

## Peginterferon Alfa-2b Redipen Formulation

Version 7.0      Revision Date: 2023/09/26      SDS Number: 19434-00022      Date of last issue: 2023/03/20  
Date of first issue: 2014/10/07

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Peginterferon Alfa-2b Redipen Formulation

#### Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Reproductive toxicity : Category 1B

Short-term (acute) aquatic hazard : Category 3

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H360FD May damage fertility. May damage the unborn child.  
H402 Harmful to aquatic life.

Precautionary statements :

#### Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/attention.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

Important symptoms and out- : Dust contact with the eyes can lead to mechanical irritation.  
lines of the emergency as- : Contact with dust can cause mechanical irritation or drying of  
sumed : the skin.  
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)	ENCS No.
$\alpha$ -D-Glucopyranoside, $\alpha$ -D-glucopyranosyl, dihydrate	6138-23-4	$\geq 90 - \leq 100$	8-674
Peginterferon Alfa-2b	215647-85-1	$\geq 0.3 - < 1$	

### 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 : May damage fertility. May damage the unborn child.  
Contact with dust can cause mechanical irritation or drying of

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delayed 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.

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### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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

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.

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### 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

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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.  
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
- 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.

#### Storage

- Conditions for safe storage : Keep in properly labelled 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
- Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type	Control parame-	Basis
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		(Form of exposure)	ters / Reference concentration / Permissible concentration	
Peginterferon Alfa-2b	215647-85-1	TWA (inhalable fraction)	0.2 µg/m <sup>3</sup> (OEB 5)	Internal

**Engineering measures** : Minimize workplace exposure concentrations.  
 Apply measures to prevent dust explosions.  
 Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).  
 If sufficient ventilation is unavailable, use with local exhaust ventilation.

### 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

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:  
 Safety goggles

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
 Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : off-white

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

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Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : soluble

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Density and / or relative density  
Relative density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics  
Particle size : No data available

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### 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.

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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#### Acute toxicity

Not classified based on available information.

#### Components:

##### **$\alpha$ -D-Glucopyranoside, $\alpha$ -D-glucopyranosyl, dihydrate:**

Acute oral toxicity	:	LD50 (Rat): > 16,000 mg/kg Method: OECD Test Guideline 401
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##### **Peginterferon Alfa-2b:**

Acute toxicity (other routes of administration)	:	LD50 (Rat): > 20.1 mg/kg Application Route: Intravenous  LD50 (Monkey): > 9.8 mg/kg
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#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### **$\alpha$ -D-Glucopyranoside, $\alpha$ -D-glucopyranosyl, dihydrate:**

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

##### **Peginterferon Alfa-2b:**

Species	:	Rabbit
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Result : Mild skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### $\alpha$ -D-Glucopyranoside, $\alpha$ -D-glucopyranosyl, dihydrate:

Species : Rabbit  
 Result : No eye irritation  
 Method : OECD Test Guideline 405

#### Peginterferon Alfa-2b:

Species : Rabbit  
 Result : Mild eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### $\alpha$ -D-Glucopyranoside, $\alpha$ -D-glucopyranosyl, dihydrate:

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

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
 Species: Mouse  
 Application Route: Intraperitoneal injection  
 Result: negative

#### Peginterferon Alfa-2b:

Genotoxicity in vitro : Test Type: reverse mutation assay  
 Result: negative



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Genotoxicity in vivo	:	Test Type: Chromosomal aberration Test system: Human lymphocytes Result: negative
	:	Test Type: In vivo micronucleus test Species: Mouse Result: negative

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

May damage fertility. May damage the unborn child.

### Components:

#### **$\alpha$ -D-Glucopyranoside, $\alpha$ -D-glucopyranosyl, dihydrate:**

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative
	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative

#### **Peginterferon Alfa-2b:**

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Monkey, female Application Route: Subcutaneous Dose: 0.35 milligram per kilogram Symptoms: Effect on estrous cycle
	:	Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments., Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### **Peginterferon Alfa-2b:**

Target Organs	:	Gastrointestinal tract, Immune system, Cardio-vascular system, Endocrine system, Central nervous system, Liver, Res-
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Assessment	piratory Tract, Eye
	: Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

##### **$\alpha$ -D-Glucopyranoside, $\alpha$ -D-glucopyranosyl, dihydrate:**

Species	: Mouse
NOAEL	: 8,289 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days
Method	: OECD Test Guideline 408

##### **Peginterferon Alfa-2b:**

Species	: Mouse
NOAEL	: 0.0038 mg/kg
Application Route	: Subcutaneous
Exposure time	: 9 d

Species	: Rat
NOAEL	: 0.0042 mg/kg
Application Route	: Subcutaneous
Exposure time	: 30 d

Species	: Monkey
LOAEL	: 0.12 mg/kg
Application Route	: Subcutaneous
Exposure time	: 30 d
Target Organs	: Blood, Bone marrow, Immune system

Species	: Monkey
NOAEL	: 0.015 mg/kg
LOAEL	: 0.077 mg/kg
Exposure time	: 3 Months
Target Organs	: Respiratory Tract, Cardio-vascular system, Central nervous system, Bone marrow

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### **Peginterferon Alfa-2b:**

Inhalation	: Symptoms: flu-like symptoms, Gastrointestinal disturbance, mental depression, tingling
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### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **$\alpha$ -D-Glucopyranoside, $\alpha$ -D-glucopyranosyl, dihydrate:**

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): 33.6 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		EC10 (Desmodesmus subspicatus (green algae)): 13.82 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

##### **Peginterferon Alfa-2b:**

##### **Ecotoxicology Assessment**

Acute aquatic toxicity	:	No data available
Chronic aquatic toxicity	:	No data available

##### **Persistence and degradability**

##### Components:

##### **$\alpha$ -D-Glucopyranoside, $\alpha$ -D-glucopyranosyl, dihydrate:**

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 68 - 74 % Exposure time: 28 d
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##### **Peginterferon Alfa-2b:**

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 63 % Exposure time: 28 d Method: OECD Test Guideline 301B
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##### **Bioaccumulative potential**

##### Components:

##### **$\alpha$ -D-Glucopyranoside, $\alpha$ -D-glucopyranosyl, dihydrate:**

Partition coefficient: n-	:	log Pow: < 0.3
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|| Octanol/water

Method: OECD Test Guideline 117

### Mobility in soil

No data available

### Hazardous to the ozone layer

Not applicable

### Other adverse effects

No data available

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## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
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.

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## 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable

#### 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

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Marine pollutant : Not applicable

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

Not applicable for product as supplied.

**National Regulations**

Refer to section 15 for specific national regulation.

**Special precautions for user**

Not applicable

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**15. REGULATORY INFORMATION****Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

**Industrial Safety and Health Law****Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Not applicable

**Substances Subject to be Indicated Names**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

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**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

|| Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Not regulated as a dangerous good

**Aviation Law**

Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**16. OTHER INFORMATION****Further information**

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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; KECl - 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

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.

# SAFETY DATA SHEET



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