SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	:	Mixture
PRODUCT NAME	:	Opsite Spray Dressing
Product code	:	66000679, 66004978, 66004979, 66004980, 66803130
Type of product	:	Medical devices
Vaporizer	:	Aerosol
Product group	:	Consumer use

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

Relevant identified uses

Intended for general public

Main use category	:	Professional use,Consumer use
Use of the substance/mixture	:	Medicinal Use Spray dressing for wounds.
Function or use category	:	Consumer uses: Private households (= general public = consumers)

1.3. Details of the supplier of the safety data sheet

Supplier
Smith & Nephew Medical Ltd
101 Hessle Road
HU3 2BN Hull, East Ridings of Yorkshire
T +44 (0) 1482 225181
https://www.smith-nephew.com/en/contact-us#general

REACH Legal Entity
Smith & Nephew Operation B.V.
Bloemlaan 2
2132 NP Hoofddorp
Netherlands

1.4. Emergency telephone number

Emergency number : (UK) or 112 (EU) - 24 Hours, +1-703-527-3887 (Chemtrec 24 Hours)

Country/Area	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH	0344 892 0111	Only for healthcare professionals

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Aerosol, Category 1	H222;H229
Serious eye damage/eye irritation, Category 2	H319
Specific target organ toxicity – Single exposure, Category 3, Narcosis	H336

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

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2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS02 GHS07

Signal word (CLP) : Danger

Contains : Acetone; ethyl acetate; Isopropanol

Hazard statements (CLP) : H222 - Extremely flammable aerosol.
H229 - Pressurised container: May burst if heated.
H319 - Causes serious eye irritation.
H336 - May cause drowsiness or dizziness.

Precautionary statements (CLP) : P101 - If medical advice is needed, have product container or label at hand.
P102 - Keep out of reach of children.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P211 - Do not spray on an open flame or other ignition source.
P251 - Do not pierce or burn, even after use.
P271 - Use only outdoors or in a well-ventilated area.
P405 - Store locked up.
P410+P412 - Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Contains no PBT and/or vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

Component	
Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	2-methoxyethanol; ethylene glycol monomethyl ether (109-86-4)(1)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	2-methoxyethanol; ethylene glycol monomethyl ether (109-86-4)(1)

(1) Substance(s) in concentration below 0.1 % and displayed on a voluntary basis

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

Component	
Substance(s) not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605	2-methoxyethanol; ethylene glycol monomethyl ether (109-86-4)(1)

(1) Substance(s) in concentration below 0.1 % and displayed on a voluntary basis

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Acetone substance with national workplace exposure limit(s) (AT, BE, BG, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, IS, NO, CH); substance with a Community workplace exposure limit	CAS-No.: 67-64-1 EC-No.: 200-662-2 EC Index-No.: 606-001-00-8 REACH-no: 01-2119471330-49	≥ 20 – < 50	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
dimethyl ether (Propellant gas (Aerosol)) substance with national workplace exposure limit(s) (AT, BE, BG, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LT, LU, LV, MT, NL, PL, RO, SE, SI, SK, IS, NO, CH); substance with a Community workplace exposure limit	CAS-No.: 115-10-6 EC-No.: 204-065-8 EC Index-No.: 603-019-00-8 REACH-no: 01-2119472128-37	≥ 20 – < 50	Flam. Gas 1A, H220 Press. Gas (Comp.), H280
Butane (Propellant gas (Aerosol)) substance with national workplace exposure limit(s) (AT, BE, BG, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, LV, PL, PT, SI, SK, IS, NO, CH)	CAS-No.: 106-97-8 EC-No.: 203-448-7 EC Index-No.: 601-004-00-0 REACH-no: 01-2119474691-32	≥ 10 – < 15	Flam. Gas 1A, H220 Press. Gas
Isopropanol substance with national workplace exposure limit(s) (AT, BE, BG, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, LT, LV, NL, PL, PT, RO, SE, SI, SK, IS, NO, CH)	CAS-No.: 67-63-0 EC-No.: 200-661-7 EC Index-No.: 603-117-00-0	≥ 10 – < 15	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
isobutane (Propellant gas (Aerosol)) substance with national workplace exposure limit(s) (AT, BE, DE, EE, FI, IE, PT, SI, SK, CH)	CAS-No.: 75-28-5 EC-No.: 200-857-2 EC Index-No.: 601-004-00-0 REACH-no: 01-2119485395-27	≥ 5 – < 10	Flam. Gas 1A, H220 Press. Gas
propane (Propellant gas (Aerosol)) substance with national workplace exposure limit(s) (AT, BE, BG, DE, DK, EE, ES, FI, GR, LV, PL, RO, SI, IS, NO, CH)	CAS-No.: 74-98-6 EC-No.: 200-827-9 EC Index-No.: 601-003-00-5 REACH-no: 01-2119486944-21	≥ 5 – < 10	Flam. Gas 1A, H220 Press. Gas
ethyl acetate substance with national workplace exposure limit(s) (AT, BE, BG, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, IS, NO, CH); substance with a Community workplace exposure limit	CAS-No.: 141-78-6 EC-No.: 205-500-4 EC Index-No.: 607-022-00-5 REACH-no: 01-2119475103-46-XXXX	≥ 3 – < 5	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
2-ETHOXYETHYL METHACRYLATE	CAS-No.: 2370-63-0 EC-No.: 219-135-3 REACH-no: 01-2120762842-49	< 0.1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Repr. 1B, H360FD STOT SE 3, H335

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-methoxyethanol; ethylene glycol monomethyl ether substance listed on REACH Candidate List (2-Methoxyethanol)	CAS-No.: 109-86-4 EC-No.: 203-713-7 EC Index-No.: 603-011-00-4 REACH-no: 01-2120764681-49	< 0.1	Flam. Liq. 3, H226 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist), H332 Repr. 1B, H360FD

Product subject to CLP Annex I, item 1.1.3.7. The disclosure rules of the components is modified in this case.
Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.

First-aid measures after skin contact : Not expected to present a significant skin hazard under anticipated conditions of normal use. In case of skin irritation, stop using the product. When symptoms occur: rinse immediately with plenty of water.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Not expected to present a significant ingestion hazard under anticipated conditions of normal use. If swallowed, seek medical advice immediately and show this container or label. Do not induce vomiting/risk of damage to lungs exceeds poisoning risk. Give water to drink.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : May cause drowsiness or dizziness.

Symptoms/effects after skin contact : Not expected to present a significant skin hazard under anticipated conditions of normal use.

Symptoms/effects after eye contact : Causes serious eye irritation. redness, itching, tears. stinging.

Symptoms/effects after ingestion : Ingestion is not considered a potential route of exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Dry powder. Water spray or fog.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Flammable aerosol. Pressurised container: May burst if heated.

Explosion hazard : 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.'.

Hazardous decomposition products in case of fire : Toxic fumes may be released.

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5.3. Advice for firefighters

Precautionary measures fire	:	Evacuate area. Eliminate all ignition sources if safe to do so. Cool down the containers exposed to heat with a water spray. Fight fire remotely due to the risk of explosion.
Firefighting instructions	:	Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Avoid fire-fighting water entering the environment.
Protection during firefighting	:	Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	:	Evacuate area. For further information refer to section 8: "Exposure controls/personal protection". Eliminate ignition sources. Ensure adequate ventilation, especially in confined areas.

For non-emergency personnel

Protective equipment	:	Wear respiratory protection.
Emergency procedures	:	Avoid breathing spray, mist.

For emergency responders

Protective equipment	:	Equip cleanup crew with proper protection. Do not breathe mist, spray.
Emergency procedures	:	Ventilate area.

6.2. Environmental precautions

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.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	:	Small quantities of liquid spill: take up in non-combustible absorbent material and shovel into container for disposal. Store away from other materials. 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

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing mist, spray.
Hygiene measures	:	Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures	:	Store in a dry, well ventilated place away from sources of heat, ignition and direct sunlight. Avoid storing in basements.
Storage conditions	:	Keep only in the original container in a cool, well ventilated place away from : Direct sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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Incompatible materials	:	Please note the product contains acetone which may react with non-latex / synthetic gloves.
Storage temperature	:	< 50 °C
Heat and ignition sources	:	No flames, no sparks. Eliminate all sources of ignition.
Packaging materials	:	Keep only in original container.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

National occupational exposure and biological limit values

Acetone (67-64-1)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Acetone
IOEL TWA	1210 mg/m³
	500 ppm
Regulatory reference	COMMISSION DIRECTIVE 2000/39/EC
United Kingdom - Occupational Exposure Limits	
Local name	Acetone
WEL TWA (OEL TWA)	1210 mg/m³
	500 ppm
WEL STEL (OEL STEL)	3620 mg/m³
	1500 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

Butane (106-97-8)	
United Kingdom - Occupational Exposure Limits	
Local name	Butane
WEL TWA (OEL TWA)	1450 mg/m³
	600 ppm
WEL STEL (OEL STEL)	1810 mg/m³
	750 ppm
Remark	Carc (Capable of causing cancer and/or heritable genetic damage. See paragraphs 49–51), (only applies if Butane contains more than 0.1% of buta-1,3-diene)
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

ethyl acetate (141-78-6)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Ethyl acetate
IOEL TWA	734 mg/m³

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ethyl acetate (141-78-6)	
	200 ppm
IOEL STEL	1486 mg/m³
	400 ppm
Regulatory reference	COMMISSION DIRECTIVE (EU) 2017/164
United Kingdom - Occupational Exposure Limits	
Local name	Ethyl acetate
WEL TWA (OEL TWA)	734 mg/m³
	200 ppm
WEL STEL (OEL STEL)	1468 mg/m³
	400 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

Isopropanol (67-63-0)	
United Kingdom - Occupational Exposure Limits	
Local name	Propan-2-ol
WEL TWA (OEL TWA)	999 mg/m³
	400 ppm
WEL STEL (OEL STEL)	1250 mg/m³
	500 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

dimethyl ether (115-10-6)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Dimethylether
IOEL TWA	1920 mg/m³
	1000 ppm
Regulatory reference	COMMISSION DIRECTIVE 2000/39/EC
United Kingdom - Occupational Exposure Limits	
Local name	Dimethyl ether
WEL TWA (OEL TWA)	766 mg/m³
	400 ppm
WEL STEL (OEL STEL)	958 mg/m³
	500 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

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DNEL and PNEC

Acetone (67-64-1)	
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	2420 mg/m³
Long-term - systemic effects, dermal	186 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	1210 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects,oral	62 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	200 mg/m³
Long-term - systemic effects, dermal	62 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	10.6 mg/l
PNEC aqua (marine water)	1.06 mg/l
PNEC aqua (intermittent, freshwater)	21 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	30.4 mg/kg dwt
PNEC sediment (marine water)	3.04 mg/kg dwt
PNEC (Soil)	
PNEC soil	29.5 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	100 mg/l

ethyl acetate (141-78-6)	
DNEL/DMEL (Workers)	
Acute - systemic effects, inhalation	1468 mg/m³
Acute - local effects, inhalation	1468 mg/m³
Long-term - systemic effects, dermal	63 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	734 mg/m³
Long-term - local effects, inhalation	734 mg/m³
DNEL/DMEL (General population)	
Acute - systemic effects, inhalation	734 mg/m³
Acute - local effects, inhalation	734 mg/m³
Long-term - systemic effects,oral	4.5 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	367 mg/m³
Long-term - systemic effects, dermal	37 mg/kg bodyweight/day
Long-term - local effects, inhalation	367 mg/m³
PNEC (Water)	
PNEC aqua (freshwater)	0.24 mg/l

ethyl acetate (141-78-6)	
PNEC aqua (marine water)	0.024 mg/l
PNEC aqua (intermittent, freshwater)	1.65 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	1.15 mg/kg dwt
PNEC sediment (marine water)	0.115 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.148 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	0.2 g/kg food
PNEC (STP)	
PNEC sewage treatment plant	650 mg/l

8.2. Exposure controls

Personal protection equipment

Personal protective equipment:
Avoid all unnecessary exposure.
Personal protective equipment symbol(s):

Eye and face protection

Eye protection:
Safety glasses. Eye protection should only be necessary where liquid could be splashed or sprayed

Skin protection

Hand protection:
Not required for normal conditions of use

Respiratory protection

Respiratory protection:
Not required for normal conditions of use. [In case of inadequate ventilation] wear respiratory protection.

Environmental exposure controls

Other information:
Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Colourless.
Odour	:	Solvent-like. characteristic.
Odour threshold	:	Not available
Melting point	:	Not available
Freezing point	:	Not available
Boiling point	:	Not available

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Flammability	:	Not available
Explosive properties	:	Pressurised container: May burst if heated. Heating may cause a fire or explosion.
Lower explosion limit	:	Not available
Upper explosion limit	:	Not available
Flash point	:	Flammable
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	Not available
Viscosity, kinematic	:	Not available
Solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not available
Particle characteristics	:	Not applicable

9.2. Other information

Information with regard to physical hazard classes

% of flammable ingredients	:	96.2 %

Other safety characteristics

Gas group	:	Press. Gas (Liq.)

SECTION 10: Stability and reactivity

10.1. Reactivity

Non-reactive under normal conditions of use.

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizing agents. Please note the product contains acetone which may react with non-latex / synthetic gloves.

10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	:	Not classified
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified

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Acetone (67-64-1)	
LD50 oral rat	5800 mg/kg bodyweight Animal: rat, Animal sex: female
LD50 oral	5800 mg/kg bodyweight
LD50 dermal	> 15688 mg/kg bodyweight
LC50 Inhalation - Rat	76 mg/l air Animal: rat, Animal sex: female, 95% CL: 65,2 - 88,4
LC50 Inhalation - Rat (Dust/Mist)	50100 mg/l

ethyl acetate (141-78-6)	
LD50 oral	5620 mg/kg bodyweight
LD50 dermal rabbit	> 20000 mg/kg bodyweight Animal: rabbit, Animal sex: male
LD50 dermal	> 18000 mg/kg bodyweight
LC50 Inhalation - Rat (Dust/Mist)	57700 mg/l

Isopropanol (67-63-0)	
LD50 oral	4396 mg/kg bodyweight
LD50 dermal	12800 mg/kg bodyweight
LC50 Inhalation - Rat (Dust/Mist)	46600 mg/l

dimethyl ether (115-10-6)	
LC50 Inhalation - Rat [ppm]	164000 ppm Animal: rat, Animal sex: male, 95% CL: 142000 - 203000

2-ETHOXYETHYL METHACRYLATE (2370-63-0)	
LD50 oral rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity)
LD50 dermal rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity)

2-methoxyethanol; ethylene glycol monomethyl ether (109-86-4)	
LD50 dermal rabbit	3930 mg/kg bodyweight Animal: rabbit, Animal sex: male, Guideline: OECD Guideline 402 (Acute Dermal Toxicity), 95% CL: 2979 - 5138

Skin corrosion/irritation : Not classified
Additional information : Based on available data, the classification criteria are not met
Serious eye damage/irritation : Causes serious eye irritation.
Respiratory or skin sensitisation : Not classified
Additional information : Based on available data, the classification criteria are not met
Germ cell mutagenicity : Not classified
Additional information : Based on available data, the classification criteria are not met
Carcinogenicity : Not classified
Additional information : Based on available data, the classification criteria are not met

Isopropanol (67-63-0)	
IARC group	3 - Not classifiable

Reproductive toxicity : Not classified
Additional information : Based on available data, the classification criteria are not met

Acetone (67-64-1)	
LOAEL (animal/female, F0/P)	11298 mg/kg bodyweight Animal: mouse, Animal sex: female

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Acetone (67-64-1)	
NOAEL (animal/male, F0/P)	900 mg/kg bodyweight Animal: rat, Animal sex: male, Remarks on results: other:Generation not specified (migrated information)

STOT-single exposure : May cause drowsiness or dizziness.

Acetone (67-64-1)	
STOT-single exposure	May cause drowsiness or dizziness.

ethyl acetate (141-78-6)	
STOT-single exposure	May cause drowsiness or dizziness.

Isopropanol (67-63-0)	
STOT-single exposure	May cause drowsiness or dizziness.

2-ETHOXYETHYL METHACRYLATE (2370-63-0)	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure : Not classified
Additional information : Based on available data, the classification criteria are not met

ethyl acetate (141-78-6)	
LOAEL (oral, rat, 90 days)	3600 mg/kg bodyweight Animal: rat, Guideline: EPA OTS 795.2600 (Subchronic Oral Toxicity Test)
NOAEL (oral, rat, 90 days)	900 mg/kg bodyweight Animal: rat, Guideline: EPA OTS 795.2600 (Subchronic Oral Toxicity Test)

2-ETHOXYETHYL METHACRYLATE (2370-63-0)	
LOAEC (inhalation, rat, gas, 90 days)	350 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study)

2-methoxyethanol; ethylene glycol monomethyl ether (109-86-4)	
LOAEL (dermal, rat/rabbit, 90 days)	1000 mg/kg bodyweight Animal: rat, Animal sex: male

Aspiration hazard : Not classified
Additional information : Based on available data, the classification criteria are not met

Opsite Spray Dressing	
Vaporizer	Aerosol

2-methoxyethanol; ethylene glycol monomethyl ether (109-86-4)	
Viscosity, kinematic	1.773 mm²/s

11.2. Information on other hazards

Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute) : Not classified

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Hazardous to the aquatic environment, long–term (chronic) : Not classified

Acetone (67-64-1)	
LC50 - Fish [1]	5540 mg/l
EC50 - Other aquatic organisms [1]	12600 mg/l waterflea
EC50 - Other aquatic organisms [2]	3400 mg/l
LOEC (chronic)	> 79 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	≥ 79 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

ethyl acetate (141-78-6)	
LC50 - Fish [1]	230 mg/l
EC50 - Other aquatic organisms [1]	717 mg/l waterflea
EC50 - Other aquatic organisms [2]	3300 mg/l
NOEC (chronic)	2.4 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

Isopropanol (67-63-0)	
LC50 - Fish [1]	9640 mg/l
EC50 - Other aquatic organisms [1]	13299 mg/l waterflea
EC50 - Other aquatic organisms [2]	> 1000 mg/l

dimethyl ether (115-10-6)	
LC50 - Fish [1]	> 4.1 g/l Test organisms (species): Poecilia reticulata
EC50 - Crustacea [1]	> 4.4 g/l Test organisms (species): Daphnia magna
EC50 96h - Algae [1]	154.917 mg/l Test organisms (species): other:

2-ETHOXYETHYL METHACRYLATE (2370-63-0)	
LC50 - Fish [1]	48.7 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
EC50 72h - Algae [1]	> 184.2 mg/l Test organisms (species): Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum)
EC50 72h - Algae [2]	37 mg/l Test organisms (species): Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum)

2-methoxyethanol; ethylene glycol monomethyl ether (109-86-4)	
LC50 - Fish [1]	> 10000 mg/l Test organisms (species): Lepomis macrochirus
EC50 - Crustacea [1]	27000 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	25500 mg/l Test organisms (species): Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum)
EC50 72h - Algae [2]	12000 mg/l Test organisms (species): Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum)
NOEC (chronic)	> 500 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

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12.2. Persistence and degradability

Opsite Spray Dressing	
Persistence and degradability	Not established.
Acetone (67-64-1)	
Persistence and degradability	Not established.
Butane (106-97-8)	
Persistence and degradability	Rapidly degradable
ethyl acetate (141-78-6)	
Persistence and degradability	Rapidly degradable
isobutane (75-28-5)	
Persistence and degradability	Rapidly degradable
propane (74-98-6)	
Persistence and degradability	Rapidly degradable
Isopropanol (67-63-0)	
Persistence and degradability	Rapidly degradable
dimethyl ether (115-10-6)	
Persistence and degradability	Rapidly degradable
2-ETHOXYETHYL METHACRYLATE (2370-63-0)	
Persistence and degradability	Rapidly degradable
2-methoxyethanol; ethylene glycol monomethyl ether (109-86-4)	
Persistence and degradability	Rapidly degradable

12.3. Bioaccumulative potential

Opsite Spray Dressing	
Bioaccumulative potential	Not established.
Acetone (67-64-1)	
Partition coefficient n-octanol/water (Log Pow)	-0.24
Bioaccumulative potential	Not established.
ethyl acetate (141-78-6)	
Partition coefficient n-octanol/water (Log Pow)	0.7
Isopropanol (67-63-0)	
Partition coefficient n-octanol/water (Log Pow)	0.05

12.4. Mobility in soil

No additional information available

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12.5. Results of PBT and vPvB assessment

Component	
Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	2-methoxyethanol; ethylene glycol monomethyl ether (109-86-4)(1)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	2-methoxyethanol; ethylene glycol monomethyl ether (109-86-4)(1)

(1) Substance(s) in concentration below 0.1 % and displayed on a voluntary basis

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Opsite Spray Dressing	
Other information	Avoid release to the environment.

Acetone (67-64-1)	
Other information	Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecological waste information : Avoid release to the environment.

HP Code : HP3 - "Flammable:"
– flammable liquid waste: liquid waste having a flash point below 60 °C or waste gas oil, diesel and light heating oils having a flash point > 55 °C and ≤ 75 °C;
– flammable pyrophoric liquid and solid waste: solid or liquid waste which, even in small quantities, is liable to ignite within five minutes after coming into contact with air;
– flammable solid waste: solid waste which is readily combustible or may cause or contribute to fire through friction;
– flammable gaseous waste: gaseous waste which is flammable in air at 20 °C and a standard pressure of 101.3 kPa;
– water reactive waste: waste which, in contact with water, emits flammable gases in dangerous quantities;
– other flammable waste: flammable aerosols, flammable self-heating waste, flammable organic peroxides and flammable self-reactive waste.
HP4 - "Irritant – skin irritation and eye damage:" waste which on application can cause skin irritation or damage to the eye.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 1950	UN 1950	UN 1950	UN 1950	UN 1950

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ADR	IMDG	IATA	ADN	RID
14.2. UN proper shipping name				
AEROSOLS	AEROSOLS	Aerosols, flammable	AEROSOLS	AEROSOLS
Transport document description				
UN 1950 AEROSOLS, 2.1, (D)	UN 1950 AEROSOLS, 2.1	UN 1950 Aerosols, flammable, 2.1	UN 1950 AEROSOLS, 2.1	UN 1950 AEROSOLS, 2.1
14.3. Transport hazard class(es)				
2.1	2.1	2.1	2.1	2.1
				
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No EmS-No. (Fire): F-D EmS-No. (Spillage): S-U	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No
No supplementary information available				

14.6. Special precautions for user

Overland transport

Classification code (ADR)	:	5F
Special provisions (ADR)	:	190, 327, 344, 625
Limited quantities (ADR)	:	1l
Excepted quantities (ADR)	:	E0
Packing instructions (ADR)	:	P207
Special packing provisions (ADR)	:	PP87, RR6, L2
Mixed packing provisions (ADR)	:	MP9
Transport category (ADR)	:	2
Special provisions for carriage - Packages (ADR)	:	V14
Special provisions for carriage - Loading, unloading and handling (ADR)	:	CV9, CV12
Special provisions for carriage - Operation (ADR)	:	S2
Tunnel restriction code (ADR)	:	D

Transport by sea

Special provisions (IMDG)	:	63, 190, 277, 327, 344, 381, 959
Limited quantities (IMDG)	:	SP277
Excepted quantities (IMDG)	:	E0
Packing instructions (IMDG)	:	P207, LP200
Special packing provisions (IMDG)	:	PP87, L2
Stowage category (IMDG)	:	None
Stowage and handling (IMDG)	:	SW1, SW22
Segregation (IMDG)	:	SG69

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Air transport

PCA Excepted quantities (IATA)	:	E0
PCA Limited quantities (IATA)	:	Y203
PCA limited quantity max net quantity (IATA)	:	30kgG
PCA packing instructions (IATA)	:	203
PCA max net quantity (IATA)	:	75kg
CAO packing instructions (IATA)	:	203
CAO max net quantity (IATA)	:	150kg
Special provisions (IATA)	:	A145, A167, A802
ERG code (IATA)	:	10L

Inland waterway transport

Classification code (ADN)	:	5F
Special provisions (ADN)	:	190, 327, 344, 625
Limited quantities (ADN)	:	1 L
Excepted quantities (ADN)	:	E0
Equipment required (ADN)	:	PP, EX, A
Ventilation (ADN)	:	VE01, VE04
Number of blue cones/lights (ADN)	:	1

Rail transport

Classification code (RID)	:	5F
Special provisions (RID)	:	190, 327, 344, 625
Limited quantities (RID)	:	1L
Excepted quantities (RID)	:	E0
Packing instructions (RID)	:	P207, LP200
Special packing provisions (RID)	:	PP87, RR6, L2
Mixed packing provisions (RID)	:	MP9
Transport category (RID)	:	2
Special provisions for carriage – Packages (RID)	:	W14
Special provisions for carriage - Loading, unloading and handling (RID)	:	CW9, CW12
Colis express (express parcels) (RID)	:	CE2
Hazard identification number (RID)	:	23

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains substance(s) listed on the REACH Candidate List < 0.1% or SCL: 2-Methoxyethanol (EC 203-713-7, CAS 109-86-4).

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (2024/590)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 2024/590 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

Explosives Precursors Regulation (EU 2019/1148)

Contains substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)
ANNEX II REPORTABLE EXPLOSIVES PRECURSORS
List of substances on their own or in mixtures or in substances for which suspicious transactions and significant disappearances and thefts are to be reported within 24 hours.

Name	CAS-No.	Combined Nomenclature code (CN)	Combined Nomenclature code for mixture without constituents which would determine classification under another CN code
Acetone	67-64-1	2914 11 00	ex 3824 99 92

Drug Precursors Regulation (EC 273/2004)

Contains substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

Name	CN designation	CAS-No.	CN code	Category, Subcategory	Threshold	Annex
Acetone		67-64-1	2914 11 00	Category 3		Annex I

National regulations

France

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Gas 1A	Flammable gases, Category 1A
Flam. Liq. 2	Flammable liquids, Category 2
Flam. Liq. 3	Flammable liquids, Category 3
Press. Gas	Gases under pressure
Press. Gas (Comp.)	Gases under pressure : Compressed gas

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Full text of H- and EUH-statements:	
Repr. 1B	Reproductive toxicity, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis
H220	Extremely flammable gas.
H222	Extremely flammable aerosol.
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H229	Pressurised container: May burst if heated.
H280	Contains gas under pressure; may explode if heated.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H360FD	May damage fertility. May damage the unborn child.

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.