# SAFETY DATA SHEET



# 1. Identification

Product identifier	Allopurinol		
Other means of identification			
Catalog number	1013002		
CAS number	315-30-0		
Chemical name	1,5-Dihydro-4H-pyrazolo[3,4-d]pyrimidin-4-one		
Recommended use	For analytical laboratory use only.		
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.		
Manufacturer/Importer/Supplier	/Distributor information		
Manufacturer			
Company name Address	U. S. Pharmacopeia 12601 Twinbrook Parkway Rockville MD 20852-1790 United States		
Telephone	Technical Services 301-816-8129		
Website	www.usp.org		
E-mail	RSTECH@usp.org		
Emergency phone number	CHEMTREC within US & 1-800-424-9300 Canada CHEMTREC outside US & +1 703-527-3887 Canada		
2. Hazard(s) identification			
Physical hazards	Not classified.		
Health hazards	Not classified.		
Environmental hazards	Not classified.		
OSHA defined hazards	Not classified.		
Label elements			
Hazard symbol	None.		
Signal word	None.		
Hazard statement	Not available.		
Precautionary statement			
Prevention	Not available.		
Response	Not available.		
Storage	Not available.		
Disposal	Not available.		
Hazard(s) not otherwise classified (HNOC)	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.		
Supplemental information	Pharmacologically active material.		

# 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Allopurinol		315-30-0	100

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

# 4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.			
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.			
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.			
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.			
Most important symptoms/effects, acute and delayed	Pharmacologically active material. Occupational exposure may cause physiological effects.			
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must			

receive immediate medical attention.

# 5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

# 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
7. Handling and storage	
Precautions for safe handling	As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
Conditions for safe storage, including any incompatibilities	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

#### 8. Exposure controls/personal protection

#### **Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values Industrial Use Material	Туре	Value	
Allopurinol (CAS 315-30-0)	TWA	5 mg/m3	
Biological limit values	No biological exposure limits noted	for the ingredient(s).	
Appropriate engineering controls	For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.		
Individual protection measures	, such as personal protective equip	ment	
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.		
Skin protection			
Hand protection		ves if skin contact is possible. When the material is dissolved , wear gloves that provide protection against the solvent.	
Other	Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. I not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.		
Respiratory protection	Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the ta and the level of existing engineering controls.		
Thermal hazards	Wear appropriate thermal protectiv	e clothing, when necessary.	
General hygiene considerations	Handling practices in this SDS are	recommendations for laboratory use of USP materials.	

# 9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Powder.
Color	White.
Odor	Odorless.
Odor threshold	Not available.
рН	Not available.
Melting point/freezing point	662 °F (350 °C) (decomposes)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or exp	losive limits
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa (77 °F (25 °C))
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Very slightly soluble.
Solubility (other)	Alcohol: Very slightly soluble. Chloroform: Practically insoluble.

	Dimethylsulfoxide: Soluble.
Partition coefficient (n-octanol/water)	-0.33 = Log Pow (at pH 6)
	-0.55
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Pyrazolo-pyrimidine.
Dust explosion properties	
Kst	228 bar.m/s
St class	2 Strong explosion.
Minimum ignition energy (MIE) - dust cloud	26 - 28 mJ
Molecular formula	C5H4N4O
Molecular weight	136.11
10. Stability and reactivity	,

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.		
Chemical stability	Stable at normal conditions.		
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.		
Conditions to avoid	Avoid temperatures exceeding the decomposition temperature. Contact with incompatible materials.		
Incompatible materials	Strong oxidizing agents.		
Hazardous decomposition products	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.		

# 11. Toxicological information

# Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical and toxicological characteristics	Skin rash. Hives. Itching. Peeling skin. Nausea. Vomiting. Diarrhea. Stomach pain. Yellow eyes and/or skin. Hair loss. Headache. Drowsiness. Chills. Fever. Musculoskeletal pain. Numbness, pain, tingling, or weakness in hands or feet. Difficulty breathing.

# Information on toxicological effects

#### Acute toxicity

Product	Species	Test Results	
Allopurinol (CAS 315-30-0)			
Acute			
Oral			
LD50	Mouse	700 mg/kg	
		78 mg/kg	
	Rat	6000 mg/kg	
Skin corrosion/irritation	Based on available data, the classification criteria are not met.		
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.		
<b>Local effects</b> Skin irritation Result: Negative. Species: Rabbit			

#### Respiratory or skin sensitization

Respiratory sensitization	Knowledge about health hazard is in	complete.
	5	

Skin sensitization Knowledge about health hazard is incomplete.

#### Germ cell mutagenicity

Knowledge about mutagenicity is incomplete.

#### Mutagenicity

Ames test in S. typhimurium Result: Negative. In vitro cytogenetics studies Result: Chromosome aberrations induced. In vivo and in vitro studies with human lymphocytes Result: No evidence of clastogenicity. In vivo micronucleus test in rats Result: Negative. Mouse lymphoma test system Result: Negative.

#### Carcinogenicity

Based on available data, the classification criteria are not met.

20 mg/kg/day Carcinogenicity study Result: No evidence of carcinogenicity. Species: Rodent

#### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed. **Reproductive toxicity** 

Based on available data, the classification criteria are not met.

#### Reproductivity

100 mg/kg/day Reproductivity and development study	
Result: No adverse fetal effects noted.	
Species: Rabbit	
20 mg/kg/day Fertility study	
Result: No impairment of maie or female fertility. Species: Rabbit	
200 mg/kg/day Reproductivity and development study	
Result: No adverse fetal effects noted.	
Species: Rat	
50 - 100 mg/kg Reproductivity and development study,	
administered as single intraperitoneal dose.	
Result: Increase in fetal death and abnormalities.	
Species: Mouse	
Controlled therapeutic study in women treated with allopurinol, administered during the third trimester of	
pregnancy.	
Result: No adverse effects in newborns noted.	

Specific target organ toxicity -Knowledge about health hazard is incomplete.

single exposure	
Specific target organ toxicity - repeated exposure	Knowledge about health hazard is incomplete.
Aspiration hazard	Based on available data, the classification criteria are not met.
Further information	Pharmacologically active material. Occupational exposure may cause physiological effects.

# 12. Ecological information

Ecotoxicity			
Product		Species	Test Results
Allopurinol (CAS 315-30-0)			
Aquatic			
Acute			
Crustacea	EC50	Daphnia magna	130 mg/l, 48 hours
Fish	EC50	Oncorhynchus mykiss	> 100 mg/l, 96 hours
Persistence and degradability	Not readil	y biodegradable.	

#### **Bioaccumulative potential**

# Octanol/water partition coefficient log Kow -0.33, = Log Pow (at pH 6) -0.55 No data available. Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component. 13. Disposal considerations Volume

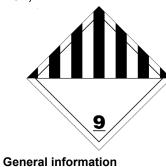
Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

# 14. Transport information

#### DOT

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Allopurinol)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Packaging non bulk	213
Packaging bulk	240
ΙΑΤΑ	
UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Allopurinol)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

DOT; IATA



It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

# 15. Regulatory information

not known to be a "Hazardous Chemical" as defined a Standard, 29 CFR 1910.1200. (40 CFR 707, Subpt. D)	by the OSHA Hazard
(40 CFR 707, Subpt. D)	
(40 CFR 707, Subpt. D)	
R 302.4)	
9 CFR 1910.1001-1053)	
ct of 1986 (SARA)	
Air Pollutants (HAPs) List	
al Release Prevention (40 CFR 68.130)	
Drinking Water and Toxic Enforcement Act of 1986 ( contain any chemicals currently listed as carcinogen	
e	On inventory (yes/no)*
ntory of Chemical Substances (AICS)	Yes
tances List (DSL)	Yes
Substances List (NDSL)	No
isting Chemical Substances in China (IECSC)	No
ntory of Existing Commercial Chemical NECS)	Yes
of Notified Chemical Substances (ELINCS)	No
isting and New Chemical Substances (ENCS)	Yes
cals List (ECL)	Yes
iventory	Yes
ntory of Chemicals and Chemical Substances	Yes
	Yes
al Substance Inventory (TCSI)	Yes
	Inventory entory of Chemicals and Chemical Substances ical Substance Inventory (TCSI) ices Control Act (TSCA) Inventory

<sup>•</sup>A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

# 16. Other information, including date of preparation or last revision

Issue date	05-15-2006
Revision date	10-12-2021
Version #	03
Further information	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

USP materials are sold for analytical laboratory use only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.