

1. Identification

Product identifier	Mercaptopurine Tablets USP, 50mg	
Other means of identification		
Product code	50 mg biconvex tablet, imprinted with "54 420" on one side, and scored on the other	
Recommended use	Indicated for maintenance therapy of acute lymphatic (lymphocytic, lymphoblastic) leukemia.	
Recommended restrictions	None known.	
Manufacturer/Importer/Supplier/Distributor information		
Company name	Boehringer Ingelheim Roxane Inc.	
Address	1809 Wilson Road Columbus, Ohio 43228	
Telephone	(614) 276-4000	
Emergency phone number	(614) 276-4000	

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Germ cell mutagenicity	Category 1B
	Carcinogenicity	Category 1B
	Reproductive toxicity	Category 1B
OSHA defined hazards	Not classified.	
Label elements		
Hazard symbol	None.	
Signal word	Danger	
Hazard statement	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.	
Precautionary statement		
Prevention	Observe good industrial hygiene practices.	
Response	Wash hands after handling.	
Storage	Store at 20 – 25 °C (68 - 77°F). Store in a dry place.	
Disposal	Incineration of waste at an approved USEPA incinerator is recommended.	
Hazard(s) not otherwise classified (HNOC)	None known.	

3. Composition/information on ingredients

Substances

Chemical name	Common name and synonyms	CAS number	%
1,7-dihydro-6H-purine-6-thione monohydrate		6112-76-1	50 mg

4. First-aid measures

Inhalation	If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed	Exposed individuals may experience vomiting, nausea, and diarrhea.
Indication of immediate medical attention and special treatment needed	Overdosage should be managed with supportive measures, including appropriate treatment for any concurrent infection. It may be useful to induce emesis.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
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. Wear appropriate personal protective equipment (See Section 8).
Methods and materials for containment and cleaning up	Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Store at 20 – 25 °C (68 - 77°F). Store in a dry place. Dispense in well-closed container as defined in the USP/NF Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Dust	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Dust	TWA	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Dust	TWA	3 mg/m ³	Respirable particles.
		10 mg/m ³	Inhalable particles.

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Appropriate engineering controls Ventilation should be matched to conditions.

Individual protection measures, such as personal protective equipment

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin protection

Hand protection For consumer use, no unusual precautions are necessary.

Other None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory protection None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state Solid.

Form Tablet.

Color Pale yellow.

Odor None.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

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 explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.

Skin contact Not expected to be hazardous in final pharmaceutical form. Dust may irritate skin.

Eye contact Not expected to be hazardous in final pharmaceutical form. Dust may irritate the eyes.

Ingestion Ingestion may cause irritation and malaise.

Symptoms related to the physical, chemical and toxicological characteristics Exposed individuals may experience vomiting, nausea, and diarrhea.

Information on toxicological effects

Acute toxicity Not expected to be acutely toxic.

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation Dust may irritate the eyes.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization Skin rash occurs occasionally in patients receiving the drug. Pigmentation of the skin and changes in nails can occur

Germ cell mutagenicity Causes chromosomal aberrations in animals and humans and induces dominant-lethal mutations in male mice.

Carcinogenicity Possible cancer hazard based on tests with laboratory animals.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity This product has been rated Pregnancy Category D-POSITIVE EVIDENCE OR RISK, There is a risk to fetus after drug is administered, but under certain circumstances (e.g., treatment of life threatening illnesses) the benefits can outweigh the risk. Animal reproduction studies have not been conducted with product

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure May cause hepatotoxic effects in animals and humans.

Aspiration hazard Due to the physical form of the product it is not an aspiration hazard.

Further information See package insert.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.
Other adverse effects None.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
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
Not regulated as dangerous goods.
IATA
Not regulated as dangerous goods.
IMDG
Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.
Over-the-counter drugs in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.
OSHA GHS: GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Not listed.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

1,7-dihydro-6H-purine-6-thione monohydrate (CAS 6112-76-1)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies 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	25-April-2015
Revision date	-
Version #	01
References	1) Mercaptopurine Tablets USP, 50mg, Package Insert, Roxane Laboratories, Inc., Columbus, Ohio. 2) PDR – Physicians Desk Reference. 3) Ariel Webinsight. Regulatory and ChemExpert Database.

Disclaimer

Boehringer Ingelheim Roxane Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.