

Valaciclovir hydrochloride, hydrated

Safety Data Sheet

900883

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 2.0

Date of issue: 18/04/2017 Revision date 12/12/2018

Supersedes 18/04/2017

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

1.1. Product identifier

Product form : Substance
Substance name : Valaciclovir hydrochloride, hydrated
IUPAC name : 2-[(2-Amino-6-oxo-1,6-dihydro-9H-purin-9-yl)methoxy]-ethyl L-valinate hydrochloride
CAS-No. : 124832-27-5
Product code : 900883
Formula : C₁₃H₂₁CLN₆O₄.XH₂O
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry
Industrial/Professional use spec : For professional use only
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	+44 20 7188 7188	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4 H302
Reproductive toxicity, Category 1B H360

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard pictograms (CLP)



GHS07

GHS08

Signal word (CLP) : Danger

Hazard statements (CLP) : H302 - Harmful if swallowed.
H360 - May damage fertility or the unborn child.Precautionary statements (CLP) : P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330 - Rinse mouth.
P308+P313 - IF exposed or concerned: Get medical advice/attention.**2.3. Other hazards**

Other hazards not contributing to the classification : No additional information available.

SECTION 3: Composition/information on ingredients**3.1. Substances**

Substance type : Mono-constituent

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Valaciclovir hydrochloride, hydrated	(CAS-No.) 124832-27-5	100	Acute Tox. 4 (Oral), H302 Repr. 1B, H360

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures**4.1. Description of first aid measures**

First-aid measures general : If possible show this sheet, if not available show packaging or label. Never give anything by mouth to an unconscious person.

First-aid measures after inhalation : Assure fresh air breathing. Call a POISON CENTER/doctor.

First-aid measures after skin contact : Gently wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes. If eye irritation persists, take medical advice.

First-aid measures after ingestion : Rinse mouth. Drink 200-300 ml of water. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : dry chemical powder, alcohol-resistant foam, carbon dioxide (CO2).

5.2. Special hazards arising from the substance or mixture

Fire hazard : not fire-propagating.

Explosion hazard : Product is not explosive.

Hazardous decomposition products in case of fire : Toxic and irritating gases are released.

5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Use the personal protective equipment as indicated in chapter 8.

Emergency procedures : Evacuate unnecessary personnel.

Measures in case of dust release : Avoid dust to spread.

6.1.2. For emergency responders

Protective equipment : In case of inadequate ventilation wear respiratory protection.

6.2. Environmental precautions

6.3. Methods and material for containment and cleaning up

For containment : Sweeping or shovelling without dust for disposal.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station.

Handling temperature : 15 - 25

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at room temperature. Keep container tightly closed. Protect from moisture.

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Incompatible products : Strong oxidizing agent.
Storage temperature : 15 - 25 °C
Storage area : Store in a well-ventilated place.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Dust/aerosol mask with filter type P3. Safety glasses. Gloves. Dustproof clothing.

Hand protection:

Wear gloves according to EN374 to protect against skin effects from powders.

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filtertype P3



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : Powder.
Molecular mass : 360.8 g/mol (anhydrous substance)
Colour : White.
Odour : odourless.
Odour threshold : No data available
pH : No data available
Relative evaporation rate (butylacetate=1) : No data available
Melting point : No data available

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Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Freely soluble in water.

Log Pow	: -2.89
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available

Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Hygroscopic. Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

On heating/burning: release of harmful gases/vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

Valaciclovir hydrochloride, hydrated (124832-27-5)	
LD50 oral rat	904 mg/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified

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Carcinogenicity	: Not classified
Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : There are no available data for a classification.

Valaciclovir hydrochloride, hydrated (124832-27-5)	
EC50 Daphnia 1	340 mg/l

12.2. Persistence and degradability

Valaciclovir hydrochloride, hydrated (124832-27-5)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Valaciclovir hydrochloride, hydrated (124832-27-5)	
Log Pow	-2.89
Bioaccumulative potential	Not established.

12.4. Mobility in soil

Valaciclovir hydrochloride, hydrated (124832-27-5)	
Ecology - soil	There are no available data for a classification.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable

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ADR	IATA
14.5. Environmental hazards	
Not applicable	Not applicable
No supplementary information available	

14.6. Special precautions for user

- Overland transport

Not applicable

- Air transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Valaciclovir hydrochloride, hydrated is not on the REACH Candidate List

Valaciclovir hydrochloride, hydrated is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.1	Name	Modified	
1.2	Industrial/Professional use spec	Added	
2.2	Hazard statements (CLP)	Added	H360
5.1	Suitable extinguishing media	Modified	
8.2	Respiratory protection	Modified	
8.2	Personal protective equipment	Modified	

Abbreviations and acronyms:

REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : Supplier.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Repr. 1B	Reproductive toxicity, Category 1B
H302	Harmful if swallowed.
H360	May damage fertility or the unborn child.

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SDS EU (REACH Annex II) Version 2018

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product