

SAFETY DATA SHEET



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

Material	ALKERAN TABLETS
Synonym(s)	ALKERAN TABLETS 2 MG * ALKERAN TABLETS 5 MG * GR 64466X TABLETS * ALKERANA TABLETS * MELPHALAN, FORMULATED PRODUCT
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>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</p> <p>GlaxoSmithKline Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

2. HAZARDS IDENTIFICATION

Fire and Explosion Hazards	Expected to be non-combustible.
Health	<p>Caution - Potent pharmaceutical agent. Exposure might occur via ingestion; skin; eyes. May cause cancer. May produce adverse effects on human fertility. May produce adverse effects on the development of human offspring. May produce allergic skin reactions. Health effects information is based on hazards of components.</p>
Environment	No information is available about the potential of this product to produce adverse environmental effects.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
MELPHALAN	148-82-3	2	205-726-3
NON-HAZARDOUS INGREDIENTS	Unassigned	98	

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.

Material ALKERAN TABLETS

Skin contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of a cytotoxic agent. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Health Surveillance Procedures	The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should undergo appropriate health surveillance that may include symptom enquiry, clinical examination and monitoring of lead organ effects (e.g. full blood counts). In the event of overexposure, individuals should receive post exposure health surveillance focused on the most likely health effects (e.g. full blood counts).
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard. For all spills, isolate the spill area, restrict access, post the area for a carcinogen and immediately implement emergency procedures for cleanup and control of occupational carcinogens.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	Water can be used for clean-up and decontamination operations. Neutralize with caustic soda or soda ash.

7. HANDLING AND STORAGE

HANDLING

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

STORAGE

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

Material ALKERAN TABLETS

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE LIMITS

INGREDIENT	MELPHALAN	
GSK Occupational Hazard Category	5	
GSK Occupational Exposure Limit	1 mcg/m ³ (8 HR TWA)	CARCINOGEN, REPRODUCTIVE HAZARD, SKIN SENSITISER

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.

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. TOXICOLOGY INFORMATION

Pharmacological Effects	This product contains active ingredient(s) with the following activity: a cytotoxic agent.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells; toxicity to rapidly dividing cells.

Material ALKERAN TABLETS

Routes of Exposure

Oral Toxicity	Adverse effects might occur following ingestion.									
Inhalation Toxicity	No studies have been conducted.									
Skin Effects	Irritation is not expected following direct contact.									
Eye Effects	Irritation is not expected following direct contact with eyes.									
Sensitisation	Allergic skin reactions might occur following dermal exposure.									
Genetic Toxicity	Known or probable human mutagen.									
Carcinogenicity	Contains a material classified as a carcinogen by external agencies. Human carcinogen (IARC); (NTP). Ingredient: MELPHALAN									
	<table border="1"> <thead> <tr> <th>Listings</th> <th>Known Human Carcinogen</th> <th>Probable Human Carcinogen</th> </tr> </thead> <tbody> <tr> <td>IARC</td> <td>X</td> <td></td> </tr> <tr> <td>NTP</td> <td>X</td> <td></td> </tr> </tbody> </table>	Listings	Known Human Carcinogen	Probable Human Carcinogen	IARC	X		NTP	X	
Listings	Known Human Carcinogen	Probable Human Carcinogen								
IARC	X									
NTP	X									
Reproductive Effects	Contains components which have been classified as: Known or presumed to impair fertility in human females. Known or presumed to cause toxicity in developing human offspring.									
Other Adverse Effects	None known for occupational exposure.									

12. ECOLOGICAL INFORMATION

Summary

This material contains an active pharmaceutical ingredient that has had limited testing and no adverse environmental effects were observed in the tests conducted. There is insufficient information to determine the scope of the environmental effects this material may cause. Until there is additional testing to determine other potential adverse effects on the environment, appropriate precautions should be taken to limit release of this compound to the environment. Local regulations and procedures should be consulted prior to environmental release.

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 very low solubility in water.

Volatility

This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant 4.20E-13 atm m³/mol, Estimated at 25 C

Partitioning

This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION**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: 4.9 Hours, , pH 7 Buffer Solution

Half-Life, Acidic: 4.9 Hours, , pH 5 Buffer Solution

Half-Life, Basic: 3.9 Hours

Material ALKERAN TABLETS

BIOACCUMULATION

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

Bioconcentration Factor: 1 Estimated

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

SDS Version Number 16

SDS Sections Updated**Sections**

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY

Subsections

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.