

**SAFETY DATA SHEET**

according to the OSHA Hazard Communication Standard

**CLADRIBINE 10MG TABLETS**

Version	Revision Date:	SDS Number:	Date of last issue: 11/15/2023
2.1	04/16/2024	90MDGM302635	Date of first issue: 02/13/2023

**SECTION 1. IDENTIFICATION**

Product name : CLADRIBINE 10MG TABLETS

**Manufacturer or supplier's details**

Company : EMD Serono, Inc.  
One Technology Place  
MA-02370 Rockland  
United States of America

Responsible Department : e-mail: HealthcareSDS@emdgroup.com

Emergency telephone number : 800-424-9300 CHEMTREC (USA)  
+1-703-527-3887 CHEMTREC (International)  
613-996-6666 CANUTEC (Canada)  
24 Hours/day; 7 Days/week

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

Recommended use : Use restricted under TSCA to research and development or as analytical reagent. Uses regulated under FDA or FIFRA are not affected.  
finished pharmaceutical

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Acute toxicity (Oral) : Category 4

Germ cell mutagenicity : Category 2

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure : Category 1

**GHS label elements**

Hazard pictograms :

Signal word : Danger

Hazard statements : H302 Harmful if swallowed.  
H341 Suspected of causing genetic defects.  
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.  
H372 Causes damage to organs through prolonged or repeated exposure.

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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 dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.  
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

None known.

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## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture  
Chemical nature : Mixture of organic compounds

### Components

Chemical name	CAS-No.	Concentration (% w/w)
cladribine	4291-63-8	>= 1 - < 5
magnesium distearate	557-04-0	>= 1 - < 5

Actual concentration is withheld as a trade secret

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## SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.  
Show this safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.

If inhaled : Move to fresh air.  
If symptoms persist, call a physician.

In case of skin contact : Rinse with water.  
Remove contaminated clothing.  
If symptoms persist, call a physician.

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- In case of eye contact : Flush eyes with water as a precaution.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.
- Most important symptoms and effects, both acute and delayed : Gastrointestinal discomfort  
Headache  
Nausea  
immune system effects  
Harmful if swallowed.  
Suspected of causing genetic defects.  
Suspected of damaging fertility. Suspected of damaging the unborn child.  
Causes damage to organs through prolonged or repeated exposure.
- Notes to physician : Treat symptomatically.
- 

### SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water  
Foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry powder
- Unsuitable extinguishing media : For this substance/mixture no limitations of extinguishing agents are given.
- Specific hazards during fire-fighting : Combustible.  
  
Development of hazardous combustion gases or vapours possible in the event of fire.  
  
Fire may cause evolution of:  
  
Hydrogen chloride gas  
nitrogen oxides  
  
nitrogen oxides  
Hydrogen chloride gas
- Hazardous combustion products : No hazardous combustion products are known
- Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local cir-
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cumstances and the surrounding environment.  
Suppress (knock down) gases/vapours/mists with a water spray jet.  
(contamination risk)

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Advice for non-emergency personnel:  
Avoid inhalation of dusts.  
Evacuate the danger area, observe emergency procedures, consult an expert.  
Advice for emergency responders:  
Protective equipment see section 8.

Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
If the product contaminates rivers and lakes or drains inform respective authorities.

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.  
Cover drains. Collect, bind, and pump off spills.  
Observe possible material restrictions (see sections 7 and 10).  
Take up dry. Dispose of properly. Clean up affected area.  
Avoid generation of dusts.

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### SECTION 7. HANDLING AND STORAGE

Technical measures : Install appropriate equipment and wear appropriate personal protective equipment (see "8. Exposure control/personal protection").

Local/Total ventilation : Ensure adequate ventilation.

Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Observe label precautions.  
  
Avoid formation of respirable particles.  
Do not breathe vapours/dust.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.

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Observe label precautions.  
Electrical installations / working materials must comply with the technological safety standards.

Further information on storage stability : No decomposition if stored and applied as directed.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
magnesium distearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH

**Engineering measures** : Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

#### Personal protective equipment

Respiratory protection : required when dusts are generated.

Filter type : Filter P 3 (acc. to DIN 3181) for solid and liquid particles of toxic and very toxic substances

#### Hand protection

Material : Nitrile rubber  
Break through time : > 480 min  
Glove thickness : 0.11 mm  
Manufacturer : KCL 741 Dermatril® L

Remarks : The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles

Skin and body protection : Dust impervious protective suit  
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Protective measures : The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

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Hygiene measures : Wash hands before breaks and at the end of workday.  
Change contaminated clothing.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	tablets
Colour	:	white
Odour	:	odourless
Odour Threshold	:	Not applicable
pH	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	No data available
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
		soluble
Partition coefficient: n-	:	No data available

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octanol/water

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not classified as explosive.

Oxidizing properties : none

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : No decomposition if stored and applied as directed.

Chemical stability : The product is chemically stable under standard ambient conditions (room temperature) .

Possibility of hazardous reactions : Violent reactions possible with:  
Strong oxidizing agents

Conditions to avoid : no information available

Incompatible materials : Not applicable

Hazardous decomposition products : in the event of fire: See section 5.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

Harmful if swallowed.

#### Product:

Acute oral toxicity : Remarks: No data available

Acute toxicity estimate: 1,102 mg/kg  
Method: Calculation method

Remarks: absorption

Acute toxicity estimate: 1,098 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

#### Components:

**cladribine:**

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Acute oral toxicity : Acute toxicity estimate (Rat): 50.1 mg/kg  
Method: Expert judgement

### **magnesium distearate:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: (External MSDS)

Assessment: The substance or mixture has no acute oral toxicity

### **Skin corrosion/irritation**

Not classified due to lack of data.

#### **Product:**

Remarks : No data available

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

Not classified due to lack of data.

#### **Product:**

Remarks : No data available

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified due to lack of data.

#### **Respiratory sensitisation**

Not classified due to lack of data.

#### **Product:**

Remarks : No data available

### **Germ cell mutagenicity**

Suspected of causing genetic defects.

#### **Product:**

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Germ cell mutagenicity - Assessment : Evidence of genetic defects.

#### **Components:**

##### **cladribine:**

Genotoxicity in vivo : Remarks: In vivo tests showed mutagenic effects

Germ cell mutagenicity - Assessment : In vitro tests showed mutagenic effects



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### **Carcinogenicity**

Not classified due to lack of data.

### **Components:**

#### **cladribine:**

Remarks : No substantiated information from toxicological studies available.

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

**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 component 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**

Suspected of damaging fertility. Suspected of damaging the unborn child.

### **Product:**

Reproductive toxicity - Assessment : Evidence to impair fertility.  
Evidence of harm to the unborn child.

### **Components:**

#### **cladribine:**

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments.  
Some evidence of adverse effects on development, based on animal experiments.

### **STOT - single exposure**

Not classified due to lack of data.

### **STOT - repeated exposure**

Causes damage to organs through prolonged or repeated exposure.

### **Product:**

Assessment : Mixture may cause damage to organs through prolonged or repeated exposure.

### **Components:**

#### **cladribine:**

Assessment : The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 1.

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### Repeated dose toxicity

**Product:**

Remarks : No data available

**Components:**

**cladribine:**

Species : Mouse  
NOAEL : 15 mg/kg  
Application Route : Oral  
Exposure time : 26 Weeks  
Target Organs : Kidney, thymus, Testes

### Aspiration toxicity

Not classified due to lack of data.

### Further information

**Product:**

Remarks : Physiologically active substance.

Remarks : Other dangerous properties can not be excluded.

Remarks : Therapeutically used substance.

Remarks : Handle in accordance with good industrial hygiene and safety practice.

Remarks : Other dangerous properties can not be excluded.

Remarks : Handle in accordance with good industrial hygiene and safety practice.

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

**Product:**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic) : Remarks: No data available

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ic toxicity)

Toxicity to microorganisms : Remarks: No data available

### Components:

#### **cladribine:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): 233 mg/l  
Exposure time: 48 h  
Remarks: (External MSDS)

### **Persistence and degradability**

No data available

### **Bioaccumulative potential**

### Components:

#### **magnesium distearate:**

Partition coefficient: n-octanol/water : log Pow: 0.8  
Method: OECD Test Guideline 107  
Remarks: Bioaccumulation is not expected.

### **Mobility in soil**

No data available

### **Other adverse effects**

### Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information : Discharge into the environment must be avoided.

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## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.

Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

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Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Do not re-use empty containers.

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### 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.

#### National Regulations

##### Special precautions for user

Remarks : Not classified as dangerous in the meaning of transport regulations.

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### SECTION 15. REGULATORY INFORMATION

#### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

#### 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** : Acute toxicity (any route of exposure)  
Germ cell mutagenicity  
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.

#### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

### Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

### US State Regulations

#### Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

#### Pennsylvania Right To Know

2-hydroxypropyl- $\beta$ -cyclodextrin	128446-35-5
D-sorbitol	50-70-4
cladribine	4291-63-8

#### Maine Chemicals of High Concern

Product does not contain any listed chemicals

#### Vermont Chemicals of High Concern

Product does not contain any listed chemicals

#### Washington Chemicals of High Concern

Product does not contain any listed chemicals

#### California Prop. 65

WARNING: This product can expose you to chemicals including cladribine, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

#### California Permissible Exposure Limits for Chemical Contaminants

magnesium distearate	557-04-0
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#### The components of this product are reported in the following inventories:

TCSI	: On the inventory, or in compliance with the inventory
TSCA	: Product contains substance(s) not listed on TSCA inventory.
AIIC	: Not in compliance with the inventory
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL.  cladribine

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2-hydroxypropyl- $\beta$ -cyclodextrin

ENCS : Not in compliance with the inventory  
ISHL : Not in compliance with the inventory  
KECI : Not in compliance with the inventory  
PICCS : Not in compliance with the inventory  
IECSC : Not in compliance with the inventory  
NZIoC : Not in compliance with the inventory  
TECI : Not in compliance with the inventory

### TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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## SECTION 16. OTHER INFORMATION

### Company internal Occupational Exposure Limit (MOEL)

*cladribine (4291-63-8)* : 0.2  $\mu\text{g}/\text{m}^3$

Short Term Exposure (15 min) : 4  
Factor

Pregnancy risk groups : D

Either there are no data for an assessment of damage to the embryo, or foetus or the currently available data are not sufficient for classification in one of the other groups.

### Further information

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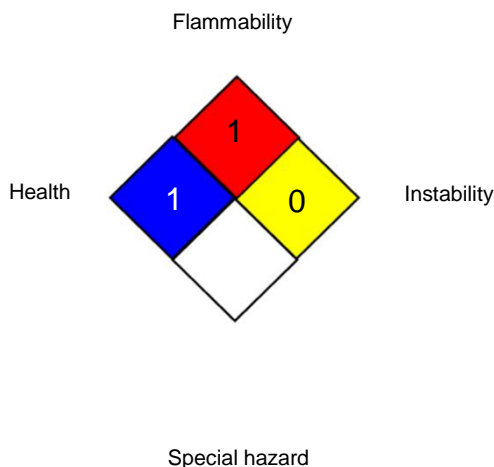
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### NFPA 704:



### HMIS® IV:

HEALTH	*	3
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)  
ACGIH / 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 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; 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 Sub-

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stance 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

Revision Date : 04/16/2024

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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