SAFETY DATA SHEET

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

Material THIOGUANINE TABLETS

Synonym(s) THIOGUANIN GSK TABLETTEN 40 MG * TABLOID BRAND THIOGUANINE TABLETS 40 MG * TABLOID COMPRIMIDOS * TIOGUANINE TABLET 40 MG * TIOGUANINA WELLCOME COMPRIMIDOS * LANVIS TABLETS 40 MG * NDC NO 0173-0880-25 * THIOGUANINE, FORMULATED PRODUCT

Company Name

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information: +44-20-8047-5000

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
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Email Address: msds@gsk.com
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EMERGENCY PHONE NUMBERS -
Transport Emergencies (by country / geographic region):

Africa (Arab-speaking):	+961-3-487-287 (Lebanon)
Africa (English, French, Portuguese-speaking):	+44-208-762-8322 (UK)
Asia Pacific (except China):	+65-633-44-177 (Singapore)
China:	+86-10-5100-3039 (Beijing)
EU:	+44-208-762-8322 (UK)
Israel:	+44-208-762-8322 (UK)
Middle East (except Israel):	+961-3-487-287 (Lebanon)
US:	+1-703-527-3887 (US)

available 24 hrs/7 days; multi-language response

Medical Emergencies: +1-612-221-3999, Ext 221 (US)
available 24 hrs/7 days; multi-language response

* 2. HAZARDS IDENTIFICATION

Fire and Explosion Hazards

Expected to be non-combustible.

Health

Caution - Potent pharmaceutical agent.
Exposure might occur via ingestion; skin; eyes.
May cause cancer.
May produce mutagenic effects in human cells.
May produce adverse effects on the development of human offspring.
Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching).
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.
THIOGUANINE	154-42-7	16.8 to 18	205-827-2
Other components below reportable levels		82.0 to 83.2	

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 None for occupational exposure.

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

OCCUPATIONAL EXPOSURE LIMITS

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

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. Wash hands and arms thoroughly after handling. This product is listed by US NIOSH as a hazardous drug when handled in health care settings. For additional information about the NIOSH hazardous drugs programme and recommendations for preventing exposure see US NIOSH publication No. 2004-165, "Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings."

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

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 preparation contains ingredient(s) with the following activity: a nucleoside analogue.

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

Routes of Exposure

Oral Toxicity Not expected to be toxic following ingestion.

Inhalation Toxicity No studies have been conducted.

Skin Effects Irritation is not expected following direct contact.

Eye Effects Irritation is not expected following direct contact with eyes.

Sensitisation Allergic skin reactions might occur following dermal exposure.

Genetic Toxicity Possible human mutagen.

Carcinogenicity Contains a component listed as a carcinogen by: (GSK) Known or probable human carcinogen. No components are listed as carcinogens by: (IARC); (NTP); (US OSHA); (EU).

Reproductive Effects Contains components which have been classified as: Possible risk of toxicity in developing human offspring.

Other Adverse Effects None known for occupational exposure.

* 12. ECOLOGICAL INFORMATION

Summary No information is available about the potential of this product to produce adverse environmental effects. This material contains an active ingredient (thioguanine) that has been tested and which may be very toxic to aquatic organisms if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. 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.

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 Not regulated in transport.

* 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 and formation of blood cells; liver.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 13

SDS Sections Updated

Sections	Subsections
ACCIDENTAL RELEASE MEASURES	Personal Precautions
COMPOSITION / INFORMATION ON INGREDIENTS	
ECOLOGICAL INFORMATION	Activated Sludge Respiration
	Adsorption
	Algal
	Algal Degradation
	Bioaccumulation
	Biodegradation

SDS Sections Updated

Sections	Subsections
ECOLOGICAL INFORMATION	Crustacea
	Daphnid
	Desorption
	Distribution
	Earthworm
	Ecotoxicity
	EHAC Notation
	Fish
	GSK Environmental Hazard Category
	Hydrolysis
	Log Kow
	Microbial Growth Inhibition
	Microtox
	Mobility
	Other Adverse Effects
	Other Species - Aquatic
	Other Species - Terrestrial
	Partitioning
	PBT Assessment
	Persistence/Degradation
	Photolysis
	Solubility
	Summary
	Very bioaccumulative
	Very persistent
	Volatility
EXPOSURE CONTROLS / PERSONAL PROTECTION	Administrative
	Containment
	Exposure Controls
HAZARDS IDENTIFICATION	Health
IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY	
REGULATORY INFORMATION	US OSHA Standard (29 CFR Part 1910.1200) - Target Organ Stat
TRANSPORT INFORMATION	

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.