

SAFETY DATA SHEET

VALCYTE(R) Powder for Oral Solution (50 mg/ml)

Version 1.0 Revision Date: 02-28-2020 Date of last issue: -
Date of first issue: 02-28-2020

SECTION 1. IDENTIFICATION

Product name : VALCYTE(R) Powder for Oral Solution (50 mg/ml)
Product code : 00010090308

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.

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	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.

In case of skin contact

:

If on skin, rinse well with water.

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- 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.
Take victim immediately to hospital.
Rinse mouth with water.

- 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 : Carbon oxides
In case of fire hazardous decomposition products may be produced such as:
Carbon monoxide
Ammonia
Nitrogen oxides (NOx)
Gaseous hydrogen chloride (HCl).

- 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.

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- Avoid exposure
- 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/m3	Roche Industrial Hygiene Committee

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			(RIHC)
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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 : granular

Color : off-white

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

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

Components:**Valganciclovir:**

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

2-Butenedioic acid (2E)-:

Acute oral toxicity : LD50 Oral (Rat): 9,300 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC0 (Rat): > 1,306 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 Dermal (Rabbit): 20,000 mg/kg
Method: OECD Test Guideline 402

Skin corrosion/irritation

Not classified based on available information.

Components:**Valganciclovir:**

Species : Rabbit
Result : No skin irritation

2-Butenedioic acid (2E)-:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Mild skin irritation

Serious eye damage/eye irritation

Not classified based 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.

Product:

Assessment : High Potential Substances (HPS)

Components:

Valganciclovir:

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

2-Butenedioic acid (2E)-:

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

2-Butenedioic acid (2E)-:

Germ cell mutagenicity - Assessment : Not mutagenic in Ames Test.

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.

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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 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

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.

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

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

STOT-repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:
Valganciclovir:

Assessment : Causes damage to organs through prolonged or repeated exposure.

2-Butenedioic acid (2E)-:

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

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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.

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

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 1,010 mg/l
aquatic invertebrates Exposure time: 48 h

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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 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

2-Butenedioic acid (2E)-:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 245 mg/l
Exposure time: 48 h

LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

NOEC (Brachydanio rerio (zebrafish)): 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 212 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : IC50 (Desmodesmus subspicatus (green algae)): 41 mg/l
Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10 (Pseudomonas putida): 23.2 mg/l
Exposure time: 6 h

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic to aquatic life.

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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

2-Butenedioic acid (2E)-:

 Biodegradability : Biodegradation: 98 %
 Exposure time: 21 d
 Method: OECD Test Guideline 301
 Remarks: According to the results of tests of biodegradability this product is considered as being readily biodegradable.

 Biodegradation: 67.5 %
 Exposure time: 28 d
 Method: OECD Test Guideline 301B

 Biodegradation: 60.3 %
 Exposure time: 11 d
 Method: OECD Test Guideline 301B

Bioaccumulative potential
Components:
Valganciclovir:

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

2-Butenedioic acid (2E)-:

 Partition coefficient: n-octanol/water : log Pow: -4.02 (68 °F / 20 °C)
 pH: 5.9
 Method: OECD Test Guideline 107

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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.

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 for product as supplied.

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

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)

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2-Butenedioic acid (2E)-	110-17-8	5000	*
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*: 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

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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

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

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

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

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

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:

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- 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

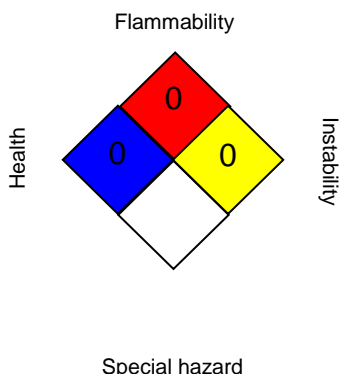
TSCA list

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

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AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 1810