

## SAFETY DATA SHEET



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

<b>Material</b>	ALKERAN INJECTION																
<b>Synonym(s)</b>	ALKERAN INJECTION 50 MG * ALKERAN IV INJECTION 50 MG * ALKERAN INJECTION 50 MG/10 ML * NDC NO. 0173-0130-93 * MELPHALAN HYDROCHLORIDE, FORMULATED PRODUCT																
<b>Recommended Use</b>	Medicinal Product																
<b>Company Name</b>	<p>GlaxoSmithKline UK 980 Great West Road Brentford, Middlesex TW8 9GS UK UK General Information: +44-20-8047-5000</p> <p>GlaxoSmithKline US 5 Moore Drive Research Triangle Park, NC 27709 USA US General Information: +1-888-825-5249</p> <p>Email Address: <a href="mailto:msds@gsk.com">msds@gsk.com</a> Website: <a href="http://www.gsk.com">www.gsk.com</a></p> <p><b>EMERGENCY PHONE NUMBERS -</b> Transport Emergencies (by country / geographic region):</p> <table border="0" style="margin-left: 20px;"> <tr> <td>Africa (Arab-speaking):</td> <td>+961-3-487-287 (Lebanon)</td> </tr> <tr> <td>Africa (English, French, Portuguese-speaking):</td> <td>+44-208-762-8322 (UK)</td> </tr> <tr> <td>Asia Pacific (except China):</td> <td>+65-633-44-177 (Singapore)</td> </tr> <tr> <td>China:</td> <td>+86-10-5100-3039 (Beijing)</td> </tr> <tr> <td>EU:</td> <td>+44-208-762-8322 (UK)</td> </tr> <tr> <td>Israel:</td> <td>+44-208-762-8322 (UK)</td> </tr> <tr> <td>Middle East (except Israel):</td> <td>+961-3-487-287 (Lebanon)</td> </tr> <tr> <td>US:</td> <td>+1-703-527-3887 (US)</td> </tr> </table> <p>available 24 hrs/7 days; multi-language response</p> <p>Medical Emergencies: +1-612-221-3999, Ext 221 (US) available 24 hrs/7 days; multi-language response</p>	Africa (Arab-speaking):	+961-3-487-287 (Lebanon)	Africa (English, French, Portuguese-speaking):	+44-208-762-8322 (UK)	Asia Pacific (except China):	+65-633-44-177 (Singapore)	China:	+86-10-5100-3039 (Beijing)	EU:	+44-208-762-8322 (UK)	Israel:	+44-208-762-8322 (UK)	Middle East (except Israel):	+961-3-487-287 (Lebanon)	US:	+1-703-527-3887 (US)
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### 2. HAZARDS IDENTIFICATION

<b>Fire and Explosion Hazards</b>	Expected to be non-combustible.
<b>Health</b>	<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>
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

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## \* 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
MELPHALAN HYDROCHLORIDE	3223-07-2	71.4	205-726-3
NON-HAZARDOUS INGREDIENTS	Unassigned	28.6	

## \* 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>	Using appropriate personal protective equipment, move exposed subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible over exposure, or with symptoms including chest pain, difficulty breathing, loss of consciousness or other adverse effects, which may be delayed.
<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>	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.
<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.

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

* 7. HANDLING AND STORAGE
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**HANDLING**

**General Requirements** Isolation or enclosure is recommended to control exposure to this material.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION
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**OCCUPATIONAL EXPOSURE LIMITS**

<b>INGREDIENT</b>	MELPHALAN HYDROCHLORIDE		
<b>GSK Occupational Hazard Category</b>	5		
<b>GSK Occupational Exposure Limit</b>	1 mcg/m3 (8 HR TWA)	CARCINOGEN, REPRODUCTIVE HAZARD,	SKIN SENSITISER

**ENGINEERING CONTROLS**

<b>Exposure Controls</b>	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.
<b>Containment</b>	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.
<b>Ventilation</b>	Local exhaust ventilation (LEV) is not appropriate at this level, since total containment should usually be used.
<b>Administrative</b>	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**

<b>Eye Protection</b>	When isolation is not possible, chemical splash goggles or equivalent eye protection must be used with other applicable protective equipment.
<b>Gloves</b>	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.
<b>Respirators</b>	When isolation is not possible, respiratory protective equipment (RPE) should be combined with applicable protective equipment.
<b>Other Equipment or Procedures</b>	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
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**Appearance**

<b>Colour</b>	White/off-white.
<b>Physical Form</b>	Freeze dried powder.

10. STABILITY AND REACTIVITY
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<b>Stability</b>	This product is expected to be stable.
<b>Conditions to Avoid</b>	None for normal handling of this product.

**Material** ALKERAN INJECTION**11. TOXICOLOGY INFORMATION**

<b>Pharmacological Effects</b>	This product contains active ingredient(s) with the following activity: a cytotoxic agent.
<b>Target Organ Effects</b>	Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells; toxicity to rapidly dividing cells.
<b>Routes of Exposure</b>	
<b>Oral Toxicity</b>	Adverse effects might occur following ingestion.
<b>Inhalation Toxicity</b>	No studies have been conducted.
<b>Skin Effects</b>	Irritation is not expected following direct contact.
<b>Eye Effects</b>	Irritation is not expected following direct contact with eyes.
<b>Sensitisation</b>	Allergic skin reactions might occur following dermal exposure.
<b>Genetic Toxicity</b>	Known or probable human mutagen.
<b>Carcinogenicity</b>	Contains a material classified as a carcinogen by external agencies. Human carcinogen (IARC); (NTP).
<b>Reproductive Effects</b>	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.
<b>Other Adverse Effects</b>	None known for occupational exposure.

**12. ECOLOGICAL INFORMATION**

<b>Summary</b>	This material contains an active 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.
<b>ECOTOXICITY</b>	
<b>Aquatic</b>	
<b>Activated Sludge Respiration</b>	This material contains an active ingredient that is not toxic to activated sludge microorganisms. IC50: > 100 mg/l, 3 Hours, Activated sludge
<b>Daphnid</b>	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
<b>MOBILITY</b>	
<b>Solubility</b>	This material contains an active ingredient that for environmental fate predictions has very low solubility in water.
<b>Volatility</b>	This material contains an active ingredient that will not readily enter into air from water. Henry's Law Constant 4.20E-13 atm m <sup>3</sup> /mol, Estimated at 25 C
<b>Partitioning</b>	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.
<b>PERSISTENCE/DEGRADATION</b>	
<b>Hydrolysis</b>	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
<b>BIOACCUMULATION</b>	
<b>Bioaccumulation</b>	This material contains an active ingredient that will not have a tendency to bioaccumulate in the food chain.
<b>Bioconcentration Factor:</b>	1 Estimated

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## 13. DISPOSAL CONSIDERATIONS

<b>Disposal Recommendations</b>	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.
<b>Regulatory Requirements</b>	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**

<b>Proper Shipping Name</b>	Medicine, solid, toxic, nos (MELPHALAN HYDROCHLORIDE, FORMULATED PRODUCT)
<b>UN Number</b>	UN 3249
<b>Class/Division</b>	6.1
<b>Packing Group</b>	II
<b>Risk Label(s)</b>	Class 6.1 Toxic

**International Air Transport (IATA Requirements)**

**Classification and Labelling** See 2.7

**International Maritime Transport (IMDG Requirements)**

**Classification and Labelling** See 3.5 (new as of 2008)

**US Domestic Transport (DOT Requirements)**

**Classification and Labelling** See 173.4 or 173.153

**European Ground Transport (ADR/RID Requirements)**

**Classification and Labelling** Not subject to ADR, see SP 601.

## \* 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 and formation of blood cells; toxicity to rapidly dividing cells.

**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** 25

**SDS Sections Updated**

**Sections**

- COMPOSITION / INFORMATION ON INGREDIENTS
- FIRST-AID MEASURES
- HANDLING AND STORAGE
  
- IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY
- REGULATORY INFORMATION

**Subsections**

- Inhalation
- General Requirements
- Storage
  
- US OSHA Standard (29 CFR Part 1910.1200) - Target Organ Stat

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.