

TAMIFLU(R) Powder for Susp. 30 mg/5ml

Version Revision Date: Date of last issue: 02-27-2020 1.6 10-18-2021 Date of first issue: 12-10-2015

SECTION 1. IDENTIFICATION

Product name : TAMIFLU(R) Powder for Susp. 30 mg/5ml

Product code : 00010158710

Common name(s), : TAMIFLU DRY SYRUP

synonym(s) of the substance

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.

Address : 1 DNA Way

South San Francisco, CA 94080

USA

Telephone : 001-(650) 225-1000 E-mail address : info.sds@roche.com

Emergency telephone

Emergency telephone : US Chemtrec phone

number

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

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

Skin sensitization : Category 1

Carcinogenicity : Category 2

GHS label elements

Hazard pictograms :





Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

H351 Suspected of causing cancer.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

(800)-424-9300

and understood.



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P261 Avoid breathing dust.

P272 Contaminated work clothing must not be allowed out of

the workplace.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/

attention.

P363 Wash contaminated clothing before reuse.

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)
Oseltamivir phosphate	204255-11-8	3.9
D-Glucitol	50-70-4	86.0
1,2,3-Propanetricarboxylic acid, 2-	18996-35-5	5.5
hydroxy-, sodium salt (1:1)		
Titanium oxide (TiO2)	13463-67-7	1.5
Xanthan gum	11138-66-2	1.5
non hazardous compounds	Not Assigned	1.34
Benzoic acid, sodium salt (1:1)	532-32-1	0.25
1,2-Benzisothiazol-3(2H)-one, 1,1-	128-44-9	0.01
dioxide, sodium salt (1:1)		

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 an allergic skin reaction.

Suspected of causing cancer.

Notes to physician : The first aid procedure should be established in consultation

with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire

fighting

No information available.

Hazardous combustion

products

Carbon oxides Sodium oxides

In case of fire hazardous decomposition products may be

produced such as: Nitrogen oxides (NOx) Oxides of phosphorus

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

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.

Ensure adequate ventilation.

Environmental precautions : Prevent product from entering drains.



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Prevent further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against

fire and explosion

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.

Provide sufficient air exchange and/or exhaust in work rooms. Dispose of rinse water in accordance with local and national

regulations.

Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being

used.

Conditions for safe storage : Keep container tightly

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

storage conditions

See label, package insert or internal guidelines

Storage temperature : Protected from heat and light

Protect from moisture.

Further information on

storage stability

Keep in a dry place.

No decomposition if stored and applied as directed.

Packaging material : Suitable material: glass

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control	Basis
		(Form of	parameters /	
		exposure)	Permissible	
			concentration	



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Oseltamivir phosphate	204255-11-8	IOEL	0.2 mg/m3	Roche Industrial Hygiene Committee (RIHC)
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

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Oseltamivir phosphate	Surface waters	100 μg/l
	Remarks:	
	Based on chronic data	

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an

approved filter.

Dust safety masks are recommended when the dust

concentration is more than 10 mg/m3.

Effective dust mask

Hand protection

In case of contact through splashing:

Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0.11 mm

In case of full contact:

Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water

Tightly fitting safety goggles

Skin and body protection : Dust impervious protective suit

Choose body protection according to the amount and

concentration of the dangerous substance at the work place.

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 : powder

Color : white, light yellow

Odor : odorless

Odor Threshold : Not applicable

pH : 3.0 - 5.0 (68 °F / 20 °C)

suspension

Melting point/range : No data available

Boiling point/boiling range : No data available

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

log Pow: 0.36

pH: 7.4

The value is given in analogy to the following substances:

Oseltamivir phosphate

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

reactions

: No decomposition if stored and applied as directed.

Dust may form explosive mixture in air.

Conditions to avoid : Exposure to light.

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 inhalation toxicity : Acute toxicity estimate: > 200 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Components:

Oseltamivir phosphate:

Acute oral toxicity : MNLD (Maximum No Lethal Dose) (Rat): > 2,000 mg/kg

Assessment: The component/mixture is minimally toxic after

single ingestion.

Titanium oxide (TiO2):

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

Method: OECD Test Guideline 425

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:

Titanium oxide (TiO2):



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Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks : Product dust may be irritating to eyes, skin and respiratory

system.

Components:

Oseltamivir phosphate:

Species : Rabbit Result : Eye irritation

Method : OECD Test Guideline 405

GLP : yes

Remarks : May cause irreversible eye damage.

Titanium oxide (TiO2):

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Product:

Remarks : Causes sensitization.

Components:

Oseltamivir phosphate:

Species : Guinea pig

Assessment : May cause sensitization by skin contact.

Method : OECD Test Guideline 406

GLP : yes

Titanium oxide (TiO2):

Species : Guinea pig

Assessment : Does not cause skin sensitization.

Method : OECD Test Guideline 406

Germ cell mutagenicity

Not classified based on available information.



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Components:

Oseltamivir phosphate:

Genotoxicity in vitro : Result: negative

Remarks: In vitro tests did not show mutagenic effects

Carcinogenicity

Suspected of causing cancer.

IARC Group 2B: Possibly carcinogenic to humans

Titanium oxide (TiO2) 13463-67-7

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Oseltamivir phosphate:

Effects on fertility : Species: laboratory animal

Result: Animal testing did not show any effects on fertility.

Effects on fetal development : Species: laboratory animal

Result: No teratogenic effects.

STOT-single exposure

Not classified based on available information.

Components:

Oseltamivir phosphate:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

STOT-repeated exposure

Not classified based on available information.

Components:

Oseltamivir phosphate:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

Oseltamivir phosphate:

Species : Rat NOAEL : 250 mg/kg



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Application Route : Oral Exposure time : 4 Weeks GLP : yes

Remarks : Subchronic toxicity

Aspiration toxicity

Not classified based on available information.

Components:

Oseltamivir phosphate:

No data available

Further information

Components:

Oseltamivir phosphate:

Remarks : Not phototoxic (in vitro)

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Oseltamivir phosphate:

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 33 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Selenastrum capricornutum (green algae)): 463 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

EyC50 (Selenastrum capricornutum (green algae)): 59 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

NOErC (Selenastrum capricornutum (green algae)): 46 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

NOEyC (Selenastrum capricornutum (green algae)): 10 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : (activated sludge): 30 mg/l



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Exposure time: 14 d

Method: OECD Test Guideline 302C

GLP: no

Remarks: no adverse influence on substrate biodegradation

Titanium oxide (TiO2):

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l

Exposure time: 96 h Test Type: static test

LC50 (Cyprinodon variegatus (sheepshead minnow)): >

10,000 mg/l

Exposure time: 96 h
Test Type: semi-static test

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

LC50 (Daphnia magna (Water flea)): > 1,000 mg/l

Exposure time: 48 h Test Type: static test

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h Test Type: static test

Method: OECD Test Guideline 201

EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l

Exposure time: 72 h Method: ISO 10253

NOEC (Skeletonema costatum (marine diatom)): 5,600 mg/l

Exposure time: 72 h Method: ISO 10253

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:

Oseltamivir phosphate:

Biodegradability : Biodegradation: 3.0 %

Exposure time: 28 d

Method: OECD Test Guideline 301B

Biodegradation: 2.8 % Exposure time: 14 d

Method: OECD Test Guideline 301B



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Titanium oxide (TiO2):

Biodegradability : Remarks: Not applicable

Bioaccumulative potential

Components:

Oseltamivir phosphate:

Partition coefficient: n-

octanol/water

: log Pow: 0.36

pH: 7.4

Titanium dioxide:

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.

Can be disposed as waste water, when in compliance with

local regulations.

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



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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

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 : Respiratory or skin sensitization

Carcinogenicity

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 SOCMI 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

Titanium oxide (TiO2) 13463-67-7 1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt (1:1) 128-44-9



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Pennsylvania Right To Know

D-Glucitol 50-70-4
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, sodium salt (1:1) 18996-35-5
Oseltamivir phosphate 204255-11-8
Titanium oxide (TiO2) 13463-67-7
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 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 Permissible Exposure Limits for Chemical Contaminants

Titanium oxide (TiO2) 13463-67-7

The ingredients of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Oseltamivir phosphate

non hazardous compounds

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.

TECI: Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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



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SECTION 16. OTHER INFORMATION

NFPA 704:

Health 2 0 Instability

Special hazard

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

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

OSHA PO : 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 OSHA P0 / TWA : 8-hour time weighted average OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification 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



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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 Cooperation 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 10-18-2021

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

US / Z8 / 2010