

TAMIFLU Capsules 30 mgVersion
1.0Revision Date:
06/14/2025Date of last issue: -
Date of first issue: 06/14/2025**SECTION 1. IDENTIFICATION**

Product name : TAMIFLU Capsules 30 mg

Product code : RO064-0796/F06-00

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)**

Eye irritation : Category 2A

Skin sensitization : Category 1

Carcinogenicity : Category 2

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
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 dust.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing must not be allowed out of

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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.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

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

P337 + P313 If eye irritation persists: 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	37.88
Gelatins	9000-70-8	34.64
Amylodextrin	9005-84-9	17.85
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	3.19
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8	2.58
Titanium oxide (TiO ₂)	13463-67-7	1.6
Croscarmellose sodium	74811-65-7	1.31
sodium octadecyl fumarate	4070-80-8	0.65
non hazardous compounds	Not Assigned	0.3

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.

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		If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water.
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	:	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. Causes serious eye irritation. 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	:	Do not allow run-off from fire fighting to enter drains or water courses.
Hazardous combustion products	:	Nitrogen oxides (NO _x) Oxides of phosphorus Carbon oxides
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

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SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.
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 : 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.
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.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.
- Storage temperature : Protect from heat and light
Protect from moisture.
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Blister packages, Plastic container of HDPE, Stainless steel, glass

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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)
Talc (Mg3H2(SiO3)4)	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (respirable dust fraction)	2 mg/m3	OSHA P0
		TWA (Respirable)	2 mg/m3	NIOSH REL
		TWA (Respirable particulate matter)	2 mg/m3	ACGIH
Titanium oxide (TiO2)	13463-67-7	TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA (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.

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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
Wear face-shield and protective suit for abnormal processing problems.

Skin and body protection : 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 : capsules

Color : light yellow

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 : Not applicable

Evaporation rate : No data available

Self-ignition : No data available

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flammability limit : No data availableLower explosion limit / Lower
flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : Not applicable

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 : Not applicable

Viscosity, kinematic : Not applicable

Explosive properties : No data available

Oxidizing properties : No data available

Particle characteristics
Particle Size Distribution : 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.Conditions to avoid : No data available
No data availableIncompatible materials : No data available
Not applicable

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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.

Product:

Acute inhalation toxicity : Acute toxicity estimate: 124.86 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 due to lack of data.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:**Talc (Mg₃H₂(SiO₃)₄):**

Remarks : This information is not available.

Titanium oxide (TiO₂):

Species : Rabbit

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Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Remarks : May cause irreversible eye damage.

Components:**Oseltamivir phosphate:**

Species : Rabbit
Result : Eye irritation
Method : OECD Test Guideline 405
GLP : yes
Remarks : May cause irreversible eye damage.

Talc (Mg₃H₂(SiO₃)₄):

Remarks : This information is not available.

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

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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 - : Limited evidence of a carcinogenic effect.
Assessment

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.

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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.

Talc (Mg₃H₂(SiO₃)₄):

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

Talc (Mg₃H₂(SiO₃)₄):

No data available

Further information**Product:**

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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

Talc (Mg₃H₂(SiO₃)₄):

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 100,000 mg/l Exposure time: 24 h
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Ecotoxicology Assessment

Acute aquatic toxicity	:	This product has no known ecotoxicological effects.
Chronic aquatic toxicity	:	This product has no known ecotoxicological effects.

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Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to
the environment : No data available**Titanium oxide (TiO₂):**Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
Exposure time: 96 h
Test Type: static testLC50 (Cyprinodon variegatus (sheepshead minnow)): >
10,000 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203Toxicity to daphnia and other : LC50 (Daphnia magna (Water flea)): > 1,000 mg/l
aquatic invertebrates Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100
plants mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h
Method: ISO 10253NOEC (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 : No data available
the environment**Persistence and degradability****Components:****Oseltamivir phosphate:**Biodegradability : Biodegradation: 3.0 %
Exposure time: 28 d
Method: OECD Test Guideline 301BBiodegradation: 2.8 %
Exposure time: 14 d
Method: OECD Test Guideline 301B

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Biodegradability : Remarks: Not applicable

Bioaccumulative potential**Components:****Oseltamivir phosphate:**Partition coefficient: n-
octanol/water : log Pow: 0.36
pH: 7.4**Talc (Mg₃H₂(SiO₃)₄):**Partition coefficient: n-
octanol/water : Remarks: No data available**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 : An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.**Components:****Talc (Mg₃H₂(SiO₃)₄):**Adsorbed organic bound
halogens (AOX) : Remarks: Not applicableAdditional ecological
information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**Waste from residues : The product should not be allowed to enter drains, water
courses or the soil.
Do not contaminate ponds, waterways or ditches with

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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 Serious eye damage or eye irritation	

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

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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**

Talc ($\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$)	14807-96-6
Titanium oxide (TiO_2)	13463-67-7

Pennsylvania Right To Know

Oseltamivir phosphate	204255-11-8
Gelatins	9000-70-8
Amylodextrin	9005-84-9
Talc ($\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$)	14807-96-6
Titanium oxide (TiO_2)	13463-67-7

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 (TiO_2), which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

Talc ($\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$)	14807-96-6
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8

California Permissible Exposure Limits for Chemical Contaminants

Talc ($\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$)	14807-96-6
Titanium oxide (TiO_2)	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

Croscarmellose sodium

sodium octadecyl fumarate

non hazardous compounds

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

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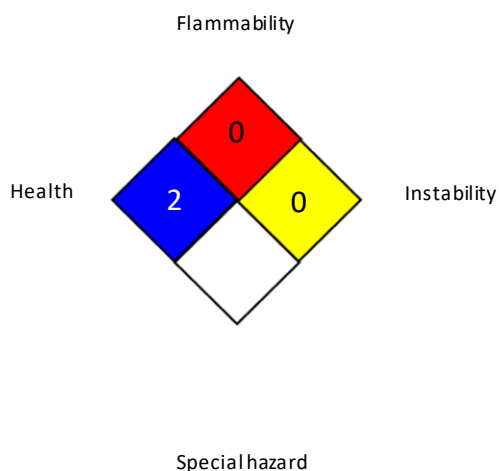
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ISHL	: Not in compliance with the inventory
KECI	: Not in compliance with the inventory
PICCS	: Not in compliance with the inventory
IECSC	: Not in compliance with the inventory
TCSI	: Not in compliance with the inventory
TSCA	: Product contains substance(s) 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:

HEALTH	*	2
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	: USA. NIOSH Recommended Exposure Limits
OSHA P0	: USA. 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

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OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / 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; TCEI - 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

The GHS classification for skin irritation and/or sensitization of the pure ingredients causes a corresponding GHS classification for the whole formulation. In view of the nature of the formulated product (film-coated tablet, capsule, etc.), an over-interpretation of the potential hazard is possible.

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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

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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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