

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

Version
1.3

Revision Date:
02-28-2020

Date of last issue: 06-10-2017
Date of first issue: 12-10-2015

SECTION 1. IDENTIFICATION

Product name : VALCYTE(R) F.C. Tablets (450 mg)
Product code : 00010069575

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 number : US Chemtrec phone (800)-424-9300

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 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.
H372 Causes damage to organs through prolonged or repeated exposure.

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Precautionary Statements

:

Prevention:

P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust/ 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 ₂)	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.
 If symptoms persist, call a physician.

In case of skin contact

:

If on skin, rinse well with water.

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- In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

- If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.

- Most important symptoms and effects, both acute and delayed : May cause genetic defects.
May cause cancer.
May damage fertility. May damage the unborn child.
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:
Carbon monoxide
Ammonia
Nitrogen oxides (NOx)
Gaseous hydrogen chloride (HCl).
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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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- Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities.
- Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : Avoid formation of respirable particles.
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 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 : Protected from heat and light
Protect from moisture.
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, glass, Polyethylene bag in metal drum

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Valganciclovir	175865-59-5	IOEL	0.008 mg/m ³	Roche Industrial Hygiene Committee (RIHC)

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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
Octadecanoic acid	57-11-4	TWA (Inhalable fraction)	10 mg/m3	ACGIH
		TWA (Respirable fraction)	3 mg/m3	ACGIH
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

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Appearance	:	tablet
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

SECTION 10. STABILITY AND REACTIVITY

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

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

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 method

Acute inhalation toxicity : Acute toxicity estimate: 66.92 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:**Valganciclovir:**

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

Cellulose:

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

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

Octadecanoic acid:

Acute oral toxicity : LD50 Oral (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 Dermal (Rat): > 5,000 mg/kg

Titanium oxide (TiO₂):

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

Skin corrosion/irritation

Not classified based on available information.

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Components:

Valganciclovir:

Species : Rabbit
Result : No skin irritation

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.

Product:

Assessment : High Potential Substances (HPS)

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

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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.

Octadecanoic acid:

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

May damage fertility. May damage the unborn child.

Components:

Valganciclovir:

Effects on fertility : Species: laboratory animal
Symptoms: Effects on fertility.
The value is given in analogy to the following substances:
Ganciclovir

Effects on fetal development : Species: laboratory animal
Result: Teratogenic effects., Embryotoxic effects.
The value is given in analogy to the following substances:
Ganciclovir

Reproductive toxicity - Assessment : Presumed human reproductive toxicant, May damage fertility.
May damage the unborn child.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:

Valganciclovir:

Assessment : Causes damage to organs through prolonged or repeated

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exposure.

Repeated dose toxicity**Product:**Repeated dose toxicity -
Assessment : High Potential Substances (HPS)**Components:****Valganciclovir:**Species : Rat
NOAEL : mg/kg bw/day, 2
Application Route : Oral
Exposure time : 90 d
Remarks : Subchronic toxicity**Aspiration toxicity**

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Valganciclovir:**

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 : EC50 (Daphnia magna (Water flea)): > 1,010 mg/l
aquatic invertebrates : 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

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- 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 microorganisms : NOEC (Natural microorganism): 1,000 mg/l
Exposure time: 12 d
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 (TiO₂):

- Toxicity to fish : LC0 (Leuciscus idus (Golden orfe)): > 1,000 mg/l
Exposure time: 48 h
- Toxicity to daphnia and other aquatic invertebrates : EC0 (Daphnia magna (Water flea)): 3 mg/l
Exposure time: 720 h

Ecotoxicology Assessment

- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

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

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Octadecanoic acid:

Biodegradability : Biodegradation: 44 %

Bioaccumulative potential

Components:

Valganciclovir:

Partition coefficient: n-octanol/water : log Pow: 0.009
pH: 6.9

Cellulose:

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

Octadecanoic acid:

Partition coefficient: n-octanol/water : log Pow: 8.23

Titanium oxide (TiO2):

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

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).

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.

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

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 : Germ cell mutagenicity
Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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

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

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

California Prop. 65

WARNING: This product can expose you to chemicals including Titanium oxide (TiO₂), which is/are known to the State of California to cause cancer. For more information go to 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

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.

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 : Substance(s) not listed on TSCA inventory

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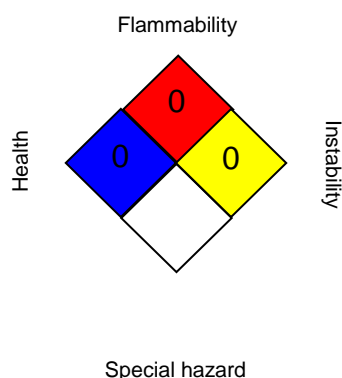
TSCA list

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:

HEALTH	*	3
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

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; 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

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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