

**1. Product and Company Identification**

Product name	TAMIFLU (R) Oral Suspension	
Product code	09 8100 1	
Use	- TAMIFLU(R) is a pharmaceutical product used to treat influenza.	
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	Local representation:
	Phone 001-973/235 50 00 E-Mail info.sds@roche.com	
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	

2. Hazards identification**Emergency Overview**

Form	suspension
Color	white
Hazard Overview	- May cause allergic reactions.
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact - Target Organs: eye, skin, gastrointestinal system, Immune System - Acute Effects: May cause eye irritation., May cause skin irritation., This material has not been tested as a whole; therefore, the information described below is based on one or more of its ingredients., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite. - Chronic Effects: May cause allergic reactions. - Carcinogenicity: formulation not listed by NTP, IARC or OSHA - Carcinogenicity: IARC Gr3 not classifiable *1
*1 referring to:	Titanium dioxide

3. Composition/Information on ingredients

TAMIFLU (R) Oral Suspension

Ingredients	Concentration
Oseltamivir phosphate CAS: 204255-11-8	~ 4 %
Monosodium citrate anhydrous powder CAS: 18996-35-5	~ 6 %
Titanium dioxide CAS: 13463-67-7	~ 2 %
4. First-aid measures	
Eye contact	- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
Skin contact	- remove immediately contaminated clothes, wash affected skin with plenty of water
Inhalation	- in case of inhalation remove to fresh air and seek medical aid
Ingestion	- consult physician
5. Fire-fighting measures	
Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	(Flash point not established)
Protection of fire-fighters	- use self-contained breathing apparatus
6. Accidental release measures	
Personal precautions	- ensure adequate ventilation
Methods for cleaning up	- Absorb small spills with noncombustible absorbent material - Put saturated absorbent material into a suitable labeled open head drum. - mop or flush the contaminated area with water - Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal. - Check area for residual material and repeat clean up if detected

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7. Handling and storage

Handling

Technical measures - Use with adequate ventilation

Note - Storage in a refrigerator at 2 to 8 degrees C (36 to 46 degrees F) is acceptable.

Storage

Storage conditions - dry and ventilated place
- do not freeze

8. Exposure controls/Personal protection

Engineering Measures - see 7.

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

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.2 mg/m³ *2

Personal protective equipment

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

Eye protection - tightly fitting safety glasses

Body protection - protective clothing

General protective and hygiene measures - instruction of employees mandatory
- shower after work recommended

*1 referring to: Titanium dioxide

*2 referring to: Oseltamivir phosphate (NS)

9. Physical and chemical properties

Color white

Form suspension

TAMIFLU (R) Oral Suspension

10. Stability and reactivity

- Stability - stable under normal conditions
- Materials to avoid - strong oxidizing agents, strong acids

11. Toxicological information

- Acute toxicity
- LD₅₀ 1'348 (i.p., rat) *3
 - LD₅₀ 49 (i.v., rat) *3
 - MNLD 100 mg/kg (i.v., mouse) *2
 - MNLD > 2'000 mg/kg (oral, mouse) *2
 - MNLD > 2'000 mg/kg (oral, rat) *2
- Local effects
- eye: irritant (rabbit; OECD No. 405) *2
 - not phototoxic (in vitro) *2
- Sensitization
- sensitizing (guinea pig) (OECD No. 406) *2
- Subchronic toxicity
- NOAEL 250 mg/kg/d (oral, rat; 4 weeks) *2
 - NOAEL 500 mg/kg/d (oral, marmoset; 7 days) *2
- Mutagenicity
- not mutagenic (Ames test) *2
 - not mutagenic (various in vitro test systems) *2
- Reproduction toxicity
- does not lower parental fertility (several species) *2
 - not teratogenic (several species) *2
- Note
- side effects: nausea, vomiting *2
 - therapeutic dose: 2 x 75 mg/d p.o. for 5 days *2

*2 referring to:

Oseltamivir phosphate (NS)

*3 referring to:

Monosodium citrate anhydrous powder

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12. Ecological information

Ready biodegradability	<ul style="list-style-type: none"> - not readily biodegradable 3 %, 28 days 2.8 %, 14 days (CO₂ Evolution Test, Modified Sturm Test, OECD No. 301B) 	*2
Inherent biodegradability	<ul style="list-style-type: none"> - not inherently biodegradable 12 %, 28 days 12 %, 15 days 0 %, 8 days (flask shaking test Roche Basel, inherent biodegradation) 	*2
Abiotic degradation	<ul style="list-style-type: none"> - 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 	*2
Ecotoxicity	<ul style="list-style-type: none"> - moderately toxic for algae (<i>Selenastrum capricornutum</i>) EbC₅₀ (96 h) 59 mg/l ErC₅₀ (96 h) 463 mg/l NOEbC (96 h) 10 mg/l NOErC (96 h) 46 mg/l (OECD No. 201) - moderately toxic for planktonic crustaceans (<i>Daphnia magna</i>) EC₅₀ (48 h) 33 mg/l (OECD No. 202) - barely toxic for fish (carp) LC₅₀ (96 h) > 100 mg/l (OECD No. 203) - no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 30 mg/l (nominal concentration) (MITI Test II, OECD No. 302C) 	*2 *2 *2 *2
Mobility	<ul style="list-style-type: none"> - moderate to strong adsorption (water-activated sludge, 28 d, ~22 °C) K_d = 99 l/kg (activated sludge, 24 h) K_d = 3247 l/kg (activated sludge, 28 d) (Adsorption to activated sludge in biodegradability test) 	*2
Air pollution	<ul style="list-style-type: none"> - observe local/national regulations 	*2
*2 referring to:	Osetamivir phosphate (NS)	

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13. Disposal considerations

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|---------------------|---|
| Waste from residues | <ul style="list-style-type: none">- 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. |
| RCRA waste | <ul style="list-style-type: none">- not regulated under RCRA |

14. Transport information

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| Note | <ul style="list-style-type: none">- not classified by transport regulations, proper shipping name non-regulated |
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15. Regulatory information

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| TSCA Status | <ul style="list-style-type: none">- FDA Exemption - not on inventory |
| Reporting Requirements | <ul style="list-style-type: none">- 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. |

16. Other information

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| Edition documentation | <ul style="list-style-type: none">- changes from previous version in sections 16 |
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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.