

**Florfenicol Solid Formulation**

Version 6.0      Revision Date: 04.04.2023      SDS Number: 412403-00017      Date of last issue: 01.10.2022  
Date of first issue: 07.01.2016

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Florfenicol Solid Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification in accordance with ABNT NBR 14725 Standard**

Acute toxicity (Oral) : Category 5

Reproductive toxicity : Category 2

Specific target organ toxicity - : Category 1 (Liver, Brain, Testis, Spinal cord, Blood,  
repeated exposure gallbladder)

Short-term (acute) aquatic : Category 1  
hazard

Long-term (chronic) aquatic : Category 1  
hazard

**GHS label elements in accordance with ABNT NBR 14725 Standard**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H303 May be harmful if swallowed.  
H361fd Suspected of damaging fertility. Suspected of  
damaging the unborn child.

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H372 Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements :

**Prevention:**

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P312 Call a POISON CENTER/ doctor if you feel unwell.

P391 Collect spillage.

**Other hazards which do not result in classification**

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Florfenicol	73231-34-2	Acute toxicity (Oral), Category 5 Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Liver, Brain, Testis, Spinal cord, Blood, gallbladder), Category 1 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	>= 50 -< 70

### 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.

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- In case of skin contact : Get medical attention.  
: 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 : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.  
May be harmful if swallowed.  
Suspected of damaging fertility. Suspected of damaging 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.
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### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)
- 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.
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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
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.

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### SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
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.
- Conditions for safe storage : Keep in properly labeled containers.

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Materials to avoid : Store locked up.  
 Store in accordance with the particular national regulations.  
 : Do not store with the following product types:  
 Strong oxidizing agents  
 Self-reactive substances and mixtures  
 Organic peroxides  
 Explosives  
 Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Florfenicol	73231-34-2	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal

**Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### 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 : Particulates type

Hand protection  
 Material : Chemical-resistant gloves

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 potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : white

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

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Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

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 : Not applicable

Relative density : No data available

Density : No data available

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 : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle size : No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

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Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION**

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

**Acute toxicity**

May be harmful if swallowed.

**Product:**

Acute oral toxicity : Acute toxicity estimate: 5.000 mg/kg  
Method: Calculation method

**Components:****Florfenicol:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg  
LD50 (Mouse): > 2.000 mg/kg  
LD50 (Dog): > 1.280 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 0,28 mg/l  
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  
Application Route: Intraperitoneal  
LD50 (Mouse): 100 mg/kg  
Application Route: Intravenous

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Florfenicol:**

Species : Rabbit  
Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

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**Components:****Florfenicol:**

Species : Rabbit  
Result : Mild eye irritation

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Florfenicol:**

Test Type : Maximization Test  
Species : Guinea pig  
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

**Carcinogenicity**

Not classified based on available information.



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### 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

#### Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

### Components:

#### Florfenicol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Oral  
 Fertility: LOAEL: 12 mg/kg body weight  
 Result: decreased pup survival, reduced lactation

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 General Toxicity Maternal: NOAEL: 4 mg/kg body weight  
 Embryo-fetal toxicity.: LOAEL: 40 mg/kg body weight  
 Result: No teratogenic effects., Fetotoxicity.  
 Remarks: The effects were seen only at maternally toxic doses.

Test Type: Embryo-fetal development  
 Species: Mouse  
 Application Route: oral (gavage)  
 General Toxicity Maternal: NOAEL: 120 mg/kg body weight  
 Embryo-fetal toxicity.: LOAEL: 40 mg/kg body weight  
 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.

#### STOT-single exposure

Not classified based on available information.

#### STOT-repeated exposure

Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.

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### Components:

#### Florfenicol:

Target Organs : Liver, Brain, Testis, Spinal cord, Blood, gallbladder  
 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

### Aspiration toxicity

Not classified based on available information.

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Florfenicol:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 830 mg/l  
 Exposure time: 96 h  
 Method: FDA 4.11  
 LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l

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	Exposure time: 96 h Method: FDA 4.11
Toxicity to daphnia and other aquatic invertebrates	: EC50 ( <i>Daphnia magna</i> (Water flea)): > 330 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): > 2,9 mg/l Exposure time: 14 d Method: FDA 4.01
	NOEC ( <i>Pseudokirchneriella subcapitata</i> (green algae)): 2,9 mg/l Exposure time: 14 d Method: FDA 4.01
	IC50 ( <i>Skeletonema costatum</i> (marine diatom)): 0,0336 mg/l Exposure time: 72 h Method: ISO 10253
	NOEC ( <i>Skeletonema costatum</i> (marine diatom)): 0,00423 mg/l Exposure time: 72 h Method: ISO 10253
	EC50 ( <i>Lemna gibba</i> (gibbous duckweed)): 0,76 mg/l Exposure time: 7 d Method: OECD Test Guideline 221
	NOEC ( <i>Lemna gibba</i> (gibbous duckweed)): 0,39 mg/l Exposure time: 7 d Method: OECD Test Guideline 221
	EC50 ( <i>Navicula pelliculosa</i> (Freshwater diatom)): 61 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	NOEC ( <i>Navicula pelliculosa</i> (Freshwater diatom)): 19 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	EC50 ( <i>Anabaena flos-aquae</i> ): 0,066 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	NOEC ( <i>Anabaena flos-aquae</i> ): 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 ( <i>Pimephales promelas</i> (fathead minnow)): 5,5 mg/l Exposure time: 32 d Method: OECD Test Guideline 210

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1,5 mg/l  
 Exposure time: 21 d  
 Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

### Persistence and degradability

No data available

### Bioaccumulative potential

#### Components:

##### Florfenicol:

Partition coefficient: n-octanol/water : log Pow: 0,373  
 pH: 7

### Mobility in soil

#### Components:

##### Florfenicol:

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

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
 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

### International Regulations

#### UNRTDG

UN number : UN 3077  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Florfenicol)  
 Class : 9  
 Packing group : III  
 Labels : 9

#### IATA-DGR

UN/ID No. : UN 3077  
 Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Florfenicol)

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Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

### IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Florfenicol)

Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

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

Not applicable for product as supplied.

### Domestic regulation

#### ANTT

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Florfenicol)

Class	:	9
Packing group	:	III
Labels	:	9
Hazard Identification Number	:	90

### 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.

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## SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH)	:	Not applicable
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Brazil. List of chemicals controlled by the Federal Police	:	Not applicable
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### The ingredients of this product are reported in the following inventories:

AICS	:	not determined
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DSL : not determined

IECSC : not determined

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**SECTION 16. OTHER INFORMATION**

Revision Date : 04.04.2023  
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.

**Full text of other abbreviations**

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; 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; 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; 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; 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

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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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