

## Interferon Alfa-2b Liquid Formulation

Version            Revision Date:            SDS Number:            Date of last issue: 04/09/2022  
7.3                10/01/2022                42818-00017            Date of first issue: 01/07/2015

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### SECTION 1. IDENTIFICATION

Product name                                : Interferon Alfa-2b Liquid Formulation

#### 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                          : Pharmaceutical  
  
Restrictions on use                         : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity                      : Category 1B  
  
Specific target organ toxicity             : Category 2 (Blood, Bone marrow)  
- repeated exposure

#### GHS label elements

Hazard pictograms                         :



Signal Word                                 : Danger

Hazard Statements                         : H360FD May damage fertility. May damage the unborn child.  
H373 May cause damage to organs (Blood, Bone marrow) through prolonged or repeated exposure.

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 and face protection.

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

**Storage:**  
P405 Store locked up.

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### Disposal:

P501 Dispose of contents and 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)
m-Cresol	108-39-4	$\geq 0.1 - < 1$
Interferon alfa-2b	98530-12-2	$\geq 0.001 - < 0.1$

Actual concentration 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 : 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 : 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.

## SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 Dry chemical
- Unsuitable extinguishing media : None known.

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- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : No hazardous combustion products are known
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### SECTION 6. ACCIDENTAL RELEASE MEASURES

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

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- 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 mist or vapors.  
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

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- assessment  
 Keep container tightly closed.  
 Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
 Store locked up.  
 Keep tightly closed.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents  
 Self-reactive substances and mixtures  
 Organic peroxides  
 Explosives  
 Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
m-Cresol	108-39-4	TWA	2.3 ppm 10 mg/m <sup>3</sup>	NIOSH REL
		TWA	5 ppm 22 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Inhalable fraction and vapor)	20 mg/m <sup>3</sup>	ACGIH
Interferon alfa-2b	98530-12-2	TWA	0.2 µg/m <sup>3</sup> (OEB 5)	Internal
		Wipe limit	2 µg/100 cm <sup>2</sup>	Internal

- Engineering measures** : 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 workplace.

#### Personal protective equipment

- Respiratory protection : No personal respiratory protective equipment normally required.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.

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- 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.  
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.
- 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.
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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- Appearance : liquid
- Color : colorless
- Odor : No data available
- Odor Threshold : No data available
- pH : 6.5 - 8
- 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

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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 : Not applicable

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 : Not applicable

Particle size : Not applicable

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

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Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

**Components:****m-Cresol:**

Acute oral toxicity : LD50 (Rat): 121 mg/kg  
Remarks: Based on data from similar materials

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

Acute dermal toxicity : LD50 (Rabbit): 301 mg/kg  
Remarks: Based on data from similar materials

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****m-Cresol:**

Species : Rabbit  
Result : Corrosive after 3 minutes to 1 hour of exposure

**Interferon alfa-2b:**

Species : Rat  
Result : Skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****m-Cresol:**

Species : Rabbit  
Result : Irreversible effects on the eye

**Interferon alfa-2b:**

Species : Rabbit  
Remarks : slight irritation

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

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

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### Components:

#### **m-Cresol:**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
 Method: OECD Test Guideline 473  
 Result: positive

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

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
 Species: Mouse  
 Application Route: Ingestion  
 Method: OECD Test Guideline 475  
 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  
 Result: negative  
 Remarks: Based on data from similar materials

### **Carcinogenicity**

Not classified based on available information.

### Components:

#### **m-Cresol:**

Species : Mouse, males  
 Application Route : Ingestion  
 Exposure time : 105 weeks  
 Result : equivocal  
 Remarks : Based on data from similar materials

Species : Mouse, female  
 Application Route : Ingestion  
 Exposure time : 106 - 107 weeks  
 Result : positive  
 Remarks : Based on data from similar materials

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.



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**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

May damage fertility. May damage the unborn child.

#### Components:

##### **m-Cresol:**

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

Effects on fetal development : Test Type: Prenatal development toxicity study (teratogenicity)  
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 fetal development : Test Type: Fertility/early embryonic development  
Species: Monkey  
Developmental Toxicity: LOAEL: 3.8 µg/kg body weight  
Result: Embryo-lethal 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 (Blood, Bone marrow) 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.

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**Repeated dose toxicity****Components:****m-Cresol:**

Species : Rat  
NOAEL : 150 mg/kg  
Application Route : Ingestion  
Exposure time : 13 Weeks  
Method : OECD Test Guideline 408

**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

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****m-Cresol:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 8.6 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia pulex (Water flea)): > 99.5 mg/l  
Exposure time: 48 h
- Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 1.35 mg/l  
Exposure time: 32 d  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1 mg/l  
Exposure time: 21 d  
Remarks: Based on data from similar materials

**Persistence and degradability****Components:****m-Cresol:**

- Biodegradability : Result: Readily biodegradable.  
Biodegradation: 90 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301D

**Bioaccumulative potential****Components:****m-Cresol:**

- Bioaccumulation : Species: Leuciscus idus (Golden orfe)  
Bioconcentration factor (BCF): 17 - 20
- Partition coefficient: n-octanol/water : log Pow: 1.96

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**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.

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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

##### 49 CFR

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

### SECTION 15. REGULATORY INFORMATION

#### CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
m-Cresol	108-39-4	100	66666

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Reproductive toxicity  
 Specific target organ toxicity (single or repeated exposure)

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### US State Regulations

##### Pennsylvania Right To Know

Water	7732-18-5
Disodium hydrogenorthophosphate	7558-79-4
m-Cresol	108-39-4

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

AICS : not determined

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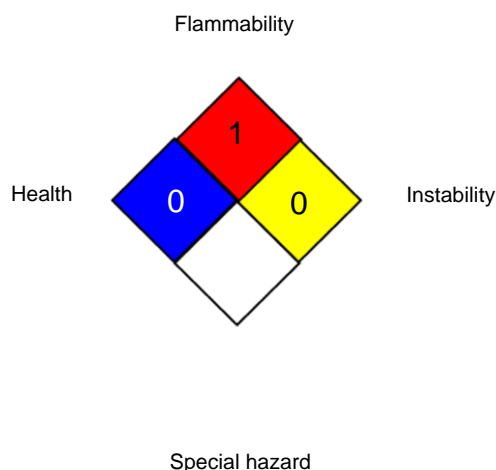
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DSL : not determined  
 IECSC : not determined

## SECTION 16. OTHER INFORMATION

## Further information

## NFPA 704:



## HMIS® IV:

HEALTH	*	2
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

## Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
 NIOSH REL : USA. NIOSH Recommended Exposure Limits  
 OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants  
 ACGIH / TWA : 8-hour, time-weighted average  
 NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek  
 OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Chemi-

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icals 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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.

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