

Wound Management  
Smith & Nephew  
Medical Ltd.  
101 Hessle Road  
Hull HU3 2BN  
England

T 44 (0) 1482 225 181  
F 44 (0) 1482 328 326  
www.smith-nephew.com



## **SPECIFICATION**

### **Opsite Spray Dressing – Product Safety Data Sheet**

#### Approvals

Author Name: Caroline Watson  
Signature Date/Time: 20 FEB 2020 15:44 UTC  
Global Date/Time: 20 FEB 2020 15:44 UTC  
Representation: Author Signature  
Signature Reason: Document Management: Status Change

Signatory Name: Paul Sewell  
Signature Date/Time: 20 FEB 2020 15:51 UK  
Global Date/Time: 20 FEB 2020 15:51 UTC  
Representation: Engineering Signature  
Signature Reason: Document Management: Status Change

---

Document Number:	2002090	Document Part:	000
Document Version:	09	Document Status:	Released

## Product Safety Data Sheet

### 1a) PRODUCT NAME(S):

Product Name : Opsite Spray  
Brand : Smith & Nephew  
Index No. : N/A  
REACH No. : N/A  
CAS-No. : N/A

### 1b) INTENDED USE(S):

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.

### 1c) Details of Supplier of the Product Safety Data Sheet:

Company : Smith & Nephew  
101 Hessle Road  
Hull, HU3 2BN  
UNITED KINGDOM  
Telephone : +44 (0) 1482 225181 (24 hours)  
Email : Advice.Healthcare@smith-nephew.com  
Emergency Phone : 00-1-703-527-3887 (Chemtrec, 24 hours, all languages)

## 2. HAZARD INFORMATION:

### 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
Pressurised Container: May burst if heated		H229

P102 Keep out of reach of children  
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.  
P305 + P351 + P338 If in eyes rinse cautiously with water for several minutes. Remove contact lenses if easy to do. Continue rinsing.

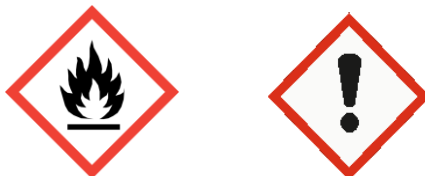
Full text of the statements listed above is given in section 16.

Document Number: 2002090  
Document Version: 09

Document Part: 000  
Document Status: Released

## 2.2 Label Elements

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



**Pictogram:**

**Signal word:** DANGER

### Hazard statements

H222 Extremely Flammable Aerosol  
H229 Pressurised Container: May Burst if Heated  
H319 Eye Irritant

### 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.  
P305 + P351 + P338 If in eyes rinse cautiously with water for several minutes. Remove contact lenses if easy to do. Continue rinsing.

### Supplemental Hazard information (EU)

None.

## 2.3 Other Hazards

H336 May cause drowsiness or dizziness

## 3. COMPOSITION / INFORMATION ON INGREDIENTS:

### Substance / Mixture :

Moisture Vapour Permeable Spray Dressing (<5% acrylic polymer in solvent / propellant mixture)

### Hazardous Components (Nmt = no more than):

Component	Identification	Classification	Concentration
Acetone (solvent)	Formula: C <sub>3</sub> H <sub>6</sub> O Molecular weight: 58.08 g/mol CAS-No. 67-64-1 EC-No. 200-662-2 Index-No. 606-001-00-8 REACH Registration No. 01-2119471330-49-xxxx	(EC) No 1272/2008: Flammable liquid: Cat 2 Eye Irritant: Cat 2 STOT-SE Cat 3 H225 Highly Flammable H319 Eye Irritant H336 May cause drowsiness or dizziness	Nmt 35%
Dimethyl ether	Formula: C <sub>2</sub> H <sub>6</sub> O CAS-No. 115-10-6	(EC) No 1272/2008: Flammable gas: Cat 1	Nmt 26%

Document Number: 2002090  
Document Version: 09

Document Part: 000  
Document Status: Released

(propellant)	EC-No. 204-065-8 Index-No. 603-019-00-8 REACH Registration No. 01-2119472128-37-xxxx	Press. Gas (liquefied gas) H220 Extremely Flammable Gas H280 Gas under pressure	
Isopropanol (solvent)	Formula: C <sub>3</sub> H <sub>8</sub> O Molecular weight: 60.10 g/mol CAS-No. 67-63-0 EC-No. 200-661-7 Index-No. 603-117-00-0 REACH Registration No. Not available	(EC) No 1272/2008: Flammable liquid: Cat 2 Eye Irritant: Cat 2 STOT-SE Cat 3 H225 Highly Flammable H319 Eye Irritant H336 May cause drowsiness or dizziness	Nmt 11%
n-Butane (propellant)	Formula: C <sub>4</sub> H <sub>10</sub> CAS-No. 106-97-8 EC-No. 203-448-7 Index-No. 601-004-00-0 REACH Registration No. 01-2119474691-32-xxxx	(EC) No 1272/2008: Flammable gas: Cat 1 Press. Gas (liquefied gas) H220 Extremely Flammable Gas H280 Gas under pressure	Nmt 11%
Propane (propellant)	Formula: C <sub>3</sub> H <sub>8</sub> CAS-No. 74-98-6 EC-No. 200-827-9 Index-No. 601-003-00-5 REACH Registration No. 01-2119486944-21-xxxx	(EC) No 1272/2008: Flammable gas: Cat 1 Press. Gas (liquefied gas) H220 Extremely Flammable Gas H280 Gas under pressure	Nmt 5%
Ethyl Acetate (solvent)	Formula: C <sub>4</sub> H <sub>8</sub> O <sub>2</sub> Molecular weight: 88.11 g/mol CAS-No. 141-78-6 EC-No. 205-500-4 Index-No. 607-022-00-5 REACH Registration No. 01-2119475103-46-xxxx	(EC) No 1272/2008: Flammable liquid: Cat 2 Eye Irritant: Cat 2 STOT-SE Cat 3 H225 Highly Flammable H319 Eye Irritant H336 May cause drowsiness or dizziness	Nmt 5%
Isobutane (propellant)	Formula: C <sub>4</sub> H <sub>10</sub> CAS-No. 72-28-5 EC-No. 200-857-2 Index-No. 601-004-00-0 REACH Registration No. 01-2119485395-27-xxxx	(EC) No 1272/2008: Flammable gas: Cat 1 Press. Gas (liquefied gas) H220 Extremely Flammable Gas H280 Gas under pressure	Nmt 5%

Full text of the statements listed above is given in section 16.

#### 4. FIRST AID:

##### 4.1 First Aid General Information:

Remove victim to uncontaminated area. Keep victim warm and rested, 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.

##### 4.3 Indication of any immediate medical attention and special treatment needed:

None.

Document Number: 2002090  
Document Version: 09

Document Part: 000  
Document Status: Released

<b>a) Inhalation</b>	Remove to fresh air, if unconscious move to recovery position. Seek medical aid.
<b>b) Contact with skin</b>	Not anticipated if used as directed. If skin reddening occurs, wash skin with soap and water, seek medical aid.
<b>c) Contact with eyes</b>	Remove contact lens(es) if present and easy to do so. Flush with clean water for 10 minutes. Seek medical aid.
<b>d) Ingestion</b>	Do not induce vomiting. If patient vomits turn to recovery position. Give water to drink. Seek medical aid.

<p><b>5. FIRE AND EMERGENCY MEASURES:</b></p> <p><b>Suitable extinguishing media</b> Use water spray, dry powder or vaporising liquid fire-fighting equipment.</p> <p><b>Unsuitable extinguishing media</b> Solid water stream</p> <p><b>5.2 Special hazards arising from the substance or mixture</b> 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.</p> <p><b>5.3 Advice for firefighters</b> Wear self-contained breathing apparatus.</p> <p><b>5.4 Further information</b> Use water spray to cool unopened containers.</p>
--

<p><b>6. ACCIDENTAL RELEASE MEASURES:</b></p> <p><b>In event of product release:</b></p> <p><b>6.1 Personal precautions, protective equipment and emergency procedures</b> Evacuate area. Ensure adequate air ventilation. Wear respiratory protection. Eliminate all sources of ignition.</p> <p><b>6.2 Environmental precautions</b> Prevent leakage or further spillage if safe to do so. Prevent escaping material from entering drains or water courses. Advise authorities if material has entered water course or sewer or has contaminated soil or vegetation.</p> <p><b>6.3 Methods and material for containment and cleaning up</b> 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.</p> <p><b>6.4 Reference to other sections</b> If product is undamaged, treat mechanically and sweep into suitable containers. See Section 13. for suitable disposal considerations.</p>
---

---

Document Number:	2002090	Document Part:	000
Document Version:	09	Document Status:	Released

## 7. HANDLING AND STORAGE PRECAUTIONS:

### 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. Protect from heat and direct sunlight. 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 1b)

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION:

### 8.1 Control Parameters

Component	Control Parameters	Basis	Concentration
Acetone	STEL 1500ppm TWA 500ppm	UK EH40 Workplace exposure limits	Nmt 35%
Dimethyl ether	LTEL 400ppm STEL 500ppm	UK EH40 Workplace exposure limits	Nmt 26%
Isopropyl Alcohol	STEL 500ppm, TWA 400ppm	UK EH40 Workplace exposure limits	Nmt 11%
n-Butane	LTEL 600ppm STEL 750ppm TLV 1000ppm	UK EH40 Workplace exposure limits ACGIH 2012	Nmt 11%
Propane	As LPG: LTEL 1000ppm STEL 1250ppm	UK EH40 Workplace exposure limits	Nmt 5%
Ethyl Acetate	STEL 400ppm, TWA 200ppm	UK EH40 Workplace exposure limits	Nmt 5%
Isobutane	TWA 800ppm	Based on worst case EU DFR MAK List (Germany / Romania) ACGIH 1979	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.

Opsite Spray when used in a medical situation is relatively safe to work with occasionally or in small amounts and the normal gloves used in hospitals are acceptable. With sensitive skin, or prolonged exposure to the acetone in the spray, there is benefit from wearing butyl rubber gloves.

Document Number: 2002090  
Document Version: 09

Document Part: 000  
Document Status: Released

## 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
Vapour density	No data	1.6	No data	2.1	1.5	No data	2
Relative density	0.791 g/cm <sup>3</sup> at 25°C	No data	0.785 g/cm <sup>3</sup> 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

Document Number: 2002090  
Document Version: 09

Document Part: 000  
Document Status: Released

## 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 and 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.

## 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 <sup>3</sup>	Rat 4h: 164000ppm	Rat 8h: 16000 ppm	Rat 4h: 658mg/L	Rat 0.25h: 800000 ppm	Mouse, 2h: 45000 mg/m <sup>3</sup>	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

Document Number: 2002090  
Document Version: 09

Document Part: 000  
Document Status: Released



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.

## 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.

## 13. DISPOSAL CONSIDERATIONS:

### 13.1 Waste treatment methods

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

Document Number: 2002090  
Document Version: 09

Document Part: 000  
Document Status: Released

## 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).

## 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, Hessle 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.

## 16. ADDITIONAL INFORMATION: Not applicable

### 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
H229	Pressurised Container: May Burst if Heated
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

Document Number: 2002090

Document Version: 09

Document Part: 000

Document Status: Released

**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

P305 + P351 + P338 If in eyes rinse cautiously with water for several minutes. Remove contact lenses if easy to do. Continue rinsing.

<b>17a) REFERENCE NUMBER</b>	2002090
<b>17b) DATE OF ISSUE</b>	April 2019

*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). Provision of this information does not preclude users from seeking advice from other sources as indicated in the COSHH guides. 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 patient.*

---

Document Number: 2002090  
Document Version: 09

Document Part: 000  
Document Status: Released

## 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
4	Issue date Reverification table	Periodic review – no change to content Updated issue date and removed reverification table	20/10/16
5	All (Document Updated into new format) Section 2.2 Section 16	Updated issue to include the hazard statement H229: "Pressurised container: May burst if heated";	07/Apr/2017
6	Changes throughout document	Updated with current requirements under REACH	19/11/18
7	Section 2	Addition of Eye Irritant and associated symbol which was omitted in error at update. Product codes moved to 'Additional Data'	09/04/19
8	Section 8.2	Specific information relating to type of gloves to be used	25/06/19
9	Section 1c	Additional of Advice.Healthcare@smith-nephew.com email address, clarification of telephone numbers	20/02/2020

Document Number: 2002090  
Document Version: 09

Document Part: 000  
Document Status: Released

Plant Number(s):

None

Product Code(s):

66000679, 66004978, 66004979, 66004980, 66800653

\*\*\* END OF DOCUMENT \*\*\*

---

Document Number: 2002090  
Document Version: 09

Document Part: 000  
Document Status: Released