

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Flunixin Liquid (with Alcohol) Formulation

Version 6.0 Revision Date: 06.07.2024 SDS Number: 9372833-00009 Date of last issue: 06.04.2024
Date of first issue: 27.08.2021

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

1.1 Product identifier

Trade name : Flunixin Liquid (with Alcohol) Formulation

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

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Flammable liquids, Category 3	H226: Flammable liquid and vapour.
Acute toxicity, Category 4	H302: Harmful if swallowed.
Acute toxicity, Category 2	H330: Fatal if inhaled.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Reproductive toxicity, Category 1B	H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H226 Flammable liquid and vapour. H302 Harmful if swallowed. H318 Causes serious eye damage. H330 Fatal if inhaled. H360FD May damage fertility. May damage the unborn child. H372 Causes damage to organs through prolonged or repeated exposure. H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	:	Prevention: P201 Obtain special instructions before use. P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor. P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

Hazardous components which must be listed on the label:

- 2-Pyrrolidone
- Benzyl alcohol
- 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
Vapours may form explosive mixture with air.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
2-Pyrrolidone	616-45-5 210-483-1	Eye Irrit. 2; H319 Repr. 1B; H360FD specific concentra- tion limit Repr. 1B; H360FD > 3 % Repr. 1B; H360FD > 3 %	>= 30 - < 50
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319	>= 20 - < 30
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3- (perfluoromethyl)anilino]nicotinate	42461-84-7 255-836-0	Acute Tox. 3; H301 Acute Tox. 2; H330 Eye Dam. 1; H318 STOT SE 3; H335 STOT RE 1; H372 (Gastrointestinal tract, Kidney, Blood) Aquatic Chronic 2; H411	>= 10 - < 20
L-Menthol	2216-51-5 218-690-9	Skin Irrit. 2; H315 Eye Irrit. 2; H319 specific concentra- tion limit Skin Irrit. 2; H315 > 25 % Eye Irrit. 2; H319 > 25 % Skin Irrit. 2; H315 > 25 % Eye Irrit. 2; H319 > 25 %	>= 10 - < 20
Propan-2-ol	67-63-0 200-661-7 603-117-00-0	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	>= 1 - < 10

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention immediately.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Harmful if swallowed.
Causes serious eye damage.
Fatal if inhaled.
May damage fertility. May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.
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SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
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Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Fluorine compounds
Nitrogen oxides (NO_x)

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Evacuate personnel to safe areas.
Only trained personnel should re-enter the area.
Remove all sources of ignition.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Non-sparking tools should be used.

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Soak up with inert absorbent material.
Suppress (knock down) gases/vapours/mists with a water spray jet.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- | | | |
|-------------------------|---|--|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment. |
| Advice on safe handling | : | Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

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7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Flammable liquids
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures, which in contact with water, emit flammable gases
Explosives
Gases
Very acutely toxic substances and mixtures

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	TWA	40 µg/m ³ (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	400 µg/100 cm ²	Internal
Propan-2-ol	67-63-0	STEL	500 ppm 1,250 mg/m ³	GB EH40
		TWA	400 ppm 999 mg/m ³	GB EH40

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
2-Pyrrolidone	Workers	Inhalation	Long-term systemic	57.8 mg/m ³

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			effects	
	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	277 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	17.1 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	167 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	5.2 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	33.3 mg/kg bw/day
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m ³
	Workers	Inhalation	Acute systemic effects	110 mg/m ³
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5.4 mg/m ³
	Consumers	Inhalation	Acute systemic effects	27 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	20 mg/kg bw/day
L-Menthol	Workers	Inhalation	Long-term systemic effects	132 mg/m ³
	Workers	Skin contact	Long-term systemic effects	19 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	33 mg/m ³
	Workers	Inhalation	Long-term local effects	10 mg/m ³
	Consumers	Inhalation	Long-term local effects	1.7 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	9.4 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	9.4 mg/kg bw/day
Propan-2-ol	Workers	Inhalation	Long-term systemic effects	500 mg/m ³
	Workers	Skin contact	Long-term systemic effects	888 mg/kg

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			effects	bw/day
	Consumers	Inhalation	Long-term systemic effects	89 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	319 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	26 mg/kg bw/day

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Decanoic acid, mixed diesters with octanoic acid and propylene glycol	Soil	0.2638 mg/kg
	Fresh water	0.5 mg/l
	Freshwater - intermittent	0.5 mg/l
	Marine water	0.05 mg/l
	Sewage treatment plant	10 mg/l
2-Pyrrolidone	Fresh water sediment	0.4205 mg/kg dry weight (d.w.)
	Soil	0.0612 mg/kg dry weight (d.w.)
	Fresh water	1 mg/l
	Marine water	0.1 mg/l
	Intermittent use/release	2.3 mg/l
Benzyl alcohol	Sewage treatment plant	39 mg/l
	Fresh water sediment	5.27 mg/kg
	Marine sediment	0.527 mg/kg
	Soil	0.456 mg/kg
	Fresh water	15.6 µg/l
L-Menthol	Marine water	1.56 µg/l
	Intermittent use/release	156 µg/l
	Sewage treatment plant	2.37 mg/l
	Fresh water sediment	289 µg/l
	Marine sediment	28.9 µg/l
Propan-2-ol	Soil	48.4 µg/l
	Fresh water	140.9 mg/l
	Marine water	140.9 mg/l
	Intermittent use/release	140.9 mg/l
	Sewage treatment plant	2251 mg/l
	Fresh water sediment	552 mg/kg dry weight (d.w.)
	Marine sediment	552 mg/kg dry weight (d.w.)
	Soil	28 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	160 mg/kg food

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

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All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	liquid
Colour	:	yellow
Odour	:	mint-like
Odour Threshold	:	No data available
pH	:	8.0
Melting point/freezing point	:	< -20 °C
Initial boiling point and boiling range	:	No data available
Flash point	:	43.33 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable

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Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1.05 g/cm ³
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids)	:	No data available
Molecular weight	:	No data available
Particle size	:	Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	Flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
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10.4 Conditions to avoid

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Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Harmful if swallowed.
Fatal if inhaled.

Product:

Acute oral toxicity : Acute toxicity estimate: 306.94 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 0.3027 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

2-Pyrrolidone:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

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1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Acute oral toxicity : LD50 (Rat): 53 - 157 mg/kg
LD50 (Mouse): 176 - 249 mg/kg
LD50 (Guinea pig): 488.3 mg/kg
LD50 (Monkey): 300 mg/kg

Acute inhalation toxicity : LC50 (Rat): < 0.52 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute toxicity (other routes of administration) : LD50 (Rat): 59.4 - 185.3 mg/kg
Application Route: Intraperitoneal
LD50 (Mouse): 164 - 363 mg/kg
Application Route: Intraperitoneal

L-Menthol:

Acute inhalation toxicity : LC50 (Rat): 5.289 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg
Method: OECD Test Guideline 402

Propan-2-ol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 25 mg/l
Exposure time: 6 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

2-Pyrrolidone:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Benzyl alcohol:

Species : Rabbit
Method : OECD Test Guideline 404

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Result : No skin irritation

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Species : Rabbit
Result : Mild skin irritation

L-Menthol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Skin irritation

Propan-2-ol:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

2-Pyrrolidone:

Species : Rabbit
Result : Irritation to eyes, reversing within 7 days

Benzyl alcohol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Species : Rabbit
Result : Irreversible effects on the eye

L-Menthol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 7 days

Propan-2-ol:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

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Respiratory sensitisation

Not classified based on available information.

Components:

2-Pyrrolidone:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

Benzyl alcohol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Test Type : Maximisation Test
Exposure routes : Dermal
Species : Guinea pig
Assessment : Does not cause skin sensitisation.
Result : negative

L-Menthol:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative

Propan-2-ol:

Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

2-Pyrrolidone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative

Benzyl alcohol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: in vitro assay
Test system: mouse lymphoma cells
Result: positive

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: positive

Test Type: in vitro assay
Test system: Escherichia coli
Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

L-Menthol:

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Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

Propan-2-ol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

2-Pyrrolidone:

Species : Mouse
Application Route : Ingestion
Exposure time : 18 month(s)
Result : negative
Remarks : Based on data from similar materials

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Method : OECD Test Guideline 451
Result : negative

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Species : Rat
Application Route : oral (feed)
Exposure time : 104 w
LOAEL : 2 mg/kg body weight
Result : negative

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Target Organs : Gastrointestinal tract
Remarks : Significant toxicity observed in testing

Species : Mouse
Application Route : oral (feed)
Exposure time : 97 w
NOAEL : 0.6 mg/kg body weight
Result : negative
Target Organs : Gastrointestinal tract
Remarks : Significant toxicity observed in testing

L-Menthol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Method : OECD Test Guideline 453
Result : negative
Remarks : Based on data from similar materials

Propan-2-ol:

Species : Rat
Application Route : inhalation (vapour)
Exposure time : 104 weeks
Method : OECD Test Guideline 451
Result : negative

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

2-Pyrrolidone:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: positive
Remarks: Based on data from similar materials

Effects on foetal develop-ment : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: positive

Reproductive toxicity - As-sessment : Clear evidence of adverse effects on sexual function and fertil-ity, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat

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Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
General Toxicity - Parent: LOAEL: 1 - 1.5 mg/kg body weight
Symptoms: No foetal abnormalities
Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 2 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 2 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
General Toxicity Maternal: LOAEL: 3 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 3 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

L-Menthol:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Propan-2-ol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

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STOT - single exposure

Not classified based on available information.

Components:

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Assessment : May cause respiratory irritation.

Propan-2-ol:

Assessment : May cause drowsiness or dizziness.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Target Organs : Gastrointestinal tract, Kidney, Blood
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

2-Pyrrolidone:

Species : Rat
NOAEL : 207 mg/kg
Application Route : Ingestion
Exposure time : 3 Months
Method : OECD Test Guideline 408

Benzyl alcohol:

Species : Rat
NOAEL : 1.072 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 28 Days
Method : OECD Test Guideline 412

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Species : Rat
NOAEL : 2 mg/kg
LOAEL : < 4 mg/kg
Application Route : Oral
Exposure time : 6 w
Target Organs : Gastrointestinal tract

Species : Rat
NOAEL : 1 mg/kg
Application Route : Oral

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Exposure time : 1 y
Target Organs : Gastrointestinal tract, Kidney

Species : Monkey
NOAEL : 15 mg/kg
Application Route : Oral
Exposure time : 90 d
Target Organs : Gastrointestinal tract, Blood

Species : Rabbit
LOAEL : 80 mg/kg
Application Route : Dermal
Exposure time : 21 d
Symptoms : Severe irritation

Species : Dog
LOAEL : 11 mg/kg
Application Route : Oral
Exposure time : 9 d
Target Organs : Gastrointestinal tract
Symptoms : Vomiting

L-Menthol:

Species : Mouse
NOAEL : 1,250 mg/kg
Application Route : Ingestion
Exposure time : 91 Days
Method : OECD Test Guideline 408
Remarks : Based on data from similar materials

Propan-2-ol:

Species : Rat
NOAEL : 12.5 mg/l
Application Route : inhalation (vapour)
Exposure time : 104 Weeks

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Inhalation : Symptoms: respiratory tract irritation
Skin contact : Symptoms: Skin irritation
Eye contact : Symptoms: Severe irritation
Ingestion : Symptoms: Gastrointestinal disturbance, bleeding, hypertension, Kidney disorders

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SECTION 12: Ecological information

12.1 Toxicity

Components:

2-Pyrrolidone:

- Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h
- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h
- EC10 (Desmodesmus subspicatus (green algae)): 22.2 mg/l
Exposure time: 72 h
- Toxicity to microorganisms : EC50 : > 1,000 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

Benzyl alcohol:

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 51 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

- Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 28 mg/l
Exposure time: 96 h
Method: FDA 4.11

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LC50 (Oncorhynchus mykiss (rainbow trout)): 5.5 mg/l
Exposure time: 96 h
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 15 mg/l
Exposure time: 48 h
Method: FDA 4.08

Toxicity to algae/aquatic plants : NOEC (Microcystis aeruginosa (blue-green algae)): 97 mg/l
Exposure time: 13 d
Method: FDA 4.01

NOEC (Selenastrum capricornutum (green algae)): 96 mg/l
Exposure time: 12 d

L-Menthol:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 15.6 mg/l
Exposure time: 96 h
Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 26.6 mg/l
Exposure time: 48 h
Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): 21.4 mg/l
Exposure time: 72 h
Method: Directive 67/548/EEC, Annex V, C.3.

NOEC (Desmodesmus subspicatus (green algae)): 9.65 mg/l
Exposure time: 72 h
Method: Directive 67/548/EEC, Annex V, C.3.

Toxicity to microorganisms : EC50 : 237 mg/l
Exposure time: 96 h
Test Type: Respiration inhibition of activated sludge
Method: OECD Test Guideline 209

Propan-2-ol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 24 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 1,050 mg/l
Exposure time: 16 h

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12.2 Persistence and degradability

Components:

2-Pyrrolidone:

Biodegradability : Result: Readily biodegradable.
Remarks: Based on data from similar materials

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Stability in water : Hydrolysis: 0 %(28 d)

L-Menthol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 64 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

Propan-2-ol:

Biodegradability : Result: rapidly degradable

BOD/COD : BOD: 1,19 (BOD5)
COD: 2,23
BOD/COD: 53 %

12.3 Bioaccumulative potential

Components:

2-Pyrrolidone:

Partition coefficient: n-octanol/water : log Pow: -0.71
Method: OECD Test Guideline 107

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Partition coefficient: n-octanol/water : log Pow: 1.34

L-Menthol:

Bioaccumulation : Species: Cyprinus carpio (Carp)
Exposure time: 6 Weeks
Bioconcentration factor (BCF): 0.5 - 15
Method: OECD Test Guideline 305

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Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: 3.15

Propan-2-ol:

Partition coefficient: n-octanol/water : log Pow: 0.05

12.4 Mobility in soil

Components:

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Distribution among environmental compartments : log Koc: 1.92

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

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ADN : UN 1993
ADR : UN 1993
RID : UN 1993
IMDG : UN 1993
IATA : UN 1993

14.2 UN proper shipping name

ADN : FLAMMABLE LIQUID, N.O.S.
(Propan-2-ol)
ADR : FLAMMABLE LIQUID, N.O.S.
(Propan-2-ol)
RID : FLAMMABLE LIQUID, N.O.S.
(Propan-2-ol)
IMDG : FLAMMABLE LIQUID, N.O.S.
(Propan-2-ol)
IATA : Flammable liquid, n.o.s.
(Propan-2-ol)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 3	
ADR	: 3	
RID	: 3	
IMDG	: 3	
IATA	: 3	

14.4 Packing group

ADN
Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3

ADR
Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3
Tunnel restriction code : (D/E)

RID
Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3

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IMDG

Packing group : III
Labels : 3
EmS Code : F-E, S-E

IATA (Cargo)

Packing instruction (cargo aircraft) : 366
Packing instruction (LQ) : Y344
Packing group : III
Labels : Flammable Liquids

IATA (Passenger)

Packing instruction (passenger aircraft) : 355
Packing instruction (LQ) : Y344
Packing group : III
Labels : Flammable Liquids

14.5 Environmental hazards

ADN

Environmentally hazardous : no

ADR

Environmentally hazardous : no

RID

Environmentally hazardous : no

IMDG

Marine pollutant : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the following entries should be considered:
Number on list 3
Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the

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restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable
Control of Major Accident Hazards Regulations 2015 (COMAH)

		Quantity 1	Quantity 2
H2	ACUTE TOXIC	50 t	200 t
P5c	FLAMMABLE LIQUIDS	5,000 t	50,000 t

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H225 : Highly flammable liquid and vapour.

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H301	: Toxic if swallowed.
H302	: Harmful if swallowed.
H315	: Causes skin irritation.
H318	: Causes serious eye damage.
H319	: Causes serious eye irritation.
H330	: Fatal if inhaled.
H332	: Harmful if inhaled.
H335	: May cause respiratory irritation.
H336	: May cause drowsiness or dizziness.
H360FD	: May damage fertility. May damage the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure.
H411	: Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Eye Dam.	: Serious eye damage
Eye Irrit.	: Eye irritation
Flam. Liq.	: Flammable liquids
Repr.	: Reproductive toxicity
Skin Irrit.	: Skin irritation
STOT RE	: Specific target organ toxicity - repeated exposure
STOT SE	: Specific target organ toxicity - single exposure
GB EH40	: UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	: Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	: Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Re-

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striction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

Flam. Liq. 3	H226
Acute Tox. 4	H302
Acute Tox. 2	H330
Eye Dam. 1	H318
Repr. 1B	H360FD
STOT RE 1	H372
Aquatic Chronic 3	H412

Classification procedure:

Based on product data or assessment
Calculation method
Calculation method
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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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