local regulations and safety the packaging is to be disposed of as household waste.
<b>Waste classification</b>	Not classified as a hazardous waste and may be disposed of in ordinary landfill.

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**15. TRANSPORT INFORMATION:**

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Special Precautions applicable to transport of the product:- **None**

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**16. REGULATORY INFORMATION:**

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**Health, Safety and Environmental information on the product labeling** -Arterial insufficiency. If skin sensitivity develops discontinue use and consult a physician. Store below 86 °F, avoid freezing. Cover Unna's Boot with gauze, adhesive or tubular bandage to keep clothing clean.

**Specific provisions in relation to man or the environment (including national Laws)** None

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**17. OTHER INFORMATION:**

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Key to Phrases Used:-  
N/A

This information is intended to cover potential hazards at the place of work and does not detail medical uses, indications, contraindications and precautions for the treatment of patients. Please refer to the product labeling or package insert for full instructions on the safe use of these product.

### HISTORY LOG

Revision number	Changes Made	Date
Original	Original Issue	August 2014