

**VALIUM(R) Tablets (2 mg)**Version  
1.5Revision Date:  
10-14-2021Date of last issue: 11-01-2019  
Date of first issue: 12-04-2015**SECTION 1. IDENTIFICATION**

Product name : VALIUM(R) Tablets (2 mg)

Product code : 00010039874

**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

Emergency telephone : US Chemtrec phone (800)-424-9300  
number**Recommended use of the chemical and restrictions on use**

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

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

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture.

**Other hazards**

None known.

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

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-	439-14-5	1.2
Lactose-monohydrate	10039-26-6	58.9
Starch	9005-25-8	39.5
Octadecanoic acid, magnesium salt (2:1)	557-04-0	0.4

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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.  
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : None known.
- 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 : No information available.
- Hazardous combustion products : Carbon oxides  
In case of fire hazardous decomposition products may be produced such as:  
Nitrogen oxides (NOx)  
Gaseous hydrogen chloride (HCl).
- Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment : Wear self-contained breathing apparatus for firefighting if

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for fire-fighters

necessary.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Avoid exposure  
Avoid dust formation.  
Avoid breathing dust.
- Environmental precautions : 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**

- 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.  
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 : Protect against light.  
Protect from moisture.
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Polyethylene bag in metal drum, Blister packages, glass bottles

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

**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of	Control parameters /	Basis
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		exposure)	Permissible concentration	
Starch	9005-25-8	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
2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-	439-14-5	IOEL	0.02 mg/m3	Roche Industrial Hygiene Committee (RIHC)

### Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Diazepam	Surface waters	27.3 µg/l
	Remarks: Based on chronic data	

**Engineering measures** : No data available

### Personal protective equipment

Hand protection

In case of contact through splashing:  
 Material : Nitrile rubber  
 Break through time : > 30 min  
 Glove thickness : > 0.11 mm

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

Protective measures : Instruction of employees recommended

Hygiene measures : When using do not eat or drink.

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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	:	tablet
Color	:	off-white
Odor	:	Not applicable
Odor Threshold	:	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
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
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

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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.
Conditions to avoid	:	Exposure to moisture. Exposure to light. Heat.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

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

Not classified based on available information.

**Product:**Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method**Components:****Lactose-monohydrate:**

Acute oral toxicity : LD50 Oral (Rat): &gt; 10,000 mg/kg

**Starch:**Acute oral toxicity : Acute toxicity estimate: > 5,001 mg/kg  
Method: Expert judgmentAcute inhalation toxicity : Acute toxicity estimate: > 30 mg/l  
Test atmosphere: dust/mist  
Method: Expert judgmentAcute dermal toxicity : Acute toxicity estimate: > 5,001 mg/kg  
Method: Expert judgment**2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:**Acute oral toxicity : LD50 Oral (Rat): 249 mg/kg  
LD50 Oral (Mouse): > 1,000 mg/kg**Skin corrosion/irritation**

Not classified based on available information.

**Components:****2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:**

Remarks : This information is not available.

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### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### 2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:

Remarks : This information is not available.

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### 2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:

Genotoxicity in vitro : Remarks: In vitro tests did not show mutagenic effects

### Carcinogenicity

Not classified based on available information.

### Components:

#### Lactose-monohydrate:

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

Not classified based on available information.

### Components:

#### 2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:

Effects on fetal development : Remarks: No significant adverse effects were reported

### STOT-single exposure

Not classified based on available information.

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

**2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:**Target Organs : Central nervous system  
Assessment : May cause drowsiness or dizziness.**STOT-repeated exposure**

Not classified based on available information.

**Components:****Starch:**

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

**Aspiration toxicity**

Not classified based on available information.

**Components:****Starch:**

No data available

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Starch:**Toxicity to fish : LC50: > 100 mg/l  
Exposure time: 96 h**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 the environment : No data available

**2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:**Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 84 mg/l  
Exposure time: 96 h



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Exposure time: 96 hNOEC (Danio rerio (zebra fish)): 0.273 mg/l  
Exposure time: 35 d  
GLP: yesToxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 4.3 mg/l  
aquatic invertebrates Exposure time: 24 hToxicity to algae/aquatic : ErC50 (Desmodesmus subspicatus (green algae)): 3.11 mg/l  
plants Exposure time: 72 hNOEC (Desmodesmus subspicatus (green algae)): 0.035 mg/l  
Exposure time: 72 hNOEC (Desmodesmus subspicatus (green algae)): 2.56 mg/l  
Exposure time: 336 hErC50 (Synechococcus leopoliensis (blue-green algae)): >  
11.9 mg/l  
Exposure time: 72 hNOEC (Synechococcus leopoliensis (blue-green algae)):  
0.667 mg/l  
Exposure time: 72 hEC50 (Synechococcus leopoliensis (blue-green algae)): > 100  
mg/l  
Exposure time: 168 hNOEC (Synechococcus leopoliensis (blue-green algae)): 16  
mg/l  
Exposure time: 168 hToxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 0.91 mg/l  
aquatic invertebrates Exposure time: 21 d  
(Chronic toxicity) Remarks: nominal concentration**Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic to aquatic life.

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.

Other organisms relevant to : No data available  
the environment**Persistence and degradability****Components:****2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:**Biodegradability : Biodegradation: 0 %  
Exposure time: 21 d

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Biochemical Oxygen Demand (BOD)/Theoretical oxygen demand (ThOD) : &lt; 5 %

**Bioaccumulative potential**
**Components:**
**Lactose-monohydrate:**

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow &lt;= 4).

Partition coefficient: n-octanol/water : log Pow: -5.03

**Starch:**

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

**Diazepam:**

 Partition coefficient: n-octanol/water : log Pow: 2.58  
 pH: 7.2

**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:**
**2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:**

 Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.  
 Toxic to aquatic life with long lasting effects.

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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.

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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

Not regulated as a dangerous good

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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** : No SARA Hazards

**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).

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).

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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**

Starch	9005-25-8
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**Pennsylvania Right To Know**

Lactose-monohydrate	10039-26-6
Starch	9005-25-8

**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 2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-, 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**

Starch	9005-25-8
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**The ingredients of this product are reported in the following inventories:**

- AIIC : Not in compliance with the inventory
- DSL : All components of this product are on the Canadian DSL
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : On the inventory, or in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : On the inventory, or in compliance with the inventory
- TSCA : All substances listed as active on the TSCA inventory

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TECI : Not in compliance with the inventory

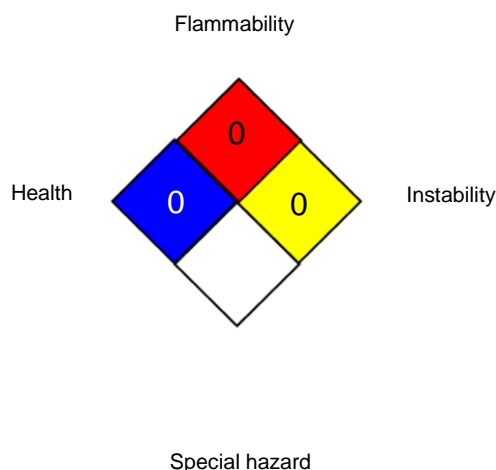
### TSCA list

No substances are subject to a Significant New Use Rule.

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

## SECTION 16. OTHER INFORMATION

### 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

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

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

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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 Substance Inventory; TECL - 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

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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 / 2010