Smith & Nephew
Wound Management Division PO Box 81 Hessle Road Hull, HU3 2BN

Specification Form

Specification Form Title: Opsite Spray Dressing

Specification No. PSDS 063
Revision:6

Department: Supply Chain
Area: Manufacturing Strategy
Product Code: 4828
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Plant No:

Approved & Released Specification Form

Help for Implementation Date
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☐ Admin ☐ Quality
☐ Environmental ☒ Safety

1. PRODUCT NAME(S): OPSITE Moisture Vapour Permeable Spray Dressing

2. INTENDED USES:

Spray dressing for dry wounds. Always invert can for use. DO NOT spray near eyes. Avoid inhalation. DO NOT spray near naked lights as contents are highly flammable. AVOID USE in confined spaces.

3. COMPOSITION:

Contains an acrylic copolymer, ethyl acetate, acetone, isopropyl alcohol, and propellants, (butane 40 and dimethyl ether), within an aluminium monobloc can. The container is pressurised.

4: PHYSICAL AND CHEMICAL PROPERTIES:

	Flash Point (°C)	Explosive Limit (%)	Autoignition Temp. (°C)
Ethyl Acetate	-9	2.6 - 12.8	465

Acetone	-20	3.0 - 13.0	465
Butane 40	<0	1.8 - 10.0	410
Dimethyl Ether	-41	3.4 - 27.0	350
Isopropyl Alcohol	12	2.0 - 12.0	460

Contents are highly flammable

Contents are pressurised

5. HEALTH HAZARDS:

No health hazard is anticipated if used as directed, however, avoid contact with eyes and inhalation (over exposure may have narcotic effect, extreme exposure may cause suffocation). Acetone, ethyl acetate and dimethyl ether can degrease the skin. Prolonged inhalation may cause liver and kidney damage.

Occupational Exposure Limits

	LTEL (8hr TWA) (ppm)	STEL (15 min ref period) (ppm)
Ethyl acetate	200	400
Acetone	500	1500
Butane 40	600	750
Dimethyl ether	400	500
Isopropyl alcohol (propan-2-ol)	400	500

6. FIRST AID:

a) Inhalation - Remove to fresh air. If unconscious move to recovery position. Seek Medical aid.

b) Contact with skin - Not applicable.

c) Contact with eyes - Flush with clean water for 10 minutes. Seek medical aid.

d) Ingestion - Do not induce vomiting. If patient vomits turn into recovery position. Give water to drink. Seek medical aid.

7. FIRE HAZARD AND EMERGENCY ACTION:

The contents are highly flammable and are pressurised. Containers may explode if incinerated.

Undamaged aerosols are unlikely to be the cause of fire, but they can be ignited in a fire situation and contribute fuel to a fire. Aerosols containing flammable materials may produce a fierce fire with toxic gases evolved such as carbon monoxide and carbon dioxide.
Use water spray, dry powder or vapourising liquid fire fighting equipment. Wear self-contained breathing apparatus.

8. Accidental Release Measures:

a) Personal Precautions - Wear protective clothing and respiratory protection. Eliminate all sources ignition.

b) Environmental Precautions - Prevent material from entering drains or water courses.

Advise authorities if material has entered water course or sewer or has

contaminated soil or vegetation.

c) Spillages - Contain and absorb using earth, sand or other inert material.

Transfer into suitable containers for recovery or disposal then flush

area with plenty of water.

Cans can be retrieved by mechanical means.

9. HANDLING/USE/PROTECTIVE CLOTHING:

Handle carefully - avoid puncturing the can(s). The wearing of eye protection and gloves

is advisable. AVOID USE in confined space.

10. STORAGE PRECAUTIONS:

Always handle carefully, especially in pallet quantities. Store in a cool, dry place. Keep away from sources of ignition. Do not store near exits. Avoid storing in basements.

11. EXPOSURE CONTROLS/PERSONAL PROTECTION:

a) UK Occupational Exposure (based on ethyl acetate) EH40/2002 OES standards	-	200ppm (8hr TWA) 400ppm (15min)
b) Control measures depending on the potential process or personal enclosure. or local exhaust and personal use may be used depending	-	Use appropriate engineering controls for exposure. Methods include Mechanical ventilation e.g. dilution protective equipment for short term on exposure.
c) Respiratory Protection risk of exposure to high	-	Use respiratory protection if their is a vapour concentrations.
d) Hand Protection gloves.	-	Use PVC, PVA,rubber or Neoprene
e) Eye Protection	-	Use chemical goggles or face shield

12. STABILITY AND REACTIVITY:

a) Stability - Stable under normal conditions, hydrolysed by strong acids

b) Conditions to avoid - High temperatures, exposure to direct sunlight

c) Materials to avoid - Strong acids, strong bases, strong oxidising agents.

d) Hazardous decomposition Products - Acetic acid, combustion will generate oxides of carbon.

13. TOXICOLOGY INFORMATION (BASED ON ETHYL ACETATE):

a) Acute toxicity >18000mg/kg	- Low order of acute toxicity. Oral LD50 (rat) 5600mg/kg inhalation LC50 (rat) 5600mg/litre/4hr. dermal LD50 (rabbit)
b) Irritancy -Eyes conjuctival irritation.	- Single application to the rabbit eye produced minimal
c) Irritancy -Skin irritation	- Application to the rabbit skin produced no sign of dermal
d) Sub-acute /subchronic Toxicity developed minor blood 1 hour per day and enlargement	- Mice exposed to 4300ppm for 6 hours per day for 7 days changes and loss of appetite. Rabbits exposed to 4400ppm for for 40days developed secondary anaemia, minor blood effects of the spleen
e) Chronic toxicity	- No evidence of carcinogenicity was seen in mice.
f) Genotoxicity	- No consistent mutagenic activity has been reported
g) Reproductive/Developmental Toxicity hen eggs	- The material did not affect the development of fertilised

14. ECOLOGICAL INFORMATION:

a) Mobility	- The product is volatile/gaseous and will partition to the air phase.
b) Persistence/Degradability salt water or fresh	- The product is readily biodegrable in aerobic systems using either water innocula. The polymeric material will initially coagulate.
c) Ecotoxicity	- Rated as practically non-toxic to acquatic species.

15. DISPOSAL:

Never incinerate even when empty. Local authorities will allow occasional cans for landfill or normal refuse but require notification for large quantities.

16. TRANSPORT PRECAUTIONS:

Handle carefully, especially in pallet quantities. Flammable gas. Flash point -20°C.

17. ADDITIONAL INFORMATION:

1. Guide to Good Practice for the storage of Aerosols in Manufacturing/Wholesale, Warehouses and Retail Stores (British Aerosol Manufacturers Association 1989).

2. Health and Safety Executive Guidance Note EH40.

18. REGULATORY INFORMATION

N/A

19. NAME, ADDRESS AND TELEPHONE NUMBER OF SUPPLIER:

Customer Relations Manager
Smith & Nephew Medical Limited
PO Box 81
Hessle Road
Hull
HU3 2BN Tel: 01482 225181

This information is provided in accordance with the requirements of the UK Health and Safety at Work Act 1974, and specifically in order to assist users of the product to make their ' assessment of health risks' as required by the UK Control of Substances Hazardous to Health Regulation 1999 (COSHH assessments). Provision of this information does not preclude users from seeking advice from other sources as indicated in the COSHH guides.

This information is intended to cover potential hazards at the place of work and does not detail medical uses, indications, contra-indications and precautions for the treatment of patients.