

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Orbifloxacin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	801075-00019	Date of first issue: 07/15/2016

### SECTION 1. IDENTIFICATION

Product name : Orbifloxacin Solid Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
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@merck.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 in accordance with the Hazardous Products Regulations

Reproductive toxicity : Category 2

#### GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H361d Suspected of damaging the unborn child.

Precautionary Statements :

**Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.

**Storage:**  
P405 Store locked up.

**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

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### Other hazards

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	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Orbifloxacin	No data available	113617-63-3	$\geq 5 - < 10$ *
Magnesium stearate	Octadecanoic acid, magnesium salt (2:1)	557-04-0	$\geq 1 - < 5$ *

\* Actual concentration or concentration range is withheld as a trade secret

### 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 : 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 : Suspected of damaging the unborn child.  
Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.

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<sub>2</sub>)

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Unsuitable extinguishing media	:	Dry chemical 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 (NOx) 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. 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.

### 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.
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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.  
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.  
Take care to prevent spills, waste and minimize release to the environment.  
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

### 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 <sup>3</sup> (OEB 2)	Internal
Magnesium stearate	557-04-0	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV	10 mg/m <sup>3</sup>	CA QC OEL
		TWA (Inhalable)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Respirable)	3 mg/m <sup>3</sup>	CA BC OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH

**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

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Filter type	:	exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Hand protection	:	Particulates type
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.
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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	No data available
Odor	:	No data available
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	:	Not applicable
Evaporation rate	:	No data available
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	:	No data available

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flammability limit

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.

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

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

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

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Ingestion  
Eye contact

### Acute toxicity

Not classified based on available information.

### Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
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

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

#### Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Assessment: The substance or mixture has no acute oral toxicity  
Remarks: Based on data from similar materials

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

### Skin corrosion/irritation

Not classified based on available information.

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### **Components:**

#### **Orbifloxacin:**

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

#### **Magnesium stearate:**

Species	:	Rabbit
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Components:**

#### **Orbifloxacin:**

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

#### **Magnesium stearate:**

Species	:	Rabbit
Result	:	No eye irritation
Remarks	:	Based on data from similar materials

### **Respiratory or skin sensitization**

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

### **Components:**

#### **Orbifloxacin:**

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

#### **Magnesium stearate:**

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

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### 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.

##### **Magnesium stearate:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

### Carcinogenicity

Not classified based on available information.

#### Components:

##### **Orbifloxacin:**

Species : Rat  
Application Route : Oral

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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

### 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  
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.

#### Magnesium stearate:

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Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### 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

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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

### Magnesium stearate:

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

### 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:

#### Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Method: DIN 38412  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l  
Exposure time: 47 h  
Test substance: Water Accommodated Fraction  
Method: Directive 67/548/EEC, Annex V, C.2.  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l

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Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.

NOELR (*Pseudokirchneriella subcapitata* (green algae)): > 1 mg/l

Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (*Pseudomonas putida*): > 100 mg/l  
Exposure time: 16 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

### Persistence and degradability

#### Components:

##### **Magnesium stearate:**

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

### Bioaccumulative potential

#### Components:

##### **Magnesium stearate:**

Partition coefficient: n-octanol/water : log Pow: > 4

##### **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**

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### 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

### TDG

Not regulated as a dangerous good

### Special precautions for user

Not applicable

## SECTION 15. REGULATORY INFORMATION

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

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

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	: Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	: Canada. British Columbia OEL
CA QC OEL	: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for air-borne contaminants
ACGIH / TWA	: 8-hour, time-weighted average
CA AB OEL / TWA	: 8-hour Occupational exposure limit
CA BC OEL / TWA	: 8-hour time weighted average
CA QC OEL / TWA EV	: Time-weighted average exposure value

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

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- 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; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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/>

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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.

CA / Z8