



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

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)MERCAPTOPURINE 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

Inhalation	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 advice from poison control center.
Personal protection for first-aid responders	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.
Symptoms caused by 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.
Medical attention and special treatment	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

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	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

For non-emergency personnel	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.
For emergency responders	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

Conditions for safe storage, including any incompatibilities	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.
	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)		
Acute		
<i>Oral</i>		
LD50	Rat	400 mg/kg
SODIUM HYDROXIDE (CAS 1310-73-2)		
Acute		
<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.

Skin corrosion/irritation	May be irritating to the skin.
Serious eye damage/irritation	Health injuries are not known or expected under normal use. May be irritating to eyes.
Respiratory or skin sensitisation	
Respiratory sensitisation	No studies have been conducted.
Sensitisation	
AZATHIOPRINE	Occupational exposure, Literature data Result: Low incidence of contact hypersensitivity. Species: Human
Germ cell mutagenicity	May cause genetic defects.
Mutagenicity	
AZATHIOPRINE	Ames Assay, GLP assay; Literature data Result: positive Micronucleus Test, GLP assay; Literature data Result: positive
Carcinogenicity	Contains a material (AZATHIOPRINE) classified as a carcinogen by external agencies.
AZATHIOPRINE	Literature search Result: positive
IARC Monographs. Overall Evaluation of Carcinogenicity	
AZATHIOPRINE (CAS 446-86-6)	1 Carcinogenic to humans.
Reproductive toxicity	May damage fertility or the unborn child.
Specific target organ toxicity - single exposure	Causes damage to organs (bone marrow, respiratory system).
Specific target organ toxicity - repeated exposure	Causes damage to organs through prolonged or repeated exposure.
AZATHIOPRINE	Literature search Organ: Immune system, Bone marrow and formation of blood cells, Liver, Kidney
Aspiration hazard	No studies have been conducted.
Chronic effects	Prolonged exposure may cause chronic effects.
Other information	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)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
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)			
Aquatic			
Acute			
Fish	EC50	Mosquito fish (Adult <i>Gambusia affinis</i>)	125 mg/l, 96 hours Static test
		Rainbow trout (Adult <i>Oncorhynchus mykiss</i>)	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 ³ /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.
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-sold 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 Deleting 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