

TAMIFLU(R) Capsules (45 mg)Version
0.0Revision Date:
02-20-2020Date of last issue: 06-10-2017
Date of first issue: 03-31-2017**SECTION 1. IDENTIFICATION**

Product name : TAMIFLU(R) Capsules (45 mg)
Product code : 00010075901

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 number : US Chemtrec phone (800)-424-9300

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**

Eye irritation : Category 2A
Skin sensitization : Category 1
Carcinogenicity : Category 1A

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H350 May cause cancer.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.

TAMIFLU(R) Capsules (45 mg)Version
0.0Revision Date:
02-20-2020Date of last issue: 06-10-2017
Date of first issue: 03-31-2017

P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
 P264 Wash skin thoroughly after handling.
 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.
 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	43.0
Gelatins	9000-70-8	<= 26.5
Amylodextrin	9005-84-9	20.3
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	3.6
2-Pyrrolidinone, 1-ethenyl-, homo-polymer	9003-39-8	2.9
Titanium oxide (TiO ₂)	13463-67-7	<= 1.5
Croscarmellose sodium	74811-65-7	1.5
sodium octadecyl fumarate	4070-80-8	0.7

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.

TAMIFLU(R) Capsules (45 mg)

Version 0.0	Revision Date: 02-20-2020	Date of last issue: 06-10-2017 Date of first issue: 03-31-2017
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- 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.
- 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.
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
Causes serious eye irritation.
May cause 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 : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:
Nitrogen oxides (NOx)
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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency measures : Use personal protective equipment.
Avoid dust formation.

SAFETY DATA SHEET

TAMIFLU(R) Capsules (45 mg)

Version
0.0

Revision Date:
02-20-2020

Date of last issue: 06-10-2017
Date of first issue: 03-31-2017

		(Form of exposure)	ters / Permissible concentration	
Oseltamivir phosphate	204255-11-8	IOEL	0.2 mg/m ³	Roche Industrial Hygiene Committee (RIHC)
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (Respirable fraction)	2 mg/m ³	ACGIH
Titanium oxide (TiO ₂)	13463-67-7	TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (Total dust)	10 mg/m ³	OSHA P0
		TWA	10 mg/m ³ (Titanium dioxide)	ACGIH

Engineering measures : No data available

Personal protective equipment

Hand protection

Material : 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
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, gray

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

TAMIFLU(R) Capsules (45 mg)Version
0.0Revision Date:
02-20-2020Date of last issue: 06-10-2017
Date of first issue: 03-31-2017

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	:	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

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
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

TAMIFLU(R) Capsules (45 mg)Version
0.0Revision Date:
02-20-2020Date of last issue: 06-10-2017
Date of first issue: 03-31-2017**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified based on available information.

Product:

Acute inhalation toxicity : Acute toxicity estimate: 118.57 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): > 7,500 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 10,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:**Talc (Mg₃H₂(SiO₃)₄):**

Remarks : This information is not available.

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

TAMIFLU(R) Capsules (45 mg)

Version
0.0

Revision Date:
02-20-2020

Date of last issue: 06-10-2017
Date of first issue: 03-31-2017

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.

Talc (Mg₃H₂(SiO₃)₄):

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.

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 based on available information.

Components:

Oseltamivir phosphate:

No data available

Talc (Mg₃H₂(SiO₃)₄):

No data available

TAMIFLU(R) Capsules (45 mg)Version
0.0Revision Date:
02-20-2020Date of last issue: 06-10-2017
Date of first issue: 03-31-2017**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
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

Ecotoxicology Assessment

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

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

TAMIFLU(R) Capsules (45 mg)

Version 0.0 Revision Date: 02-20-2020 Date of last issue: 06-10-2017
Date of first issue: 03-31-2017

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 : LC₀ (Leuciscus idus (Golden orfe)): > 1,000 mg/l
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates : EC₀ (Daphnia magna (Water flea)): 3 mg/l
Exposure time: 720 h

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

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

TAMIFLU(R) Capsules (45 mg)

Version
0.0

Revision Date:
02-20-2020

Date of last issue: 06-10-2017
Date of first issue: 03-31-2017

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 applicable

Additional 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 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

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

TAMIFLU(R) Capsules (45 mg)

Version 0.0 Revision Date: 02-20-2020 Date of last issue: 06-10-2017
 Date of first issue: 03-31-2017

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

EPCRA - Emergency Planning and Community Right-to-Know

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	:	Serious eye damage or eye irritation 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 SOCM I 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

US State Regulations

Massachusetts Right To Know

Talc (Mg3H2(SiO3)4) 14807-96-6
 Titanium oxide (TiO2) 13463-67-7

Pennsylvania Right To Know

Oseltamivir phosphate 204255-11-8
 Gelatins 9000-70-8
 Amylodextrin 9005-84-9
 Talc (Mg3H2(SiO3)4) 14807-96-6
 Titanium oxide (TiO2) 13463-67-7

TAMIFLU(R) Capsules (45 mg)

Version 0.0 Revision Date: 02-20-2020 Date of last issue: 06-10-2017
Date of first issue: 03-31-2017

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.

California List of Hazardous Substances

Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8

California Permissible Exposure Limits for Chemical Contaminants

Titanium oxide (TiO ₂)	13463-67-7
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The ingredients of this product are reported in the following inventories:

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

- Osetamivir phosphate
- Croscarmellose sodium
- sodium octadecyl fumarate

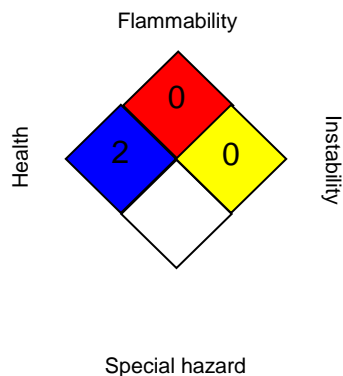
- AICS : Not in compliance with the inventory
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance 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

TAMIFLU(R) Capsules (45 mg)Version
0.0Revision Date:
02-20-2020Date of last issue: 06-10-2017
Date of first issue: 03-31-2017**NFPA:****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)
OSHA P0	:	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
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
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

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; 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;

TAMIFLU(R) Capsules (45 mg)

Version
0.0

Revision Date:
02-20-2020

Date of last issue: 06-10-2017
Date of first issue: 03-31-2017

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

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.

Revision Date : 02-20-2020

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