

**PEGASYS(R) Vials (180 mcg/ml)**

Version 2.0                                      Revision Date: 04-20-2021                                      Date of last issue: 02-27-2020  
Date of first issue: 02-27-2020

**SECTION 1. IDENTIFICATION**

Product name                                      : PEGASYS(R) Vials (180 mcg/ml)  
Product code                                      : 00010049980

**Manufacturer or supplier's details**

Company name of supplier                      : Genentech, Inc.  
Address    : 1 DNA Way  
    South San Francisco, CA 94080  
    USA  
Telephone     : 001-(650) 225-1000  
E-mail address                                    : info.sds@roche.com  
Emergency telephone                           : US Chemtrec phone                              (800)-424-9300  
Emergency telephone number

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

Recommended use                                : Formulated pharmaceutical active substance  
Restrictions on use                               : For professional users only.


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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

**GHS label elements**

Hazard pictograms                              : 

Signal Word                                       : Danger  
Hazard Statements                               : H360FD May damage fertility. May damage the unborn child.

Precautionary Statements                   : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

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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

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
PEG-Interferon-alpha-2a	198153-51-4	0.18
Benzenemethanol	100-51-6	1.0
Sodium chloride (NaCl)	7647-14-5	0.8
Sodium acetate trihydrate	6131-90-4	< 0.3
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.	9005-65-6	< 0.01
Water	7732-18-5	> 97.0

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**SECTION 4. FIRST AID MEASURES**

- General advice : Move out of dangerous area.  
Show this material safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
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.  
Take victim immediately to hospital.  
Rinse mouth with water.

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Most important symptoms and effects, both acute and delayed : May damage fertility. May damage the unborn child.

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products : Carbon oxides

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. 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 (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

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### SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Advice on safe handling : Do not breathe vapors/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the

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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.  
Observe label precautions.  
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Storage temperature : Protected from heat and light
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, glass, Prefilled syringes, Autoinjector

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Benzenemethanol	100-51-6	TWA	10 ppm	US WEEL
PEG-Interferon-alpha-2a	198153-51-4	IOEL	1,2 microgram per cubic meter	Roche Industrial Hygiene Committee (RIHC)

**Predicted No Effect Concentration (PNEC):**

Substance name	Environmental Compartment	Value
PEG-Interferon-alpha-2a	Surface waters	300 µg/l
	Remarks: Based on acute data	

**Engineering measures** : No data available

**Personal protective equipment**

Respiratory protection : In the case of vapor formation use a respirator with an approved filter.

Hand protection

In case of contact through splashing:

- Material : Nitrile rubber
- Break through time : > 30 min
- Glove thickness : > 0.11 mm

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	In case of full contact:
Material	: butyl-rubber
Break through time	: > 480 min
Glove thickness	: > 0.4 mm
Remarks	: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Eye protection	: Eye wash bottle with pure water Tightly fitting safety goggles
Skin and body protection	: Impervious clothing Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hygiene measures	: When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	: Aqueous solution, sterile
Color	: colorless, light yellow
Odor	: No data available
Odor Threshold	: No data available
pH	: 5.5 - 6.5
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Evaporation rate	: 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
Relative vapor density	: No data available
Relative density	: No data available
Density	: 1.004 g/cm <sup>3</sup>
Solubility(ies)	





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Species : Rabbit  
Exposure time : 72 h  
Method : Draize Test  
Result : No skin irritation  
GLP : No information available.  
Test substance : anhydrous substance

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Benzenemethanol:**

Remarks : This information is not available.

**Sodium chloride (NaCl):**

Species : Rabbit  
Result : No eye irritation

**Sodium acetate trihydrate:**

Remarks : This information is not available.

**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**

Species : Rabbit  
Result : No eye irritation  
Exposure time : 168 h  
Method : Draize Test  
GLP : No information available.  
Test substance : anhydrous substance

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

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Sodium chloride (NaCl):**

Remarks : This information is not available.

**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**

Species : Humans  
Method : see user defined free text  
Result : Not a skin sensitizer.  
GLP : No information available.  
Test substance : anhydrous substance



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Not classified based on available information.

**Components:****PEG-Interferon-alpha-2a:**Genotoxicity in vitro : Result: negative  
Remarks: In vitro tests did not show mutagenic effectsGerm cell mutagenicity - Assessment : In vitro tests did not show mutagenic effects  
Remarks: Expert judgmentIn vivo tests did not show mutagenic effects  
Remarks: Expert judgment**Sodium chloride (NaCl):**Genotoxicity in vitro : Test Type: Micronucleus test  
Test system: mammalian cells  
Method: Mutagenicity (micronucleus test)  
Result: negativeTest Type: Ames test  
Result: negative**Carcinogenicity**

Not classified based on available information.

**Components:****Benzenemethanol:**

Remarks : 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.

**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**

Remarks : 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.

**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.**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:****PEG-Interferon-alpha-2a:**

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Reproductive toxicity -  
Assessment : Presumed human reproductive toxicant  
Remarks: Expert judgment

May damage fertility. May damage the unborn child.  
Remarks: Expert judgment

**STOT-single exposure**

Not classified based on available information.

**Components:****Benzenemethanol:**

Assessment : The substance or mixture is not classified as specific target  
organ toxicant, single exposure.

**Sodium acetate trihydrate:**

Assessment : The substance or mixture is not classified as specific target  
organ toxicant, single exposure.

**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**

Assessment : The substance or mixture is not classified as specific target  
organ toxicant, single exposure.

**STOT-repeated exposure**

Not classified based on available information.

**Components:****Benzenemethanol:**

Assessment : The substance or mixture is not classified as specific target  
organ toxicant, repeated exposure.

**Sodium acetate trihydrate:**

Assessment : The substance or mixture is not classified as specific target  
organ toxicant, repeated exposure.

**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**

Assessment : The substance or mixture is not classified as specific target  
organ toxicant, repeated exposure.

**Aspiration toxicity**

Not classified based on available information.

**Components:****Benzenemethanol:**

No data available

**Sodium acetate trihydrate:**

No data available

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No data available

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****PEG-Interferon-alpha-2a:**

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 300 mg/l  
Exposure time: 96 h  
Test Type: semi-static test  
Method: OECD Test Guideline 203  
GLP: yes

NOEC (Cyprinus carpio (Carp)): 300 mg/l  
Exposure time: 96 h  
Test Type: semi-static test  
Method: OECD Test Guideline 203  
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 300 mg/l  
Exposure time: 48 h  
Test Type: semi-static test  
Method: OECD Test Guideline 202  
GLP: yes

NOEC (Daphnia magna (Water flea)): 300 mg/l  
Exposure time: 48 h  
Test Type: semi-static test  
Method: OECD Test Guideline 202  
GLP: yes

Toxicity to microorganisms : (activated sludge): 3.3 mg/l  
Exposure time: 28 d  
Method: OECD Test Guideline 301D  
GLP: yes  
Remarks: Barely inhibitory on aerobic bacterial respiration

**Benzenemethanol:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 315 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

LC50 (Lepomis macrochirus (Bluegill sunfish)): 10 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 400 mg/l



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**Ecotoxicology Assessment**

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**

 Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 471 mg/l  
 Exposure time: 96 h  
 Test Type: static test  
 GLP: No information available.

 Toxicity to daphnia and other aquatic invertebrates : LC50 (Mysidopsis bahia (opossum shrimp)): 165 mg/l  
 Exposure time: 96 h  
 Test Type: static test  
 GLP: No information available.

**Ecotoxicology Assessment**

 Acute aquatic toxicity : This product has no known ecotoxicological effects.  
 Remarks: Expert judgment

 Chronic aquatic toxicity : This product has no known ecotoxicological effects.  
 Remarks: Expert judgment

 Toxicity Data on Soil : Not expected to adsorb on soil.  
 Remarks: Expert judgment

 Other organisms relevant to the environment : No data available  
 Remarks: Expert judgment

**Persistence and degradability**
**Product:**

 Biodegradability : Biodegradation: <= 22 %  
 Exposure time: 28 d  
 Method: OECD Test Guideline 301D  
 Remarks: The value is given in analogy to the following substances:  
 The value is given in analogy to the following substances:  
 PEG-Interferon-alpha-2a

**Components:**
**PEG-Interferon-alpha-2a:**

 Biodegradability : Concentration: 3.3 mg/l  
 Result: Not readily biodegradable.  
 Biodegradation: <= 22 %  
 Exposure time: 28 d  
 Method: OECD Test Guideline 301D  
 GLP: yes

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Exposure time: 2 d  
Method: OECD Test Guideline 302B**Sodium chloride (NaCl):**

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

**Sodium acetate trihydrate:**Biodegradability : Biodegradation: 99 %  
Exposure time: 28 d**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**Biodegradability : Result: Biodegradable  
Biodegradation: 64 %  
Exposure time: 29 d  
Method: OECD Test Guideline 301B  
GLP: yes**Bioaccumulative potential****Components:****PEG-Interferon-alpha-2a:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Benzenemethanol:**Partition coefficient: n-  
octanol/water : log Pow: 1.10**Sodium chloride (NaCl):**Partition coefficient: n-  
octanol/water : Remarks: No data available**Sodium acetate trihydrate:**Partition coefficient: n-  
octanol/water : log Pow: -4.22**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Water:**Partition coefficient: n-  
octanol/water : Remarks: No data available

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### 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).

#### Components:

##### **Benzenemethanol:**

Additional ecological information : No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not contaminate ponds, waterways or ditches with  
chemical or used container.  
Send to a licensed waste management company.  
Can be disposed as waste water, when in compliance with  
local regulations.

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste  
handling site for recycling or disposal.  
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

#### **Domestic regulation**

**49 CFR**

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Not regulated as a dangerous good

**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** : Reproductive toxicity**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).

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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Benzenemethanol	100-51-6	>= 1 - < 5 %
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**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**

Benzenemethanol	100-51-6
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**Pennsylvania Right To Know**

Water	7732-18-5
Benzenemethanol	100-51-6

**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



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

- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
  
PEG-Interferon-alpha-2a
- AICS : Not in compliance with the inventory
- NZIoC : Not in compliance with the inventory
- 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
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA 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**

# SAFETY DATA SHEET

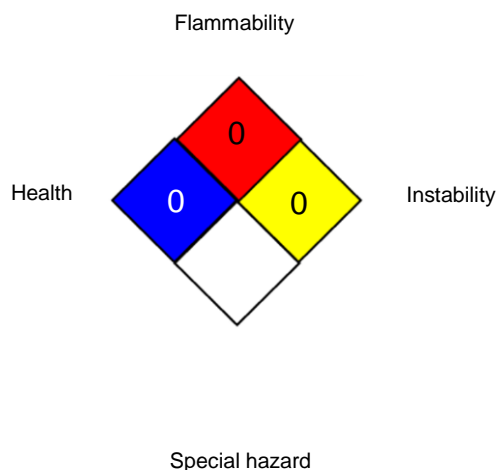
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### NFPA 704:



### HMIS® IV:

HEALTH	*	0
FLAMMABILITY		0
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

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)  
US WEEL / TWA : 8-hr TWA

AICS - Australian Inventory of Chemical Substances; 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); EC<sub>x</sub> - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL<sub>x</sub> - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC<sub>x</sub> - 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; IC<sub>50</sub> - 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; LC<sub>50</sub> - Lethal Concentration to 50 % of a test population; LD<sub>50</sub> - 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

# SAFETY DATA SHEET

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Substance 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

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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 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.

US / Z8 / 2004