

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture THIOGUANINE TABLETS

Registration number -

Synonyms

THIOGUANIN GSK TABLETTEN 40 MG * TABLOID BRAND THIOGUANINE TABLETS 40 MG * TABLOID COMPRIMIDOS * TIOGUANINE TABLET 40 MG * TIOGUANINA WELLCOME COMPRIMIDOS * LANVIS TABLETS 40 MG * THIOGUANINE, FORMULATED PRODUCT

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1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses 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.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES:
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information None.

2.3. Other hazards

Caution - Potent pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
THIOGUANINE	10 - < 20	154-42-7 2058272	-	-	M=100
Classification:	DSD: Carc. Cat. 3;R40, Muta. Cat. 3;R68, Repr. Cat. 2;R60-61, Xn;R22, N;R50/53 CLP: Acute Tox. 4;H302, Muta. 2;H341, Carc. 2;H351, Repr. 1B;H360, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				
Starch	5 - < 10	9005-25-8 232-679-6	-	-	
Classification:	DSD: - CLP: -				
MAGNESIUM STEARATE	< 0,2	557-04-0 209-150-3	-	-	
Classification:	DSD: - CLP: -				

Other components below reportable levels 70 - < 80

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

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.

4.1. Description of first aid measures

Inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact

Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

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). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without medical advice.

4.2. Most important symptoms and effects, both acute and delayed

Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching).

4.3. Indication of any immediate medical attention and special treatment needed

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards

No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media

Foam. Dry chemical powder. Carbon dioxide (CO₂). Water.

Unsuitable extinguishing media

None known.

5.2. Special hazards arising from the substance or mixture

During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
SECTION 6: Accidental release measures	
6.1. 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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
6.2. Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid prolonged exposure.
7.2. Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
7.3. Specific end use(s)	Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK Components	Type	Value	Note
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
THIOGUANINE (CAS 154-42-7)	8 HR TWA	10 mcg/m3	
	OHC	4	Carcinogen
		4	Reproductive hazard

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

Recommended monitoring procedures Not available.

Derived no-effect level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

Appropriate engineering controls General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)
Skin protection	
- Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust)
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
Environmental exposure controls	
Hazard guidance and control recommendations	Contain spills and prevent releases and observe national regulations on emissions. Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic 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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.

9.2. Other information

No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Not available.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Peroxides. Phenols.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information

This preparation contains ingredient(s) with the following activity: a nucleoside analogue. Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Ingestion	May be harmful if swallowed. Health injuries are not known or expected under normal use.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Symptoms	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching).

11.1. Information on toxicological effects

Acute toxicity	May be harmful if swallowed.	
Components	Species	Test results
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
THIOGUANINE (CAS 154-42-7)		
Acute		
<i>Oral</i>		
LD50	Rat	650 mg/kg
* Estimates for product may be based on additional component data not shown.		
Skin corrosion/irritation	Health injuries are not known or expected under normal use.	
Irritation Corrosion - Skin		
THIOGUANINE		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.	
Eye		
THIOGUANINE		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 sensitisation	Knowledge about health hazard is incomplete.	
Skin sensitisation	Health injuries are not known or expected under normal use.	
Germ cell mutagenicity	Possible human mutagen.	
Mutagenicity		
THIOGUANINE		Ames Assay, GLP assay Result: negative Chromosomal Aberration Assay In Vitro, CHO cells, Literature data Result: positive Dominant lethal assay, Literature data Result: positive Species: Mouse GreenScreen Assay Result: positive
Carcinogenicity	Known or probable human carcinogen. Contains a component listed as a carcinogen by: (GSK) No components are listed as carcinogens by: (IARC); (NTP); (US OSHA); (EU).	
THIOGUANINE		SAR / QSAR Result: Plausible structural alert identified
Reproductive toxicity	Possible reproductive hazard. Possible risk of toxicity in developing human offspring.	
Specific target organ toxicity - single exposure	Not established.	
Specific target organ toxicity - repeated exposure	May cause damage to organs.	

**Specific target organ toxicity -
repeated exposure**

THIOGUANINE

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

Aspiration hazard Not likely, due to the form of the product.

**Mixture versus substance
information** No information available.

Other information Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity Contains a substance which causes risk of hazardous effects to the environment. The product contains a substance which may cause long-term adverse effects in the environment.

Components	Species	Test results
MAGNESIUM STEARATE (CAS 557-04-0)		
Aquatic		
Acute		
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)
		130 mg/l, 96 hours
THIOGUANINE (CAS 154-42-7)		
Acute		
	IC50	Activated sludge
		> 1000 mg/l, 3 hours
Aquatic		
Acute		
Algae	EC50	Green algae (Scenedesmus subspicatus)
	NOEC	Green algae (Scenedesmus subspicatus)
		0,0034 mg/l, 72 hours Static test
		0,0005 mg/l, 72 hours Static test
Crustacea	EC50	Water flea (Daphnia magna)
		16,5 mg/l, 48 hours

* Estimates for product may be based on additional component data not shown.

**12.2. 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)

THIOGUANINE 62 Days Measured, Deionized Water

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE 77 %, 28 days BOD
THIOGUANINE 0 %, 28 days Modified MITI (II) Test., Activated sludge

68 %, 28 days Modified Zahn-Wellens, primary
biodegradation, loss of parent., Activated sludge

MAGNESIUM STEARATE 95 %, 22 days Sturm test

50 %, 13 days

12.3. Bioaccumulative potential

Partition coefficient

n-octanol/water (log Kow)

THIOGUANINE -0,07

< 1

Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5,86 Estimated

Mobility in general

Volatility

Henry's law
THIOGUANINE

0 atm m³/mol Calculated, 25 C

12.5. Results of PBT and vPvB assessment

12.6. Other adverse effects

Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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.

EU waste code

The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose in accordance with all applicable regulations.

Special precautions

Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

General

Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

ADR

14.1. UN number

UN3077

14.2. UN proper shipping name

Environmentally hazardous substances, solid, n.o.s. (THIOGUANINE TABLETS)

14.3. Transport hazard class(es)

Class

9

Subsidiary risk

-

Label(s)

9

Hazard No. (ADR)

Not available.

Tunnel code

Not available.

14.4. Packing group

III

14.5. Environmental hazards

Yes

14.6. Special precautions for user

Not available.

IATA

14.1. UN number

UN3077

14.2. UN proper shipping name

Environmentally hazardous substance, solid, n.o.s. (THIOGUANINE TABLETS)

14.3. Transport hazard class(es)

9

Subsidiary class(es)

-

14.4. Packing group

III

Labels required

9

14.5. Environmental hazards

No.

ERG Code

9L

14.6. Special precautions for user

Not available.

Other information

Cargo aircraft only

Allowed.

Additional Information:

Passenger & cargo

Allowed.

IMDG

14.1. UN number

UN3077

14.2. UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (THIOGUANINE TABLETS)

14.3. Transport hazard class(es)

Class 9

Subsidiary risk -

Label(s) 9

14.4. Packing group III

14.5. Environmental hazards

Marine pollutant Yes

EmS F-A, S-F

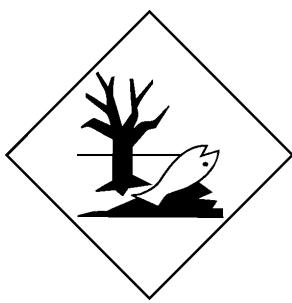
14.6. Special precautions for user

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

ADR; IATA; IMDG



Marine pollutant



General information

Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations**Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended**

Not listed.

Restrictions on use**Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations**Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances**

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. Pregnant women should not work with the product, if there is the least risk of exposure.

National regulations

Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information**List of abbreviations**

Not available.

References

GSK Hazard Determination

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R22 Harmful if swallowed.

R40 Limited evidence of a carcinogenic effect.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R60 May impair fertility.

R61 May cause harm to the unborn child.

R68 Possible risk of irreversible effects.

H302 Harmful if swallowed.

H341 Suspected of causing genetic defects.

H351 Suspected of causing cancer.

H360 May damage fertility or the unborn child.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Physical & Chemical Properties:

Ecological Information: Mobility

Transport Information: Material Transportation Information

Regulatory Information: United States

GHS: Classification

Training information

Follow training instructions when handling this material.

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.