

BSN-0256Rev. 2
Doc. Ref: QC-OP-009**BSN** medical*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: ...SDS200.....

PRODUCT NAME: Delta Lite Plus

PRODUCT CODES:			
73458-00000-00	73458-00021-00	73458-00036-00	73458-00052-00
73458-00001-00	73458-00022-00	73458-00037-00	73458-00055-00
73458-00002-00	73458-00023-00	73458-00038-00	73458-00056-00
73458-00003-00	73458-00025-00	73458-00040-00	73458-00057-00
73458-00004-00	73458-00026-00	73458-00041-00	73458-00060-00
73458-00010-00	73458-00027-00	73458-00042-00	73458-00061-00
73458-00011-00	73458-00028-00	73458-00045-00	73458-00062-00
73458-00012-00	73458-00030-00	73458-00046-00	73458-00065-00
73458-00013-00	73458-00031-00	73458-00047-00	73458-00066-00
73458-00014-00	73458-00032-00	73458-00050-00	73458-00067-00
73458-00020-00	73458-00035-00	73458-00051-00	73458-00070-00
73458-00071-00	73458-00072-00	73458-00073-00	

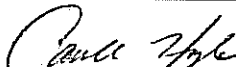
COMPILED BY: Carroll Hoyle

DATE: 17 March 2008

CURRENT REVISION: NEW

REVIEW DATE: New Issue

AUTHORISED BY:

Position	Signature	Date
Regulatory Affairs Manager		17 Mar 08

CIRCULATION: Original held with Technical File



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

1. PRODUCT NAME(S): Delta Lite Plus

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73458-00020-00	73458-00035-00	73458-00051-00	73458-00070-00
73458-00071-00	73458-00072-00	73458-00073-00	

USE OF SUBSTANCE / PREPARATION

Provides rigid external immobilization for fractures and other Orthopaedic indications.

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:

Ingredients:	%	CAS No.:	Risk Phrases*:
Polypropylene Glycol	< 34.0	25322-69-4	R20-30/37/38-42/43
Polyethylene Oxide	< 4.0	25322-68-3	R20-34

Polyurethane pre-polymer
Fiberglass substrate

* see other information for key to Risk Phrases

4. HAZARDS IDENTIFICATION:

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

Excessive exposure may cause irritation of the respiratory tract and lungs resulting in pulmonary edema. Single dose oral toxicity is extremely low. Small amounts incidental to normal handling conditions are not likely to cause injury.

May cause sensitization by inhalation or asthmatic signs and symptoms in hypersensitive persons.
Removal by use of cast saw may produce dust.

5. FIRST AID MEASURES:

Inhalation	Move patient to fresh air, seek medical advice
Contact with skin	Wash area with soap and soap and rinse thoroughly
Contact with eyes	Rinse open eye under running water for 15 minutes, seek medical advice
Ingestion	Do not induce vomiting. Seek medical advice immediately
Advice for doctor	Treatment on basis of Physician judgment in response to reactions of the patient. Treatment should only be administered by a physician.

6. FIREFIGHTING MEASURES:

Fire extinguishing agents	Water fog, carbon dioxide, dry chemical
Restrictions	N/A
Fire / Explosion hazards	N/A
Main combustion gas	N/A
Personal Protection	Wear self contained breathing apparatus

7. ACCIDENTAL RELEASE MEASURES:

Personal Protection	Respiratory protection not needed in normal application. If needed, use respirator rated for organic vapors / isocyanates.
Environmental Protection	No special measures required; incinerate or bury as if household waste.
Spillage Procedure	Ventilate area if needed. Spilled product will activate and harden upon exposure to ambient atmosphere moisture. Ensure hardening is completed prior to disposal
Additional Information	Moisture contamination may form CO ₂ gas.

8. HANDLING and STORAGE

Occupational hygiene	Standard examination gloves should be used when handling product. Basic mask can be worn during cast removal to protect from any dust.
Storage facility	Cool and dry
Fire precautions	N/A
Storage Conditions	Store in a cool dry place.
Segregation	Not required

9. EXPOSURE CONTROLS / PERSONAL PROTECTION:

Respiratory protection	Not necessary during proper use of the product
Hand protection	Standard examination gloves
Eye protection	Not necessary during proper use of the product
Skin protection	Do not apply direct onto skin

10. PHYSICAL & CHEMICAL PROPERTIES:

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

Appearance	Low tack resin coated knitted fiberglass, covered with padding material and stockinette. Available in a range of colors.
Odor	Characteristic
pH	N/A
Boiling point / range	Resin decomposes above 200 °C

Melting point / range	Resin only ~150°C
Flash point	~ 220 °C
Flammability (solid, gas)	not known
Auto flammability	not known
Explosive properties	N/A
Oxidizing properties	N/A
Vapor pressure	0.0002mmHg at ~25°C
Relative density	1.2g/m ³
Solubility	Water - insoluble
Other data	

11. STABILITY & REACTIVITY:

Conditions to avoid	Polymerization may occur if exposed to heat for an extended period
Materials to avoid	Water, strong bases, alcohols, metal compounds, surface active agents
Hazardous Decomposition	
Products	N/A
Other data	

12. TOXICOLOGICAL INFORMATION:

Acute toxicity (LD₅₀)	MDI oral (rats) is >2000 mg / kg
Irritant to eyes	May cause minor eye irritation.
Irritant to skin	MDI for skin absorption (rabbits) is >200 mg / kg
Respiratory / dermal sensitiser	Skin sensitization may occur with prolonged, repeated skin contact with the uncured resin.
Chronic toxicity / carcinogenicity	No links evident
Genotoxicity	No links evident
Reproductive toxicity	No links evident
Other data	

13. ECOLOGICAL INFORMATION:

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 (CO₂ generation)

Photochemical ozone creation (CO₂ generation)

Global warming potential (CO₂ generation)

14. DISPOSAL CONSIDERATIONS:

Product	According to local or national regulations
Contaminated packaging	According to local or national regulations
Waste classification	Hardened cast material is not considered hazardous and may be disposed of in a normal landfill.

15. TRANSPORT INFORMATION:

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

16. REGULATORY INFORMATION:

Health, Safety and Environmental information on the product labeling - Cautions on skin contact and dust during removal

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

17. OTHER INFORMATION:

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 document	March 2008