

Flunixin Liquid (with Alcohol) Formulation

Version 6.0 Revision Date: 06.07.2024 SDS Number: 1004392-00021 Date of last issue: 06.04.2024
Date of first issue: 28.10.2016

SECTION 1. IDENTIFICATION

Product name : Flunixin Liquid (with Alcohol) Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Flammable liquids : Category 3

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 2

Serious eye damage/eye
irritation : Category 1

Reproductive toxicity : Category 1B

Specific target organ toxicity -
repeated exposure : Category 1 (Gastrointestinal tract, Kidney, Blood)





Short-term (acute) aquatic
hazard : Category 3

Long-term (chronic) aquatic
hazard : Category 3

GHS label elements

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Hazard pictograms	:	   
Signal Word	:	Danger
Hazard Statements	:	H226 Flammable liquid and vapor. 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 (Gastrointestinal tract, Kidney, Blood) through prolonged or repeated exposure. H412 Harmful to aquatic life with long lasting effects.
Precautionary Statements	:	Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. P284 Wear respiratory protection. Response: P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. 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. P308 + P313 IF exposed or concerned: Get medical advice/ attention. Storage: P405 Store locked up. Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.

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Other hazards which do not result in classification

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
2-Pyrrolidone	616-45-5	>= 30 -< 50
Benzyl alcohol	100-51-6	>= 20 -< 30
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	>= 10 -< 20
L-Menthol	2216-51-5	>= 10 -< 20
Propan-2-ol	67-63-0	>= 5 -< 10

SECTION 4. 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.
- 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.
- Most important symptoms and effects, both acute and delayed : 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.
- 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).
- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

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Unsuitable extinguishing media	:	Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical High volume water jet
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. Vapors 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)
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.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	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).
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. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapors/mists with a water spray jet. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

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Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

- 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 vapors.
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.
- Conditions for safe storage : Keep in properly labeled 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.
- Materials to avoid : 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis
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		exposure)	concentration	
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	CMP	400 ppm	AR OEL
		CMP - CPT	500 ppm	AR OEL
		TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam-pling time	Permissible concentra-tion	Basis
Propan-2-ol	67-63-0	Acetone	Urine		2 mg/g creatinine	AR BEI
		Acetone	Urine	End of shift at end of work-week	40 mg/l	ACGIH BEI

Engineering measures

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

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
 - Filter type : Combined particulates and organic vapor type
- 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.
- Eye 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

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Skin and body protection	:	<p>potential for direct contact to the face with dusts, mists, or aerosols.</p> <p>Work uniform or laboratory coat.</p> <p>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.</p> <p>Use appropriate degowning techniques to remove potentially contaminated clothing.</p>
Hygiene measures	:	<p>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</p> <p>When using do not eat, drink or smoke.</p> <p>Wash contaminated clothing before re-use.</p> <p>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.</p>

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	yellow
Odor	:	mint-like
Odor 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
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available

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Relative density : No data available

Density : 1,05 g/cm³

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Autoignition 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.

Molecular weight : No data available

Particle characteristics
Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Flammable liquid and vapor.
Vapors may form explosive mixture with air.
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

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Acute inhalation toxicity : Acute toxicity estimate: 0,301 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

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

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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: vapor
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
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

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

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

Propan-2-ol:

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

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

2-Pyrrolidone:

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

Benzyl alcohol:

Test Type : Maximization Test
 Routes of exposure : 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 : Maximization Test
 Routes of exposure : Dermal
 Species : Guinea pig
 Assessment : Does not cause skin sensitization.
 Result : negative

L-Menthol:

Test Type : Local lymph node assay (LLNA)
 Routes of exposure : Skin contact

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Species : Mouse
 Method : OECD Test Guideline 429
 Result : negative

Propan-2-ol:

Test Type : Buehler Test
 Routes of exposure : 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

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 test
 Test system: mouse lymphoma cells

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

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)

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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
 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 (vapor)
 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

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Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Ingestion
 Result: positive

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, 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
 Application Route: Ingestion
 Result: negative
 Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal 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 fetal abnormalities.
 Result: No effects on fertility and early embryonic development were detected.

Effects on fetal development : Test Type: Development
 Species: Rat
 Application Route: Oral
 General Toxicity Maternal: LOAEL: 2 mg/kg body weight
 Embryo-fetal 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-fetal development
 Species: Rabbit
 Application Route: Oral
 General Toxicity Maternal: LOAEL: 3 mg/kg body weight
 Embryo-fetal 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 fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Ingestion

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Result: negative

Propan-2-ol:

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

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

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 (Gastrointestinal tract, Kidney, Blood) 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

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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
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 (vapor)
Exposure time : 104 Weeks

Aspiration toxicity

Not classified based on available information.

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 Date of first issue: 28.10.2016

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

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	:	NOEC (Daphnia magna (Water flea)): 51 mg/l

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aquatic invertebrates (Chronic toxicity) Exposure time: 21 d
 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

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

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Exposure time: 16 h

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 %

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)
Bioconcentration factor (BCF): 0,5 - 15
Exposure time: 6 Weeks

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Method: OECD Test Guideline 305
 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

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

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.

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

International Regulations

UNRTDG

UN number : UN 1993
 Proper shipping name : FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)
 Class : 3
 Packing group : III
 Labels : 3
 Environmentally hazardous : no

IATA-DGR

UN/ID No. : UN 1993
 Proper shipping name : Flammable liquid, n.o.s. (Propan-2-ol)
 Class : 3
 Packing group : III
 Labels : Flammable Liquids
 Packing instruction (cargo) : 366

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aircraft)
Packing instruction (passenger aircraft) : 355

IMDG-Code

UN number : UN 1993
Proper shipping name : FLAMMABLE LIQUID, N.O.S.
(Propan-2-ol)
Class : 3
Packing group : III
Labels : 3
EmS Code : F-E, S-E
Marine pollutant : no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

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.

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry : Not applicable

Control of precursors and essential chemicals for the preparation of drugs : Propan-2-ol

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 06.07.2024
Date format : dd.mm.yyyy

Further information

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

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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Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
AR BEI	:	Argentina. Biological Exposure Indices
AR OEL	:	Argentina. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
AR OEL / CMP	:	TLV (Threshold Limit Value)
AR OEL / CMP - CPT	:	STEL (Short Term Limit Value)

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; KECl - 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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 Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - 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; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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