SAFETY DATA SHEET

GlaxoSmithKline

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

Material **TABLOID BRAND THIOGUANINE TABLETS**

Synonyms TABLOID BRAND THIOGUANINE 40MG * LANVIS TABLET 40MG * NDC NO 0173-0880-25 * THIOGUANINE, FORMULATED PRODUCT

Company Name

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Transport Emergency (non EU)	+1-703-527-3887
	US number, available 24 hours
	Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
THIOGUANINE	154-42-7	16.8 to 18
NON-HAZARDOUS INGREDIENTS	Unassigned	82 to 83.2

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

*** Health** Caution - Potent pharmaceutical agent.
Exposure might occur via skin; eyes; ingestion.
May cause cancer.
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.

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

ENGINEERING CONTROLS

Exposure 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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them.
Containment	Open handling may result in overexposure. Consider segregating operations, use of enclosures and sealed transfer systems.
*** Administrative**	Entry to the working area should be controlled. Restrict access to authorised personnel.
Other Equipment or Procedures	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

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. TOXICOLOGICAL INFORMATION

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

*** Pharmacological Effects** This preparation contains ingredient(s) with the following activity: a nucleoside analogue.

*** 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. 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.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

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

IC50: > 1000 mg/l, 3 Hours, Activated sludge

*** Algal** This material contains an active pharmaceutical ingredient that is very toxic to algae.

IC50: 0.0034 mg/l, 72 Hours, Scenedesmus subspicatus, green algae, Static test

NOEL: 0.0005 mg/l, 72 Hours, Scenedesmus subspicatus, green algae, Static test

*** Daphnid** This material contains an active pharmaceutical ingredient that is harmful to daphids.

EC50: 16.5 mg/l, 48 Hours, Daphnia magna

MOBILITY

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

*** Volatility** This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant 1.42E-14 atm m^3/mol, Calculated at 25 C

*** Partitioning** This material 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

*** Hydrolysis** This material contains an active pharmaceutical ingredient that may be chemically unstable under basic conditions. Hydrolysis may be a significant depletion mechanism.

Half-Life, Neutral: 62 Days, Measured, Deionized Water

*** Biodegradation** This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

Aerobic - Inherent

Percent Degradation:	0 %, 28 days, Modified MITI (II) Test., Activated sludge
Percent Degradation:	68 %, 28 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

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. The recommended method of disposal is incineration.

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 dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 01-Nov-2004 **SDS Version Number** 6

SDS Sections Updated

Sections	Subsections
ECOLOGICAL INFORMATION	Activated Sludge Respiration
	Adsorption
	Algal
	Algal Degradation
	Bioaccumulation
	Biodegradation
	Daphnid
	Distribution

SDS Sections Updated

Sections	Subsections
ECOLOGICAL INFORMATION	Earthworm
	Ecotoxicity
	Fish
	Hydrolysis
	Microbial Growth Inhibition
	Microtox
	Mobility
	Other Adverse Effects
	Other Species - Aquatic
	Other Species - Terrestrial
	Partitioning
	Persistence/Degradation
	Photolysis
	Solubility
	Summary
	Volatility
EXPOSURE CONTROLS / PERSONAL PROTECTION	Administrative
HAZARDS IDENTIFICATION	Health
REGULATORY INFORMATION	European Union Classification and Labelling Requirements
TOXICOLOGY INFORMATION	Other Adverse Effects
	Pharmacological Effects
	Sensitisation

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.