

Wound Management
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SPECIFICATION

Opsite Spray Dressing – Product Safety Data Sheet

Approvals

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SPECIFICATION

Opsite Spray Dressing

Product Safety Data Sheet

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifiers:

Product Name : Opsite Spray
Product Number : 66000679, 66004978, 66004979, 66004980, 66800653
Brand : Smith & Nephew
Index No. : N/A
REACH No. : N/A
CAS-No. : N/A

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Spray dressing for 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.

1.3 Details of the supplier of the safety data sheet

Company : Smith & Nephew Healthcare
Compliance and Regulatory Department
Healthcare House
101 Hessle Road
Hull, HU3 2BN
UNITED KINGDOM
Telephone : +44 (0) 1482 222200
Fax : +44 (0) 1482 222211
Email : advice@smith-nephew.com

1.4 Emergency Telephone Number

Emergency Phone : 00-1-703-527-3887 (Chemtrec)

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) no. 1272/2008, based on extremely flammable aerosol / worst case component;

Extremely Flammable Aerosol:	Category 1	H222
Eye Irritant:	Category 2	H319
STOT-SE	Category 3	H336

Classification according to EU Directives 67/548/EEC or 1999/45/EC, based on worst case;

F+	Extremely Flammable	R12
Xi	Irritant	R36
		R66
		R67

Contains no other components or impurities which will influence the classification of the product.
Full text of the statements listed above is given in section 16.

2.2 Label Elements

Labelling according to Regulation ADD/75/324/EEC:

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Pictogram:

Labelling according to Regulation (EC) no. 1272/2008/EC (CLP/GHS)



Pictogram:

Signal word: DANGER

Hazard statements

H222 Extremely Flammable Aerosol

Precautionary statements

P210 Keep away from heat / sparks / open flames / hot surfaces. No smoking.

P211 Do not spray on an open flame or other ignition source

P251 Pressurised container – do not pierce or burn, even after use

P410 & 412 Protect from sunlight. Do not expose to temperatures exceeding 50°C.

Supplemental Hazard information (EU)

None.

2.3 Other Hazards

None

SECTION3: Composition / Information on ingredients

Substance / Mixture : Mixture

Component	Identification	Classification	Concentration
Acetone (solvent)	Formula: C ₃ H ₆ O Molecular weight: 58.08 g/mol CAS-No. 67-64-1 EC-No. 200-662-2 Index-No. 606-001-00-8	(EC) No 1272/2008: Flammable liquid: Cat 2, H225 Eye Irritant: Cat 2, H319 STOT-SE Cat 3, H336 EU 67/548/EEC or 1999/45/EC: F Highly Flammable, R11 Xi Irritant, R36, R66, R67	Nmt 35%
Dimethyl ether (propellant)	Formula: C ₂ H ₆ O CAS-No. 115-10-6 EC-No. 204-065-8 Index-No. 603-019-00-8 Registration Number 01-2119472128-37	(EC) No 1272/2008: Flammable gas: Cat 1, H220 Press. Gas (liquefied gas), H280 EU 67/548/EEC or 1999/45/EC: F+ Extremely Flammable, R12	Nmt 26%
Isopropyl Alcohol (solvent)	Formula: C ₃ H ₈ O Molecular weight: 60.10 g/mol CAS-No. 67-63-0 EC-No. 200-661-7 Index-No. 603-117-00-0 Registration Number N/A	(EC) No 1272/2008: Flammable liquid: Cat 2, H225 Eye Irritant: Cat 2, H319 STOT-SE Cat 3, H336 EU 67/548/EEC or 1999/45/EC: F Highly Flammable, R11	Nmt 11%

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		Xi Irritant, R36, R67	
n-Butane (propellant)	Formula: C ₄ H ₁₀ CAS-No. 106-97-8 EC-No. 203-448-7 Index-No. 601-004-00-0 Registration Number N/A	(EC) No 1272/2008: Flammable gas: Cat 1, H220 Press. Gas (liquefied gas), H280 EU 67/548/EEC or 1999/45/EC: F+ Extremely Flammable, R12	Nmt 11%
Propane (propellant)	Formula: C ₃ H ₈ CAS-No. 74-98-6 EC-No. 200-827-9 Index-No. 601-003-00-5 Registration Number 01-2119486944-21	(EC) No 1272/2008: Flammable gas: Cat 1, H220 Press. Gas (liquefied gas), H280 EU 67/548/EEC or 1999/45/EC: F+ Extremely Flammable, R12	Nmt 5%
Ethyl Acetate (solvent)	Formula: C ₄ H ₈ O ₂ Molecular weight: 88.11 g/mol CAS-No. 141-78-6 EC-No. 205-500-4 Index-No. 607-022-00-5 Registration Number 01-2119475103-46	(EC) No 1272/2008: Flammable liquid: Cat 2, H225 Eye Irritant: Cat 2, H319 STOT-SE Cat 3, H336 EU 67/548/EEC or 1999/45/EC: F Highly Flammable, R11 Xi Irritant, R36, R66, R67	Nmt 5%
Isobutane (propellant)	Formula: C ₄ H ₁₀ CAS-No. 72-28-5 EC-No. 200-857-2 Index-No. 601-004-00-0 Registration Number N/A	(EC) No 1272/2008: Flammable gas: Cat 1, H220 Press. Gas (liquefied gas), H280 EU 67/548/EEC or 1999/45/EC: F+ Extremely Flammable, R12	Nmt 5%

Contains no other components or impurities which will influence the classification of the product.
Full text of the statements listed above is given in section 16.

SECTION 4: First Aid Measures

4.1 First Aid General Information:

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

First Aid Inhalation:

Remove to fresh air, if unconscious move to recovery position. Seek medical aid.

First Aid Skin / Eye:

Skin: N/A. Eye: Remove contact lens(es) if present and easy to do. Flush with clean water for 10 minutes. Seek medical aid.

First Aid Ingestion:

Do not induce vomiting. If patient vomits turn to recovery position. Give water to drink. Seek medical aid.

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 any immediate medical attention and special treatment needed:

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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

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 Advice for firefighters

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 sewer 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.

6.4 Reference to other sections

None.

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.

7.3 Specific end use(s)

See section 1.2.

SECTION 8: Exposure Controls / Personal Protection

8.1 Control Parameters

Component	Control Parameters	Basis	Concentration
Acetone	STEL 1500ppm TWA 500ppm	UK EH40 Workplace exposure limits UK EH40 Workplace exposure	Nmt 35%

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		limits and EC directive 2000/39/EC (indicative)	
Dimethyl ether	LTEL 400ppm STEL 500ppm	UK EH40 Workplace exposure limits UK EH40 Workplace exposure limits	Nmt 26%
Isopropyl Alcohol	STEL 500ppm, TWA 400ppm	UK EH40 Workplace exposure limits UK EH40 Workplace exposure limits	Nmt 11%
n-Butane	LTEL 600ppm STEL 750ppm TLV 800ppm	UK EH40 Workplace exposure limits UK EH40 Workplace exposure limits ACGIH 1995-1996	Nmt 11%
Propane	TLV 1000ppm	ACGIH 2009	Nmt 5%
Ethyl Acetate	STEL 400ppm, TWA 200ppm	UK EH40 Workplace exposure limits UK EH40 Workplace exposure limits	Nmt 5%
Isobutane	TWA 800ppm	UK EH40 Workplace exposure limits	Nmt 5%

8.2 Exposure Controls

Ensure adequate ventilation. Do not smoke whilst handling product.

Personal protective Equipment

The wearing of eye protection and gloves is advisable.

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Component	Acetone	Dimethyl Ether	Isopropyl alcohol	n-Butane	Propane	Ethyl Acetate	Isobutane
Appearance	Clear, colourless liquid	Colourless gas	Colourless liquid	Colourless gas	Colourless gas	Clear, colourless liquid	Colourless gas
Odour	No data	Ether-like	Alcohol-like	Sweetish	Sweetish	No data	Sweetish
Odour Threshold	No data	No data	No data	No data	No data	No data	No data
pH	No data	No data	No data	No data	No data	No data	No data
Melting point	-94°C	-141.5°C	-89.5°C	-138°C	-188 °C	-84 °C	-159°C
Boiling point	56°C	-24.8°C	82°C	-0.5°C	-42.1 °C	76.5 – 77.5 °C	-12°C
Flash point	-17.0 °C	N/A	12.0°C	N/A	N/A	-3.0 °C	N/A
Evaporation rate	No data	N/A	3.0	N/A	No data	No data	N/A
Flammability	No data	See below	No data	See below	See below	No data	See below
Upper/Lower flammability or explosive limits	Upper Exp: 13% (V) Lower Exp: 2% (V)	Upper Fl: 32% (V) Lower Fl: 2.7% (V)	Upper Exp: 12.7% (V) Lower Exp: 2% (V)	Upper Fl: 9.4% (V) Lower Fl: 1.4% (V)	Upper Fl: 10.8% (V) Lower Fl: 1.7% (V)	Upper Exp: 11.5% (V) Lower Exp: 2.2% (V)	Upper Fl: 9.4% (V) Lower Fl: 1.5% (V)
Vapour Pressure	245.3 hPa at 20.0°C	5.1 bar at 20°C	43.2 hPa at 20.0°C	2bar at 20.0°C	8.3bar at 20.0°C	97.3hPa at 20.0°C	3 bar at 20°C

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Vapour density	No data	1.6	No data	2.1	1.5	No data	2
Relative density	0.791 g/cm ³ at 25°C	No data	0.785 g/cm ³ at 25°C	0.6	No data	0.902 g/mL at 25°C	No data
Water solubility	Completely miscible	No data	Completely soluble	88 mg/L	75 mg/L	Soluble	54 mg/L
Partition coefficient n-octanol/water	Log Pow: -0.24	Log Pow: 0.1	Log Pow: 0.05	Log Pow: 2.89	Log Pow: 2.36	Log Pow: 0.73	Log Pow: 2.76
Auto-ignition temperature	465 °C	235 °C	425°C	365 °C	470°C	427°C	460°C
Decomposition temperature	No data	No data	No data	No data	No data	No data	No data
Viscosity	No data	No data	No data	No data	No data	No data	No data
Explosive properties	No data	Not explosive	No data	No data	Not explosive	No data	Not explosive
Oxidising properties	No data	No data	No data	No data	N/A	No data	No data

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.

10.4 Conditions to avoid

Avoid strong acids, strong bases, strong oxidising agents. Heat, flames, sparks. Extremes of temperature 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 Information on toxicological effects

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:	Not classified as	Rabbit 24h: irritation	Not classified as	No data	No data	Not classified as

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	irritation	irritant		irritant			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

11.2 Additional toxicological information

Studies on Opsite Spray product;

Guinea pig maximisation test: no evidence of delayed contact hypersensitivity.

Rabbit primary irritation test: Non-irritant.

Cytotoxicity, subchronic toxicity, genotoxicity: No data available.

SECTION 12: Ecological information

12.1 Toxicity

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 / not applicable

12.5 Results of PBT and vPvB assessment - Not required / not conducted

12.6 Other adverse effects – No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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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

ADR/RID: 1950 IMDG: 1950 IATA: 1950

14.2 UN proper shipping name

ADR/RID: Aerosol, Flammable IMDG: AEROSOLS IATA: Aerosol, Flammable

14.3 Transport Hazard Classes

ADR/RID: 2.1 IMDG: 2.1 IATA: 2.1

14.4 Packaging Group

ADR/RID: II IMDG: EmS F-D IATA: II

14.5 Environmental Hazards

ADR/RID: N/A IMDG: S-U IATA: N/A

14.6 Special precautions for the user

ADR Tunnel Restriction code (D).

SECTION 15: Regulatory Information

This safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008.

This product is registered as a medical device in the EU.

The ETF holder is Smith & Nephew Medical, Ltd, Hesse Road, Hull HU3 2BN, United Kingdom.

The ETF / Declaration of conformity reference is HU/040.

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

No data available.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16: Other Information

Full text of H-statements referred to in other sections

Eye Irrit.	Eye irritation
Flam. Liq.	Flammable Liquid
H220	Extremely Flammable Gas
H222	Extremely Flammable Aerosol
H225	Highly flammable liquid and vapour
H280	Contains gas under pressure; may explode if heated.
H319	Causes serious eye irritation
H336	May cause drowsiness or dizziness
STOT SE	Specific Target Organ Toxicity – single exposure

Full text of R-phrases referred to in other sections

F	Highly Flammable
F+	Extremely Flammable
Xi	Irritant
R11	Highly Flammable
R12	Extremely Flammable
R36	Irritating to Eyes

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R66 Repeated exposure may cause skin dryness or cracking
R67 Vapours may cause drowsiness and dizziness

Full text of P-statements referred to in other sections

P210 Keep away from heat / sparks / open flames / hot surfaces. – No smoking.
P211 Do not spray on an open flame or other ignition source
P251 Pressurised container – do not pierce or burn, even after use
P261 Avoid breathing dust / fume / gas / mist / vapours / spray.
P410 & 412 Protect from sunlight. Do not expose to temperatures exceeding 50°C

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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 2002 (COSHH assessments). It has been updated in accordance with CLP regulation (Regulation (EC) No. 1272/2008) to meet the requirements of the United Nations Globally Harmonised System (GHS) of Classification and Labelling of Chemicals in the EU. The safety data sheet has been compiled according to the first revision to REACH Annex II. Provision of this information does not preclude users from seeking advice from other sources. The 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 the patient.

REASON FOR CHANGE

Document Version	Section/Paragraph Changed	Change Made	Date
1	NA	Initial issue of document. Supercedes 1002509.	03/02/09
2	All (Format) Section 16	Update of format and inclusion of hazard symbols	13/08/2012
3	All	Update to meet CLP regulation	01/10/13

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RE-VERIFICATION OF DOCUMENT SUITABILITY

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