6-Mercaptopurine Monohydrate

sc-205585

Material Safety Data Sheet



The Power to Oscotion

Hazard Alert Code Key: EXTREME HIGH MODERATE LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

6-Mercaptopurine Monohydrate

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

Santa Cruz Biotechnology, Inc. 2145 Delaware Avenue Santa Cruz, California 95060 800.457.3801 or 831.457.3800

EMERGENCY:

ChemWatch

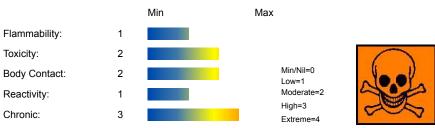
Within the US & Canada: 877-715-9305 Outside the US & Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS

C5-H4-N4-S, 6-mercaptopurine, "purine-6-thiol, monohydrate", "1, 7-dihydro-6H-purine-6-thione", "6H-purine-6-thione, 1, 7-dihydro-", 6-thiolhypoxanthine, "antineoplastic/ cytotoxic"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

Harmful if swallowed.

Limited evidence of a carcinogenic effect.

May impair fertility.

May cause harm to the unborn child.

Irritating to eyes, respiratory system and skin.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
- The killing action of antineoplastic drugs used for cancer chemotherapy is not selective for cancerous cells alone but affect all dividing cells. Acute side effects include loss of appetite, nausea and vomiting, allergic reaction (skin rash, itch, redness, low blood pressure, unwellness and anaphylactic shock) and local irritation.

<\p>. **EYE**

■ This material can cause eye irritation and damage in some persons.

SKIN

- This material can cause inflammation of the skin oncontact in some persons.
- The material may accentuate any pre-existing dermatitis condition.
- Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

- The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
- Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

■ There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment. Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.

Ample evidence exists from experimentation that reduced human fertility is directly caused by exposure to the material.

Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.

<\p>

Anti-cancer drugs used for chemotherapy can depress the bone marrow with reduction in the number of white blood cells and platelets and bleeding. Susceptibility to infections and bleeding is increased, which can be life- threatening. <\p>.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
6-Mercaptopurine Monohydrate	6112-76-1	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

· IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. · Where Medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:

EYE

■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED

· If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

NOTES TO PHYSICIAN

■ Treat symptomatically.

For employees potentially exposed to antineoplastic and/ or cytotoxic agents on a regular basis, a preplacement physical examination and history (noting risk factors) is recommended. Periodic follow-up examinations should also be undertaken and should be overseen by a physician familiar with the toxic effects of the substance and full details of the nature of work undertaken by the employee.

Readily absorbed form the gastrointestinal tract. Plasma half-life ranges from 10 to 90 minutes. Activated in the body by intracellular conversion to nucleotides. About half the oral dose is recovered in the urine within 24 hours mainly as metabolites.

Section 5 - FIRE FIGHTING MEASURES				
Vapour Pressure (mmHG):	Negligible			
Upper Explosive Limit (%):	Not available			
Specific Gravity (water=1):	Not available			
Lower Explosive Limit (%):	Not available			

EXTINGUISHING MEDIA

- · Foam.
- · Dry chemical powder.

FIRE FIGHTING

- · Alert Emergency Responders and tell them location and nature of hazard.
- · Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- · Combustible solid which burns but propagates flame with difficulty.
- · Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), nitrogen oxides (NOx), sulfur oxides (SOx), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

May emit corrosive fumes.

FIRE INCOMPATIBILITY

■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids,chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses:

Gloves:

Respirator:

Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- · Clean up waste regularly and abnormal spills immediately.
- · Avoid breathing dust and contact with skin and eyes.
- · Wear protective clothing, gloves, safety glasses and dust respirator.
- · Use dry clean up procedures and avoid generating dust.
- · Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- · Dampen with water to prevent dusting before sweeping.
- · Place in suitable containers for disposal.

It is recommended that areas handling final finished product have cytotoxic spill kits available.

Spill kits should include:

- · impermeable body covering,
- · shoe covers,
- · latex and utility latex gloves,
- · goggles,
- · approved HEPA respirator,
- · disposable dust pan and scoop,
- absorbent towels.
- · spill control pillows,
- · disposable sponges,
- · sharps container,
- · disposable garbage bag and

· hazardous waste label.

To avoid accidental exposure due to waste handling of cytotoxics:

- · Place waste residue in a segregated sealed plastic container.
- · Used syringes, needles and sharps should not be crushed, clipped, recapped, but placed directly into an approved sharps container.
- Dispose of any cleanup materials and waste residue according to all applicable laws and regulations e.g, secure chemical landfill disposal. All personnel likely to involved in a antineoplastic (cytotoxic) spill must receive practical training in:
- the correct procedures for handling cytotoxic drugs or waste in order to prevent and minimize the risk of spills
- · the location of the skill kit in the area.

MAJOR SPILLS

- Moderate hazard.
- · CAUTION: Advise personnel in area.
- · Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- The National Institute of Health (USA) recommends that the preparation of injectable antineoplastic drugs should be performed in a Class II laminar flow biological safety cabinet and that personnel preparing drugs of this class should wear appropriate personal protective gear. Emphasise controls on containment.
- · Avoid all personal contact, including inhalation.
- · Wear protective clothing when risk of exposure occurs.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

- · Do NOT cut, drill, grind or weld such containers.
- · In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

- Glass container.
- · Polyethylene or polypropylene container.
- · Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

- Antineoplastics (cytotoxics):
- · should be clearly identifiable to all personnel involved in their handling
- should be stored in impervious break-resistant containers.
- · Store in original containers.
- · Keep containers securely sealed.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records
• mercaptopurine: CAS:50-44-2 CAS:6112-76-1

PERSONAL PROTECTION



RESPIRATOR

Particulate

Consult your EHS staff for recommendations

EYE

- · Chemical protective goggles with full seal
- Shielded mask (gas-type)
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

- Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
- · frequency and duration of contact,

- · chemical resistance of glove material,
- · glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- · When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- · Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- · Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- · Double gloving should be considered.
- · PVC gloves.
- · Protective shoe covers.
- · Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- · polychloroprene
- · nitrile rubber
- · butyl rubber
- · fluorocaoutchouc
- · polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

OTHER

- · When handling antineoplastic materials, it is recommended that a disposal work-uniform (such as Tyvek or closed front surgical-type gown with knit cuffs) is worn.
- · For quantities up to 500 grams a laboratory coat may be suitable.
- · For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- · For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- · For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- · Eve wash unit
- · Ensure there is ready access to an emergency shower.
- · For Emergencies: Vinyl suit.

ENGINEERING CONTROLS

■ For potent pharmacological agents:

Powders

To prevent contamination and overexposure, no open handling of powder should be allowed.

- Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system.
- · In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used.
- · Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.
- · An air-purifying respirator should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.).
- \cdot Powder should be put into solution or a closed or covered container after handling.
- · If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.

Solutions Handling:

- · Solutions can be handled outside a containment system or without local exhaust ventilation during procedures with no potential for aerosolisation. If the procedures have a potential for aerosolisation, an air-purifying respirator is to be worn by all personnel in the immediate area.
- · Solutions used for procedures where aerosolisation may occur (e.g., vortexing, pumping) are to be handled within a containment system or with local exhaust ventilation.
- · In situations where this is not feasible (may include animal dosing), an air-purifying respirator is to be worn by all personnel in the immediate area. If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.
- · Ensure gloves are protective against solvents in use.

Unless written procedures, specific to the workplace are available, the following is intended as a guide:

- · For Laboratory-scale handling of Substances assessed to be toxic by inhalation. Quantities of up to 25 grams may be handled in Class II biological safety cabinets *; Quantities of 25 grams to 1 kilogram may be handled in Class II biological safety cabinets* or equivalent containment systems Quantities exceeding 1 kg may be handled either using specific containment, a hood or Class II biological safety cabinet*
- · HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Does not mix with water.

State	Divided solid	Molecular Weight	170.2 (1H2O)
Melting Range (°F)	>586.4(decomposes)	Viscosity	Not Applicable
Boiling Range (°F)	Not applicable	Solubility in water (g/L)	Immiscible
Flash Point (°F)	Not available	pH (1% solution)	Not applicable
Decomposition Temp (°F)	Not Available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	Not applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE

Yellow, odourless, tasteless, crystalline powder; does not mix with water. Soluble in dilute solutions of alkali hydroxides and hot alcohol.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- · Presence of incompatible materials.
- · Product is considered stable.

STORAGE INCOMPATIBILITY

■ Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

MERCAPTOPURINE

TOXICITY AND IRRITATION

MERCAPTOPURINE:

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY IRRITATION
Oral (mouse) LD50: 1250 mg/kg Nil Reported

Intraperitoneal (mouse) LD50: 224 mg/kg

■ Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Effects on fertility, extra embryonic structures, foetoxicity,

foetolethality, specific developmental abnormalities (musculoskeletal)

recorded.

Section 12 - ECOLOGICAL INFORMATION

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
mercaptopurine	HIGH		LOW	HIGH

GESAMP/EHS COMPOSITE LIST - GESAMP Hazard Profiles

Legend: EHS=EHS Number (EHS=GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships) NRT=Net Register Tonnage, A1a=Bioaccumulation log Pow, A1b=Bioaccumulation BCF, A1=Bioaccumulation, A2=Biodegradation, B1=Acuteaquatic toxicity LC/ECIC50 (mg/l), B2=Chronic aquatic toxicity NOEC (mg/l), C1=Acute mammalian oral toxicity LD50 (mg/kg),

C2=Acutemammalian dermal toxicity LD50 (mg/kg), C3=Acute mammalian inhalation toxicity LC50 (mg/kg), D1=Skin irritation & corrosion, D2=Eye irritation& corrosion, D3=Long-term health effects, E1=Tainting, E2=Physical effects on wildlife & benthic habitats, E3=Interference with coastal amenities, For column A2: R=Readily biodegradable, NR=Not readily biodegradable. For column D3: C=Carcinogen, M=Mutagenic, R=Reprotoxic, S=Sensitising, A=Aspiration hazard, T=Target organ systemic toxicity, L=Lunginjury, N=Neurotoxic, I=Immunotoxic. For column E1: NT=Not tainting (tested), T=Tainting test positive. For column E2: Fp=Persistent floater, F=Floater, S=Sinking substances. The numerical scales start from 0 (no hazard), while higher numbers reflect increasing hazard. (GESAMP/EHS Composite List of Hazard Profiles - Hazard evaluation of substances transported by ships)

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- · Reduction
- · Reuse
- · Recycling
- · Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- · Antineoplastic (cytotoxic) wastes must be packed directly, ready for incineration, into color-coded, secure, labelled, leak-proof containers sufficiently robust to withstand handling without breaking, bursting or leaking.
- Containers of special design are available for particular needs (such as disposal of sharps) and should be used.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

mercaptopurine (CAS: 50-44-2,6112-76-1) is found on the following regulatory lists;

"Canada Domestic Substances List (DSL)","International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs","US - California Proposition 65 - Priority List for the Development of MADLs for Chemicals Causing Reproductive Toxicity","US - Connecticut Hazardous Air Pollutants"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Inhalation and/or skin contact may produce health damage*.
- Cumulative effects may result following exposure*.
- * (limited evidence).

ND

Substance CAS Suggested codes mercaptopurine 50- 44- 2 mercaptopurine 6112- 76- 1

Germany Hazard classification and labelling of medicines with antineoplastic effects (ATC Code L01 and L02)

INN CAS Danger CMR effects CMR effects Other

Cat 1&2 Cat 3

Mercaptopurin 50- 44- 2 T, N R 60 R 61 R 22 R 52 R 53

(monohydrat)

Ingredients with multiple CAS Nos

Ingredient Name CAS mercaptopurine 50-44-2, 6112-76-1

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- Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.
- A list of reference resources used to assist the committee may be found at: www.chemwatch.net/references.
- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the

reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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