Safety Data Sheet

TAMIFLU(R) Oral Suspension

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	TAMIFLU(R) Oral Suspension
Product code	CSE-3172
Synonyms	- TAMIFLU Oral Suspension (6mg/ml) - TAMIFLU Reconstituted Suspension (6mg/ml)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use	- pharmaceutical active substance with antiviral effect	*1

1.3. Details of the supplier of the safety data sheet

Company information

Enquiries:
Genentech, Inc.
1 DNA Way
South San Francisco
USA-CA 94080
United States of America

Phone 001-(650) 225-1000
E-Mail info.sds@roche.com
US Chemtrec phone:
(800)-424-9300

Local representation:

1.4. Emergency telephone number

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

1 referring to: Oseltamivir phosphate

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification: no classification and labelling according to GHS

Other hazards

Note - no information available

SECTION 3: Composition/information on ingredients

Characterization	Oseltamivir phosphate and other inactive ingredients	
Ingredients	**Concentration**	**GHS-Classification (pure ingredient)**
Oseltamivir phosphate 204255-11-8	~ 4 %	- Combustible dust (No category), USH003 - Serious eye damage/eye irritation (Category 2A), H319 - Skin sensitization (Category 1), H317
Monosodium citrate anhydrous powder 18996-35-5	~ 6 %	
Titanium dioxide 13463-67-7	~ 2 %	

For the full text of the H-phrases mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	- rinse immediately with tap water for 10 minutes - open eyelids forcibly - consult a physician if irritation persists
Skin contact	- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
Inhalation	- remove the casualty to fresh air and keep him/her calm - in the event of symptoms get medical treatment

4.2. Most important symptoms and effects, both acute and delayed

Note	- no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician	- treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	- adapt extinguishing media to surrounding fire conditions
Flash point (liquid)	not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards	- formation of toxic and corrosive combustion gases (nitrous oxides, phosphorous oxides) possible

5.3. Advice for firefighters

Protection of fire-fighters	- precipitate gases/vapours/mists with water spray

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	- no special precautions required

6.2. Environmental precautions

Environmental protection	- do not allow to enter drains or waterways

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	- take up mechanically and dispose of

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials	- dark glass

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	- do not freeze
Validity	- ≤ 17 days, 2 to 8 °C - ≤ 10 days, 25 °C
Packaging materials	- amber glass bottles with child resistant plastic closure

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (USA) air	- ACGIH-TLV: 10 mg/m3 (not classifiable as a human carcinogen) - OSHA-PEL: 15 mg/m3 (total dust) - NIOSH-REL: 0.2 mg/m3	*2 *2 *2
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.2 mg/m3	*1

8.2. Exposure controls

Respiratory protection	-	Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
	-	respiratory protection not necessary during normal operations
Hand protection	-	protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection	-	safety glasses

1 referring to: Oseltamivir phosphate
2 referring to: Titanium dioxide

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	white	
Form	aqueous suspension	
Odor	almost odourless	
Partition coefficient	log P_{ow} 0.36 (octanol/water) pH 7.4	*1
pH value (20 °C)	3.0 to 5.0	

9.2. Other information

Note	-	no information available

1 referring to: Oseltamivir phosphate

SECTION 10: Stability and reactivity

10.1. Reactivity

Note	-	no information available

10.2. Chemical stability

Stability	-	stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note	-	no information available

10.4. Conditions to avoid

Note	-	no information available

10.5. Incompatible materials

Note	-	no information available

10.6. Hazardous decomposition products

Note	-	no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	-	MNLD > 2'000 mg/kg (oral, rat)	*1
Local effects	-	eye: irritant (rabbit; OECD No. 405)	*1
	-	not phototoxic (in vitro)	*1
Sensitization	-	sensitizing (guinea pig) (OECD No. 406)	*1
Subchronic toxicity	-	NOAEL 250 mg/kg/d (oral, rat; 4 weeks)	*1
Mutagenicity	-	not mutagenic (various in vitro test systems)	*1
Reproductive toxicity	-	does not lower parental fertility (several species)	*1
	-	not teratogenic (several species)	*1
Note	-	side effects: nausea, vomiting	*1
	-	therapeutic dose: 2 x 75 mg/d p.o. for 5 days	*1
Potential Health Effects	-	Exposure: Inhalation, Ingestion, Skin contact, Eye contact	
	-	Carcinogenicity: formulation not listed by NTP, IARC or OSHA	
	-	Carcinogenicity: IARC Gr3 not classifiable	*2

1 referring to: Oseltamivir phosphate
2 referring to: Titanium dioxide

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	-	moderately toxic for algae (Selenastrum capricornutum) EbC_{50} (96 h) 59 mg/l ErC_{50} (96 h) 463 mg/l NOEbC (96 h) 10 mg/l NOErC (96 h) 46 mg/l (OECD No. 201) *1

- moderately toxic for planktonic crustaceans (Daphnia magna)
  EC_{50} (48 h) 33 mg/l
  (OECD No. 202) *1
- barely toxic for fish (carp)
  LC_{50} (96 h) > 100 mg/l
  (OECD No. 203) *1
- no adverse influence on substrate biodegradation (activated sludge)
  concentration (14 d) 30 mg/l (nominal concentration)
  (MITI Test II, OECD No. 302C) *1

12.2. Persistence and degradability

Ready biodegradability	- not readily biodegradable 3 %, 28 days 2.8 %, 14 days (CO_2 Evolution Test, Modified Sturm Test, OECD No. 301B) *1
Abiotic degradation	- slow degradation, photodegradation, no significant hydrolysis 204 mg/l (measured initial concentration), water; HPLC ~ 13 %, 120 h, ~ 22 °C, under illumination ~ 2 %, 120 h, ~ 22 °C, dark *1

12.3. Bioaccumulative potential

Note	- no information available

12.4. Mobility in soil

Note	- no information available

12.5. Results of PBT and vPvB assessment

Note	- no information available

12.6. Other adverse effects

Note	- no information available

1 referring to: Oseltamivir phosphate

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues	- return to supplier or hand over to authorized disposal company - observe local/national regulations regarding waste disposal - incinerate in qualified installation with flue gas scrubbing - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

SECTION 14: Transport information

Note	- not classified by transport regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

TSCA Status	- FDA Exemption - not on inventory
Reporting Requirements	- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. - In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials. - State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Full text of H-Statements referred to under section 3

H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
USH003	May form combustible dust concentrations in the air

Note	- Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.
Edition documentation	- changes from previous version in sections 7

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.