

**ESBRIET(R) Capsules (267 mg)**Version  
1.3Revision Date:  
01-29-2020Date of last issue: 06-10-2017  
Date of first issue: 12-09-2015**SECTION 1. IDENTIFICATION**

Product name : ESBRIET(R) Capsules (267 mg)

Product code : RO022-0912/F04

Common name(s), syno- : ESBRIET Capsules (hard) 267 mg  
nym(s) of the substance**Manufacturer or supplier's details**

Company name of supplier : Genentech, Inc.

Address : DNA Way 1  
94080 South San Francisco  
CA  
USA

Telephone : 001-(650) 225-1000

E-mail address : info.sds@roche.com

Emergency telephone

Emergency telephone num- : US Chemtrec phone (800)-424-9300  
ber**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 29 CFR 1910.1200**

Acute toxicity (Oral) : Category 4

Carcinogenicity : Category 2

**GHS label elements**

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H302 Harmful if swallowed.  
H351 Suspected of causing cancer.Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read  
and understood.  
P264 Wash skin thoroughly after handling.

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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 dis-  
posal plant.

**Other hazards**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Pirfenidone	53179-13-8	66.8
Croscarmellose sodium	74811-65-7	6.6
Cellulose	9004-34-6	6.0
2-Pyrrolidinone, 1-ethenyl-, homo- polymer	9003-39-8	1.5
Octadecanoic acid, magnesium salt (2:1)	557-04-0	0.4
Titanium oxide (TiO <sub>2</sub> )	13463-67-7	<= 1.0
non hazardous compounds	Not Assigned	18.2

**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.

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- 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.  
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.  
Suspected of causing cancer.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

**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 : In case of fire hazardous decomposition products may be produced such as:  
Carbon oxides  
Nitrogen oxides (NOx)
- 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.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Avoid dust formation.  
Avoid breathing dust.
- 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 : Keep in suitable, closed containers for disposal.

**SECTION 7. HANDLING AND STORAGE**

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- Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapors/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.  
Containers which are opened must be carefully resealed and kept upright to prevent leakage.  
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

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

**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Pirfenidone	53179-13-8	IOEL	2 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Titanium oxide (TiO2)	13463-67-7	TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA	10 mg/m3	ACGIH

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			(Titanium dioxide)	
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable fraction)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable fraction)	3 mg/m <sup>3</sup>	ACGIH

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

Substance name	Environmental Compartment	Value
Pirfenidone	Surface waters	1.06 mg/l

**Engineering measures** : No data available**Personal protective equipment**

Hand protection

Material : Protective gloves

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

Appearance : capsules

Color : white

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

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Self-ignition : 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 : Not applicable

Relative density : No data available

Solubility(ies)

    Water solubility : No data available

    Solubility in other solvents : No data available

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

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

    Viscosity, dynamic : Not applicable

    Viscosity, kinematic : Not applicable

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : No decomposition if stored and applied as directed.

Incompatible materials : No data available

Hazardous decomposition products : No data available

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Harmful if swallowed.

**Product:**

Acute oral toxicity : Acute toxicity estimate: 1,911 mg/kg  
Method: Calculation method

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Acute inhalation toxicity : Acute toxicity estimate: > 200 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

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

**Components:****Pirfenidone:**

Acute oral toxicity : LD50 Oral (Rat): 1,295 mg/kg

**Cellulose:**

Acute oral toxicity : LD50 Oral (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg

**Titanium oxide (TiO<sub>2</sub>):**

Acute oral toxicity : LD50 (Rat): > 7,500 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 10,000 mg/kg

**Octadecanoic acid, magnesium salt (2:1):**

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Pirfenidone:**

Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Pirfenidone:**

Result : No eye irritation

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

Not classified based on available information.

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**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

**Carcinogenicity**

Suspected of causing cancer.

**Components:**

**Cellulose:**

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** Group 2B: Possibly carcinogenic to humans  
Titanium oxide (TiO2) 13463-67-7

**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**

Not classified based on available information.

**Components:**

**Pirfenidone:**

Effects on fertility : Species: laboratory animal  
Symptoms: No effects on fertility.

Effects on fetal development : Species: laboratory animal  
Result: No teratogenic potential.

**STOT-single exposure**

Not classified based on available information.

**Components:**

**Octadecanoic acid, magnesium salt (2:1):**

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:**

**Octadecanoic acid, magnesium salt (2:1):**

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



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Not classified based on available information.

**Components:****Octadecanoic acid, magnesium salt (2:1):**

No data available

**Experience with human exposure****Components:****Pirfenidone:**General Information : Symptoms: Nausea, Rash, Dizziness, digestive disorder,  
Vomiting, decrease in appetite, joint pain

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Pirfenidone:**Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 67.1 mg/l  
Method: OECD Test Guideline 201EbC50 (Pseudokirchneriella subcapitata (green algae)): 44 mg/l  
Method: OECD Test Guideline 201NOEC (Pseudokirchneriella subcapitata (green algae)): 18.3 mg/l  
Method: OECD Test Guideline 201Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 10.6 mg/l  
Exposure time: 28 d  
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)  
Method: OECD Test Guideline 210  
Remarks: average measured concentrationToxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 94 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
Remarks: average measured concentrationToxicity to microorganisms : NOEC (activated sludge): 100 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
Remarks: Barely inhibitory on aerobic bacterial respiration  
  
(activated sludge): 578 mg/l  
Exposure time: 3 h

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Test Type: Respiration inhibition  
 Method: OECD Test Guideline 209  
 Remarks: Barely inhibitory on aerobic bacterial respiration

**Cellulose:****Ecotoxicology Assessment**

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

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

**Titanium oxide (TiO<sub>2</sub>):**Toxicity to fish : LC<sub>0</sub> (Leuciscus idus (Golden orfe)): > 1,000 mg/l  
Exposure time: 48 hToxicity to daphnia and other : EC<sub>0</sub> (Daphnia magna (Water flea)): 3 mg/l  
aquatic invertebrates : Exposure time: 720 h**Ecotoxicology Assessment**

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

Other organisms relevant to : No data available  
the environment**Octadecanoic acid, magnesium salt (2:1):****Ecotoxicology Assessment**

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

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

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

Other organisms relevant to : No data available  
the environment**Persistence and degradability****Components:****Pirfenidone:**Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 9 %  
Exposure time: 29 d  
Method: OECD Test Guideline 301B**Bioaccumulative potential****Components:****Pirfenidone:**Partition coefficient: n- : log Pow: 0.9  
octanol/water

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

**Titanium oxide (TiO<sub>2</sub>):**

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

**Octadecanoic acid, magnesium salt (2:1):**Partition coefficient: n-octanol/water : log Pow: 0.8  
Method: OECD Test Guideline 107**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 : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.  
Harmful to aquatic life.**Components:****Pirfenidone:**

Results of PBT and vPvB assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulating (vPvB).

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**Waste from residues : The product should not be allowed to enter drains, water courses or the soil.  
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

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handling site for recycling or disposal.  
Do not re-use empty containers.

**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**

Not regulated as a dangerous good

**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know****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**

Components	CAS-No.	Component TPQ (lbs)
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**SARA 311/312 Hazards** : Acute toxicity (any route of exposure)  
Carcinogenicity

**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).

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.

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

**US State Regulations**

**Massachusetts Right To Know**

Cellulose 9004-34-6

**Pennsylvania Right To Know**

Pirfenidone 53179-13-8  
non hazardous compounds Not Assigned  
Croscarmellose sodium 74811-65-7  
Cellulose 9004-34-6

**Maine Chemicals of High Concern**

**Vermont Chemicals of High Concern**

**Washington Chemicals of High Concern**

**California Prop. 65**

WARNING: This product can expose you to chemicals including Titanium oxide (TiO<sub>2</sub>), which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**California List of Hazardous Substances**

2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

**California Permissible Exposure Limits for Chemical Contaminants**

Cellulose 9004-34-6

**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.
  - Pirfenidone
  - non hazardous compounds
  - Croscarmellose sodium
- 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 : Substance(s) not listed on TSCA inventory

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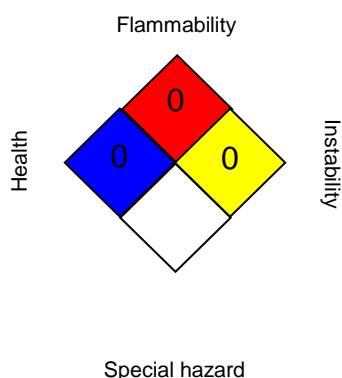
**TSCA list**

No substances are subject to a Significant New Use Rule.

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

**SECTION 16. OTHER INFORMATION**

**NFPA:**



**HMIS® IV:**

<b>HEALTH</b>	*	1
<b>FLAMMABILITY</b>		0
<b>PHYSICAL HAZARD</b>		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 P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
- 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 P0 / TWA : 8-hour time weighted average
- OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; 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; IECS - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health

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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 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 Material 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 / 1810