SAFETY DATA SHEET

GlaxoSmithKline

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material **PURINETHOL TABLETS**

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

Company Name

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Multi-language response

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Multi-language response

2. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health Caution - Potent pharmaceutical agent.
Exposure might occur via ingestion; skin; eyes.
May cause cancer.
May produce adverse effects on human fertility.
May produce adverse effects on the development of human offspring.
Health effects information is based on hazards of components.

Environment No information is available about the potential of this product to produce adverse environmental effects.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
MERCAPTOPURINE MONOHYDRATE	6112-76-1	16 to 40.3	
NON-HAZARDOUS INGREDIENTS	Unassigned	59.7 to 84	

4. FIRST-AID MEASURES

Ingestion Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of a cytotoxic agent. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Health Surveillance Procedures	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).
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard. For all spills, isolate the spill area, restrict access, post the area for a carcinogen and immediately implement emergency procedures for cleanup and control of occupational carcinogens.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements	Avoid breaking or crushing tablets.
STORAGE	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	MERCAPTOPURINE MONOHYDRATE	
GSK Occupational Hazard Category	4	
GSK Occupational Exposure Limit	10 mcg/m3 (8 HR TWA)	REPRODUCTIVE HAZARD, CARCINOGEN

ENGINEERING CONTROLS

Containment	Open handling may result in overexposure. Consider use of enclosures.
Administrative	Strict control of access to the working area is essential. Restrict access to authorised personnel.
Other Equipment or Procedures	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Wear appropriate clothing to avoid skin contact. When isolation is not possible in production areas, appropriate personal protective equipment must be used. Consider additional control procedures for maintenance, cleaning and emergencies.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour	Light yellow.
Physical Form	Tablet.

10. STABILITY AND REACTIVITY

Stability	This product is expected to be stable.
Conditions to Avoid	None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Pharmacological Effects	This product contains active ingredient(s) with the following activity: a cytotoxic agent.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells; dividing cells; gastro-intestinal tract; liver.

Routes of Exposure

Oral Toxicity	Adverse effects might occur following ingestion.
Inhalation Toxicity	No studies have been conducted.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Irritation might occur following direct contact with eyes.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Known or probable human mutagen.
Carcinogenicity	Possible human carcinogen. (GSK). No components are listed as carcinogens by IARC, NTP or US OSHA.
Reproductive Effects	This material contains components which have been classified as: Known or presumed to impair fertility in humans. Known or presumed to cause toxicity in developing human offspring.
Other Adverse Effects	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary	This material contains an active pharmaceutical ingredient that has been tested and which may be harmful if released directly to the environment. Appropriate precautions should be taken to limit release of this mixture to the environment. Local regulations and procedures should be consulted prior to environmental release.

ECOTOXICITY

Aquatic

Activated Sludge Respiration	This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

Daphnid This mixture contains an active pharmaceutical ingredient that is harmful to daphnids.

MOBILITY

Solubility This mixture contains an active pharmaceutical ingredient that for environmental fate predictions has limited solubility in water.

Partitioning This mixture contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

Persistence/Degradation

Biodegradation This mixture contains an active pharmaceutical ingredient that is not readily nor inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and may persist in the environment.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used. Wherever possible, disposal should be in an on-site licenced chemical incinerator, if allowed by the incinerator licence or permit. If no on-site incinerator is available, dispose of material in a licenced commercial chemical incinerator.

Regulatory Requirements Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification This product is classified as hazardous according to the OSHA Hazard Communication Standard. However, products that are subject to the labelling requirements of the Food and Drug Administration are exempt from the labelling provisions of the standard.

Target Organ Statement May cause adverse effects on bone marrow; dividing cells; gastrointestinal tract; liver.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 15

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.