



Safety Data Sheet dated 5/24/2016, version 6

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

1.1. Product identifier

Mixture identification:

Trade name: ACYCLOVIR

Trade code: SOLMU076

Chemical name: 6H-Purin-6-one, 1,9-dihydro-2-amino-9-((2-hydroxyethoxy)methyl)-

Molecular formula: C₈H₁₁N₅O₃

Molecular weight: 225.21

CAS number: 59277-89-3

EC number: 261-685-1

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

Recommended use:

active pharmaceutical ingredient

1.3. Details of the supplier of the safety data sheet

Company:

NAME OLON S.p.A

Strada Rivoltana km 6 / 7 - RODANO (MI) - Italy

Competent person responsible for the safety data sheet:

msds@olonspa.it


1.4. Emergency telephone number telephone number: +39 0382 8250.1


available Monday through Friday from 9:00 am to 18:00


SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

 Warning, Skin Irrit. 2, Causes skin irritation.

 Warning, Eye Irrit. 2, Causes serious eye irritation.

 Warning, STOT SE 3, May cause respiratory irritation.

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

Symbols:



Warning

Hazard statements:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Precautionary statements:

P264 Wash ... Thoroughly after handling.

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P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P312 Call a POISON CENTER/ doctor/if you feel unwell.
P337+P313 If eye irritation persists: Get medical advice/attention.
P501 Dispose of contents/container in accordance with applicable regulations.

Special Provisions:

Not classified

Contents:

6H-Purin-6-one, 1,9-dihydro-2-amino-9-((2-hydroxyethoxy)methyl)-

Special provisions according to Annex XVII of REACH and subsequent amendments:

Not classified

2.3. Other hazards

The product can support combustion. The ignition of dust in certain conditions can cause an explosion. Dust may be sensitive to electrostatic ignition sources. In case of fire, may emit toxic fumes (oxides of nitrogen, carbon).

vPvB Substances: Not classified - PBT Substances: Not classified

Other Hazards:




No other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

Identification of the substance

Trade code: SOLMU076
Product type and use: Active pharmaceutical ingredient
CAS number: 59277-89-3
EC number: 261-685-1

Qty	Name	Ident. Number	Classification
>= 100%	6H-Purin-6-one, 1,9-dihydro-2-amino-9-((2-hydroxyethoxy)methyl)-	CAS: 59277-89-3	 3.2/2 Skin Irrit. 2 H315
		EC: 261-685-1	 3.3/2 Eye Irrit. 2 H319
		-	 3.8/3 STOT SE 3 H335

3.2. Mixtures

N.A.

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Areas of the body that have - or are only even suspected of having - come into contact with the product must be rinsed immediately with plenty of running water and possibly with soap. Wash thoroughly the body (shower or bath).

Remove contaminated clothing immediately and dispose off safely.

In case of eyes contact:

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

Protect uninjured eye.

In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

In case of inhalation, consult a doctor immediately and show him packing or label.

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

None

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

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In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Treatment:

None

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO₂).

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

Substance that can sustain combustion when exposed to heat and ignition sources. Thermal decomposition produces toxic fumes of oxides of nitrogen and carbon. In the absence of oxygen may generate other toxic gases. Like most organic powders, may cause an explosion if the powder is dispersed into the air and set off.

Substance that can sustain combustion when exposed to heat. Thermal decomposition produces toxic fumes of oxides carbon and hydrogen chloride.

Substance that can sustain combustion when exposed to heat and ignition sources. Thermal decomposition produces toxic fumes of oxides of nitrogen and carbon. In the absence of oxygen may generate other toxic gases.

5.3. Advice for firefighters

Use suitable breathing apparatus .

Wear respirator, gloves, protective footwear. CAUTION: Pressurized containers may explode when exposed to fire. It's recommended the use of breathing apparatus and full protection for fire fighting, since the combustion of this substance may generate toxic fumes, corrosive and flammable. If possible, contain water used for fire fighting and collect for later disposal. Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment.

Remove all sources of ignition.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

Provide adequate ventilation.

Use appropriate respiratory protection.

See protective measures under point 7 and 8.

6.2. Environmental precautions

Circumscribe the area of the spill and prevent the staff will come into contact if not properly protected. Avoid flames, sparks and prevent static buildup. Avoid generation of dust.

Circumscribe the area of the spill and prevent the staff will come into contact if not properly protected. Avoid flames, sparks and prevent static buildup.

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

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- 6.4. Reference to other sections
See also section 8 and 13

SECTION 7: Handling and storage

- 7.1. Precautions for safe handling
Avoid contact with skin and eyes, inhalation of vapours and mists.
Use localized ventilation system.
Don't use empty container before they have been cleaned.
Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.
Contaminated clothing should be changed before entering eating areas.
Do not eat or drink while working.
See also section 8 for recommended protective equipment.
- 7.2. Conditions for safe storage, including any incompatibilities
Keep away from food, drink and feed.
Incompatible materials:
None in particular. See also paragraph 10 below
Instructions as regards storage premises:
Adequately ventilated premises.
- 7.3. Specific end use(s)
None in particular

SECTION 8: Exposure controls/personal protection

- 8.1. Control parameters
No occupational exposure limit available
DNEL Exposure Limit Values
N.A.
PNEC Exposure Limit Values
N.A.
- 8.2. Exposure controls
Eye protection:
Use close fitting safety goggles, don't use eye lens.
Safety glasses with side protection or estate or visor. Must be available eye wash station.
Work, however, according to good working practices.
- Protection for skin:
Use clothing that provides comprehensive protection to the skin, e.g. cotton, rubber, PVC or viton.
- Protection for hands:
Use protective gloves that provides comprehensive protection, e.g. P.V.C., neoprene or rubber.
- Respiratory protection:
Provide exhaust systems in the workplace. Avoid inhalation of vapors and dust. Adequate ventilation to the premises where the product is stored and / or manipulated, however, avoid excessive ventilation and dust dispersed generation. Change clothes at the end of shift.

Use respiratory protection where ventilation is insufficient or exposure is prolonged.

Thermal Hazards:
None

Environmental exposure controls:
None

Appropriate engineering controls:
None

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Method:	Notes:
Appearance and colour:	white or almost white crystalline powder	--	--
Odour:	N.A.	--	--
Odour threshold:	N.A.	--	--
pH:	N.A.	--	--
Melting point / freezing point:	255 °C	--	--
Initial boiling point and boiling range:	N.A.	--	--
Flash point:	N.A.	--	--
Evaporation rate:	N.A.	--	--
Solid/gas flammability:	480 °C	--	--
Upper/lower flammability or explosive limits:	N.A.	--	--
Vapour pressure:	7.47 e -15 Pa	--	--
Vapour density:	N.A.	--	--
Relative density:	N.A.	--	--
Solubility in water:	1621 mg/l	--	--
Solubility in oil:	N.A.	--	--
Partition coefficient (n-octanol/water):	Log Pow - 1.56	--	--
Auto-ignition temperature:	N.A.	--	--
Decomposition temperature:	N.A.	--	--
Viscosity:	N.A.	--	--
Explosive properties:	LIE =30 mg/l		
max explosion pression = 236 bar			
Class explosion: ST1			
resistivity = 8,7 x 10E14 om	--	--	
Oxidizing properties:	N.A.	--	--

9.2. Other information

Properties	Value	Method:	Notes:
Miscibility:	N.A.	--	--
Fat Solubility:	N.A.	--	--
Conductivity:	N.A.	--	--
Substance Groups relevant properties	N.A.	--	--

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions

10.2. Chemical stability

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- Stable under normal conditions
- 10.3. Possibility of hazardous reactions
N.D.
- 10.4. Conditions to avoid
Stable under normal conditions.
- 10.5. Incompatible materials
N.D.
- 10.6. Hazardous decomposition products
None.

SECTION 11: Toxicological information

- 11.1. Information on toxicological effects
Toxicological information of the substance:
ACYCLOVIR - CAS: 59277-89-3

If not differently specified, the information required in Regulation 453/2010/EC listed below must be considered as N.A.:

- a) acute toxicity;
- b) skin corrosion/irritation;
- c) serious eye damage/irritation;
- d) respiratory or skin sensitisation;
- e) germ cell mutagenicity;
- f) carcinogenicity;
- g) reproductive toxicity;
- h) STOT-single exposure;
- i) STOT-repeated exposure;
- j) aspiration hazard.

SECTION 12: Ecological information

- 12.1. Toxicity
Adopt good working practices, so that the product is not released into the environment.

TRANSPORT AND DISTRIBUTION:

Henry's Law constant (H) in Pa m³ / mol cm³/molecule-sec 7.94E-011
Ref.: MEYLAN, WM & HOWARD, PH (1993)

- 12.2. Persistence and degradability
None
N.A.
- 12.3. Bioaccumulative potential
N.A.
- 12.4. Mobility in soil
N.A.
- 12.5. Results of PBT and vPvB assessment
vPvB Substances: Not classified - PBT Substances: Not classified
- 12.6. Other adverse effects
None

SECTION 13: Disposal considerations

- 13.1. Waste treatment methods
Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

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- 14.1. UN number
- 14.2. UN proper shipping name
ADR-Shipping Name: Not classified as dangerous in the meaning of transport regulations
IATA-Shipping Name: Not classified as dangerous in the meaning of transport regulations
IMDG-Shipping Name: Not classified as dangerous in the meaning of transport regulations
- 14.3. Transport hazard class(es)
- 14.4. Packing group
- 14.5. Environmental hazards
ADR-Environmental Pollutant: No
IMDG-Marine pollutant: No
- 14.6. Special precautions for user
- 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
No

SECTION 15: Regulatory information

- 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Dir. 98/24/EC (Risks related to chemical agents at work)
Dir. 2000/39/EC (Occupational exposure limit values)
Regulation (EC) n. 1907/2006 (REACH)
Regulation (EC) n. 1272/2008 (CLP)
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
Regulation (EU) n. 453/2010 (Annex II)
Regulation (EU) n. 286/2011 (ATP 2 CLP)
Regulation (EU) n. 618/2012 (ATP 3 CLP)
Regulation (EU) n. 487/2013 (ATP 4 CLP)
Regulation (EU) n. 944/2013 (ATP 5 CLP)
Regulation (EU) n. 605/2014 (ATP 6 CLP)
Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:
Not classified
Where applicable, refer to the following regulatory provisions :
Directive 2003/105/CE ('Activities linked to risks of serious accidents') and subsequent amendments.
Regulation (EC) nr 648/2004 (detergents).
1999/13/EC (VOC directive)

Provisions related to directives 82/501/EC(Seveso), 96/82/EC(Seveso II):
N.A.
- 15.2. Chemical safety assessment
No

SECTION 16: Other information

Full text of phrases referred to in Section 3:
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
Paragraphs modified from the previous revision: Section 2: Hazards identification
Section 11: Toxicological information
This safety data sheet has been completely updated in compliance to Regulation 453/2010/EU.

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This document was prepared by a competent person who has received appropriate training.
Main bibliographic sources: Abbreviations and Acronyms:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre,
Commission of the European Communities
SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van
Nostrand Reinold
CCNL - Appendix 1

Insert further consulted bibliography

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.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS:	Chemical Abstracts Service (division of the American Chemical Society).
CLP:	Classification, Labeling, Packaging.
DNEL:	Derived No Effect Level.
EINECS:	European Inventory of Existing Commercial Chemical Substances.
GefStoffVO:	Ordinance on Hazardous Substances, Germany.
GHS:	Globally Harmonized System of Classification and Labeling of Chemicals.
IATA:	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
LTE:	Long-term exposure.
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STE:	Short-term exposure.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWATLV:	Threshold Limit Value for the Time Weighted Average 8 hour day. (ACGIH Standard).
WGK:	German Water Hazard Class.