



SAFETY DATA SHEET

1. Identification

Product identifier

PURINETHOL TABLETS

Other means of identification

Synonyms

PURI-NETHOL TABLETS * PURINETHOL TABLETS 25 MG * PURI-NETHOL TABLETS 50 MG * MERCAPTOPURINA WELLCOME COMPRIMIDOS * MERCAPTOPURINE MONOHYDRATE, FORMULATED PRODUCT

Recommended use

Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions

No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
MERCAPTOPURINE MONOHYDRATE	CCI 3734 * 6-MERCAPTOPURINE * 6-MERCAPTOPURINE MONOHYDRATE * 1,7-DIHYDRO-6H-PURINE-6-THIONE MONOHYDRATE * THIOHYPOXANTHINE * 6-MERCAPTO-9H-PURINE MONOHYDRATE * 1673 (GW ACN)	6112-76-1	16 - < 40.3
STARCH	ARROWROOT STARCH * CORN STARCH * POTATO STARCH * RICE STARCH	9005-25-8	10 - < 20
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	< 1

Chemical name	Common name and synonyms	CAS number	%
STEARIC ACID	1-HEPTADECANECARBOXYLIC ACID * OCTADECANOIC ACID * STEAROPHANIC ACID * N-OCTADECANOIC ACID * C18H36O2 * OHS21873 * RTECS WI2800000	57-11-4	< 1

Other components below reportable levels

50 - < 60

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation	If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.
Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate contaminated clothing and shoes. Get medical attention immediately.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	Prolonged exposure may cause chronic effects. The following adverse effects have been noted with therapeutic use of this material: bone marrow toxicity; nausea; vomiting; diarrhoea; anorexia; rash; hair loss.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should undergo appropriate health surveillance that may include symptom enquiry, clinical examination and monitoring of lead organ effects (e.g. full blood counts). In the event of overexposure, individuals should receive post exposure health surveillance focused on the most likely health effects (e.g. full blood counts).

5. Fire-fighting measures

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO ₂). Water.
Unsuitable extinguishing media	None known.
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	Assume that this product is capable of sustaining combustion.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Collect spillage. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not taste or swallow. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

Components	Type	Value	Note
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
MERCAPTOPYRINE MONOHYDRATE (CAS 6112-76-1)	8 HR TWA	10 mcg/m3	REPRODUCTIVE HAZARD, CARCINOGEN
	OHC	4	REPRODUCTIVE HAZARD, CARCINOGEN

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

Components	Type	Value	Form
STARCH (CAS 9005-25-8)	PEL	5 mg/m3 15 mg/m3	Respirable fraction. Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
STARCH (CAS 9005-25-8)	TWA	10 mg/m3
STEARIC ACID (CAS 57-11-4)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
STARCH (CAS 9005-25-8)	TWA	5 mg/m3 10 mg/m3	Respirable. Total

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Eye/face protection

Eye wash fountain is recommended. Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection

The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

Other

Wear appropriate chemical resistant clothing.

Respiratory protection

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

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. Do not get this material on clothing. Wash contaminated clothing before reuse. When using, do not eat, drink or smoke. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Tablet.
Color	Not available.

Odor Not available.

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.

Incompatible materials Alkaline metals. Isocyanates.

Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Health injuries are not known or expected under normal use. Inhalation of dusts may cause respiratory irritation.
Skin contact	Health injuries are not known or expected under normal use. Dust or powder may irritate the skin.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation. Dust or powder may irritate eye tissue.
Ingestion	Health injuries are not known or expected under normal use. Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Irritant effects. Prolonged exposure may cause chronic effects.
The following adverse effects have been noted with therapeutic use of this material: bone marrow toxicity; nausea; vomiting; diarrhoea; anorexia; rash; hair loss;.

Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells; liver; immune system.

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use. Harmful if swallowed.

Components	Species	Test Results
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MAGNESIUM STEARATE (CAS 557-04-0)

Acute

Oral

LD50	Rat	> 2000 mg/kg
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MERCAPTOPURINE MONOHYDRATE (CAS 6112-76-1)

Acute

Oral

LD50	Mouse	1250 mg/kg
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Chronic

Oral

LD	Rat	20 mg/kg/day, 6 months
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NOAEL	Rat	< 5 mg/kg/day, 6 months
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STEARIC ACID (CAS 57-11-4)

Acute

Oral

LD50	Rat	> 5000 mg/kg
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Skin corrosion/irritation Health injuries are not known or expected under normal use. Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin

MERCAPTOPURINE MONOHYDRATE

Acute dermal irritation; OECD 404, Primary Irritation Index: 0
Result: Negative
Species: Rabbit

Irritation Corrosion - Skin: P.I.I. value

MAGNESIUM STEARATE

0

Serious eye damage/eye irritation Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Eye

MERCAPTOPURINE MONOHYDRATE

Acute ocular irritation; OECD 405, Kay and Calandra score = 4; maximum group mean score = 9.3
Result: Mild irritant
Species: Rabbit
IRE Assay
Result: Negative; not likely to be a severe irritant

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE

4
Recovery Period: 2 days

Respiratory or skin sensitization

Respiratory sensitization Not available.

Skin sensitization Health injuries are not known or expected under normal use.

Germ cell mutagenicity Health injuries are not known or expected under normal use. Contains a component that produced mutagenicity in laboratory tests.

Mutagenicity

MERCAPTOPURINE MONOHYDRATE

Ames Assay, GLP assay
 Result: Positive
 Chromosomal Aberration Assay In Vitro, human peripheral lymphocytes
 Result: Positive
 Mammalian cell mutation assay (CHO/HGPRT forward mutation assay)
 Result: Positive
 Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay
 Result: Positive
 Unscheduled DNA Synthesis, in vivo - in vitro
 Result: Negative

Carcinogenicity Health injuries are not known or expected under normal use. Contains a component listed as a carcinogen by: (GSK).

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity This material contains components which have been classified as: Possible reproductive hazard. May damage fertility. Potential embryo-fetal toxicity and teratogenicity. May cause harm to breastfed babies.

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure May cause damage to organs through prolonged or repeated exposure.

MERCAPTOPURINE MONOHYDRATE

Repeat dose non-clinical studies; clinical observation
 Organ: Bone marrow; liver; immune system

Aspiration hazard Not available.

Chronic effects Prolonged inhalation may be harmful. May cause damage to organs through prolonged or repeated exposure.

Further information Symptoms may be delayed.

12. Ecological information

Ecotoxicity Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
MERCAPTOPURINE MONOHYDRATE (CAS 6112-76-1)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Scenedesmus subspicatus)	> 100 mg/l, 72 hours Static test
	NOEC	Green algae (Scenedesmus subspicatus)	100 mg/l, 72 hours Static test
Crustacea	EC50	Water flea (Daphnia magna)	72 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Static test
STEARIC ACID (CAS 57-11-4)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	> 32 mg/l, 47 hours EU Method C.2
Fish	LC0	Carp (Cyprinus carpio)	1000 mg/l, 48 hours OECD 203

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated
STEARIC ACID 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm
STEARIC ACID 210 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

MERCAPTOPYRINE MONOHYDRATE 34 - 88 Days Measured, pH 7 Buffer Solution

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE 77 %, 28 days BOD
MERCAPTOPYRINE MONOHYDRATE < 1 %, 28 days Modified Zahn-Wellens, Activated sludge
STEARIC ACID 77 %, 28 days BOD

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days
STEARIC ACID 50 %, 13 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

MERCAPTOPYRINE MONOHYDRATE < -2.03
STEARIC ACID 8.23
8.42

Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated
STEARIC ACID > 9999 Estimated

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5.86 Estimated
STEARIC ACID 5.86 Estimated

Mobility in general Not available.

Volatility

Henry's law

STEARIC ACID 0.000051 Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

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 a dangerous good.

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 One or more components are not listed on TSCA.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

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.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

STARCH (CAS 9005-25-8)

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

Not listed.

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

STARCH (CAS 9005-25-8)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Developmental toxin

MERCAPTOPYRINE MONOHYDRATE (CAS 6112-76-1) Listed: July 1, 1990

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 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	10-20-2014
Revision date	10-20-2014
Version #	17
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 0 Instability: 0
References	GSK Hazard Determination
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
Revision Information	Product and Company Identification: Physical States Hazard(s) identification: Hazard statement Hazard(s) identification: Prevention Composition / Information on Ingredients: Ingredients First-aid measures: General information Exposure controls/personal protection: General hygiene considerations Stability and reactivity: Reactivity Toxicological information: Symptoms related to the physical, chemical and toxicological characteristics Ecological information: Mobility in general Disposal considerations: Disposal instructions Other information, including date of preparation or last revision: References