



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 of the chemical and restrictions on use

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.

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia

Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

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

Label elements, including precautionary statements

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

Other hazards which do not result in classification

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

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
MERCAPTOPURINE MONOHYDRATE	6112-76-1	16 - < 40.3
CCI 3734		
6-MERCAPTOPURINE		
6-MERCAPTOPURINE MONOHYDRATE		
1,7-DIHYDRO-6H-PURINE-6-THIONE MONOHYDRATE		
THIOHYPOXANTHINE		
6-MERCAPTO-9H-PURINE MONOHYDRATE		
1673 (GW ACN)		

Starch	9005-25-8	10 - < 20
ARROWROOT STARCH CORN STARCH POTATO STARCH RICE STARCH		
MAGNESIUM STEARATE	557-04-0	< 1
STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE		
Other components below reportable levels		50 - < 60

4. First-aid measures

Description of necessary first aid measures

Inhalation	In case of accident by inhalation: remove casualty to fresh air and keep at rest. 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 centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Personal protection for first-aid responders 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).

Symptoms caused by exposure 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.

Medical attention and special treatment 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.

5. Fire-fighting measures

Extinguishing media

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 fire fighters 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.

Hazchem Code Not available.

General fire hazards Assume that this product is capable of sustaining combustion.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel 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.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 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.

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.

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. 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 and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

GSK

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

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	Inhalable dust.
Starch (CAS 9005-25-8)	TWA	10 mg/m3	Inhalable dust.

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	Inspirable dust.
Starch (CAS 9005-25-8)	TWA	10 mg/m3	Inspirable 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

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Starch (CAS 9005-25-8)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable

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

Exposure guidelines	No exposure standards allocated.
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. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Ensure adequate ventilation, especially in confined areas.
Individual protection measures, for example personal protective equipment (PPE)	
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.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	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.
Colour	Not available.
Odour	Not available.
Odour 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.
Vapour pressure	Not available.
Vapour 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	Alkali metals. Isocyanates
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on possible 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 exposure	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.

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

Components	Species	Test results
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MERCAPTOPYRINE MONOHYDRATE (CAS 6112-76-1)		
Acute		
<i>Oral</i>		
LD50	Mouse	1250 mg/kg
Chronic		
<i>Oral</i>		
LD	Rat	20 mg/kg/day, 6 months
NOAEL	Rat	< 5 mg/kg/day, 6 months
Skin corrosion/irritation	Health injuries are not known or expected under normal use. Prolonged skin contact may cause temporary irritation.	
Irritation Corrosion - Skin		
MERCAPTOPYRINE 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/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 sensitisation

Respiratory sensitisation Not available.

Skin sensitisation 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).

ACGIH Carcinogens

MAGNESIUM STEARATE (CAS 557-04-0)
 Starch (CAS 9005-25-8)

A4 Not classifiable as a human carcinogen.
 A4 Not classifiable as a human carcinogen.

Reproductive toxicity This material contains components which have been classified as: Possible reproductive hazard. May damage fertility. Potential embryo-foetal 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.

Other 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

Components		Species	Test results
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (<i>Scenedesmus subspicatus</i>)	> 100 mg/l, 72 hours Static test
	NOEC	Green algae (<i>Scenedesmus subspicatus</i>)	100 mg/l, 72 hours Static test
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	72 mg/l, 48 hours Static test
	NOEC	Water flea (<i>Daphnia magna</i>)	32 mg/l, 48 hours Static test

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 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

Percent degradation (Aerobic biodegradation-ready)

MAGNESIUM STEARATE 95 %, 22 days Sturm test

MERCAPTOPYRINE MONOHYDRATE 11 %, 28 days Modified Sturm test.

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

Bioaccumulative potential

Partition coefficient

n-octanol / water (log Kow)

MERCAPTOPYRINE MONOHYDRATE < -2.03

Bioconcentration factor

(BCF)

MAGNESIUM STEARATE > 9999 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5.86 Estimated

Mobility in general Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal methods

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.

Residual waste

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

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

Safety, health and environmental regulations

National regulations This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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

Issue date 20-October-2014

Revision date 20-October-2014

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: Product and Company Identification
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Toxicological Information:
Ecological Information: Degradation
Regulatory Information: Risk Phrases - Class.