

Safety Data Sheet

TAMIFLU(R) Capsules (45 mg)

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

1.1. Product identifier

| | | |
|--------------|-------------------------------------|----|
| Product name | TAMIFLU(R) Capsules (45 mg) | |
| Product code | SAP-10075901 | |
| Synonyms | - Neuraminidase Inhibitor RO0640796 | *1 |

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

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

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SECTION 3: Composition/information on ingredients

Characterization 45 mg free base (Oseltamivir) equivalent of the phosphate salt

| Ingredients | Concentration | GHS-Classification (pure ingredient) |
|--------------------------------------|---------------|--|
| Oseltamivir phosphate 204255-11-8 | 43.1 % | - Combustible dust (No category), USH003 - Serious eye damage/eye irritation (Category 2A), H319 - Skin sensitization (Category 1), H317 |
| Starch 9005-84-9 | 20.3 % | |
| Talc 13776-74-4 | 3.6 % | |
| Povidone K30 9003-39-8 | 2.9 % | |

For the full text of the 'Hazard statements' mentioned in this Section, see Section 16.

*1 referring to: Oseltamivir phosphate

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact - rinse with tap water for 20 minutes - open eyelids forcibly

Skin contact - when in contact with the skin, clean with soap and water

Inhalation - 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

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5.2. Special hazards arising from the substance or mixture

Specific hazards - no particular hazards known

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 - avoid release to the environment

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

Technical measures - avoid dust formation
- processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - below 25 °C

Validity - see "best use before" date stated on the label

Packaging materials - blister packages

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (USA) air - ACGIH-TLV: 10 mg/m³ *2
- OSHA-PEL: 5 mg/m³ (respirable fraction) *2
- OSHA-PEL: 15 mg/m³ (total particulate) *2
- NIOSH-REL: 5 mg/m³ (respirable fraction) *2
- NIOSH-REL: 10 mg/m³ (total dust) *2

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- ACGIH-TLV: 2 mg/m³ (respirable fraction) *3
- ACGIH-TLV: (use asbestos TLV-TWA) *3
- ACGIH-TLV: (should not exceed 2mg/m³ respirable particulates) *3
- OSHA-PEL: 2 mg/m³ (respirable fraction) *3
- NIOSH-REL: 2 mg/m³ (respirable fraction) *3

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: Starch
*3 referring to: Talc

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color grey

Form hard gelatin capsules

Solubility > 200 mg/l, water (~ 22 °C, pH 5.14, HPLC, 24 h) *1

Partition coefficient log P_{ow} 0.36 (octanol/water) pH 7.4 *1

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

Note - no information available

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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 - stable in normal conditions

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - MNLD > 2'000 mg/kg (oral, rat) *1
- LD₅₀ ~ 100'000 mg/kg (oral, rat) *4

Local effects - no information available

Sensitization - no information available

Mutagenicity - not mutagenic (various in vitro test systems) *1

Carcinogenicity - no information available

Reproductive toxicity - does not lower parental fertility (several species) *1
- not teratogenic (several species) *1

STOT-single exposure - no information available

STOT-repeated exposure - no information available

Aspiration hazard - no information available

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 *3

*1 referring to: Oseltamivir phosphate

*3 referring to: Talc

*4 referring to: Povidone K30

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SECTION 12: Ecological information

12.1. Toxicity

| | | |
|-------------|--|----|
| Ecotoxicity | - moderately toxic for algae (<i>Selenastrum capricornutum</i>) 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 (<i>Daphnia magna</i>) 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

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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 as Dangerous Good according to the Dangerous Goods 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

- Safety-lab number
- BS-6336 *1
 - BS-6775 *1
 - BS-6695 *1

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

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- 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
- *1** referring to:
- Osetamivir phosphate

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.