SAFETY DATA SHEET

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

Material **IMURAN INJECTION**

Synonym(s) IMURAN 50 MG/2 ML INJECTION * IMURAN VIAL * IMUREL INJECTION * IMUREK INJECTION * AZATHIOPRINE, FORMULATED PRODUCT

Company Name

GlaxoSmithKline, Corporate Environment, Health & Safety
980 Great West Road
Brentford, Middlesex TW8 9GS UK

UK General Information: +44-20-8047-5000
Transport Emergency (EU) +44-1865-407333
Medical Emergency +1-612-221-3999, Ext 221
Information and Advice: US number, available 24 hours
Multi-language response

GlaxoSmithKline, Corporate Environment, Health & Safety
One Franklin Plaza, 200 N 16th Street
Philadelphia, PA 19102-1225 US

US General Information: +1-888-825-5249
Transport Emergency (non EU) +1-703-527-3887
US number, available 24 hours
Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
AZATHIOPRINE	446-86-6	87.5	
NON-HAZARDOUS INGREDIENTS	Unassigned	12.5	

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health

Caution - Potent pharmaceutical agent.
Exposure might occur via ingestion; skin; eyes.
May cause cancer.
May produce adverse effects on human fertility.
May produce adverse effects on the development of human offspring.
May impair the quantity or quality of human milk production.
May produce allergic skin reactions.
Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).
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 immunosupressive agent. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions.

Medical Conditions Caused or Aggravated by Exposure Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.

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. For all spills, isolate the spill area, restrict access, post the area for a carcinogen and immediately implement emergency procedures for cleanup and control of occupational carcinogens.

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 Water can be used for clean-up and decontamination operations. Neutralize with caustic soda or soda ash.

7. HANDLING AND STORAGE

HANDLING

General Requirements No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

STORAGE No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	AZATHIOPRINE	
GSK Occupational Hazard Category	4	
GSK Occupational Exposure Limit	3 mcg/m3 (8 HR TWA)	CARCINOGEN, REPRODUCTIVE HAZARD, SKIN SENSITISER

ENGINEERING CONTROLS

Containment Open handling may result in overexposure. Consider use of enclosures.

Administrative Strict control of access to the working area is essential. Restrict access to authorised personnel.

Other Equipment or Procedures Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Wear appropriate clothing to avoid skin contact. When isolation is not possible in production areas, appropriate personal protective equipment must be used. Consider additional control procedures for maintenance, cleaning and emergencies.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Freeze dried powder.

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Pharmacological Effects This product contains active ingredient(s) with the following activity: an immunosupressive agent.

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

Routes of Exposure

Oral Toxicity Adverse effects might occur following ingestion.

Inhalation Toxicity No studies have been conducted.

Skin Effects No studies have been conducted.

Eye Effects No studies have been conducted.

Sensitisation Allergic skin reactions might occur following dermal exposure.

Genetic Toxicity Known or probable human mutagen.

Carcinogenicity Contains a material classified as a carcinogen by external agencies. Human carcinogen (IARC); (NTP).

Reproductive Effects Contains components which have been classified as: Known or presumed to cause toxicity in developing human offspring. Known or presumed to affect the quantity and quality of breast milk in humans. Possible risk of impaired fertility in humans.

Other Adverse Effects None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. 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 not toxic to algae.

IC50:	> 100 mg/l, 72 Hours, Scenedesmus subspicatus, green algae, Static test
NOEC:	100 mg/l, 72 Hours, Scenedesmus subspicatus, green algae, Static test

Daphnid This material contains an active pharmaceutical ingredient that is not toxic to daphnids.

EC50:	> 100 mg/l, 48 Hours, Daphnia magna, Static test
NOEC:	> 100 mg/l, 48 Hours, Daphnia magna, Static test

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.

Henrys Law Constant	8.10E-15 atm m3/mol, Estimated 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

Biodegradation This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines). It may persist in the environment.

Aerobic - Ready

Percent Degradation:	11 %, 28 days, Modified Sturm test.

Aerobic - Inherent

Percent Degradation:	4 %, 28 days, Modified Zahn-Wellens, DOC removal., Activated sludge

Aerobic - Inherent

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

Bioaccumulation This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

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. Wherever possible, disposal should be in an on-site licenced chemical incinerator, if allowed by the incinerator licence or permit. If no on-site incinerator is available, dispose of material in a licenced commercial chemical incinerator.

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 product is classified as hazardous according to the OSHA Hazard Communication Standard.

Target Organ Statement May cause adverse effects on immune system; bone marrow.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 11

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	

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.