# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

# Florfenicol / Flunixin Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
|---|---|---|---|
| 3.12 | 28.09.2024 | 28043-00027 | Date of first issue: 04.11.2014 |

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

### 1.1 Product identifier

Trade name : Florfenicol / Flunixin Formulation

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

### 1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

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)**

| | |
|---|---|
| Acute toxicity, Category 4 | H332: Harmful if inhaled. |
| Eye irritation, Category 2 | H319: Causes serious eye irritation. |
| 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. |
| Short-term (acute) aquatic hazard, Category 1 | H400: Very toxic to aquatic life. |
| Long-term (chronic) aquatic hazard, Category 1 | H410: Very toxic to aquatic life with long lasting effects. |

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :

Signal word : Danger

Hazard statements :

| | |
|---|---|
| H319 | Causes serious eye irritation. |
| H332 | Harmful if inhaled. |
| H360FD | May damage fertility. May damage the unborn child. |
| H372 | Causes damage to organs through prolonged or repeated exposure. |
| H410 | Very toxic to aquatic life with long lasting effects. |

Precautionary statements :

**Prevention:**

| | |
|---|---|
| P201 | Obtain special instructions before use. |
| P273 | Avoid release to the environment. |
| P280 | Wear protective gloves/ protective clothing/ eye protection/ face protection. |

**Response:**

| | |
|---|---|
| P308 + P313 | IF exposed or concerned: Get medical advice/ attention. |
| P337 + P313 | If eye irritation persists: Get medical advice/ attention. |
| P391 | Collect spillage. |

**Hazardous components which must be listed on the label:**

2-Pyrrolidone
Florfenicol
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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

**Components**

| Chemical name | CAS-No. | Classification | Concentration |
|---|---|---|---|

| | EC-No.<br>Index-No.<br>Registration number | | (% w/w) |
|---|---|---|---|
| Florfenicol | 73231-34-2 | Repr. 2; H361fd<br>STOT RE 1; H372 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder)<br>Aquatic Acute 1; H400<br>Aquatic Chronic 1; H410<br>---<br>M-Factor (Acute aquatic toxicity): 10<br>M-Factor (Chronic aquatic toxicity): 10 | >= 20 - < 25 |
| 2-Pyrrolidone | 616-45-5<br>210-483-1 | Eye Irrit. 2; H319<br>Repr. 1B; H360FD<br>---<br>specific concentration limit<br>Repr. 1B; H360FD<br>> 3 % | >= 20 - < 30 |
| Malic Acid | 6915-15-7<br>230-022-8 | Eye Irrit. 2; H319 | >= 1 - < 10 |
| 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate | 42461-84-7<br>255-836-0 | Acute Tox. 3; H301<br>Acute Tox. 2; H330<br>Eye Dam. 1; H318<br>STOT SE 3; H335<br>STOT RE 1; H372 (Gastrointestinal tract, Kidney, Blood)<br>Aquatic Chronic 2; H411 | >= 1 - < 2.5 |

For explanation of abbreviations see section 16.

## 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.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention. |
| In case of skin contact | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person. |

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

| | | |
|---|---|---|
| Risks | : | Causes serious eye irritation.<br>Harmful if inhaled.<br>May damage fertility. May damage the unborn child.<br>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. |

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | None known. |

### 5.2 Special hazards arising from the substance or mixture

| | | |
|---|---|---|
| Specific hazards during fire-fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion prod- | : | Carbon oxides |

ucts

Fluorine compounds
Nitrogen oxides (NOx)

### 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 : Use personal protective equipment.
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.
Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
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. |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe mist or vapours.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Do not eat, drink or smoke when using this product.<br>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.<br>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. |

### 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. |
| Advice on common storage | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases |

### 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 | Control parameters | Basis |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| | | of exposure) | | |
| Florfenicol | 73231-34-2 | TWA | 100 µg/m3 (OEB 2) | Internal |
| 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate | 42461-84-7 | TWA | 40 µg/m3 (OEB 3) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 400 µg/100 cm² | Internal |

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006**

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|---|---|---|---|---|
| triacetin | Workers | Inhalation | Long-term systemic effects | 35.275 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 5 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 8.7 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 2.5 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 2.5 mg/kg bw/day |
| 2-Pyrrolidone | Workers | Inhalation | Long-term systemic effects | 57.8 mg/m3 |
| | 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/m3 |
| | 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 |
| Malic Acid | Workers | Inhalation | Long-term systemic effects | 36.6 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 5.2 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 9 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 2.6 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 2.6 mg/kg bw/day |

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006**

| Substance name | Environmental Compartment | Value |
|---|---|---|
| triacetin | Fresh water | 1.88 mg/l |
| | Marine water | 0.188 mg/l |
| | Intermittent use/release | 1 mg/l |
| | Sewage treatment plant | 1088 mg/l |
| | Fresh water sediment | 4.73 mg/kg |
| | Marine sediment | 0.47 mg/kg |
| | Soil | 0.57 mg/kg |
| | Oral (Secondary Poisoning) | 69.9 mg/kg food |
| 2-Pyrrolidone | Fresh water | 0.5 mg/l |
| | Freshwater - intermittent | 0.5 mg/l |
| | Marine water | 0.05 mg/l |
| | Sewage treatment plant | 10 mg/l |
| | Fresh water sediment | 0.4205 mg/kg dry weight (d.w.) |
| | Soil | 0.0612 mg/kg dry weight (d.w.) |

## 8.2 Exposure controls

### 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.

### 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.

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 I.S. 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

| | | |
|---|---|---|
| Physical state | : | liquid |
| Colour | : | yellow |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | 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 |
| Flash point | : | No data available |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Vapour pressure | : | No data available |
| Relative density | : | 1.22 |

| | | |
|---|---|---|
| Density | : | No data available |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle size | : | Not applicable |

**9.2 Other information**

| | | |
|---|---|---|
| Explosives | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Evaporation rate | : | No data available |
| Molecular weight | : | No data available |

## 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 : Can react with strong oxidizing agents.

**10.4 Conditions to avoid**

Conditions to avoid : None known.

**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 hazard classes as defined in Regulation (EC) No 1272/2008**

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

**Acute toxicity**

Harmful if inhaled.

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: > 2,000 mg/kg<br>Method: Calculation method |
| Acute inhalation toxicity | : | Acute toxicity estimate: 2.28 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: Calculation method |

**Components:**

**Florfenicol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 2,000 mg/kg<br><br>LD50 (Mouse): > 2,000 mg/kg<br><br>LD50 (Dog): > 1,280 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 0.28 mg/l<br>Exposure time: 4 h |
| Acute dermal toxicity | : | Remarks: No data available |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 1,913 - 2,253 mg/kg<br>Application Route: Intraperitoneal<br><br>LD50 (Mouse): 100 mg/kg<br>Application Route: Intravenous |

**2-Pyrrolidone:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Method: OECD Test Guideline 401<br>Assessment: The substance or mixture has no acute oral toxicity |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg<br>Method: OECD Test Guideline 402<br>Assessment: The substance or mixture has no acute dermal toxicity |

**Malic Acid:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 3,500 mg/kg |
| Acute dermal toxicity | : | LD50 (Rabbit): > 5,000 mg/kg<br>Remarks: Based on data from similar materials |

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

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 53 - 157 mg/kg<br><br>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

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Florfenicol:**

Species : Rabbit
Result : No skin irritation

**2-Pyrrolidone:**

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

**Malic Acid:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

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

Species : Rabbit
Result : Mild skin irritation

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:**

**Florfenicol:**

Species : Rabbit
Result : Mild eye irritation

**2-Pyrrolidone:**

Species : Rabbit

Result : Irritation to eyes, reversing within 7 days

**Malic Acid:**

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days
Remarks : Based on data from similar materials

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

Species : Rabbit
Result : Irreversible effects on the eye

**Respiratory or skin sensitisation**

**Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

**Florfenicol:**

Test Type : Maximisation Test
Species : Guinea pig
Result : negative

**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

**Malic Acid:**

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

**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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Florfenicol:**

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

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: rat hepatocytes
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

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

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

**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

**Malic Acid:**

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
Result: negative
Remarks: Based on data from similar materials

**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.

**Carcinogenicity**

Not classified based on available information.

**Components:**

**Florfenicol:**

| | | |
|---|---|---|
| Species | : | Rat |
| Application Route | : | oral (gavage) |
| Exposure time | : | 2 Years |
| Result | : | negative |
| Target Organs | : | Liver, Testes |

| | | |
|---|---|---|
| Species | : | Mouse |
| Application Route | : | oral (gavage) |
| Exposure time | : | 2 Years |
| Result | : | negative |
| Target Organs | : | Testes, Blood |

**2-Pyrrolidone:**

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

**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 |

**Reproductive toxicity**

May damage fertility. May damage the unborn child.

**Components:**

**Florfenicol:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Oral<br>Fertility: LOAEL: 12 mg/kg body weight<br>Result: decreased pup survival, reduced lactation |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>General Toxicity Maternal: NOAEL: 4 mg/kg body weight<br>Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight<br>Result: No teratogenic effects, Fetotoxicity<br>Remarks: The effects were seen only at maternally toxic doses.<br><br>Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: oral (gavage)<br>General Toxicity Maternal: NOAEL: 120 mg/kg body weight<br>Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight<br>Result: Fetotoxicity |

| | | |
|---|---|---|
| Reproductive toxicity - Assessment | : | Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments. |

**2-Pyrrolidone:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: positive<br>Remarks: Based on data from similar materials |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>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. |

**Malic Acid:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>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<br>Species: Rat<br>Application Route: Oral<br>General Toxicity - Parent: LOAEL: 1 - 1.5 mg/kg body weight<br>Symptoms: No foetal abnormalities<br>Result: No effects on fertility and early embryonic development were detected. |
| Effects on foetal development | : | Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>General Toxicity Maternal: LOAEL: 2 mg/kg body weight<br>Embryo-foetal toxicity: NOAEL: 2 mg/kg body weight<br>Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses<br><br>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 off-spring were detected only at high maternally toxic doses

**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.

**STOT - repeated exposure**

Causes damage to organs through prolonged or repeated exposure.

**Components:**

**Florfenicol:**

Target Organs : Liver, Brain, Testis, Spinal cord, Blood, gallbladder
Assessment : Causes damage to organs through prolonged or repeated exposure.

**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:**

**Florfenicol:**

Species : Dog
NOAEL : 3 mg/kg
Exposure time : 13 Weeks
Target Organs : Liver, Testis, Brain, Spinal cord

Species : Mouse
NOAEL : 200 mg/kg
Exposure time : 13 Weeks
Target Organs : Liver, Testis

Species : Rat
NOAEL : 30 mg/kg
Exposure time : 13 Weeks
Target Organs : Liver, Testis

Species : Dog

| | | |
|---|---|---|
| NOAEL | : | 3 mg/kg |
| LOAEL | : | 12 mg/kg |
| Exposure time | : | 52 Weeks |
| Target Organs | : | Liver, gallbladder |

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 1 mg/kg |
| LOAEL | : | 3 mg/kg |
| Exposure time | : | 52 Weeks |
| Target Organs | : | Testis |

**2-Pyrrolidone:**

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

**Malic Acid:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | > 250 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 104 Weeks |

**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 |

**Aspiration toxicity**

Not classified based on available information.

### 11.2 Information on other hazards

**Endocrine disrupting properties**

**Product:**

| | | |
|---|---|---|
| Assessment | : | The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. |

**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

### 12.1 Toxicity

**Components:**

**Florfenicol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Lepomis macrochirus (Bluegill sunfish)): > 830 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11<br><br>LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 330 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 2.9 mg/l |

Exposure time: 14 d
Method: FDA 4.01

NOEC (Pseudokirchneriella subcapitata (green algae)): 2.9 mg/l
Exposure time: 14 d
Method: FDA 4.01

IC50 (Skeletonema costatum (marine diatom)): 0.0336 mg/l
Exposure time: 72 h
Method: ISO 10253

NOEC (Skeletonema costatum (marine diatom)): 0.00423 mg/l
Exposure time: 72 h
Method: ISO 10253

EC50 (Lemna gibba (gibbous duckweed)): 0.76 mg/l
Exposure time: 7 d
Method: OECD Test Guideline 221

NOEC (Lemna gibba (gibbous duckweed)): 0.39 mg/l
Exposure time: 7 d
Method: OECD Test Guideline 221

EC50 (Navicula pelliculosa (Freshwater diatom)): 61 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Navicula pelliculosa (Freshwater diatom)): 19 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae): 0.066 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 0.051 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 10

Toxicity to fish (Chronic toxicity) : NOEC: 5.5 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1.5 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

**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

**Malic Acid:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 240 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test substance: Neutralised product
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Test substance: Neutralised product
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50 : > 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

**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

### 12.2 Persistence and degradability

**Components:**

**2-Pyrrolidone:**

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

**Malic Acid:**

Biodegradability : Result: Readily biodegradable.
Method: OECD Test Guideline 301C
Remarks: Based on data from similar materials

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

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

### 12.3 Bioaccumulative potential

**Components:**

**Florfenicol:**

Partition coefficient: n-octanol/water : log Pow: 0.373
pH: 7

**2-Pyrrolidone:**

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

**Malic Acid:**

Partition coefficient: n-octanol/water : log Pow: -1.26

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

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

### 12.4 Mobility in soil

**Components:**

**Florfenicol:**

Distribution among environmental compartments : Koc: 52
Method: FDA 3.08

**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 Endocrine disrupting properties

**Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

## 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.
If not otherwise specified: Dispose of as unused product.

## SECTION 14: Transport information

### 14.1 UN number or ID number

| | | |
|---|---|---|
| **ADN** | : | UN 3082 |
| **ADR** | : | UN 3082 |
| **RID** | : | UN 3082 |
| **IMDG** | : | UN 3082 |
| **IATA** | : | UN 3082 |

**14.2 UN proper shipping name**

| | | |
|---|---|---|
| **ADN** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Florfenicol) |
| **ADR** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Florfenicol) |
| **RID** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Florfenicol) |
| **IMDG** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Florfenicol) |
| **IATA** | : | Environmentally hazardous substance, liquid, n.o.s.<br>(Florfenicol) |

**14.3 Transport hazard class(es)**

| | | Class | Subsidiary risks |
|---|---|---|---|
| **ADN** | : | 9 | |
| **ADR** | : | 9 | |
| **RID** | : | 9 | |
| **IMDG** | : | 9 | |
| **IATA** | : | 9 | |

**14.4 Packing group**

**ADN**

| | | |
|---|---|---|
| Packing group | : | III |
| Classification Code | : | M6 |
| Hazard Identification Number | : | 90 |
| Labels | : | 9 |

**ADR**

| | | |
|---|---|---|
| Packing group | : | III |
| Classification Code | : | M6 |
| Hazard Identification Number | : | 90 |
| Labels | : | 9 |
| Tunnel restriction code | : | (-) |

**RID**

| | | |
|---|---|---|
| Packing group | : | III |

| | | |
|---|---|---|
| Classification Code | : | M6 |
| Hazard Identification Number | : | 90 |
| Labels | : | 9 |

**IMDG**

| | | |
|---|---|---|
| Packing group | : | III |
| Labels | : | 9 |
| EmS Code | : | F-A, S-F |

**IATA (Cargo)**

| | | |
|---|---|---|
| Packing instruction (cargo aircraft) | : | 964 |
| Packing instruction (LQ) | : | Y964 |
| Packing group | : | III |
| Labels | : | Miscellaneous |

**IATA (Passenger)**

| | | |
|---|---|---|
| Packing instruction (passenger aircraft) | : | 964 |
| Packing instruction (LQ) | : | Y964 |
| Packing group | : | III |
| Labels | : | Miscellaneous |

### 14.5 Environmental hazards

**ADN**
Environmentally hazardous : yes

**ADR**
Environmentally hazardous : yes

**RID**
Environmentally hazardous : yes

**IMDG**
Marine pollutant : yes

**IATA (Passenger)**
Environmentally hazardous : yes

**IATA (Cargo)**
Environmentally hazardous : yes

### 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 Maritime transport in bulk according to IMO instruments

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

| | | |
|---|---|---|
| REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) | : | Conditions of restriction for the following entries should be considered: Number on list 3<br><br>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 restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not. |
| REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). | : | Not applicable |
| Regulation (EC) on substances that deplete the ozone layer | : | Not applicable |
| Regulation (EU) 2019/1021 on persistent organic pollutants (recast) | : | Not applicable |
| Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals | : | Not applicable |
| REACH - List of substances subject to authorisation (Annex XIV) | : | Not applicable |

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

| | | Quantity 1 | Quantity 2 |
|---|---|---|---|
| E1 | ENVIRONMENTAL HAZARDS | 100 t | 200 t |

**Other regulations:**

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

**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**

| | | |
|---|---|---|
| H301 | : | Toxic if swallowed. |
| H318 | : | Causes serious eye damage. |
| H319 | : | Causes serious eye irritation. |
| H330 | : | Fatal if inhaled. |
| H335 | : | May cause respiratory irritation. |
| H360FD | : | May damage fertility. May damage the unborn child. |
| H361fd | : | Suspected of damaging fertility. Suspected of damaging the unborn child. |
| H372 | : | Causes damage to organs through prolonged or repeated exposure. |
| H400 | : | Very toxic to aquatic life. |
| H410 | : | Very toxic to aquatic life with long lasting effects. |
| H411 | : | Toxic to aquatic life with long lasting effects. |

**Full text of other abbreviations**

| | | |
|---|---|---|
| Acute Tox. | : | Acute toxicity |
| Aquatic Acute | : | Short-term (acute) aquatic hazard |
| Aquatic Chronic | : | Long-term (chronic) aquatic hazard |
| Eye Dam. | : | Serious eye damage |
| Eye Irrit. | : | Eye irritation |
| Repr. | : | Reproductive toxicity |
| STOT RE | : | Specific target organ toxicity - repeated exposure |
| STOT SE | : | Specific target organ toxicity - single exposure |

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-

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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; 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:** | | **Classification procedure:** |
|---|---|---|
| Acute Tox. 4 | H332 | Calculation method |
| Eye Irrit. 2 | H319 | Calculation method |
| Repr. 1B | H360FD | Calculation method |
| STOT RE 1 | H372 | Calculation method |
| Aquatic Acute 1 | H400 | Calculation method |
| Aquatic Chronic 1 | H410 | Calculation method |

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.

IE / EN