**Safety Data Sheet**

# Ganciclovir sodium

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 | Ganciclovir sodium |
| Product code | RO1021592-030 |

### 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:<br>F. Hoffmann-La Roche AG<br>Postfach<br>CH-4070 Basel<br>Switzerland<br><br>Phone +41-61/688 54 80<br>Fax +41-61/681 72 76<br>E-Mail info.sds@roche.com | Local representation: |

### 1.4. Emergency telephone number

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

## SECTION 2: Hazards identification

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

GHS Classification

Health Hazards:

3.5Germ cell mutagenicity (Category 1A)
H340 May cause genetic defects.

3.6 Carcinogenicity (Category 1A)
H350 May cause cancer.

3.7 Reproductive toxicity (Category 1A)
H360FD May damage fertility. May damage the unborn child.

3.9 Specific target organ toxicity - Repeated exposure (Category 1)
H372 Causes damage to organs through prolonged or repeated exposure.

Signalword: Danger

Label:

Precautionary statements:
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe dust
- P281 Use personal protective equipment as required.
- P308 + P313 IF exposed or concerned: Get medical advice/attention.

Note
- classification and labelling are based on data of a substance of similar structure

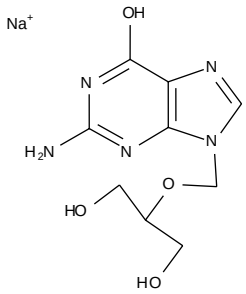
### 2.3. Other hazards

Note
- may form explosible dust-air mixture if dispersed

## SECTION 3: Composition/information on ingredients

| | |
|---|---|
| Characterization | synthetic guanine derivative |
| Chemical name | - 6H-Purin-6-one, 2-amino-1,9-dihydro-9-[[2-hydroxy-1-(hydroxymethyl)ethoxy] methyl]-, sodium salt |
| Synonyms | - RS-021592-030 |
| CAS number | 84245-13-6 |
| Roche number | Ro1021592-030 |
| Empirical formula | $C_9H_{13}N_5O_4Na$ |

Molecular mass 277.22




## 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

Skin contact
- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
- consult physician

Inhalation
- remove the casualty to fresh air and keep him/her calm
- 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
- preserve blood and urine samples

## 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 (ammonia, nitrogen oxides) possible

### 5.3. Advice for firefighters

| | |
|---|---|
| Protection of fire-fighters | - precipitate gases/vapours/mists with water spray<br>- do not inhale explosion and/or combustion gases<br>- avoid skin contact<br>- use self-contained breathing apparatus |

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

| | |
|---|---|
| Personal precautions | - avoid exposure |

### 6.2. Environmental precautions

| | |
|---|---|
| Environmental protection | - do not allow to enter drains or waterways |

### 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)<br>- local exhaust ventilation necessary<br>- avoid dust formation; consider dust explosion hazard<br>- take precautionary measures against electrostatic charging |

### 7.2. Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| Storage conditions | - below 30 °C<br>- in closed containers<br>- protected from light |

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

| | | |
|---|---|---|
| Threshold value (Roche) air | - IOEL (Internal Occupational Exposure Limit): 5 µg/m3 | *1 |

### 8.2. Exposure controls

| | |
|---|---|
| General protective and hygiene measures | - instruction of employees mandatory<br>- cleanse skin thoroughly after work, apply skin cream |

| | | |
|---|---|---|
| Respiratory protection | - | in case of open handling or accidental release:<br>particle mask or respirator with independent air supply |
| Hand protection | - | protective gloves (neoprene, nitrile or butyl rubber) |
| Eye protection | - | safety glasses |
| Analytics | - | sampling on glassfiber filter and chemical determination of the active compound (eg HPLC) |

***1*** referring to: Ganciclovir

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

| | | |
|---|---|---|
| Colour | white | |
| Form | powder | |
| Odour | odourless | |
| Solubility | 2’670 mg/l, water (pH 7) | *1 |
| Partition coefficient | log $P_{ow}$ -1.96 (n-octanol/water 25 °C) pH 5<br>(Shake Flask Method, OECD No. 107) | *1 |
| | log $P_{ow}$ -1.94 (n-octanol/water 25 °C) pH 7<br>(Shake Flask Method, OECD No. 107) | *1 |
| | log $P_{ow}$ -2.00 (n-octanol/water 25 °C) pH 9<br>(Shake Flask Method, OECD No. 107) | *1 |
| Melting temperature | 242 to 255 °C (with decomposition) | *1 |
| Vapour pressure | ≤ 0.001 hPa (22 °C) | *1 |

### 9.2. Other information

| | | |
|---|---|---|
| Note | - | no information available |

***1*** referring to: Ganciclovir

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

| | | |
|---|---|---|
| Note | - | no information available |

### 10.2. Chemical stability

| | | |
|---|---|---|
| Stability | - | stable under the conditions mentioned in chapter 7 |

### 10.3. Possibility of hazardous reactions

| | | |
|---|---|---|
| Note | - | no information available |

### 10.4. Conditions to avoid

| | | |
|---|---|---|
| Note | - | no information available |

### 10.5. Incompatible materials

| | | |
|---|---|---|
| Materials to avoid | - | strong oxidizing agents |

### 10.6. Hazardous decomposition products

| | | |
|---|---|---|
| Hazardous decomposition products | - | oxides of nitrogen |

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

| | | | |
|---|---|---|---|
| Acute toxicity | - | $LD_{50}$ > 2’000 mg/kg (oral, mouse) | *1 |
| Local effects | - | skin: non-irritant | *1 |
| Sensitization | - | no information available | |
| Mutagenicity | - | no information available | |
| Carcinogenicity | - | carcinogenic | *1 |
| Reproductive toxicity | - | teratogenic and embryotoxic | *1 |
| | - | may lower parental fertility | *1 |
| STOT-single exposure | - | no information available | |
| STOT-repeated exposure | - | no information available | |
| Aspiration hazard | - | no information available | |
| Note | - | dosage (oral): 1’000 mg (adults) | *1 |
| | - | recommended daily dose: 3’000 mg/d | *1 |
| | - | elimination half-life: 5 h | *1 |
| | - | excretion is mainly renal | *1 |
| | - | side effect(s) during therapy: changes in blood count | *1 |

***1*** referring to: Ganciclovir

## SECTION 12: Ecological information

### 12.1. Toxicity

| | | |
|---|---|---|
| Ecotoxicity | - barely toxic for planktonic crustaceans (Daphnia magna)<br>$EC_{50}$ (48 h) > 1010 mg/l (average measured concentration)<br>NOEC (48 h) 1010 mg/l (average measured concentration) | *1 |
| | - barely toxic for fish (rainbow trout)<br>$LC_{50}$ (96 h) > 1020 mg/l (average measured concentration)<br>NOEC (96 h) 1020 mg/l (average measured concentration) | *1 |
| | - barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture)<br>NOEC 1000 mg/l | *1 |

### 12.2. Persistence and degradability

| | | |
|---|---|---|
| Inherent biodegradability | - not inherently biodegradable<br>2 %, 28 days | *1 |
| | - evidence for medium-term biodegradation in surface waters | *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: Ganciclovir

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

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

## SECTION 14: Transport information

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

- transport classification is based on data of a substance of similar structure

## SECTION 15: Regulatory information

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

| | |
|---|---|
| Water hazard class (Germany) | 3: strongly hazardous for water (own classification according to directive VwVwS of 17.05.1999) *1 |
| ***1*** referring to: | Ganciclovir |

## SECTION 16: Other information

| | |
|---|---|
| Edition documentation | - changes from previous version in sections 2, 6 |

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.