



# 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**

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.

**Recommended restrictions**

No other uses are advised.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249  
Email Address: msds@gsk.com  
Website: www.gsk.com  
EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES::  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

**Classified hazards**

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

**Label elements**

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

**Hazard(s) not otherwise classified (HNOC)**

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

## 3. Composition/information on ingredients

**Mixtures**

| Chemical name    | Common name and synonyms   | CAS number | %    |
|------------------|--|------------|------|
| AZATHIOPRINE     | BW 57322 * CCI 3738 *<br>6-(1-METHYL-4-NITROIMIDAZOL-5-YL-THI<br>O)PURINE *<br>6-(1-METHYL-4-NITRO-5-IMIDAZOLYL)ME<br>RCAPTOPYRINE * 1565 (GW ACN) | 446-86-6   | < 88 |
| SODIUM HYDROXIDE | CAUSTIC SODA * SODIUM HYDRATE  | 1310-73-2  | < 13 |

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

## 4. 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.

|   |  |
|---|--|
| <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 center immediately. Do not induce vomiting without advice from poison control center.   |
| <b>Most important symptoms/effects, acute and delayed</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>Indication of immediate medical attention and special treatment needed</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 center.                   |
| <b>General information</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. |

## 5. Fire-fighting measures

|  |   |
|--|---|
| <b>Suitable extinguishing media</b>                                  | Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).                          |
| <b>Unsuitable extinguishing media</b>                                | None known.   |
| <b>Specific hazards arising from the chemical</b>                    | During fire, gases hazardous to health may be formed.   |
| <b>Special protective equipment and precautions for firefighters</b> | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| <b>Fire fighting equipment/instructions</b>                          | Move containers from fire area if you can do so without risk.                                 |
| <b>Specific methods</b>  | Use standard firefighting procedures and consider the hazards of other involved materials.    |
| <b>General fire hazards</b>  | No unusual fire or explosion hazards noted.   |

## 6. Accidental release measures

|  |   |
|--|---|
| <b>Personal precautions, protective equipment and emergency procedures</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 of the SDS. |
| <b>Methods and materials for containment and cleaning up</b>               | 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.   |
| <b>Environmental precautions</b>   | Avoid discharge into drains, water courses or onto the ground.  |

## 7. Handling and storage

|   |   |
|---|---|
| <b>Precautions for safe handling</b>                                | 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. |
| <b>Conditions for safe storage, including any incompatibilities</b> | Store locked up. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).  |

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### GSK

#### Components

AZATHIOPRINE (CAS 446-86-6)

#### Type

8 HR TWA

OHC

#### Value

3 mcg/m<sup>3</sup>

4

4

4

#### Note

REPRODUCTIVE HAZARD  
SKIN SENSITISER  
CARCINOGEN

**US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**

| Components                          | Type | Value               |
|-------------------------------------|------|---------------------|
| SODIUM HYDROXIDE<br>(CAS 1310-73-2) | PEL  | 2 mg/m <sup>3</sup> |

**US. ACGIH Threshold Limit Values**

| Components                          | Type    | Value               |
|-------------------------------------|---------|---------------------|
| SODIUM HYDROXIDE<br>(CAS 1310-73-2) | Ceiling | 2 mg/m <sup>3</sup> |

**US. NIOSH: Pocket Guide to Chemical Hazards**

| Components                          | Type    | Value               |
|-------------------------------------|---------|---------------------|
| SODIUM HYDROXIDE<br>(CAS 1310-73-2) | Ceiling | 2 mg/m <sup>3</sup> |

|  |  |
|--|--|
| <b>Biological limit values</b>   | No biological exposure limits noted for the ingredient(s).   |
| <b>Exposure guidelines</b>   |  |
| <b>Appropriate engineering controls</b>                                      | 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.  |
| <b>Individual protection measures, such as personal protective equipment</b> |  |
| <b>Eye/face protection</b>   | If contact is likely, safety glasses with side shields are recommended.  |
| <b>Skin protection</b>   |  |
| <b>Hand protection</b>   | For prolonged or repeated skin contact use suitable protective gloves.   |
| <b>Other</b>   | Wear suitable protective clothing as protection against splashing or contamination.  |
| <b>Respiratory protection</b>  | Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally required.  |
| <b>Thermal hazards</b>   | Wear appropriate thermal protective clothing, when necessary.  |
| <b>General hygiene considerations</b>  | 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**

|   |                      |
|---|----------------------|
| <b>Physical state</b>                               | Solid.               |
| <b>Form</b>   | Freeze dried powder. |
| <b>Color</b>  | Not available.       |
| <b>Odor</b>   | Not available.       |
| <b>Odor threshold</b>                               | Not available.       |
| <b>pH</b>   | Not available.       |
| <b>Melting point/freezing point</b>                 | Not available.       |
| <b>Initial boiling point and boiling range</b>      | Not available.       |
| <b>Flash point</b>                                  | Not available.       |
| <b>Evaporation rate</b>                             | Not available.       |
| <b>Flammability (solid, gas)</b>                    | Not available.       |
| <b>Upper/lower flammability or explosive limits</b> |                      |
| <b>Flammability limit - lower (%)</b>               | Not available.       |
| <b>Flammability limit - upper (%)</b>               | Not available.       |
| <b>Explosive limit - lower (%)</b>                  | Not available.       |
| <b>Explosive limit - upper (%)</b>                  | Not available.       |
| <b>Vapor pressure</b>                               | Not available.       |
| <b>Vapor density</b>                                | Not available.       |

|  |                |
|--|----------------|
| <b>Relative density</b>                        | Not available. |
| <b>Solubility(ies)</b>                         |                |
| <b>Solubility (water)</b>                      | Not available. |
| <b>Partition coefficient (n-octanol/water)</b> | Not available. |
| <b>Auto-ignition temperature</b>               | Not available. |
| <b>Decomposition temperature</b>               | Not available. |
| <b>Viscosity</b>                               | Not available. |

## 10. Stability and reactivity

|   |  |
|---|--|
| <b>Reactivity</b>                         | The product is stable and non-reactive under normal conditions of use, storage and transport.        |
| <b>Chemical stability</b>                 | Material is stable under normal conditions.  |
| <b>Possibility of hazardous reactions</b> | No dangerous reaction known under conditions of normal use.  |
| <b>Conditions to avoid</b>                | Contact with incompatible materials.   |
| <b>Incompatible materials</b>             | Strong oxidizing agents.   |
| <b>Hazardous decomposition products</b>   | None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. |

## 11. Toxicological information

### Information on likely routes of exposure

|                     |   |
|---------------------|---|
| <b>Inhalation</b>   | Under normal conditions of intended use, this material is not expected to be an inhalation hazard.                              |
| <b>Skin contact</b> | Health injuries are not known or expected under normal use. May cause an allergic skin reaction. May be irritating to the skin. |
| <b>Eye contact</b>  | Health injuries are not known or expected under normal use. May be irritating to eyes.  |
| <b>Ingestion</b>    | Harmful if swallowed. Health injuries are not known or expected under normal use.   |

|   |  |
|---|--|
| <b>Symptoms related to the physical, chemical and toxicological characteristics</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. |
|---|--|

### Information on toxicological effects

|                       |  |
|-----------------------|--|
| <b>Acute toxicity</b> | 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/eye irritation</b> | Health injuries are not known or expected under normal use. May be irritating to eyes. |
| <b>Respiratory or skin sensitization</b> |  |
| <b>Respiratory sensitization</b>         | No studies have been conducted.  |
| <b>Skin sensitization</b>                | May cause an allergic skin reaction.   |

|   |   |
|---|---|
| <b>Sensitization</b><br>AZATHIOPRINE                                      | Occupational exposure, Literature data<br>Result: Low incidence of contact hypersensitivity.<br>Species: Human  |
| <b>Germ cell mutagenicity</b><br><b>Mutagenicity</b><br>AZATHIOPRINE      | May cause genetic defects.<br><br>Ames Assay, GLP assay; Literature data<br>Result: Positive<br>Micronucleus Test, GLP assay; Literature data<br>Result: Positive         |
| <b>Carcinogenicity</b><br>AZATHIOPRINE                                    | Contains a material (AZATHIOPRINE) classified as a carcinogen by external agencies.<br><br>Literature search<br>Result: Positive  |
| <b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>             |   |
| AZATHIOPRINE (CAS 446-86-6)   | 1 Carcinogenic to humans.   |
| <b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>     |   |
| Not listed.   |   |
| <b>US. National Toxicology Program (NTP) Report on Carcinogens</b>        |   |
| AZATHIOPRINE (CAS 446-86-6)   | Known To Be Human Carcinogen.   |
| <b>Reproductive toxicity</b><br><b>Reproductivity</b><br>AZATHIOPRINE     | May damage fertility or the unborn child.<br><br>Literature search<br>Result: Positive for teratogenicity, fertility effects and may affect the quality of breast milk.   |
| <b>Specific target organ toxicity - single exposure</b>                   | Causes damage to organs (bone marrow, respiratory system).  |
| <b>Specific target organ toxicity - repeated exposure</b><br>AZATHIOPRINE | Causes damage to organs through prolonged or repeated exposure.<br><br>Literature search<br>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 inhalation may be harmful. Prolonged exposure may cause chronic effects. Causes damage to organs through prolonged or repeated exposure.                        |
| <b>Further 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)  |
|                                  | NOEC             | Green algae (Scenedesmus subspicatus)  |
| Crustacea                        | EC50             | Water flea (Daphnia magna)             |
|                                  | NOEC             | Water flea (Daphnia magna)             |
| 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         |

| Components | Species                                   | Test Results                    |
|------------|---|---------------------------------|
|            | 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

#### Bioaccumulative potential

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

AZATHIOPRINE -0.787

**Mobility in soil** No data available.

#### 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 instructions** 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.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

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

**Waste from residues / unused products** 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

#### DOT

Not regulated as a dangerous good.

#### 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** 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.

### 15. Regulatory information

#### US federal regulations

##### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

##### CERCLA Hazardous Substance List (40 CFR 302.4)

SODIUM HYDROXIDE (CAS 1310-73-2) Listed.

##### SARA 304 Emergency release notification

Not regulated.

##### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.



| <b>Country(s) or region</b> | <b>Inventory name</b>                         | <b>On inventory (yes/no)*</b> |
|-----------------------------|---|-------------------------------|
| 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, including date of preparation or last revision

|                             |  |
|-----------------------------|--|
| <b>Issue date</b>           | 11-07-2014   |
| <b>Revision date</b>        | 11-07-2014   |
| <b>Version #</b>            | 12   |
| <b>Further information</b>  | HMIS® is a registered trade and service mark of the NPCA.  |
| <b>HMIS® ratings</b>        | Health: 3*<br>Flammability: 0<br>Physical hazard: 0  |
| <b>NFPA ratings</b>         | Health: 3<br>Flammability: 0<br>Instability: 0   |
| <b>References</b>           | GSK Hazard Determination   |
| <b>Disclaimer</b>           | 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. |
| <b>Revision Information</b> | Product and Company Identification: Business Units<br>Composition / Information on Ingredients: Ingredients<br>Physical & Chemical Properties:<br>Ecological Information: Ecotoxicity<br>Transport Information: Agency Name, Packaging Type, and Transport Mode Selection<br>Regulatory Information: Risk Phrases - Class.<br>GHS: Classification                                |