# Safety Data Sheet

## Oseltamivir phosphate

according to Regulation (EU) nr. 1907/2006

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

### 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>Oseltamivir phosphate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>04 7175 5</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Company information</th>
<th>Enquiries:</th>
<th>Local representation:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>F. Hoffmann-La Roche AG Postfach CH-4070 Basel Switzerland</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td>+41-61/688 54 80</td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td>+41-61/681 72 76</td>
<td></td>
</tr>
<tr>
<td>E-Mail</td>
<td><a href="mailto:info.sds@roche.com">info.sds@roche.com</a></td>
<td></td>
</tr>
</tbody>
</table>

### 1.4. Emergency telephone number

<table>
<thead>
<tr>
<th>Emergency telephone number</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+41-61/688 54 80</td>
</tr>
</tbody>
</table>
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_{2}O_{4} \cdot PO_{4}H_{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
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
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/cm³

SECTION 10: Stability and reactivity

10.1. Reactivity

Note: no information available

10.2. Chemical stability

Stability: stable under normal conditions

10.3. Possibility of hazardous reactions

Note: no information available

10.4. Conditions to avoid

Conditions to avoid: temperatures above 140 °C (decomposition with pressure increase)

10.5. Incompatible materials

Materials to avoid: acids, bases

10.6. Hazardous decomposition products

Note: no information available
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 (Selenastrum capricornutum)
  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 (Daphnia magna)
  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)
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)
Oseltamivir phosphate

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.