

according to Regulation (EU) nr. 1907/2006

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product name Oseltamivir phosphate

Product code 04 7175 5

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

Use - pharmaceutical active substance with antiviral effect

1.3. Details of the supplier of the safety data sheet

Company information

Enquiries:
F. Hoffmann-La Roche AG
Postfach
CH-4070 Basel
Switzerland

Local representation:

Phone +41-61/688 54 80
Fax +41-61/681 72 76
E-Mail info.sds@roche.com**1.4. Emergency telephone number**

Emergency telephone number Phone +41-61/688 54 80

Oseltamivir phosphate

SECTION 2: Hazards identification

2.1. / 2.2. Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

3.3 Serious eye damage/eye irritation (Category 2A)

H319 Causes serious eye irritation.

3.4 Skin sensitization (Category 1)

H317 May cause an allergic skin reaction.

Environmental Hazards:

4.1 Hazardous to the aquatic environment (Category 3)

H412 Harmful to aquatic life with long lasting effects.

Signalword: Warning

Label:



Precautionary statements:

- P280 Wear protective gloves/ protective clothing / eye protection / face protection.
- P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
- P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P273 Avoid release to the environment.

2.3. Other hazards

Note

- may form explosible dust-air mixture if dispersed

SECTION 3: Composition/information on ingredients

Chemical name

- (3R,4R,5S)-4-Acetylamino-5-amino-3-(1-ethyl-propoxy)-cyclohex-1-enecarboxylic acid ethyl ester phosphoric acid salt (1:1)

Synonyms

- EEC-Ro 64-0796 (NS)
- Oseltamivir phosphate (NS)
- OSELTAMIVIR PHOSPHAT SK
- Oseltamivir (INN)
- Tamiflu substance

CAS number

204255-11-8

Roche number

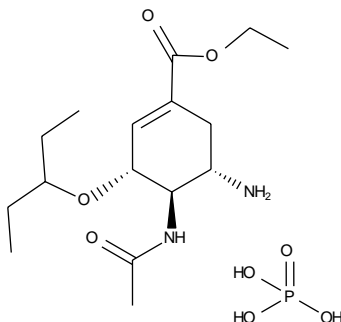
RO0640796-002

Empirical formula

$C_{16}H_{28}N_2O_4 \cdot PO_4H_3$

Oseltamivir phosphate

Molecular mass 410.41 g/mol



SECTION 4: First aid measures

4.1. Description of first aid measures

- Eye contact
- rinse immediately with tap water for at least 20 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
- water spray jet, dry powder, foam, carbon dioxide

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for firefighters

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

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - ensure adequate ventilation

6.2. Environmental precautions

Environmental protection - do not allow to enter drains or waterways
- if the substance reaches waters or the sewer system, inform the competent authority

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect solids (avoid dust formation) and hand over to waste removal

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures - processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
- local exhaust ventilation necessary
- avoid dust formation; high dust explosion hazard
- low probability of ignition: ground plant, avoid effective ignition sources

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - room temperature
- protected from heat, light and humidity

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

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

8.2. Exposure controls

Respiratory protection - respiratory protection not necessary during normal operations

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection - safety glasses

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour	white
Form	fine, crystalline powder
Odour	almost odourless
Density	1.22 g/ml
Solubility	> 200 mg/l, water (~ 22 °C, pH 5.14, HPLC, 24 h)
Partition coefficient	log P _{ow} 0.36 (octanol/water) pH 7.4
pH value	3.3 to 5.3 (10 % aqueous solution)
Melting temperature	192 to 196 °C
Ignition point (liquid)	360 °C

9.2. Other information

Bulk density	~ 0.15 g/cm ³
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SECTION 10: Stability and reactivity

10.1. Reactivity

Note	- no information available
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10.2. Chemical stability

Stability	- stable under normal conditions
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10.3. Possibility of hazardous reactions

Note	- no information available
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10.4. Conditions to avoid

Conditions to avoid	- temperatures above 140 °C (decomposition with pressure increase)
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10.5. Incompatible materials

Materials to avoid	- acids, bases
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10.6. Hazardous decomposition products

Note	- no information available
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- MNLD > 2'000 mg/kg (oral, rat) - MNLD > 2'000 mg/kg (oral, mouse)
Subchronic toxicity	- NOAEL 250 mg/kg/d (oral, rat; 4 weeks)
Local effects	- eye: irritant (rabbit; OECD No. 405) - not phototoxic (in vitro)
Sensitization	- sensitizing (guinea pig) (OECD No. 406)
Mutagenicity	- not mutagenic (various in vitro test systems)
Carcinogenicity	- no information available
Reproductive toxicity	- does not lower parental fertility (several species) - not teratogenic (several species)
STOT-single exposure	- no information available
STOT-repeated exposure	- no information available
Aspiration hazard	- no information available
Note	- side effects: nausea, vomiting - therapeutic dose: 2 x 75 mg/d p.o. for 5 days

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) - moderately toxic for planktonic crustaceans (<i>Daphnia magna</i>) EC ₅₀ (48 h) 33 mg/l (OECD No. 202) - barely toxic for fish (carp) LC ₅₀ (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)
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12.2. Persistence and degradability

- Ready biodegradability - not readily biodegradable
3 %, 28 days
2.8 %, 14 days
(CO₂ Evolution Test, Modified Sturm Test, OECD No. 301B)
- 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

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

- PBT/vPvB - not PBT, not vPvB

12.6. Other adverse effects

- Air pollution - observe local/national regulations

SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Waste from residues - observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing

SECTION 14: Transport information

- Note - not classified as Dangerous Good according to the Dangerous Goods Regulations

SECTION 15: Regulatory information

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

- Water hazard class (Germany) 1: weakly hazardous for water (own classification according to directive VwVwS of 17.05.1999)

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SECTION 16: Other information

- Safety-lab number
- BS-6336
 - BS-6775
 - BS-6695
 - BS-9189
- 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.