

SAFETY DATA SHEET

OPSITE® Moisture Vapour Permeable Spray Dressing

SECTION 1. IDENTIFICATION

1.1 Product identifier

Product Name: OPSITE Moisture Vapour Permeable Spray Dressing (66004978)

Alternate Name: OPSITE Spray

1.2 Recommended use and restrictions on use

Recommended use: OPSITE Spray is a moisture vapour permeable spray dressing indicated for clean, dry, surgical or surface wounds. It can be used in skin graft fixation.

Restrictions on use: Do not apply on children under the age of 18 months. Do not use with plastic intravascular devices.

1.3 Supplier identifier

Company Name: Smith & Nephew Inc.
2280 Argentia Road, Mississauga (Ontario) L5N 6H8

Emergency Number 1-800-463-7439 (business hours)

SECTION 2. HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture

Extremely flammable aerosol - Category 1

Eye irritant - Category 2

Specific Target Organ Toxicity – Single Exposure (STOT-SE) - Category 3

2.2 Label elements

The product is a medical device and therefore exempted from the workplace labelling. This product is labelled in accordance with the Medical Devices Regulations.

In order to meet international regulations, the following pictograms are included on the product labelling:



DANGER – Extremely Flammable Aerosol



CAUTION
ATTENTION

CAUTION - Explosive

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	CAS Number	Concentration	Notes
Acetone (solvent)	67-64-1	< 35%	[1], [2]

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Chemical Name	CAS Number	Concentration	Notes
Dimethyl Ether (propellant)	115-10-6	< 26%	[1]
Isopropyl Alcohol (solvent)	67-63-0	< 11%	[1], [2]
n-Butane (propellant)	106-97-8	< 11%	[1], [2]
Propane (propellant)	74-98-6	< 5%	[1], [2]
Ethyl Acetate (solvent)	141-78-6	< 5%	[1], [2]
Isobutane (propellant)	72-28-5	< 5%	[1], [2]

[1] Substance classified with a health or environmental hazard. [2] Substance with a workplace exposure limit.

SECTION 4. FIRST-AID MEASURES

4.1 Description of first aid measures

Remove victim to uncontaminated area wearing self-contained breathing apparatus. Keep victim warm and rested, seek medical aid.

- **Inhalation** Remove to fresh air. If unconscious move to recovery position. Seek medical aid.
- **Ingestion** Do NOT induce vomiting. If patient vomits turn to recovery position. Give water to drink. See medical aid.
- **Skin contact** N/A
- **Eye contact** Remove contact lens(es) if present and easy to do. Flush with clean water for 10 minutes. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No health hazard is anticipated if used as directed; however avoid contact with eyes and inhalation. In low concentrations inhalation may cause narcotic effects. Symptoms may include dizziness, headache, nausea and loss of coordination. Extreme exposure through inhalation may cause asphyxiation, of which victim may not be aware. Acetone, ethyl acetate and dimethyl ether can degrease the skin. Prolonged inhalation can cause kidney and liver damage.

4.3 Indication of immediate medical attention and special treatment needed, if necessary

None

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use water spray, dry powder or vapourising liquid fire fighting equipment.
 Unsuitable extinguishing media: Solid water stream

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5.2 Special hazards arising from the substance or mixture

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.

5.3 Special protective equipment and precautions for fire-fighters

Wear self-contained breathing apparatus.

5.4 Further Information

Use water spray to cool unopened containers.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Evacuate area. Ensure adequate air ventilation. Wear respiratory protection. Eliminate all sources of ignition.

6.2 Environmental precautions

Prevent leakage or further spillage if safe to do so. Prevent material from entering drains or water courses. Advise authorities if material has entered water course of sever or has contaminated soil or vegetation.

6.3 Methods and material for containment and cleaning up

Contain and absorb using earth, sand or other inert material. Transfer to suitable containers for recovery or disposal according to local regulations then flush area with plenty of water.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Handle carefully. Avoid puncturing the can(s). The wearing of eye protection and gloves is advisable. Avoid use in a confined space. Avoid inhalation of vapour or mist.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry place. Keep away from sources of ignition. Do not store near exits. Avoid storing in basements. Please note the product contains acetone which may react with non-latex / synthetic gloves.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters, including occupational exposure limit values or biological limit values

In many (but not all) Canadian jurisdictions, the exposure limits are similar to the American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs). Since legislation varies by jurisdiction, you may contact your local jurisdiction for exact details.

Component	<u>MB, NB, NF,</u> <u>NS, PEI, ON</u>	<u>AB, SK</u>	<u>BC</u>	<u>QC</u>	<u>NT, NU</u>	<u>YK</u>
Acetone CAS #67-64-1	TWA: 250ppm STEL: 500ppm	TWA: 500ppm STEL: 750ppm	TWA: 250ppm STEL: 500ppm	TWA: 500ppm STEL: 1000ppm	TWA: 500ppm STEL: 750ppm	TWA: 1000ppm STEL: 1250ppm

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Component	MB, NB, NF, NS, PEI, ON	AB, SK	BC	QC	NT, NU	YK
Isopropyl Alcohol CAS #67-63-0	TWA: 200ppm STEL: 400ppm	TWA: 200ppm STEL: 400ppm	TWA: 200ppm STEL: 400ppm	TWA: 400ppm STEL: 500ppm	TWA: 200ppm STEL: 400ppm	TWA: 400ppm STEL: 500ppm
n-Butane CAS #106-97-8	TWA: 1000ppm	TWA: 1000ppm STEL (SK): 1250ppm	TWA: 600ppm STEL: 750ppm	TWA: 800ppm	TWA: 1000ppm STEL: 1250ppm	TWA: 600ppm STEL: 750ppm
Propane CAS #74-98-6	TWA: 1000ppm	TWA: 1000ppm STEL (SK): 1250ppm	TWA: 1000ppm	TWA: 1000ppm	TWA: 1000ppm STEL: 1250ppm	N/A
Ethyl Acetate CAS #141-78-6	TWA: 400ppm	TWA: 400ppm STEL (SK): 500ppm	TWA: 150ppm	TWA: 400ppm	TWA: 400ppm STEL: 500ppm	TWA: 400ppm STEL: 400ppm
Isobutane CAS #72-28-5	TWA: 1000ppm	N/A	N/A	N/A	N/A	N/A

Exposure Guideline Comments: TLV = Threshold Limit Value. TWA = Time-Weighted Average. STEL = Short-term Exposure Limit.

8.2 Appropriate engineering controls

Ensure adequate ventilation. Do not smoke whilst handling product.

8.3 Individual protection measures

The wearing of eye protection and gloves is advisable.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear, colorless, highly viscous liquid	Vapour pressure	Not available
Odour	Compares with ethyl acetate standard	Vapour density	Not available
Odour threshold	Not available	Relative density	Not available
pH	Not available	Water solubility	Not available
Melting point	Not available	Partition coefficient – n-octanol/water	Not available
Boiling point	Not available	Auto-ignition temperature	Not available
Flash point	Not available	Decomposition temperature	Not available
Evaporation rate	Not available	Viscosity	Not available
Flammability	Not available	Explosive properties	Not available
Upper/lower flammability or explosive limits	Not available	Oxidising properties	Not available

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

Unreactive under normal conditions.

10.2 Chemical stability

Stable under normal / recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available.

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10.4 Conditions to avoid

Avoid strong acids, strong bases, strong oxidising agents. Keep away from heat, flames, sparks. Avoid exposure to extremes temperatures and direct sunlight.

10.5 Incompatible materials

The product contains acetone which may react with non-latex / synthetic gloves.

10.6 Hazardous decomposition products

Acetic acid, combustion will generate oxides of carbon.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Numerical measures of toxicity, including Acute Toxicity Estimates (ATEs)

Component	Acetone	Dimethyl Ether	Isopropyl alcohol	n-Butane	Propane	Ethyl Acetate	Isobutane
Acute toxicity LD50 Rat Oral	5800 mg/kg	N/A	5045 mg/kg	N/A	N/A	5620 mg/kg	N/A
Inhalation LC50 Rat	Rat 8h: 50100 mg/m ³	Rat 4h: 164000ppm	Rat 8h: 16000 ppm	Rat 4h: 658mg/L	Rat 0.25h: 800000 ppm	Mouse, 2h: 45000 mg/m ³	Mouse, 1h: 52 mg/L Rat, 4h: >31 mg/L
LD50 Dermal	Guinea pig: 7426 mg/kg	No data	Rabbit: 12800 mg/kg	No data	No data	Rabbit: > 180000 mg/kg	No data
Skin corrosion / irritation	Rabbit 24h: Mild skin irritation	Not classified as irritant	Rabbit 24h: Mild skin irritation	Not classified as irritant	Not classified as irritant	No data	Not classified as irritant
Eye damage / irritation	Rabbit 24h: irritation	Not classified as irritant	Rabbit 24h: irritation	Not classified as irritant	No data	No data	Not classified as irritant
Respiratory or skin sensitisation	Chronic exposure may cause dermatitis	No known effects	No data	No known effects	No known effects	No data	No known effects
Germ cell mutagenicity	No data	No evidence of mutagenicity	No data	No evidence of mutagenicity	No evidence of mutagenicity	No data	No evidence of mutagenicity
Carcinogenicity	Not identified as carcinogen	Not identified as carcinogen	Not identified as carcinogen	Not identified as carcinogen	Not identified as carcinogen	Not identified as carcinogen	Not identified as carcinogen
Reproductive toxicity	No data	No indication of toxic effects	No data	No indication of toxic effects	Rat, inhalation: 3000ppm NOEAC.	No data	No indication of toxic effects
Specific target organ toxicity – single exposure	No data	No data	No data	No data	No data	No data	No data
Specific target organ toxicity – repeated exposure	No data	No data	No data	No data	Rat, inhalation: 4000ppm NOEAC, 12000ppm LOEAC	No data	No data
Aspiration hazard	No data	No data	No data	No data	No data	No data	No data

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SECTION 12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity

Component	Acetone	Dimethyl Ether	Isopropyl alcohol	n-Butane	Propane	Ethyl Acetate	Isobutane
Toxicity to fish	Rainbow trout 96h LC50: 5540 mg/L	Guppy 96h LC50: >4000 mg/L	Fathead minnow 96h LC50: 96400 mg/L	Freshwater 96h LC50: 24.11 mg/L	Fish 96h LC50: 24mg/L	Rainbow trout 96h LC50: 350-600 mg/L	Freshwater 96h LC50: 27.98 mg/L
Toxicity to daphnia and other aquatic invertebrates	Water flea 48 h EC50: 13500 mg/L	Water flea 48 h EC50: >4000 mg/L	Water flea 24 h EC50: 6851 mg/L	Water flea 48h LC50: 14.22 mg/L	Water flea 48h EC50: 7 mg/L	Water flea 24h EC50: 2300 - 3090 mg/L	Water flea 48h LC50: 16.33 mg/L

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods

Never incinerate, even when empty. Local authorities may allow cans for recycling, landfill or normal refuse. May require notification for large quantities.

SECTION 14. TRANSPORT INFORMATION

14.1 UN number / shipping name

UN1950 - Aerosols

14.2 Transport hazard class

Class 2.1, Flammable Gases

May qualify for transportation under Limited Quantities Exemption provisions of the Transportation of Dangerous Goods (TDG) Act & Regulations (Article 1.17 - Limited Quantities Exemption).

14.3 Packing group

There are no packing groups for Class 2, Gases

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14.4 Environmental hazards

Not applicable

14.5 Special precautions

Not applicable

SECTION 15. REGULATORY INFORMATION

The product is licensed as a medical device in Canada and therefore not covered by the requirements of the Hazardous Products Act and Regulations (WHMIS 2015). This safety data sheet is supplied as a courtesy to customers.

SECTION 16. OTHER INFORMATION

Date of the latest revision: 01-Jun-2018

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.