

## VALCYTE(R) F.C. Tablets (450 mg)

Version  
1.4

Revision Date:  
01-20-2021

Date of last issue: 02-28-2020  
Date of first issue: 12-10-2015

### SECTION 1. IDENTIFICATION

Product name : VALCYTE(R) F.C. Tablets (450 mg)  
Product code : 00010069575  
Common name(s), syno- : Valganciclovir Film Coated Tablets 450 mg  
nym(s) of the substance Valganciclovir F.C. Tablets 450 mg  
**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 the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Germ cell mutagenicity : Category 1B  
Carcinogenicity : Category 1A  
Reproductive toxicity : Category 1B  
Specific target organ toxicity : Category 1  
- repeated exposure

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H340 May cause genetic defects.  
H350 May cause cancer.  
H360FD May damage fertility. May damage the unborn child.

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H372 Causes damage to organs through prolonged or repeated exposure.

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/ fume/ gas/ mist/ vapors/ spray.

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:**

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.

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

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Valganciclovir	175865-59-5	80.6
Cellulose	9004-34-6	7.8
2-Pyrrolidinone, 1-ethenyl-, homo-polymer	9003-39-8	3.9
2-Pyrrolidinone, 1-ethenyl-, homo-polymer	9003-39-8	3.9
non hazardous compounds	Not Assigned	2.0
Octadecanoic acid	57-11-4	1.0
Titanium oxide (TiO <sub>2</sub> )	13463-67-7	< 0.9

**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.

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- |  |   |  |
|--|---|--|
|  | : | If symptoms persist, call a physician. |
|--|---|--|
- |                         |   |                                    |
|-------------------------|---|------------------------------------|
| In case of skin contact | : | If on skin, rinse well with water. |
|-------------------------|---|------------------------------------|
- |                        |   |   |
|------------------------|---|---|
| In case of eye contact | : | Flush eyes with water as a precaution.<br>Remove contact lenses.<br>Protect unharmed eye.<br>Keep eye wide open while rinsing.<br>If eye irritation persists, consult a specialist. |
|------------------------|---|---|
- |              |   |   |
|--------------|---|---|
| If swallowed | : | Keep respiratory tract clear.<br>Do not give milk or alcoholic beverages.<br>Never give anything by mouth to an unconscious person.<br>If symptoms persist, call a physician.<br>Take victim immediately to hospital. |
|--------------|---|---|
- |   |   |  |
|---|---|--|
| Most important symptoms and effects, both acute and delayed | : | May cause genetic defects.<br>May cause cancer.<br>May damage fertility. May damage the unborn child.<br>Causes damage to organs through prolonged or repeated exposure. |
|---|---|--|
- |                    |   |  |
|--------------------|---|--|
| 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:<br>Carbon monoxide<br>Ammonia<br>Nitrogen oxides (NOx)<br>Gaseous hydrogen chloride (HCl).<br>Carbon oxides |
|-------------------------------|---|---|
- |                     |   |   |
|---------------------|---|---|
| Further information | : | Collect contaminated fire extinguishing water separately. This must not be discharged into drains.<br>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, protection | : | Use personal protective equipment. |
|----------------------------------|---|------------------------------------|



# SAFETY DATA SHEET

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				giene Com- mittee (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 (Titanium dioxide)	ACGIH

**Engineering measures** : No data available

### Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.  
Effective dust mask

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 : 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 mandatory

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 : tablet

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Color	:	light red
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
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 reac-	:	No decomposition if stored and applied as directed.

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tions

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: 2,960 mg/kg  
Method: Calculation methodAcute inhalation toxicity : Acute toxicity estimate: 66.92 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation methodAcute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method**Components:****Valganciclovir:**

Acute oral toxicity : LD50 Oral (Mouse): &gt; 2,000 mg/kg

**Cellulose:**

Acute oral toxicity : LD50 Oral (Rat): &gt; 5,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): &gt; 2,000 mg/kg

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

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

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Valganciclovir:**Species : Rabbit  
Result : No skin irritation

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**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Valganciclovir:**

Species : Rabbit  
Result : No eye irritation

**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:**

**Valganciclovir:**

Species : Guinea pig  
Result : Did not cause sensitization on laboratory animals.

**Germ cell mutagenicity**

May cause genetic defects.

**Components:**

**Valganciclovir:**

Genotoxicity in vitro : Result: positive  
Genotoxicity in vivo : Species: laboratory animal  
Result: positive  
Germ cell mutagenicity - Assessment : In vivo tests showed mutagenic effects

**Carcinogenicity**

May cause cancer.

**Components:**

**Valganciclovir:**

Species : laboratory animal  
Result : positive  
Symptoms : carcinogenic effects  
The value is given in analogy to the following substances: Ganciclovir

Carcinogenicity - Assessment : Human carcinogen.

**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.





**VALCYTE(R) F.C. Tablets (450 mg)**Version  
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- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 1,020 mg/l  
Exposure time: 96 h  
The value is given in analogy to the following substances:  
Ganciclovir
- NOEC (Oncorhynchus mykiss (rainbow trout)): 1,020 mg/l  
Exposure time: 96 h  
The value is given in analogy to the following substances:  
Ganciclovir
- LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1,020 mg/l  
Exposure time: 96 h  
The value is given in analogy to the following substances:  
Ganciclovir
- NOEC (Lepomis macrochirus (Bluegill sunfish)): 1,020 mg/l  
Exposure time: 96 h  
The value is given in analogy to the following substances:  
Ganciclovir
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,010 mg/l  
Exposure time: 48 h  
The value is given in analogy to the following substances:  
Ganciclovir
- NOEC (Daphnia magna (Water flea)): 1,010 mg/l  
Exposure time: 48 h  
The value is given in analogy to the following substances:  
Ganciclovir
- Toxicity to algae/aquatic plants : NOEC (blue-green algae): 1,000 mg/l  
End point: see user defined free text  
Exposure time: 12 d  
The value is given in analogy to the following substances:  
Ganciclovir
- Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.012 mg/l  
Exposure time: 35 d  
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)  
Method: OECD Test Guideline 210  
GLP: yes  
Remarks: average measured concentration  
The value is given in analogy to the following substances:  
Ganciclovir
- Toxicity to microorganisms : NOEC (Natural microorganism): 1,000 mg/l  
Exposure time: 12 d

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Test substance: see user defined free text  
The value is given in analogy to the following substances:  
Ganciclovir

**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**Persistence and degradability****Components:****Valganciclovir:**Biodegradability : Result: Not rapidly biodegradable  
Biodegradation: 2 %  
Exposure time: 28 d  
Remarks: Not inherently biodegradable.  
The value is given in analogy to the following substances:  
Ganciclovir

Result: Not rapidly biodegradable  
Biodegradation: 34 %  
Exposure time: 28 d  
Method: OECD Test Guideline 308  
Remarks: Ultimate aerobic biodegradation  
The value is given in analogy to the following substances:  
Ganciclovir

**Bioaccumulative potential****Components:****Valganciclovir:**Partition coefficient: n- : log Pow: 0.009  
octanol/water : pH: 6.9**Cellulose:**



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Packing instruction (cargo aircraft) : 956  
 Packing instruction (passenger aircraft) : 956  
 Environmentally hazardous : yes

**IMDG-Code**

UN number : UN 3077  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
 (Valganciclovir mixture)  
 Class : 9  
 Packing group : III  
 Labels : 9  
 EmS Code : F-A, S-F  
 Marine pollutant : yes

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

Not applicable

**Domestic regulation****49 CFR**

UN/ID/NA number : UN 3077  
 Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
 (Valganciclovir mixture)  
 Class : 9  
 Packing group : III  
 Labels : CLASS 9  
 ERG Code : 171  
 Marine pollutant : no

**Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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**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**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Germ cell mutagenicity  
 Carcinogenicity  
 Reproductive toxicity  
 Specific target organ toxicity (single or repeated exposure)

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**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 SOCOMI 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**

Cellulose	9004-34-6
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**Pennsylvania Right To Know**

Valganciclovir	175865-59-5
Cellulose	9004-34-6
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8

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

**California Permissible Exposure Limits for Chemical Contaminants**

Cellulose	9004-34-6
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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

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on the Canadian DSL nor NDSL.

Valganciclovir

non hazardous compounds

- 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.

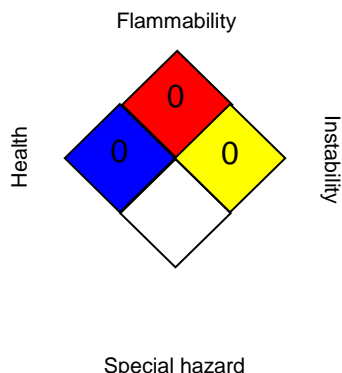
### TSCA list

No substances are subject to a Significant New Use Rule.

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

## SECTION 16. OTHER INFORMATION

### NFPA:



### HMIS® IV:

<b>HEALTH</b>	*	<b>3</b>
<b>FLAMMABILITY</b>		<b>0</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

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 -

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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; 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 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 / 1810