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	IMURAN INJECTION
Registration number	-
Synonyms	IMURAN 50 MG/2 ML INJECTION * IMURAN VIAL * IMUREL INJECTION * IMUREK INJECTION * AZATHIOPRINE, FORMULATED PRODUCT
Issue date	07-November-2014
Version number	12
Revision date	07-November-2014

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

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.

2.3. Other hazards Caution - 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
AZATHIOPRINE	< 88	446-86-6 207-175-4	-	-	

Classification: **DSD:** Carc. Cat. 1;R45, Muta. Cat. 1;R46, Muta. Cat. 2;R46, Repr. Cat. 2;R61, Xn;R22-48, Xi;R36-37-38, R43

CLP: Acute Tox. 4;H302, Skin Irrit. 2;H315, Skin Sens. 1;H317, Eye Irrit. 2;H319, STOT SE 3;H335, Muta. 1B;H340, Carc. 1A;H350, Repr. 1B;H360, STOT RE 1;H372

SODIUM HYDROXIDE	< 13	1310-73-2 215-185-5	-	011-002-00-6	

Classification: **DSD:** C;R35

CLP: Acute Tox. 3;H301, Acute Tox. 4;H312, Skin Corr. 1A;H314

List of abbreviations and symbols that may be used above

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 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.

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, and difficulty breathing), nausea, vomiting, increased susceptibility to infection.

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 current prescribing information or 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 Water. Foam. Dry chemical powder. Carbon dioxide (CO_2).

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 Move containers from fire area if you can do so without risk.

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. 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.
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 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. 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. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. Wash contaminated clothing before reuse.
7.2. 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).
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
AZATHIOPRINE (CAS 446-86-6)	8 HR TWA	3 mcg/m3	
	OHC	4	Reproductive hazard
		4	SKIN SENSITISER
		4	Carcinogen

Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no-effect level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

Exposure guidelines

8.2. Exposure controls

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, 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	If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166). Not normally needed.
Skin protection	
- Hand protection	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). Not normally needed.
- Other	Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust). Not normally needed.

Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. No personal respiratory protective equipment normally required.
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	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	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.
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	Strong acids.
10.2. Chemical stability	Material is stable under normal conditions.
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	Strong oxidising agents.
10.6. Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely 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 cause an allergic skin reaction. 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	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, vomiting, increased susceptibility to infection.

11.1. Information on toxicological effects

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		
Oral		
LD50	Rat	400 mg/kg
SODIUM HYDROXIDE (CAS 1310-73-2)		
Acute		
Dermal		
LD50	Rabbit	1350 mg/kg
Oral		
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/eye irritation	Health injuries are not known or expected under normal use. May be irritating to eyes.
Respiratory sensitisation	No studies have been conducted.
Skin sensitisation	May cause an allergic skin reaction.

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.

Reproductivity

AZATHIOPRINE	Literature search Result: Positive for teratogenicity, fertiltiy effects and may affect the quality of breast milk.

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.
Mixture versus substance information	No information available.

Other information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

SECTION 12: Ecological information

12.1. Toxicity 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 Gambusia affinis)	125 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	45,4 mg/l, 96 hours Static test

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

12.2. 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.

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

AZATHIOPRINE: -0,787

12.4. Mobility in soil No data available.

Mobility in general

Volatility

Henry's law

AZATHIOPRINE: 0 atm m^3/mol, 25 C Estimated

12.5. Results of PBT and vPvB assessment Not available.

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). 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.

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. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

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(10) 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

SODIUM HYDROXIDE (CAS 1310-73-2)

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

SODIUM HYDROXIDE (CAS 1310-73-2)

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.
National regulations	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. R35 Causes severe burns. R36 Irritating to eyes. R36/38 Irritating to eyes and skin. R37 Irritating to respiratory system. R38 Irritating to skin. R43 May cause sensitization by skin contact. R45 May cause cancer. R46 May cause heritable genetic damage. R48 Danger of serious damage to health by prolonged exposure. R61 May cause harm to the unborn child. H301 Toxic if swallowed. H302 Harmful if swallowed. H312 Harmful in contact with skin. H314 Causes severe skin burns and eye damage. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H340 May cause genetic defects. H350 May cause cancer. H360 May damage fertility or the unborn child. H372 Causes damage to organs through prolonged or repeated exposure.
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 and Packaging Type/Transport Mode Selection Regulatory Information: Risk Phrases - Class. 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.