SAFETY DATA SHEET

Albendazole Sulfoxide (1.9%) Formulation

Version 1.2 Revision Date: 02.08.2019 SDS Number: 3903442-00003 Date of last issue: 24.04.2019 Date of first issue: 10.12.2018

Section 1: Identification

Product name: Albendazole Sulfoxide (1.9%) Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 33 Whakatiki Street - Private Bag 908 Upper Hutt - New Zealand
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

Section 2: Hazard identification

GHS Classification
Skin sensitisation: Skin Sens.1

GHS label elements
Hazard pictograms: ⚠️
Signal word: Warning
Hazard statements: H317 May cause an allergic skin reaction.
Precautionary statements:

Prevention:
P261 Avoid breathing mist or vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.
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Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Albendazole Sulfoxide</td>
<td>54029-12-8</td>
<td>&gt;= 1 -&lt; 3</td>
</tr>
</tbody>
</table>

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. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.

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 (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during firefighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)
Sulphur 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 firefighters: 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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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 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.

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 get on skin or clothing. Avoid inhalation of vapour or mist. Do not swallow. Avoid contact with eyes. 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 environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working
Conditions for safe storage: Keep in properly labelled containers. 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

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>WES-TWA (Mist)</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td>Albendazole Sulfoxide</td>
<td>54029-12-8</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: DSEN

Wipe limit 100 µg/100 cm² Internal

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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 vapour 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

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<table>
<thead>
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</tbody>
</table>
SAFETY DATA SHEET

Albendazole Sulfoxide (1.9%) Formulation

<table>
<thead>
<tr>
<th>Appearance</th>
<th>: suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
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<tr>
<td>Odour</td>
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<tr>
<td>Odour Threshold</td>
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</tr>
<tr>
<td>pH</td>
<td>: No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>: No data available</td>
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<tr>
<td>Initial boiling point and boiling range</td>
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</tr>
<tr>
<td>Flash point</td>
<td>: No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
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<tr>
<td>Flammability (solid, gas)</td>
<td>: Not applicable</td>
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<tr>
<td>Flammability (liquids)</td>
<td>: No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
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</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>: No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
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<tr>
<td>Relative vapour density</td>
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</tr>
<tr>
<td>Relative density</td>
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</tr>
<tr>
<td>Density</td>
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<tr>
<td>Solubility(ies)</td>
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</tr>
<tr>
<td>Water solubility</td>
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</tr>
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<td>Partition coefficient: n-octanol/water</td>
<td>: Not applicable</td>
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<tr>
<td>Auto-ignition temperature</td>
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</tr>
<tr>
<td>Decomposition temperature</td>
<td>: No data available</td>
</tr>
<tr>
<td>Viscosity</td>
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<td>Viscosity, kinematic</td>
<td>: No data available</td>
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<tr>
<td>Explosive properties</td>
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<tr>
<td>Oxidizing properties</td>
<td>: The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>: No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Albendazole Sulfoxide (1.9%) Formulation

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
Exposure routes: Inhalation
Skin contact
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:
Glycerine:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Guinea pig): > 5,000 mg/kg

Albendazole Sulfoxide:
Acute oral toxicity: LD50 (Mouse): 1,500 mg/kg
LD50 (Rat): 2,400 mg/kg
Acute toxicity (other routes of administration): LD50 (Rat): 265 mg/kg
Application Route: Intravenous

Skin corrosion/irritation
Not classified based on available information.

Components:
Glycerine:
Species: Rabbit
Result: No skin irritation

Albendazole Sulfoxide:
**SAFETY DATA SHEET**

**Albendazole Sulfoxide (1.9%) Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>02.08.2019</td>
<td>3903442-00003</td>
<td>24.04.2019</td>
<td>10.12.2018</td>
</tr>
</tbody>
</table>

- **Species:** Rabbit
- **Result:** No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

- **Glycerine:**
  - **Species:** Rabbit
  - **Result:** No eye irritation

- **Albendazole Sulfoxide:**
  - **Species:** Rabbit
  - **Result:** No eye irritation

**Respiratory or skin sensitisation**

- **Skin sensitisation**
  May cause an allergic skin reaction.
  
- **Respiratory sensitisation**
  Not classified based on available information.

**Components:**

- **Albendazole Sulfoxide:**
  - **Test Type:** Maximisation Test
  - **Exposure routes:** Dermal
  - **Assessment:** Probability or evidence of low to moderate skin sensitisation rate in humans
  - **Result:** positive

  - **Maximisation Test**
    - **Dermal:** Sensitiser

**Chronic toxicity**

- **Germ cell mutagenicity**
  Not classified based on available information.

**Components:**

- **Glycerine:**
  - **Genotoxicity in vitro**
    - **Test Type:** In vitro mammalian cell gene mutation test
      - **Result:** negative
    - **Test Type:** Bacterial reverse mutation assay (AMES)
      - **Result:** negative
    - **Test Type:** Chromosome aberration test in vitro
      - **Result:** negative
Albendazole Sulfoxide: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Albendazole Sulfoxide:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative

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

Carcinogenicity
Not classified based on available information.

Components:

Glycerine:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Albendazole Sulfoxide:
Species: Mouse
Application Route: Oral
Exposure time: 2 Years
NOAEL: 400 mg/kg body weight
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 2 Years
NOAEL: 20 mg/kg body weight
Result: negative

Carcinogenicity - Assessment: No evidence of carcinogenicity in animal studies.

Reproductive toxicity
Not classified based on available information.

Components:

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

Albendazole Sulfoxide:
Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 30 mg/kg body weight
Result: No effects on fertility

Effects on foetal development: Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: Embryotoxic effects, Skeletal malformations

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 30 mg/kg body weight
Result: Embryotoxic effects, Skeletal malformations, Maternal toxicity observed.

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 5.8 mg/kg body weight
Result: Effects on postnatal development

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 7 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Reproductive toxicity - Assessment: Suspected of damaging the unborn child.

STOT - single exposure
Not classified based on available information.

Components:

Albendazole Sulfoxide:
Exposure routes: Oral
Target Organs: Gastrointestinal tract, Central nervous system
Assessment: May cause damage to organs.

STOT - repeated exposure
Not classified based on available information.
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Components:

Albendazole Sulfoxide:
- Exposure routes: Oral
- Target Organs: Gastrointestinal tract, Central nervous system, Immune system, Liver
- Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Glycerine:
- Species: Rat
- NOAEL: 0.167 mg/l
- LOAEL: 0.622 mg/l
- Application Route: inhalation (dust/mist/fume)
- Exposure time: 13 Weeks

Species: Rat
- NOAEL: 8,000 - 10,000 mg/kg
- Application Route: Ingestion
- Exposure time: 2 yr

Species: Rabbit
- NOAEL: 5,040 mg/kg
- Application Route: Skin contact
- Exposure time: 45 Weeks

Species: Rat
- LOAEL: 168 mg/kg
- Application Route: Oral
- Exposure time: 4 Weeks
- Target Organs: Gastrointestinal tract, Testis
- Symptoms: Diarrhoea, Vomiting

Species: Dog
- LOAEL: 48 mg/kg
- Application Route: Oral
- Exposure time: 4 Weeks
- Target Organs: Gastrointestinal tract
- Symptoms: Diarrhoea, Vomiting

Species: Mouse
- LOAEL: 40 mg/kg
- Application Route: Oral
- Exposure time: 3 Months
- Target Organs: Blood, Liver, Nose
- Symptoms: Hematologic effects, Liver effects

Species: Rat
- LOAEL: >= 30 mg/kg
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Version 1.2
Revision Date: 02.08.2019
SDS Number: 3903442-00003
Date of last issue: 24.04.2019
Date of first issue: 10.12.2018

Application Route: Oral
Exposure time: 6 Months
Target Organs: Blood
Symptoms: Hematologic effects

Species: Dog
LOAEL: 40 mg/kg
Application Route: Oral
Exposure time: 6 Months
Target Organs: Blood, Liver
Symptoms: Hematologic effects, Liver effects

Species: Rat
NOAEL: 7 mg/kg
Application Route: Oral
Exposure time: 60 d
Target Organs: Liver, Testis
Symptoms: Liver effects, male reproductive effects

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Albendazole Sulfoxide:
General Information: Symptoms: Allergic reactions, hair loss, Gastrointestinal disturbance, Headache, Dizziness
Skin contact: Target Organs: Skin
Symptoms: Allergic reactions
Remarks: May cause sensitisation by skin contact.
Ingestion: Target Organs: Gastrointestinal tract
Symptoms: Gastrointestinal disturbance, Diarrhoea, Abdominal pain
Target Organs: Central nervous system
Symptoms: Headache, Dizziness
Target Organs: Liver
Symptoms: liver function change
Target Organs: Immune system
Symptoms: immune system effects

Section 12: Ecological information

Ecotoxicity

Components:

Glycerine:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 1,955 mg/l
Exposure time: 48 h
Toxicity to microorganisms: NOEC (Pseudomonas putida): > 10,000 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8

Albendazole Sulfoxide:

Ecotoxicology Assessment
Acute aquatic toxicity: Toxic effects cannot be excluded
Chronic aquatic toxicity: Toxic effects cannot be excluded

Persistence and degradability

Components:

Glycerine:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 92%
Exposure time: 30 d
Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:

Glycerine:
Partition coefficient: n-octanol/water: log Pow: -1.75

Albendazole Sulfoxide:
Partition coefficient: n-octanol/water: log Pow: 2.7

Mobility in soil
No data available

Other adverse effects
No data available

Section 13: Disposal considerations

Disposal methods
Waste from residues: 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
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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.

National Regulations

NZS 5433
Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

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

Section 16: Other information

Further information
Date format : dd.mm.yyyy

Full text of other abbreviations
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

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

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