



Material Safety Data Sheet

TAMIFLU (R) Powder for Oral Suspension

1. Product and Company Identification

Product name	TAMIFLU (R) Powder for Oral Suspension	
Product code	03 4322 6	
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	granular powder
Color	white
Hazard Overview	- May cause allergic reactions. - Possible dust explosion hazard based on information on related materials
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

TAMIFLU (R) Powder for Oral Suspension

3. Composition/Information on ingredients

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)	not applicable
Specific hazards	- consider dust explosion hazard
Protection of fire-fighters	- use self-contained breathing apparatus
Special method of fire-fighting	- cool endangered containers with water spray

6. Accidental release measures

Personal precautions	- ensure adequate ventilation
----------------------	-------------------------------

TAMIFLU (R) Powder for Oral Suspension

7. Handling and storage

Handling

- Technical measures
- Use with adequate ventilation
 - processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
 - avoid dust formation; consider dust explosion hazard
 - take precautionary measures against electrostatic charging

Storage

- Storage conditions
- room temperature
 - dry and ventilated place

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 is recommended for dusty operations.
 - Use of a negative pressure air purifying, half face respirator with a toxic/dust/mist/fume high efficiency filter in the laboratory or a supplied-air full facepiece respirator or supplied-air hood for production operations is recommended.

- 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)

TAMIFLU (R) Powder for Oral Suspension

9. Physical and chemical properties			
Color		white	
Form		granular powder	
10. Stability and reactivity			
Stability		- stable under normal conditions	
Materials to avoid		- strong oxidizing agents, strong acids	
11. Toxicological information			
Acute toxicity	- LD ₅₀	1'348 (i.p., rat)	*3
	- LD ₅₀	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	

TAMIFLU (R) Powder for Oral Suspension

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:	Oseltamivir phosphate (NS)	

TAMIFLU (R) Powder for Oral Suspension

13. Disposal considerations

- | | |
|---------------------|---|
| 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

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

15. Regulatory information

- | | |
|------------------------|--|
| 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

- | | |
|-----------------------|---|
| Edition documentation | <ul style="list-style-type: none">- first edition |
|-----------------------|---|

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.