

## SAFETY DATA SHEET



GlaxoSmithKline

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

<b>Material</b>	<b>MYLERAN TABLETS</b>
<b>Synonyms</b>	MYLERAN TABLETS 2 MG * GW274383X TABLETS * NDC NO 0173-0713-25 * BUSULPHAN, FORMULATED PRODUCT
<b>Company Name</b>	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 RN	Percentage
BUSULPHAN	55-98-1	0.56 to 2
NON-HAZARDOUS INGREDIENTS	Unassigned	98 to 99.4

### 3. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>* Health</b>	Caution - Potent pharmaceutical agent. May cause cancer. May produce mutagenic effects in human cells. May produce adverse effects on human fertility. May produce adverse effects on the development of human offspring. Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching). Health effects information is based on hazards of components. Exposure might occur via ingestion; skin; eyes.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

#### 4. FIRST-AID MEASURES

<b>Ingestion</b>	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.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

#### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of a cytotoxic agent.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	None for occupational exposure.
<b>Health Surveillance Procedures</b>	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).
<b>Antidotes</b>	No specific antidotes are recommended.

#### 5. FIRE-FIGHTING MEASURES

<b>Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible.
<b>Extinguishing Media</b>	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
<b>Special Firefighting Procedures</b>	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.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

#### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	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.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination Procedures</b>	No specific decontamination or detoxification procedures have been identified for this product.

## 7. HANDLING AND STORAGE

### HANDLING

**General Requirements** Avoid breaking or crushing tablets.

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

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**INGREDIENT** BUSULPHAN

**GSK Occupational Hazard Category** 5

**GSK Occupational Exposure Limit** 1 mcg/m3 (8 HR TWA) **CARCINOGEN, REPRODUCTIVE HAZARD**

### ENGINEERING CONTROLS

**Exposure Controls** The active ingredient was formerly assigned to OHC 4 with the Highly Potent notation. 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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them. Special considerations apply in the planning, design, review and implementation of controls - seek specialist assistance from local occupational hygienist or safety department.

**Containment** Open handling may result in overexposure. It is strongly advised that dedicated areas and containment, such as glove boxes, isolators, and enclosed material transfer systems be used to prevent personnel exposure and spread of contamination.

**Ventilation** Local exhaust ventilation (LEV) is not appropriate at this level, since total containment should usually be used.

**Administrative** Strict control of access to the working area is essential. Only trained personnel should enter the area during operations. Adopt procedures to prevent contamination of working materials and adjacent areas.

### PERSONAL PROTECTIVE EQUIPMENT

**Eye Protection** When isolation is not possible, chemical splash goggles or equivalent eye protection must be used with other applicable protective equipment.

**Gloves** Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Glove selection must take into account any solvents and other hazards present. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided.

**Respirators** When isolation is not possible, respiratory protective equipment (RPE) should be combined with applicable protective equipment.

**\* Other Equipment or Procedures**

Follow all local regulations if personal protective equipment (PPE) is used in the workplace. When isolation is not possible in production areas, applicable protective equipment must be used. Consider additional control procedures for maintenance, cleaning and emergencies.

This product is listed by US NIOSH as a hazardous drug when handled in health care settings. For additional information about the NIOSH hazardous drugs programme and recommendations for preventing exposure see US NIOSH publication No. 2004-165, "Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings."

**9. PHYSICAL AND CHEMICAL PROPERTIES****Appearance****Colour**

White.

**Physical Form**

Tablet.

**10. STABILITY AND REACTIVITY****Stability**

This product is expected to be stable.

**Conditions to Avoid**

None for normal handling of this product.

**11. TOXICOLOGICAL INFORMATION****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.

**Target Organ Effects**

Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells; gastro-intestinal tract; liver.

**Sensitisation**

Allergic skin reactions might occur following dermal exposure. Assessment based upon effects of structurally similar substances.

**Genetic Toxicity**

Known or probable human mutagen.

**Carcinogenicity**

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

**Reproductive Effects**

Contains components which have been classified as: Known or presumed to impair fertility in humans. Known or presumed to cause toxicity in developing human offspring.

**Pharmacological Effects**

This product contains active ingredient(s) with the following activity: a cytotoxic agent.

**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: > 100 mg/l, 3 Hours, Activated sludge

**Daphnid**

No toxicity to daphnids was observed for the active pharmaceutical ingredient in this mixture, but the upper range of the test was limited by the low water solubility of this compound.

EC50: > 10 mg/l, 48 Hours, Daphnia magna

**MOBILITY****Solubility**

This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

**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****Hydrolysis**

This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water. Hydrolysis may be a significant depletion mechanism.

Half-Life, Neutral: < 24 Hours, Measured

### 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. However, products that are subject to the labelling requirements of the Food and Drug Administration are exempt from the labelling provisions of the standard.

**Target Organ Statement**

May cause adverse effects on bone marrow; gastrointestinal tract; liver.

**Other US Regulations****TSCA Status**

Exempt

**Australian Classification  
according to Hazardous  
Substance and  
Dangerous Goods  
Regulatory Framework**

This product is classified as hazardous according to the NOHSC Approved Criteria for Classifying Hazardous Substances.

**16. OTHER INFORMATION****References**

GSK Hazard Determination

**Date Approved/Revised** 23-Oct-2007**SDS Version Number** 13**SDS Sections Updated****Sections**

EXPOSURE CONTROLS / PERSONAL PROTECTION

HAZARDS IDENTIFICATION

IDENTIFICATION OF SUBSTANCE / PREPARATION AND  
OF COMPANY**Subsections**

Other Equipment or Procedures

Health

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.