



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** IMURAN INJECTION

### Other means of identification

**Synonyms** IMURAN 50 MG/2 ML INJECTION \* IMURAN VIAL \* IMUREL INJECTION \* IMUREK INJECTION \* AZATHIOPRINE, 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

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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
AZATHIOPRINE BW 57322 CCI 3738 6-(1-METHYL-4-NITROIMIDAZOL-5-YL-THIO)PURINE 6-(1-METHYL-4-NITRO-5-IMIDAZOLYL)MERCAPTOPYRINE 1565 (GW ACN)	446-86-6	< 88
SODIUM HYDROXIDE CAUSTIC SODA SODIUM HYDRATE	1310-73-2	< 13

## 4. First-aid measures

### Description of necessary first aid measures

<b>Inhalation</b>	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.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	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 advice from poison control center.
<b>Personal protection for first-aid responders</b>	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.
<b>Symptoms caused by exposure</b>	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, vomiting, increased susceptibility to infection.
<b>Medical attention and special treatment</b>	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

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	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** Move containers from fire area if you can do so without risk.

**Hazchem Code** Not available.

**General fire hazards** No unusual fire or explosion hazards noted.

**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

<b>For non-emergency personnel</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. 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.
<b>For emergency responders</b>	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

**Environmental precautions** 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. 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** Do not get in eyes, on skin, or on clothing. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices.

**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
AZATHIOPRINE (CAS 446-86-6)	8 HR TWA	3 mcg/m3	
	OHC	4	Reproductive hazard
		4	SKIN SENSITISER
		4	Carcinogen

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

Components	Type	Value
SODIUM HYDROXIDE (CAS 1310-73-2)	Ceiling	2 mg/m3

#### US. ACGIH Threshold Limit Values

Components	Type	Value
SODIUM HYDROXIDE (CAS 1310-73-2)	Ceiling	2 mg/m3

#### UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
SODIUM HYDROXIDE (CAS 1310-73-2)	STEL	2 mg/m3

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

### Exposure guidelines

**Appropriate engineering controls** General ventilation normally adequate. 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.

### Individual protection measures, for example personal protective equipment (PPE)

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended.

#### Skin protection

**Hand protection** For prolonged or repeated skin contact use suitable protective gloves.

**Other** Wear suitable protective clothing as protection against splashing or contamination.

**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** 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.

## 9. Physical and chemical properties

### Appearance

**Physical state** Solid.  
**Form** Freeze dried powder.  
**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** Strong oxidising agents.

**Hazardous decomposition products** None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on possible routes of exposure

**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. May be irritating to the skin.

**Eye contact** Health injuries are not known or expected under normal use. May be irritating to eyes.

**Ingestion** Harmful if swallowed. Health injuries are not known or expected under normal use.

**Symptoms related to exposure** Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, vomiting, increased susceptibility to infection.

**Acute toxicity** May be harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test results
AZATHIOPRINE (CAS 446-86-6)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	400 mg/kg
SODIUM HYDROXIDE (CAS 1310-73-2)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	1350 mg/kg
<i>Oral</i>		
LD50	Rat	104 - 340 mg/kg

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

<b>Skin corrosion/irritation</b>	May be irritating to the skin.
<b>Serious eye damage/irritation</b>	Health injuries are not known or expected under normal use. May be irritating to eyes.
<b>Respiratory or skin sensitisation</b>	
<b>Respiratory sensitisation</b>	No studies have been conducted.
<b>Sensitisation</b>	
AZATHIOPRINE	Occupational exposure, Literature data Result: Low incidence of contact hypersensitivity. Species: Human
<b>Germ cell mutagenicity</b>	May cause genetic defects.
<b>Mutagenicity</b>	
AZATHIOPRINE	Ames Assay, GLP assay; Literature data Result: positive Micronucleus Test, GLP assay; Literature data Result: positive
<b>Carcinogenicity</b>	Contains a material (AZATHIOPRINE) classified as a carcinogen by external agencies.
AZATHIOPRINE	Literature search Result: positive
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>	
AZATHIOPRINE (CAS 446-86-6)	1 Carcinogenic to humans.
<b>Reproductive toxicity</b>	May damage fertility or the unborn child.
<b>Specific target organ toxicity - single exposure</b>	Causes damage to organs (bone marrow, respiratory system).
<b>Specific target organ toxicity - repeated exposure</b>	Causes damage to organs through prolonged or repeated exposure.
AZATHIOPRINE	Literature search Organ: Immune system, Bone marrow and formation of blood cells, Liver, Kidney
<b>Aspiration hazard</b>	No studies have been conducted.
<b>Chronic effects</b>	Prolonged exposure may cause chronic effects.
<b>Other information</b>	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

## 12. Ecological information

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

Components		Species	Test results
AZATHIOPRINE (CAS 446-86-6)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae (Scenedesmus subspicatus)	> 100 mg/l, 72 hours Static test
	NOEC	Green algae (Scenedesmus subspicatus)	100 mg/l, 72 hours Static test
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	> 100 mg/l, 48 hours Static test
SODIUM HYDROXIDE (CAS 1310-73-2)			
<b>Aquatic</b>			
<i>Acute</i>			
Fish	EC50	Mosquito fish (Adult Gambusia affinis)	125 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhynchus mykiss)	45.4 mg/l, 96 hours Static test

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

### Persistence and degradability

### Biodegradability

#### Percent degradation (Aerobic biodegradation-inherent)

AZATHIOPRINE 4 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge

4 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

#### Percent degradation (Aerobic biodegradation-ready)

AZATHIOPRINE

11 %, 28 days Modified Sturm test.

### Bioaccumulative potential

#### Partition coefficient n-octanol / water (log Kow)

AZATHIOPRINE

-0.787

### Mobility in soil

No data available for this product.

### Mobility in general

#### Volatility

##### Henry's law

AZATHIOPRINE

0 atm m<sup>3</sup>/mol, 25 C Estimated

### 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 discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable 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). Avoid discharge into water courses or onto the ground.

### 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 available.

### Annex II of MARPOL 73/78 and the IBC Code

## 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

SODIUM HYDROXIDE (CAS 1310-73-2)

For domestic use, in liquid or semi-solid food additive preparations, PH>11.5

#### Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix E**

SODIUM HYDROXIDE (CAS 1310-73-2)

For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once)., If swallowed, do NOT induce vomiting., If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes., If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

**Australia Medicines & Poisons Appendix F**

SODIUM HYDROXIDE (CAS 1310-73-2)

in preparations Irritant. Avoid contact with eyes., Avoid contact with skin., Wash hands after use.  
in solid preparations Corrosive., May produce severe burns., Attacks skin and eyes. Wear eye protection when mixing or using., Wear protective gloves when mixing or using., Do not mix with hot water.  
liquid preparations Corrosive., May produce severe burns., Attacks skin and eyes. Wear eye protection when mixing or using., Wear protective gloves when mixing or using.

**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**

SODIUM HYDROXIDE (CAS 1310-73-2)

in preparations being: (a) solid preparations the pH of which in a 10 g/L aqueous solution is more than 11.5; (b) liquid or semi-solid preparations the pH of which is more than 11.5

**Australia Medicines & Poisons Schedule 6**

SODIUM HYDROXIDE (CAS 1310-73-2)

applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

**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)**

SODIUM HYDROXIDE (CAS 1310-73-2)

> 1000000 TONNES See the regulation for additional information.

**Importation of Ozone Depleting 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)	Yes
Canada	Domestic Substances List (DSL)	Yes
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)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
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** 07-November-2014**Revision date** 07-November-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:  
Ecological Information: Ecotoxicity  
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection  
Regulatory Information: Risk Phrases - Class.  
GHS: Classification