TAMIFLU Suspension 6 mg/ml

Version	Revision Date:	Date of last issue: -
1.0	06/16/2025	Date of first issue: 06/16/2025

SECTION 1. IDENTIFICATION

Product name	:	TAMIFLU Suspension 6 mg/ml
Product code	:	RO064-0796Z36
Common name(s), synonym(s) of the substance	:	TAMIFLU Oral Suspension (6 mg/ml)

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 In case of emergencies:	:	US CHEMTREC PHONE (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use	:	Formulated pharmaceutical active substance

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 and understood. P261 Avoid breathing mist or vapors. 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)
Water	7732-18-5	80.13
D-Glucitol	50-70-4	17
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, sodium salt (1:1)	18996-35-5	1.1
Oseltamivir phosphate	204255-11-8	0.8
Titanium oxide (TiO2)	13463-67-7	0.3
Xanthan gum	11138-66-2	0.3
non hazardous compounds	Not Assigned	0.3
Benzoic acid, sodium salt (1:1)	532-32-1	0.05
1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt (1:1)	128-44-9	0.02

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 : 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.

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	:	Induce vomiting immediately and call a physician. 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 an allergic skin reaction. Suspected of causing cancer.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection and use the recommended protective clothing
Notes to physician	:	Treat symptomatically.

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
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. Refer to protective measures listed in sections 7 and 8.
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 : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Advice on safe handling : 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.
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 closed in a dry and well-ventilated place.
Electrical installations / working materials must comply with the technological safety standards.

Storage temperature : Do not freeze.
Protect from heat and light

Further information on storage stability : No decomposition if stored and applied as directed.

Packaging material : Suitable material: Stainless steel, glass

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Oseltamivir phosphate	204255-11-8	IOEL	0.2 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Titanium oxide (TiO2)	13463-67-7	TWA (total	15 mg/m3	OSHA Z-1

		dust)		
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA (Respirable particulate matter)	0.2 mg/m3 (Titanium dioxide)	ACGIH
		TWA (Respirable particulate matter)	2.5 mg/m3 (Titanium dioxide)	ACGIH

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

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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 : Impervious clothing
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

Appearance	:	suspension
Color	:	white
Odor	:	very faint
Odor Threshold	:	No data available
pH	:	3 - 5 (68 °F / 20 °C)
Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Self-ignition	:	Not applicable
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	:	No data available
Relative density	:	No data available
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	:	No data available

Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Particle characteristics		
Particle Size Distribution	:	Not applicable

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.
Conditions to avoid	:	No data available
		No data available
Incompatible materials	:	No data available
		Not applicable
Hazardous decomposition products	:	No data available
		No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

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 due to lack of data.

Product:

Remarks	:	May cause skin irritation and/or dermatitis.

Components:

Titanium oxide (TiO2):

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified due to lack of data.

Product:

Remarks	:	Vapors may cause irritation to the eyes, respiratory system and the skin.

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 due to lack of data.

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 due to lack of data.

Components:

Oseltamivir phosphate:

Genotoxicity in vitro	:	Result: negative Remarks: In vitro tests did not show mutagenic effects

Carcinogenicity

Suspected of causing cancer.

Components:

Titanium oxide (TiO2):

Carcinogenicity - Assessment	:	Limited evidence of a carcinogenic effect.

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

Not classified due to lack of data.

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 due to lack of data.

Components:

Oseltamivir phosphate:

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

STOT-repeated exposure

Not classified due to lack of data.

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
Application Route	:	Oral
Exposure time	:	4 Weeks
GLP	:	yes
Remarks	:	Subchronic toxicity

Aspiration toxicity

Not classified due to lack of data.

Components:

Oseltamivir phosphate:

No data available

Further information

Product:

Remarks	:	No data available

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 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

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 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).

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
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.
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

Domestic regulation

49 CFR
Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

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

Components	CAS-No.	Component TPQ (lbs)

SARA 311/312 Hazards : Respiratory or skin sensitization
Carcinogenicity

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

1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt (1:1)	128-44-9

Pennsylvania Right To Know

Water	7732-18-5
D-Glucitol	50-70-4
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 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.

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

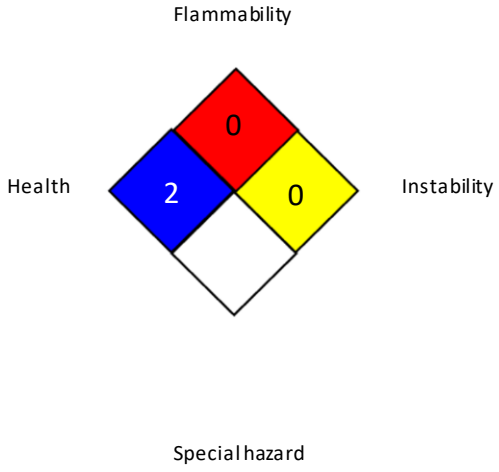
No substances are subject to a Significant New Use Rule.

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

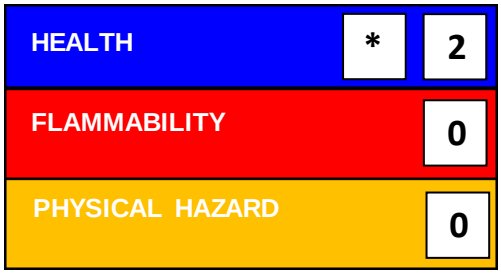
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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 P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
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 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; 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 : 06/16/2025

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.

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