

Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.8	30.09.2023	785435-00016	Date of first issue: 28.06.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Orbifloxacin Liquid Formulation

Manufacturer or supplier's details

Company name of supplier	: MSD
Address	: 126 E. Lincoln Avenue Rahway, New Jersey U.S.A. 07065
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

Reproductive toxicity	: Category 2
Specific target organ toxicity - repeated exposure (Oral)	: Category 2 (Eye)

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements	: H361d Suspected of damaging the unborn child. H373 May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.
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Precautionary Statements	: Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe mist or vapors. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention. Storage: P405 Store locked up. Disposal:
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P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Orbifloxacin	113617-63-3	≥ 1 -< 5
Lactic acid	50-21-5	≥ 1 -< 3
Sodium hydroxide	1310-73-2	≥ 1 -< 2

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. Get medical attention.
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	: Flush eyes with water as a precaution. 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	: Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed.
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 Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire	: Exposure to combustion products may be a hazard to health.

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fighting Hazardous combustion products	:	Carbon oxides Metal oxides
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	:	Use personal protective equipment. 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	:	Soak up with inert absorbent material. 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. 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	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe mist or vapors. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Take care to prevent spills, waste and minimize release to the

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- Hygiene measures : environment.
 : 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.
 : Store locked up.
 : Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
 : Strong oxidizing agents
 : 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
Orbifloxacin	113617-63-3	TWA	0.2 mg/m ³ (OEB 2)	Internal
Sodium hydroxide	1310-73-2	VLE-P	2 mg/m ³	NOM-010-STPS-2014
		C	2 mg/m ³	ACGIH

- 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.
 : Laboratory operations do not require special containment.

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 : Chemical-resistant gloves
- 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.

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Color	:	light brown
Odor	:	odorless
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
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
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
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.

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Molecular weight : No data available

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
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

Not classified based on available information.

Product:Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation methodAcute inhalation toxicity : Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method**Components:****Orbifloxacin:**Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg
Remarks: No mortality observed at this dose.LD50 (Mouse): > 2,000 mg/kg
Remarks: No mortality observed at this dose.LD50 (Dog): > 600 mg/kg
Symptoms: Vomiting
Remarks: No mortality observed at this dose.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

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Acute toxicity (other routes of administration) : LD50 (Rat): > 200 mg/kg
Application Route: Intramuscular

LD50 (Mouse): 500 mg/kg
Application Route: Intramuscular

LD50 (Rat): 233 mg/kg
Application Route: Intravenous

LD50 (Mouse): 250 mg/kg
Application Route: Intravenous

Lactic acid:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: Corrosive to the respiratory tract.
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

Sodium hydroxide:

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Skin corrosion/irritation

Not classified based on available information.

Product:

Species : Rabbit
Result : No skin irritation

Components:**Orbifloxacin:**

Species : Rabbit
Method : Draize Test
Result : No skin irritation

Lactic acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Corrosive after 1 to 4 hours of exposure
Remarks : Based on data from similar materials

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Sodium hydroxide:

Result : Corrosive after 3 minutes or less of exposure

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Species : Rabbit
Result : Mild eye irritation

Components:**Orbifloxacin:**

Species : Rabbit
Result : Mild eye irritation
Method : Draize Test

Lactic acid:

Species : Chicken eye
Remarks : Based on data from similar materials
Result : Irreversible effects on the eye

Sodium hydroxide:

Result : Irreversible effects on the eye
Remarks : Based on skin corrosivity.

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Product:

Test Type : Magnusson-Kligman-Test
Routes of exposure : Dermal
Species : Guinea pig
Result : Not a skin sensitizer.

Components:**Orbifloxacin:**

Test Type : Maximization Test
Routes of exposure : Dermal
Species : Guinea pig
Result : Not a skin sensitizer.

Lactic acid:

Test Type : Buehler Test

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Routes of exposure : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

Sodium hydroxide:

Test Type : Human repeat insult patch test (HRIPT)
Routes of exposure : Skin contact
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:**Orbifloxacin:**

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

Test Type: Mouse Lymphoma
Result: positive

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: positive

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

Test Type: unscheduled DNA synthesis assay
Species: Rat
Cell type: Liver cells
Application Route: Oral
Result: negative

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

Lactic acid:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

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

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Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:**Orbifloxacin:**

Species : Rat
Application Route : Oral
Exposure time : 2 Years
NOAEL : 200 mg/kg body weight
Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
NOAEL : 200 mg/kg body weight
Result : negative

Lactic acid:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative
Remarks : Based on data from similar materials

Reproductive toxicity

Suspected of damaging the unborn child.

Components:**Orbifloxacin:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
General Toxicity Parent: NOAEL: 50 mg/kg body weight
Early Embryonic Development: NOAEL: 50 mg/kg body weight
Result: No adverse effects.

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Embryo-fetal toxicity.: LOAEL: 333 mg/kg body weight
Result: No teratogenic effects., 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

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General Toxicity Maternal: NOAEL: 20 mg/kg body weight
Embryo-fetal toxicity.: NOAEL: 60 mg/kg body weight
Result: No effects on early embryonic development.,
Embryotoxic effects and adverse effects on the offspring were
detected only at high maternally toxic doses, Reduced
maternal body weight gain.

Test Type: Development
Species: Dog
Application Route: Oral
Developmental Toxicity: LOAEL: 2.5 mg/kg body weight
Result: Effects on postnatal development., Skeletal
malformations.

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on
animal experiments.

Lactic acid:

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

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.

Product:

Target Organs : Eye
Assessment : May cause damage to organs through prolonged or repeated
exposure.

Repeated dose toxicity**Product:**

Species : Dog
NOAEL : 22.5 mg/kg
LOAEL : 37.5 mg/kg
Application Route : Oral
Exposure time : 30 Days
Symptoms : Gastrointestinal disturbance

Species : Dog
LOAEL : 75 mg/kg
Application Route : Oral
Exposure time : 10 Days
Symptoms : Salivation, Gastrointestinal disturbance, Vomiting

Species : Cat
LOAEL : 45 mg/kg
Application Route : Oral

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Exposure time	:	30 Days
Target Organs	:	Eye
Symptoms	:	Salivation, Lachrymation, Gastrointestinal disturbance, Liver disorders

Components:**Orbifloxacin:**

Species	:	Rat
NOAEL	:	20 mg/kg
LOAEL	:	80 mg/kg
Application Route	:	Oral
Exposure time	:	3 Months
Target Organs	:	Testis, Liver, Kidney, spleen

Species	:	Mouse
NOAEL	:	80 mg/kg
LOAEL	:	250 mg/kg
Application Route	:	Oral
Exposure time	:	3 Months

Species	:	Juvenile dog
NOAEL	:	50 mg/kg
LOAEL	:	250 mg/kg
Application Route	:	Oral
Exposure time	:	14 Days
Target Organs	:	Heart, Bone
Symptoms	:	Gastrointestinal disturbance
Remarks	:	mortality observed

Species	:	Juvenile dog
NOAEL	:	2 mg/kg
LOAEL	:	3 mg/kg
Application Route	:	Oral
Exposure time	:	90 Days
Target Organs	:	Bone
Remarks	:	No significant adverse effects were reported

Species	:	Dog
NOAEL	:	37.5 mg/kg
Application Route	:	Oral
Exposure time	:	30 Days

Species	:	Cat
NOAEL	:	7.5 mg/kg
LOAEL	:	22.5 mg/kg
Application Route	:	Oral
Exposure time	:	1 Months
Symptoms	:	Gastrointestinal disturbance

Lactic acid:

Species	:	Rat
NOAEL	:	> 100 mg/kg
Application Route	:	Ingestion

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Exposure time : 13 Weeks
Remarks : Based on data from similar materials

Species : Rat
LOAEL : 886 mg/kg
Application Route : Skin contact
Exposure time : 13 Weeks

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Orbifloxacin:**

Ingestion : Symptoms: central nervous system effects, Gastrointestinal disturbance, liver function change, anaphylaxis, Rash
Remarks: May cause photosensitization.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Lactic 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)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

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

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

Toxicity to microorganisms : EC50: > 10 - 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

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Persistence and degradability**Components:****Lactic acid:**

Biodegradability : Result: Not readily biodegradable.
Remarks: Based on data from similar materials

Bioaccumulative potential**Components:****Lactic acid:**

Partition coefficient: n- : log Pow: -0.62
octanol/water

Mobility in soil

No data available

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

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation**NOM-002-SCT**

Not regulated as a dangerous good

Special precautions for user

Not applicable

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

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 : 30.09.2023
Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits

ACGIH / C : Ceiling limit
NOM-010-STPS-2014 / VLE- : Ceiling value
P

AIIC - 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

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es; (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

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/>

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8