

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Interferon Alfa-2b Solid Formulation

Version
8.0

Revision Date:
2025/04/14

SDS Number:
52727-00023

Date of last issue: 2024/12/03
Date of first issue: 2015/02/02

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Interferon Alfa-2b Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : powder
Colour : White to light yellow
Odour : No data available

Causes mild skin irritation. May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

GHS Classification

Skin corrosion/irritation : Category 3

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 2

GHS label elements

Hazard pictograms :



Signal word : Danger

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| | |
|--------------------------|---|
| Hazard statements | : H316 Causes mild skin irritation. H360FD May damage fertility. May damage the unborn child. H373 May cause damage to organs through prolonged or repeated exposure. |
| Precautionary statements | : Prevention: P203 Obtain, read and follow all safety instructions before use. P260 Do not breathe dust. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection. Response: P318 IF exposed or concerned, get medical advice. P332 + P317 If skin irritation occurs: Get medical help. Storage: P405 Store locked up. Disposal: P501 Dispose of contents/ container to an approved waste disposal plant. |

Physical and chemical hazards

Not classified based on available information.

Health hazards

Causes mild skin irritation. May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

Environmental hazards

Not classified based on available information.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--------------------|------------|-----------------------|
| Glycine | 56-40-6 | >= 70 -< 90 |
| Interferon alfa-2b | 98530-12-2 | >= 1 -< 10 |

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

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| | |
|---|---|
| | 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 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 | : Dust contact with the eyes can lead to mechanical irritation. Causes mild skin irritation. May damage fertility. May damage the unborn child. May cause 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. |

5. FIREFIGHTING MEASURES

| | |
|---------------------------------------|---|
| Suitable extinguishing media | : Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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 _x) Metal oxides Phosphorus compounds Oxides of phosphorus Carbon dioxide (CO ₂) |
| 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. |

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Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

7. HANDLING AND STORAGE

Handling

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 : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing. Do not breathe dust. 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. Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use.

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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.

Avoidance of contact : Oxidizing agents

Storage

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
|--------------------|------------|-------------------------------------|--|----------|
| Interferon alfa-2b | 98530-12-2 | TWA | 0.2 µg/m ³ (OEB 5) | Internal |
| | | Wipe limit | 2 µg/100 cm ² | Internal |

Engineering measures : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable. Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. No open handling permitted. Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the

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workplace.

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

Eye/face protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : White to light yellow

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

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| | |
|--|---|
| 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 |
| Vapour pressure | : Not applicable |
| Relative vapour 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 |
| Auto-ignition 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 characteristics | |
| Particle size | : No data available |

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. |

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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. |

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: > 5,000 mg/kg Method: Calculation method |
|---------------------|--|

Components:

Glycine:

| | |
|---------------------|-------------------------------------|
| Acute oral toxicity | : LD50 (Mouse, female): 4,920 mg/kg |
|---------------------|-------------------------------------|

Skin corrosion/irritation

Causes mild skin irritation.

Components:

Glycine:

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

Interferon alfa-2b:

| | |
|---------|-------------------|
| Species | : Rat |
| Result | : Skin irritation |

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Glycine:

| | |
|---------|---------------------|
| Species | : Rabbit |
| Result | : No eye irritation |

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Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Interferon alfa-2b:

Species : Rabbit
Remarks : slight irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Glycine:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Glycine:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Interferon alfa-2b:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Result: negative

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

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse

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Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

Glycine:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Interferon alfa-2b:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Monkey
Fertility: LOAEL: 3.8 µg/kg
Result: menstrual irregularities
Remarks: Abortion

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Monkey
Developmental Toxicity: LOAEL: 3.8 µg/kg body weight
Result: Embryolethal effects

Reproductive toxicity - Assessment : May damage fertility. May damage the unborn child.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Interferon alfa-2b:

Target Organs : Blood, Bone marrow
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Glycine:

Species : Rat, male

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| | |
|-------------------|------------------|
| NOAEL | : >= 2,000 mg/kg |
| Application Route | : Ingestion |
| Exposure time | : 28 Days |

Interferon alfa-2b:

| | |
|-------------------|--|
| Species | : Monkey |
| NOAEL | : 0.095 mg/kg |
| Application Route | : Intramuscular |
| Exposure time | : 1 Months |
| Remarks | : No significant adverse effects were reported |

| | |
|-------------------|--|
| Species | : Rat |
| NOAEL | : 0.38 mg/kg |
| Application Route | : Subcutaneous |
| Exposure time | : 3 Months |
| Remarks | : No significant adverse effects were reported |

| | |
|-------------------|--|
| Species | : Mouse |
| NOAEL | : 0.076 mg/kg |
| Application Route | : Intraperitoneal |
| Exposure time | : 9 d |
| Remarks | : No significant adverse effects were reported |

| | |
|-------------------|--|
| Species | : Monkey |
| LOAEL | : 0.38 mg/kg |
| Application Route | : Intramuscular |
| Exposure time | : 3 Months |
| Target Organs | : Blood, Bone marrow |
| Remarks | : Significant toxicity observed in testing |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Interferon alfa-2b:

| | |
|--------------|--|
| Skin contact | : Symptoms: The most common side effects are:, flu-like symptoms, Fever, chills, Fatigue |
|--------------|--|

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Glycine:

| | |
|------------------|---|
| Toxicity to fish | : LC50 (Oryzias latipes (Japanese medaka)): > 1,000 mg/l Exposure time: 96 h |
|------------------|---|

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| | | |
|---|---|--|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 220 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EbC50 (Raphidocelis subcapitata (freshwater green alga)): > 1,000 mg/l Exposure time: 72 h NOEC (Raphidocelis subcapitata (freshwater green alga)): >= 1,000 mg/l Exposure time: 72 h |

Persistence and degradability

Components:

Glycine:

| | | |
|------------------|---|--|
| Biodegradability | : | Result: Readily biodegradable. Biodegradation: 76 - 82 % Exposure time: 14 d Method: OECD Test Guideline 301C |
|------------------|---|--|

Bioaccumulative potential

Components:

Glycine:

| | | |
|--|---|----------------|
| Partition coefficient: n-octanol/water | : | log Pow: -3.21 |
|--|---|----------------|

Mobility in soil

No data available

Other adverse effects

No data available

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. |

14. TRANSPORT INFORMATION

International Regulations

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UNRTDG

| | | |
|---------------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Environmentally hazardous | : | no |

IATA-DGR

| | | |
|--|---|----------------|
| UN/ID No. | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Packing instruction (cargo aircraft) | : | Not applicable |
| Packing instruction (passenger aircraft) | : | Not applicable |

IMDG-Code

| | | |
|----------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| EmS Code | : | Not applicable |
| Marine pollutant | : | no |

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

Not applicable for product as supplied.

National Regulations

GB 6944/12268

| | | |
|----------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Marine pollutant | : | no |

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

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Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218) : Not listed

Hazardous Chemicals for Priority Management under SAWs : Not listed

Catalogue of Specially Controlled Hazardous Chemicals : Not listed

List of Explosive Precursors : Not listed

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export : Not listed

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import and Export : Not listed

List of Controlled Ozone Depleting Substances : Not listed

Environmental Protection Law

List of Priority Controlled Chemicals : Not listed

List of Key Controlled New Pollutants : Not listed

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

AICS : not determined

DSL : not determined

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IECSC : not determined

16. OTHER INFORMATION

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Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

Full text of other abbreviations

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; (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

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Disclaimer

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.

CN / EN