### VALCYTE Powder for Oral Solution 50mg/ml

VersionRevision Date:Date of last issue: 02-28-20201.101-26-2021Date of first issue: 02-28-2020

#### **SECTION 1. IDENTIFICATION**

Product name	:	VALCYTE Powder for Oral So	lution 50mg/ml		
Product code	:	RO107-9070/F01			
Manufacturer or supplier's	deta	iils			
Company name of supplier	:	Genentech, Inc.			
Address	:	DNA Way 1 94080 South San Francisco CA USA			
Telephone E-mail address Emergency telephone	:	001-(650) 225-1000 info.sds@roche.com			
Emergency telephone num- ber	:	: US Chemtrec phone (800)-424-93			
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**

Germ cell mutagenicity

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR
1910.1200)

: Category 1B

5,		
Carcinogenicity	:	Category 1A
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure	:	Category 1
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.
		A / A7

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**Precautionary Statements** 2 **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	45.9
D-Mannitol	69-65-8	48.2
2-Butenedioic acid (2E)-	110-17-8	1.7
2-Pyrrolidinone, 1-ethenyl-, homo- polymer	9003-39-8	1.7
Benzoic acid, sodium salt (1:1)	532-32-1	0.8
1,2-Benzisothiazol-3(2H)-one, 1,1- dioxide, sodium salt (1:1)	128-44-9	0.2
non hazardous compounds	Not Assigned	1.5

#### **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.

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In case of skin conta	ct : If on s	kin, rinse well with water.
In case of eye contac	Remo Protec Keep	diately flush eye(s) with plenty of water. ve contact lenses. ct unharmed eye. eye wide open while rinsing. irritation persists, consult a specialist.
If swallowed	Do no Never If sym Take	respiratory tract clear. t give milk or alcoholic beverages. give anything by mouth to an unconscious person. ptoms persist, call a physician. victim immediately to hospital. mouth with water.
Most important symp and effects, both acu delayed	ite and May c May c	ause genetic defects. ause cancer. lamage fertility. May damage the unborn child. es damage to organs through prolonged or repeated ure.
Notes to physician		rst aid procedure should be established in consultation ne 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 prod- ucts	:	Carbon oxides In case of fire hazardous decomposition products may be produced such as: Carbon monoxide Ammonia Nitrogen oxides (NOx) Gaseous hydrogen chloride (HCI).
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, protec- :	Use personal protective equipment.
tive equipment and emer-	Avoid dust formation.

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gency procedures	Avoid breath Avoid expos	5		
Environmental precaution	Prevent furth	duct from entering drains. her leakage or spillage if safe to do so. et contaminates rivers and lakes or drains inform uthorities.		
Methods and materials containment and cleaning	•	able, 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	:	<ul> <li>Avoid formation of respirable particles.</li> <li>Do not breathe vapors/dust.</li> <li>Avoid exposure - obtain special instructions before use.</li> <li>Avoid contact with skin and eyes.</li> <li>For personal protection see section 8.</li> <li>Smoking, eating and drinking should be prohibited in the application area.</li> <li>Dispose of rinse water in accordance with local and national regulations.</li> </ul>
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 stor- age conditions	:	See label, package insert or internal guidelines
Storage temperature	:	Protected from heat and light Protect from moisture.
Further information on stor- age 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 parame- ters / Permissible concentration	Basis
Valganciclovir	175865-59-5	IOEL	0.008 mg/m3	Roche In- dustrial Hy- giene Com-

Genentech

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						mittee (RIHC)	
	Engineering measure	es :	No data availa	ble			
	Personal protective e	equipment					
Respiratory protection :		:	approved filter	In the case of dust or aerosol formation use respirator with an approved filter. Effective dust mask			
	Hand protection						
	Material	:	Protective glov	/es			
Eye protection Replace to Eye wash b			propriate protective gloves to prevent skin contact. Forn or punctured gloves promptly.				
		:	Eye wash bottle with pure water Tightly fitting safety goggles				
	Skin and body protecti	ion :	Choose body p		it ding to the amount a is substance at the w		
	Protective measures	:	Instruction of e	employees man	datory		
	Hygiene measures	:	When using do When using do Wash hands b	o not smoke.	k. Id at the end of work	day.	

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	granular
Color	:	off-white
Odor	:	Not applicable
Odor Threshold	:	Not applicable
рН	:	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

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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
Explosive properties	:	No data available
Oxidizing properties	:	No data available

#### 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- tions	:	No decomposition if stored and applied as directed. Dust may form explosive mixture in air.
Conditions to avoid	:	No data available
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

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Acute inhalation to	kicity :	Acute toxicity es Exposure time: 4 Test atmosphere Method: Calcula	e: dust/mist
Components:			
Valganciclovir:			
Acute oral toxicity	:	LD50 Oral (Mou	se): > 2,000 mg/kg
2-Butenedioic acid	d (2E)-:		
Acute oral toxicity	:	LD50 Oral (Rat) Method: OECD	: 9,300 mg/kg Test Guideline 401
Acute inhalation to	kicity :	LC0 (Rat): > 1,3 Exposure time: 4 Test atmosphere Method: OECD	4 h
Acute dermal toxici	ty :		abbit): 20,000 mg/kg Test Guideline 402
Skin corrosion/irri Not classified base <u>Components:</u>		information.	
Valganciclovir:			
Species Result	:	Rabbit No skin irritation	
2-Butenedioic acio	d (2E)-:		
Species	:	Rabbit	
Method Result	:	OECD Test Guid Mild skin irritatio	
Serious eye dama	ge/eye irritat	ion	
Not classified base	d on available	information.	

Components:

### Valganciclovir:

Species	:	Rabbit
Result	:	No eye irritation

### 2-Butenedioic acid (2E)-:

Species	:	Rabbit
Result	:	Irritating to eyes.
Method	:	OECD Test Guideline 405

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#### 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 2 Result Did not cause sensitization on laboratory animals. ٠ 2-Butenedioic acid (2E)-: **Species** Guinea pig 5 Method **OECD** Test Guideline 406 : Result : Did not cause sensitization on laboratory animals. Germ cell mutagenicity May cause genetic defects. **Components:** Valganciclovir: Genotoxicity in vitro Result: positive 2 Genotoxicity in vivo 2 Species: laboratory animal Result: positive Germ cell mutagenicity -In vivo tests showed mutagenic effects : Assessment 2-Butenedioic acid (2E)-: Germ cell mutagenicity -Not mutagenic in Ames Test. : Assessment Carcinogenicity May cause cancer. **Components:** Valganciclovir: Species laboratory animal Result positive Symptoms 2 carcinogenic effects The value is given in analogy to the following substances: Ganciclovir Carcinogenicity - Assess-Human carcinogen. : ment 2-Butenedioic acid (2E)-: Remarks No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed

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	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 May damage f <u>Components</u>	ertility. May dama	age	e the unborn child.		
Valganciclovi Effects on fert		:	Species: laborato Symptoms: Effec The value is give Ganciclovir		
Effects on feta	Il development	:		ory animal nic effects., Embryotoxic effects. n in analogy to the following substances:	
Reproductive sessment	toxicity - As-	:	Presumed humar May damage the	n reproductive toxicant, May damage fertility. unborn child.	
STOT-single	exposure				
Not classified	based on availabl	le i	nformation.		
<b>Components</b>	<u>.</u>				
2-Butenedioio Assessment	c acid (2E)-:	:	The substance or organ toxicant, si	r mixture is not classified as specific target ingle exposure.	
	ge to organs throu	ugl	n prolonged or rep	peated exposure.	
<u>Components</u>	<u>.</u>				
Valganciclovi Assessment	i <b>r:</b>	:	Causes damage exposure.	to organs through prolonged or repeated	
<b>2-Butenedioi</b> Assessment	c acid (2E)-:	:		r mixture is not classified as specific target epeated exposure.	

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#### Repeated dose toxicity

#### **Components:**

#### Valganciclovir:

Species	
NOAEL	
Application Route	
Exposure time	
Remarks	

Rat mg/kg bw/day, 2 Oral : 90 d Subchronic toxicity

#### Aspiration toxicity

Not classified based on available information.

#### **Components:**

#### 2-Butenedioic acid (2E)-:

No data available

#### **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 EC50 (Daphnia magna (Water flea)): > 1,010 mg/l Toxicity to daphnia and other : 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 The value is given in analogy to the following substances: Ganciclovir

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Toxicity to algae/aquat plants	ic :	NOEC (blue-green algae) End point: see user define Exposure time: 12 d The value is given in anal Ganciclovir	
Toxicity to fish (Chroni icity)	c tox- :	Exposure time: 35 d Test Type: Fish early-life : 210) Method: OECD Test Guid GLP: yes Remarks: average measu	
Toxicity to microorgan	isms :	NOEC (Natural microorga Exposure time: 12 d Test substance: see user The value is given in anal Ganciclovir	
<b>2-Butenedioic acid (2</b> Toxicity to fish	2 <b>E)-:</b>	LC50 (Danio rerio (zebra Exposure time: 48 h	fish)): 245 mg/l
		LC50 (Brachydanio rerio ( Exposure time: 96 h Method: OECD Test Guid	
		NOEC (Brachydanio rerio Exposure time: 96 h Method: OECD Test Guid	
Toxicity to daphnia and aquatic invertebrates	d other :	EC50 (Daphnia magna (V Exposure time: 48 h	Vater flea)): 212 mg/l
Toxicity to algae/aquat plants	tic :	IC50 (Desmodesmus sub Exposure time: 72 h	spicatus (green algae)): 41 mg/l
		NOEC (Pseudokirchneriel mg/l Exposure time: 72 h Method: OECD Test Guid	lla subcapitata (green algae)): 100 Ieline 201
		ErC50 (Pseudokirchneriel mg/l Exposure time: 72 h Method: OECD Test Guid	lla subcapitata (green algae)): > 100 leline 201
Toxicity to microorgan	isms :	EC10 (Pseudomonas puti Exposure time: 6 h	ida): 23.2 mg/l

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Ecotoxicology A	ssessment		
Acute aquatic tox	icity	Toxic t	o aquatic life.
Toxicity Data on S	Soil	Not ex	pected to adsorb on soil.
Other organisms the environment	relevant to	No dat	a available
Persistence and	degradability	,	
Components:			
Valganciclovir:			
Biodegradability	:	Biodeg Exposi Remar	Not rapidly biodegradable radation: 2 % ure time: 28 d ks: Not inherently biodegradable. lue is given in analogy to the following substances lovir
		Biodeg Exposi Methoo Remar	Not rapidly biodegradable radation: 34 % ure time: 28 d d: OECD Test Guideline 308 ks: Ultimate aerobic biodegradation lue is given in analogy to the following substances lovir
2-Butenedioic a	cid (2E)-:		
Biodegradability	:	Exposi Metho Remar	radation: 98 % ure time: 21 d d: OECD Test Guideline 301 ks: According to the results of tests of biodegradate oduct is considered as being readily biodegradable
		Expos	radation: 67.5 % ure time: 28 d d: OECD Test Guideline 301B
		Expos	radation: 60.3 % ure time: 11 d d: OECD Test Guideline 301B
Bioaccumulative	e potential		
Components:			
Valganciclovir:			
Partition coefficie octanol/water	nt: n-	log Po pH: 6.9	w: 0.009
<b>2-Butenedioic</b> ad Partition coefficie		: log Po	<i>N</i> : -4.02 (68 °F / 20 °C)

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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.
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.

#### **SECTION 14. TRANSPORT INFORMATION**

#### International Regulations

UNRTDG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Valganciclovir mixture)
Class	:	9
Packing group	:	
Labels	:	9
IATA-DGR		
UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Valganciclovir mixture)
Class	:	9
Packing group	:	
Labels	:	
Packing instruction (cargo aircraft)	:	956
Packing instruction (passen- ger aircraft)	:	956

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	Environmentally hazar	dous :	: yes	
	<b>IMDG-Code</b> UN number Proper shipping name	:	: UN 3077 : ENVIRONMENT N.O.S. (Valganciclovir n	ALLY HAZARDOUS SUBSTANCE, SOLID,
	Class Packing group Labels EmS Code	:	: 9 : III : 9	, ,
	Marine pollutant	:	: F-A, S-F : yes	
	Transport in bulk acc Not applicable	cording to	o Annex II of MAR	POL 73/78 and the IBC Code
	Domestic regulation			

<b>49 CFR</b> UN/ID/NA number Proper shipping name	<ul> <li>: UN 3077</li> <li>: Environmentally hazardous substance, solid, n.o.s. (Valganciclovir mixture)</li> </ul>
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.

#### **SECTION 15. REGULATORY INFORMATION**

#### **EPCRA - Emergency Planning and Community Right-to-Know**

#### **CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
2-Butenedioic acid (2E)-	110-17-8	5000	*

\*: Calculated RQ exceeds reasonably attainable upper limit.

#### 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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489): >= 1 - < 5%

2-Butenedioic acid (2E)-110-17-8

#### **Clean Water Act**

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

2-Butenedioic acid (2E)- 110-17-8 >= 1 - < 5 % The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

2-Butenedioic acid (2E)- 110-17-8 >= 1 - < 5 % 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**

2-Butenedioic acid (2E)-	110-17-8
1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt (1:1)	128-44-9

#### Pennsylvania Right To Know

D-Mannitol	69-65-8
Valganciclovir	175865-59-5
2-Butenedioic acid (2E)-	110-17-8
1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt (1:1)	128-44-9

#### 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 List of Hazardous Substances**

2-Butenedioic acid (2E)-	110-17-8
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8

#### 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

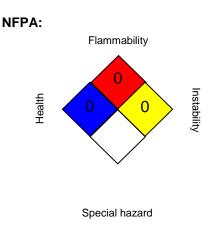
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	non hazardous c	compounds
AICS	: Not in compliance	e with the inventory
NZIoC	: Not in compliance	e with the inventory
ENCS	: Not in compliance	e with the inventory
ISHL	: Not in compliance	e with the inventory
KECI	: Not in compliance	e with the inventory
PICCS	: Not in compliance	e with the inventory
IECSC	: Not in compliance	e with the inventory
TCSI	: Not in compliance	e with the inventory
TSCA	: Product contains	s 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**



#### HMIS® IV:



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

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

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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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