SPECIFICATION
Opsite Spray Dressing – Product Safety Data Sheet

Approvals

Author Name: Hannah Booth
Signature Date/Time: 15 OCT 2013 13:17 GMTUK
Global Date/Time: 15 OCT 2013 12:17 UTC
Representation: Author Signature
Signature Reason: Document Management: Status Change

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Signature Date/Time: 15 OCT 2013 13:23 GMTUK
Global Date/Time: 15 OCT 2013 12:23 UTC
Representation: Engineering Signature
Signature Reason: Document Management: Status Change
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 (Chemetrec)

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

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Identification</th>
<th>Classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CAS-No. 67-64-1  EC-No. 200-662-2  Index-No. 606-001-00-8</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>CAS-No. 67-63-0  EC-No. 200-661-7  Index-No. 603-117-00-0  Registration Number N/A</td>
<td></td>
<td></td>
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<td>CAS-No. 67-63-0  EC-No. 200-661-7  Index-No. 603-117-00-0  Registration Number N/A</td>
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</table>

Document Number: 2002090  Document Port: 000
Document Version: 03  Document Status: Released
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Non—Controlled Document Printed on 16 OCT 2013 16:12 GMTUK by Mathew Mccoid
**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:**
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

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 or 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

<table>
<thead>
<tr>
<th>Component</th>
<th>Control Parameters</th>
<th>Basis</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>STEL 1500ppm</td>
<td>UK EH40 Workplace exposure limits</td>
<td>Nmt 35%</td>
</tr>
<tr>
<td></td>
<td>TWA 500ppm</td>
<td>UK EH40 Workplace exposure</td>
<td></td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Component</th>
<th>Acetone</th>
<th>Dimethyl ether</th>
<th>Isopropyl alcohol</th>
<th>n-Butane</th>
<th>Propane</th>
<th>Ethyl Acetate</th>
<th>Isobutane</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear, colourless liquid</td>
<td>Colourless liquid</td>
<td>Colourless liquid</td>
<td>Colourless gas</td>
<td>Colourless gas</td>
<td>Colourless liquid</td>
<td></td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
</tr>
<tr>
<td>Odour</td>
<td>No data</td>
<td>Ether-like</td>
<td>Alcohol-like</td>
<td>Sweetish</td>
<td>Sweetish</td>
<td>No data</td>
<td>Sweetish</td>
</tr>
<tr>
<td>pH</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
</tr>
<tr>
<td>Melting point</td>
<td>-94°C</td>
<td>-191.5°C</td>
<td>-89.5°C</td>
<td>-138°C</td>
<td>-188°C</td>
<td>-84°C</td>
<td>-159°C</td>
</tr>
<tr>
<td>Boiling point</td>
<td>56°C</td>
<td>-24.8°C</td>
<td>82°C</td>
<td>-0.5°C</td>
<td>-42.1°C</td>
<td>76.5 – 77.5°C</td>
<td>-12°C</td>
</tr>
<tr>
<td>Flash point</td>
<td>-17.0 °C</td>
<td>N/A</td>
<td>12.0°C</td>
<td>N/A</td>
<td>N/A</td>
<td>-3.0 °C</td>
<td>N/A</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data</td>
<td>N/A</td>
<td>3.0</td>
<td>N/A</td>
<td>No data</td>
<td>No data</td>
<td>N/A</td>
</tr>
<tr>
<td>Flammability</td>
<td>No data</td>
<td>See below</td>
<td>No data</td>
<td>See below</td>
<td>See below</td>
<td>No data</td>
<td>See below</td>
</tr>
<tr>
<td>Upper/Lower flammability or explosive limits</td>
<td>Upper Fl: 13% (V) Lower Fl: 2% (V)</td>
<td>Upper Fl: 32% (V) Lower Fl: 2.7% (V)</td>
<td>Upper Fl: 12.7% (V) Lower Fl: 2% (V)</td>
<td>Upper Fl: 9.4% (V) Lower Fl: 1.4% (V)</td>
<td>Upper Fl: 10.8% (V) Lower Fl: 1.7% (V)</td>
<td>Upper Fl: 11.5% (V) Lower Fl: 2.2% (V)</td>
<td>Upper Fl: 9.4% (V) Lower Fl: 1.5% (V)</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>245.3 hPa at 20.0°C</td>
<td>5.1 bar at 20°C</td>
<td>43.2 hPa at 20.0°C</td>
<td>2 bar at 20.0°C</td>
<td>8.3 bar at 20.0°C</td>
<td>97.3 hPa at 20.0°C</td>
<td>3 bar at 20°C</td>
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<tr>
<td>Vapour density</td>
<td>No data</td>
<td>1.6</td>
<td>No data</td>
<td>2.1</td>
<td>1.5</td>
<td>No data</td>
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<tr>
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<td>--------</td>
<td>-----</td>
<td>-----</td>
<td>--------</td>
<td>--</td>
</tr>
<tr>
<td>Relative density</td>
<td>0.791 g/cm³ at 25°C</td>
<td>No data</td>
<td>0.785 g/cm³ at 25°C</td>
<td>0.6</td>
<td>No data</td>
<td>0.902 g/mL at 25°C</td>
<td>No data</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Completely miscible</td>
<td>No data</td>
<td>Completely soluble</td>
<td>88 mg/L</td>
<td>75 mg/L</td>
<td>Soluble</td>
<td>54 mg/L</td>
</tr>
<tr>
<td>Partition coefficient n-octanol/water</td>
<td>Log Pow: -0.24</td>
<td>Log Pow: 0.1</td>
<td>Log Pow: 0.05</td>
<td>Log Pow: 2.89</td>
<td>Log Pow: 2.36</td>
<td>Log Pow: 0.73</td>
<td>Log Pow: 2.76</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>465 °C</td>
<td>235 °C</td>
<td>425°C</td>
<td>365 °C</td>
<td>470°C</td>
<td>427°C</td>
<td>460°C</td>
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<tr>
<td>Decomposition temperature</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data</td>
<td>Not explosive</td>
<td>No data</td>
<td>Not explosive</td>
<td>No data</td>
<td>Not explosive</td>
<td>No data</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>N/A</td>
<td>No data</td>
<td>No data</td>
</tr>
</tbody>
</table>

**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

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Acetone</th>
<th>Dimethyl Ether</th>
<th>Isopropyl alcohol</th>
<th>n-Butane</th>
<th>Propane</th>
<th>Ethyl Acetate</th>
<th>Isobutane</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity LD50 Rat Oral</td>
<td>5800 mg/kg</td>
<td>N/A</td>
<td>5045 mg/kg</td>
<td>N/A</td>
<td>N/A</td>
<td>5620 mg/kg</td>
<td>N/A</td>
</tr>
<tr>
<td>Inhalation LC50 Rat</td>
<td>Rat 8h: 50100 mg/m³</td>
<td>Rat 4h: 164000ppm</td>
<td>Rat 8h: 16000 ppm</td>
<td>Rat 4h: 658mg/L</td>
<td>Rat 0.25h: 800000 ppm</td>
<td>Mouse, 2h: 45000 mg/m³</td>
<td>Mouse, 1h: 52 mg/L</td>
</tr>
<tr>
<td>LD50 Dermal</td>
<td>Guinea pig: 7426 mg/kg</td>
<td>No data</td>
<td>Rabbit: 12800 mg/kg</td>
<td>No data</td>
<td>No data</td>
<td>Rabbit: &gt;180000 mg/kg</td>
<td>No data</td>
</tr>
<tr>
<td>Skin corrosion / irritation</td>
<td>Rabbit 24h: Mild skin irritation</td>
<td>Not classified as irritant</td>
<td>Rabbit 24h: Mild skin irritation</td>
<td>Not classified as irritant</td>
<td>Not classified as irritant</td>
<td>No data</td>
<td>Not classified as irritant</td>
</tr>
<tr>
<td>Eye damage / irritation</td>
<td>Rabbit 24h:</td>
<td>Not classified as</td>
<td>Rabbit 24h:</td>
<td>Not classified as</td>
<td>No data</td>
<td>No data</td>
<td>Not classified as</td>
</tr>
</tbody>
</table>
Respiratory or skin sensitisation | Chronic exposure may cause dermatitis | No known effects | No data | No known effects | No data | No known effects
---|---|---|---|---|---|---
Germ cell mutagenicity | No data | No evidence of mutagenicity | No data | 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
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

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

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
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

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, 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.

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
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 50ºC

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, contraindications and precautions for the treatment of the patient.

REASON FOR CHANGE

<table>
<thead>
<tr>
<th>Document Version</th>
<th>Section/Paragraph Changed</th>
<th>Change Made</th>
<th>Date</th>
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<tr>
<td>1</td>
<td>NA</td>
<td>Initial issue of document. Supercedes 1002509.</td>
<td>03/02/09</td>
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<td>2</td>
<td>All (Format) Section 16</td>
<td>Update of format and inclusion of hazard symbols</td>
<td>13/08/2012</td>
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<tr>
<td>3</td>
<td>All</td>
<td>Update to meet CLP regulation</td>
<td>01/10/13</td>
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“I have compared this paper copy to the original electronic copy on the date shown below and certify that both are the same version number”

<table>
<thead>
<tr>
<th>Product Code(s)</th>
<th>Signature</th>
<th>Date</th>
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<tbody>
<tr>
<td>660000679, 66004978, 66004979, 66004980, 668000653</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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