Material Safety Data Sheet

TAMIFLU(R) Capsules (75 mg)

1. Product and Company Identification

Product name	TAMIFLU(R) Capsules (75 mg)
Product code	03 4203 3
Use	- TAMIFLU(R) is a pharmaceutical product used to treat influenza.
Company information	Enquiries: Local representation: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America 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	capsules
Color	light yellow grey
Hazard Overview	- May cause allergic reactions.
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact - Target Organs: eye, skin, gastrointestinal 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:	Talc

3. Composition/Information on ingredients

Characterization	final product

Ingredients	**Concentration**
Oseltamivir phosphate CAS: 204255-11-8	~ 60 %
Modified Food Starch CAS: 9005-84-9	~ 28 %
Talc CAS: 14807-96-6	~ 5 %
Povidone CAS: 9003-39-8	~ 4 %

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	- Toxic emissions may be given off in a fire
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
Environmental protection	- avoid release to the environment
Methods for cleaning up	- Scoop or shovel spilled material into a suitable labeled open head drum - Secure the drum cover and move the container to a safe holding area - Clean spill area thoroughly - 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

7. Handling and storage

Handling

Technical measures	- local exhaust ventilation necessary

Storage

Storage conditions	- keep containers tightly closed - room temperature - store in a dry place - protected from light

8. Exposure controls/Personal protection

Engineering Measures	- see 7.	
Threshold value (USA) air	- ACGIH-TLV: 10 mg/m3	*2
	- OSHA-PEL: 15 mg/m3 (total particulate)	*2
	- OSHA-PEL: 5 mg/m3 (respirable fraction)	*2
	- NIOSH-REL: 10 mg/m3 (total dust)	*2
	- NIOSH-REL: 5 mg/m3 (respirable fraction)	*2
	- ACGIH-TLV: 2 mg/m3 (respirable fraction) (use asbestos TLV-TWA, should not exceed 2mg/m3 respirable particulates)	*1
	- OSHA-PEL: 2 mg/m3 (respirable fraction)	*1
	- NIOSH-REL: 2 mg/m3 (respirable fraction)	*1
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.2 mg/m3	*3

Personal protective equipment

Respiratory protection	- Respiratory protection is recommended as a precaution to minimze 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
Hand protection	- protective gloves

Eye protection	-	safety glasses
Body protection	-	protective clothing

*1	referring to:	Talc
*2	referring to:	Modified Food Starch
*3	referring to:	Oseltamivir phosphate (NS)

9. Physical and chemical properties

Color	light yellow grey
Form	capsules
Solubility	soluble, water

10. Stability and reactivity

Stability	-	stable under the conditions mentioned in chapter 7
Conditions to avoid	-	high temperatures
Materials to avoid	-	strong acids, oxidizing agents
Note	-	Hazardous Polymerization: Will not occur.

11. Toxicological information

Acute toxicity	-	LD_{50}	> 2'000	mg/kg	(oral, rat)	*4
	-	MNLD	100	mg/kg	(i.v., mouse)	*3
	-	MNLD	> 2'000	mg/kg	(oral, mouse)	*3
	-	MNLD	> 2'000	mg/kg	(oral, rat)	*3
Local effects	-	eye: irritant (rabbit; OECD No. 405)				*3
	-	not phototoxic (in vitro)				*3
Sensitization	-	sensitizing (guinea pig) (OECD No. 406)				*3
	-	not sensitizing (guinea pig)				*3
Subchronic toxicity	-	NOAEL 250 mg/kg/d (oral, rat; 4 weeks)				*3
	-	NOAEL 500 mg/kg/d (oral, marmoset; 7 days)				*3
Mutagenicity	-	not mutagenic (Ames test)				*3
	-	not mutagenic (various in vitro test systems)				*3
Reproduction toxicity	-	does not lower parental fertility (several species)				*3
	-	not teratogenic (several species)				*3
Note	-	side effects: nausea, vomiting				*3
	-	therapeutic dose: 2 x 75 mg/d p.o. for 5 days				*3

*3	referring to:	Oseltamivir phosphate (NS)
*4	referring to:	POVIDONE K 30

12. Ecological information

Ready biodegradability	- not readily biodegradable 3 %, 28 days 2.8 %, 14 days (CO_2 Evolution Test, Modified Sturm Test, OECD No. 301B)	*3
Inherent biodegradability	- not inherently biodegradable < 10 %, 1 d < 10 %, 16 d < 10 %, 28 d (flask shaking test Roche Basel, inherent biodegradation)	*4
	- not inherently biodegradable 12 %, 28 days 12 %, 15 days 0 %, 8 days (flask shaking test Roche Basel, inherent biodegradation)	*3
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	*3
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)	*3
	- moderately toxic for planktonic crustaceans (Daphnia magna) EC_{50} (48 h) 33 mg/l (OECD No. 202)	*3
	- barely toxic for fish (carp) LC_{50} (96 h) > 100 mg/l (OECD No. 203)	*3
	- no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 30 mg/l (nominal concentration) (MITI Test II, OECD No. 302C)	*3
Mobility	- 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)	*3
Air pollution	- observe local/national regulations	*3

*3 referring to: Oseltamivir phosphate (NS)
*4 referring to: POVIDONE K 30

13. Disposal considerations

Waste from residues	- incinerate in qualified installation with flue gas scrubbing - observe local/national regulations regarding waste disposal - 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.
Contaminated packaging	- Empty containers must be triple rinsed prior to disposal, recycling or reuse.
RCRA waste	- not regulated under RCRA

14. Transport information

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

15. Regulatory information

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.

16. Other information

Edition documentation	- 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.