

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

|                                          |                                                                                                                        |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| Trade name or designation of the mixture | IMURAN TABLETS                                                                                                         |
| Registration number                      | -                                                                                                                      |
| Synonyms                                 | IMURAN 25 MG TABLETS * IMURAN 50 MG TABLETS * IMUREK FILMTABLETTEN * IMUREL TABLETS * AZATHIOPRINE, FORMULATED PRODUCT |
| Issue date                               | 06-November-2014                                                                                                       |
| Version number                           | 13                                                                                                                     |
| Revision date                            | 06-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](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://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           | 31,4 - < 31,8 | 446-86-6<br>207-175-4                                                                                                                                    | - | - |  |
| <b>Classification:</b> | <b>DSD:</b>   | Carc. Cat. 1;R45, Muta. Cat. 1;R46, Muta. Cat. 2;R46, Repr. Cat. 2;R61, Xn;R22-48, Xi;R36-37-38, R43                                                     |   |   |  |
|                        | <b>CLP:</b>   | 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 |   |   |  |

|                        |             |                        |   |   |  |
|------------------------|-------------|------------------------|---|---|--|
| Starch                 | 10 - < 20   | 9005-25-8<br>232-679-6 | - | - |  |
| <b>Classification:</b> | <b>DSD:</b> | -                      |   |   |  |
|                        | <b>CLP:</b> | -                      |   |   |  |

|                                |             |                |   |   |  |
|--------------------------------|-------------|----------------|---|---|--|
| HYDROXYPROPYL METHYL CELLULOSE | 1 - < 3     | 9004-65-3<br>- | - | - |  |
| <b>Classification:</b>         | <b>DSD:</b> | -              |   |   |  |
|                                | <b>CLP:</b> | -              |   |   |  |

|                        |             |                       |   |   |  |
|------------------------|-------------|-----------------------|---|---|--|
| MAGNESIUM STEARATE     | < 1         | 557-04-0<br>209-150-3 | - | - |  |
| <b>Classification:</b> | <b>DSD:</b> | -                     |   |   |  |
|                        | <b>CLP:</b> | -                     |   |   |  |

|                        |             |                         |   |   |  |
|------------------------|-------------|-------------------------|---|---|--|
| Titanium dioxide       | < 0,2       | 13463-67-7<br>236-675-5 | - | - |  |
| <b>Classification:</b> | <b>DSD:</b> | -                       |   |   |  |
|                        | <b>CLP:</b> | -                       |   |   |  |

Other components below reportable levels 40 - < 50

**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**

|                     |                                                                                                                                                                                                                                         |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <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.          |

**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

|                                                                   |                                                                                               |
|-------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| <b>General fire hazards</b>                                       | No unusual fire or explosion hazards noted.                                                   |
| <b>5.1. Extinguishing media</b>                                   |                                                                                               |
| <b>Suitable extinguishing media</b>                               | Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).                          |
| <b>Unsuitable extinguishing media</b>                             | None known.                                                                                   |
| <b>5.2. Special hazards arising from the substance or mixture</b> | During fire, gases hazardous to health may be formed.                                         |
| <b>5.3. Advice for firefighters</b>                               |                                                                                               |
| <b>Special protective equipment for firefighters</b>              | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| <b>Special fire fighting procedures</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.    |

## SECTION 6: Accidental release measures

|                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|---------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>6.1. Personal precautions, protective equipment and emergency procedures</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <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.                                                                                                                                                                                                                                                                                                                                          |
| <b>6.2. Environmental precautions</b>                                           | Avoid discharge into drains, water courses or onto the ground.                                                                                                                                                                                                                                                                                                                                                                         |
| <b>6.3. Methods and material 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.                                                                                                                                                                                                                                                               |
| <b>6.4. Reference to other sections</b>                                         | For personal protection, see section 8. For waste disposal, see section 13 of the SDS.                                                                                                                                                                                                                                                                                                                                                 |

## SECTION 7: Handling and storage

|                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>7.1. Precautions for safe handling</b>                                | Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact with eyes, skin, and 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. |
| <b>7.2. 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).                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>7.3. Specific end use(s)</b>                                          | 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/m <sup>3</sup> |                     |
|                                                   | OHC                                                        | 4                    | Carcinogen          |
|                                                   |                                                            | 4                    | Reproductive hazard |
|                                                   |                                                            | 4                    | SKIN SENSITISER     |
| HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)    | OHC                                                        | 1                    |                     |
| <b>Biological limit values</b>                    | No biological exposure limits noted for the ingredient(s). |                      |                     |
| <b>Recommended monitoring procedures</b>          | Follow standard monitoring procedures.                     |                      |                     |
| <b>Derived no-effect level (DNEL)</b>             | Not available.                                             |                      |                     |
| <b>Predicted no effect concentrations (PNECs)</b> | 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

Tablet.

##### 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.

|                               |                                               |
|-------------------------------|-----------------------------------------------|
| <b>Viscosity</b>              | Not available.                                |
| <b>Explosive properties</b>   | Not available.                                |
| <b>Oxidizing properties</b>   | Not available.                                |
| <b>9.2. Other information</b> | No relevant additional information available. |

## SECTION 10: Stability and reactivity

|                                                 |                                                                                                      |
|-------------------------------------------------|------------------------------------------------------------------------------------------------------|
| <b>10.1. Reactivity</b>                         | The product is stable and non-reactive under normal conditions of use, storage and transport.        |
| <b>10.2. Chemical stability</b>                 | Material is stable under normal conditions.                                                          |
| <b>10.3. Possibility of hazardous reactions</b> | No dangerous reaction known under conditions of normal use.                                          |
| <b>10.4. Conditions to avoid</b>                | Contact with incompatible materials.                                                                 |
| <b>10.5. Incompatible materials</b>             | Strong oxidising agents.                                                                             |
| <b>10.6. Hazardous decomposition products</b>   | None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. |

## SECTION 11: Toxicological information

|                            |                                                                              |
|----------------------------|------------------------------------------------------------------------------|
| <b>General information</b> | Occupational exposure to the substance or mixture may cause adverse effects. |
|----------------------------|------------------------------------------------------------------------------|

### 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.                                        |
| <b>Eye contact</b>  | Health injuries are not known or expected under normal use.                                        |
| <b>Ingestion</b>    | Health injuries are not known or expected under normal use. May be harmful if swallowed.           |

|                 |                                                                                                                                                                                                    |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Symptoms</b> | Accidental exposure or contact might produce: nausea, vomiting, symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), increased susceptibility to infection. |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### 11.1. Information on toxicological effects

|                       |                                                                                                                            |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------|
| <b>Acute toxicity</b> | Expected to be a low hazard for usual industrial or commercial handling by trained personnel. May be harmful if swallowed. |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------|

| <b>Components</b>                              | <b>Species</b> | <b>Test results</b>                                                                                                                               |
|------------------------------------------------|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| AZATHIOPRINE (CAS 446-86-6)                    |                |                                                                                                                                                   |
| <b>Acute</b>                                   |                |                                                                                                                                                   |
| <i>Oral</i>                                    |                |                                                                                                                                                   |
| LD50                                           | Rat            | 400 mg/kg                                                                                                                                         |
| HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3) |                |                                                                                                                                                   |
| <b>Acute</b>                                   |                |                                                                                                                                                   |
| <i>Oral</i>                                    |                |                                                                                                                                                   |
| LD50                                           | Rat            | > 2000 mg/kg                                                                                                                                      |
| MAGNESIUM STEARATE (CAS 557-04-0)              |                |                                                                                                                                                   |
| <b>Acute</b>                                   |                |                                                                                                                                                   |
| <i>Oral</i>                                    |                |                                                                                                                                                   |
| LD50                                           | Rat            | > 2000 mg/kg                                                                                                                                      |
| Titanium dioxide (CAS 13463-67-7)              |                |                                                                                                                                                   |
| <b>Acute</b>                                   |                |                                                                                                                                                   |
| <i>Inhalation</i>                              |                |                                                                                                                                                   |
| LC50                                           | Rat            | 6820 mcg/m3                                                                                                                                       |
| <i>Oral</i>                                    |                |                                                                                                                                                   |
| LD50                                           | Rat            | > 24 g/kg                                                                                                                                         |
| <b>Chronic</b>                                 |                |                                                                                                                                                   |
| <i>Inhalation</i>                              |                |                                                                                                                                                   |
| LOEC                                           | Rat            | 8,6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue. |
| NOAEC                                          | Rat            | 250 mg/m3, 2 years Highest dose<br>5 mg/m3, 24 months                                                                                             |

| Components                                     | Species    | Test results                                                                                      |
|------------------------------------------------|------------|---------------------------------------------------------------------------------------------------|
| <b>Subacute</b><br><i>Inhalation</i><br>LOEL   | Rat        | 0,1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid. |
| NOAEC                                          | Guinea pig | 26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.                   |
| <i>Oral</i><br>NOAEL                           | Rat        | 100000 ppm, 14 Day Dietary study, highest dose tested.                                            |
| <b>Subchronic</b><br><i>Inhalation</i><br>LOEC | Rat        | 3,2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation. |

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

**Skin corrosion/irritation** Health injuries are not known or expected under normal use.

**Irritation Corrosion - Skin**  
TITANIUM DIOXIDE

0, Literature data  
Result: Non-irritant  
Species: Guinea pig  
0, Literature data  
Result: Non-irritant  
Species: Human  
Acute dermal irritation; OECD 404, Literature data  
Result: Non-irritant  
Species: Rabbit

**Irritation Corrosion - Skin: P.I.I. value**  
MAGNESIUM STEARATE

0

**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use.

**Eye**  
TITANIUM DIOXIDE

OECD 405, Literature data  
Result: Mild irritant  
Species: Rabbit

**Eye / Kay and Calandra class - Intact**  
MAGNESIUM STEARATE

4  
Recovery Period: 2 days

**Respiratory sensitisation** No studies have been conducted.

**Skin sensitisation** May cause an allergic skin reaction.

**Maximisation assay (Magnusson and Kligman)**  
HYDROXYPROPYL METHYL CELLULOSE

Result: negative  
Species: Guinea pig

**Sensitisation**  
TITANIUM DIOXIDE

5 % Optimisation Test, Literature data - Vehicle: petrolatum  
Result: negative  
Species: Guinea pig  
Test Duration: 48 hour exposure  
Occupational exposure, Literature data  
Result: Low incidence of contact hypersensitivity.  
Species: Human  
Patch test, Literature data  
Result: negative  
Species: Human

AZATHIOPRINE

TITANIUM DIOXIDE

**Germ cell mutagenicity** May cause genetic defects.

**Mutagenicity**  
AZATHIOPRINE

Ames Assay, GLP assay; Literature data  
Result: positive

TITANIUM DIOXIDE

Ames, Literature data  
Result: negative  
Micronucleus Assay in vitro, CHO cells, Literature data  
Result: negative

|                                                               |                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Mutagenicity</b>                                           |                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| TITANIUM DIOXIDE                                              |                                                                                                              | Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data<br>Result: positive                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| AZATHIOPRINE                                                  |                                                                                                              | Micronucleus Test, GLP assay; Literature data<br>Result: positive                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| TITANIUM DIOXIDE                                              |                                                                                                              | Syrian Hamster Embryo (SHE) cell transformation assay<br>Result: negative<br>WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data<br>Result: positive                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Carcinogenicity</b>                                        |                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| TITANIUM DIOXIDE                                              | Contains a material (Azathioprine) classified as a carcinogen by external agencies.                          | 0,5 mg/m3, Literature data<br>Result: negative<br>Species: Rat<br>Test Duration: 24 months<br>0,72 - 14,8 mg/m3, Literature data<br>Result: negative<br>Species: Mouse<br>10 - 250 mg/m3, Dietary study - Literature data.<br>Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration.<br>Species: Rat<br>Test Duration: 24 months<br>25000 - 50000 ppm, Dietary study<br>Result: negative<br>Species: Mouse<br>25000 - 50000 ppm, Dietary study - Literature data.<br>Result: negative<br>Species: Rat<br>7,2 - 14,8 mg/m3, Literature data<br>Result: Lung tumour<br>Species: Rat<br>Test Duration: 24 months<br>Literature search<br>Result: positive |
| AZATHIOPRINE                                                  |                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>IARC Monographs. Overall Evaluation of Carcinogenicity</b> |                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| AZATHIOPRINE (CAS 446-86-6)                                   |                                                                                                              | 1 Carcinogenic to humans.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Titanium dioxide (CAS 13463-67-7)                             |                                                                                                              | 2B Possibly carcinogenic to humans.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Reproductive toxicity</b>                                  | May damage fertility or the unborn child.                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Reproductivity</b>                                         |                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| AZATHIOPRINE                                                  |                                                                                                              | 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>       | Not available.                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Specific target organ toxicity - repeated exposure</b>     | Causes damage to organs through prolonged or repeated exposure.                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| AZATHIOPRINE                                                  |                                                                                                              | Literature search<br>Organ: Immune system, Bone marrow and formation of blood cells, Liver, Kidney                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Aspiration hazard</b>                                      | Not likely, due to the form of the product.                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Mixture versus substance information</b>                   | No information available.                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Other information</b>                                      | 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) |                  |                      |
| <i>Acute</i>                |                  |                      |
| IC50                        | Activated sludge | > 1000 mg/l, 3 hours |

| Components                                     |      | Species                                     | Test results                      |
|------------------------------------------------|------|---------------------------------------------|-----------------------------------|
| <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  |
| HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3) |      |                                             |                                   |
| <b>Aquatic</b>                                 |      |                                             |                                   |
| <i>Acute</i>                                   |      |                                             |                                   |
| Fish                                           | EC50 | Fish                                        | > 100 mg/l, 96 hours              |
| MAGNESIUM STEARATE (CAS 557-04-0)              |      |                                             |                                   |
| <b>Aquatic</b>                                 |      |                                             |                                   |
| <i>Acute</i>                                   |      |                                             |                                   |
| Fish                                           | EC50 | Orange-red killfish (Adult Oryzias latipes) | 130 mg/l, 96 hours                |
| Titanium dioxide (CAS 13463-67-7)              |      |                                             |                                   |
| <b>Aquatic</b>                                 |      |                                             |                                   |
| <i>Acute</i>                                   |      |                                             |                                   |
| Crustacea                                      | EC50 | Water flea (Daphnia magna)                  | > 1000 mg/l, 48 hours Static test |

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

## 12.2. Persistence and degradability

### Photolysis

#### Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

#### UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

### Biodegradability

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

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

MAGNESIUM STEARATE 4 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge  
77 %, 28 days BOD

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

AZATHIOPRINE 11 %, 28 days Modified Sturm test.

MAGNESIUM STEARATE 95 %, 22 days Sturm test

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

MAGNESIUM STEARATE 50 %, 13 days

## 12.3. Bioaccumulative potential

### Partition coefficient

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

AZATHIOPRINE -0,787

HYDROXYPROPYL METHYL CELLULOSE -5

### Bioconcentration factor (BCF)

HYDROXYPROPYL METHYL CELLULOSE 3,2 Estimated

MAGNESIUM STEARATE > 9999 Estimated

## 12.4. Mobility in soil

### Adsorption

#### Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5,86 Estimated

### Mobility in general

### Volatility

#### Henry's law

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

HYDROXYPROPYL METHYL CELLULOSE 0 atm m<sup>3</sup>/mol 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

|                                     |                                                                                                                                                                                                                                                                         |
|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Residual waste</b>               | 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. |
| <b>Contaminated packaging</b>       | 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.                                                              |
| <b>EU waste code</b>                | The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.                                                                                                                                                          |
| <b>Disposal methods/information</b> | 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.                                                             |
| <b>Special precautions</b>          | 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**

Not listed.

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

Not listed.

**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**

Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. 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.  
R36 Irritating to eyes.  
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.  
H302 Harmful if swallowed.  
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  
Exposure Controls / Personal Protection:  
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.