

## SAFETY DATA SHEET



GlaxoSmithKline

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

<b>Material</b>	<b>HYCAMTIN INJECTABLE</b>
<b>Synonyms</b>	HYCAMTIN INFUSION 1 MG/3 ML * HYCAMTIN INJECTION 1 MG/3 ML * HYCAMTIN INJECTION 4 MG/5 ML * TOPOTECAN, FORMULATED PRODUCT * NDC NO. 0007-4200-01 * NDC NO. 0007-4200-05 * NDC NO. 0007-4200-40 * NDC NO. 0007-4200-41 * NDC NO. 0007-4200-42 * NDC NO. 0007-4200-43 * NDC NO. 0007-4200-51 * NDC NO. 0007-4200-55 * NDC NO. 0007-4200-90 * NDC NO. 0007-4201-01 * NDC NO. 0007-4201-05 * NDC NO. 0007-4200-44 * NDC NO. 0007-4201-02 * NDC NO. 0007-4201-11
<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 2200 Renaissance Blvd, Suite 105 King of Prussia, PA 19406 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
TOPOTECAN	119413-54-6	< 10
NON-HAZARDOUS INGREDIENTS	Unassigned	>90

### 3. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	This product is classified as non-flammable.
<b>Health</b>	Exposure might occur via skin; eyes; ingestion. Caution - Potent pharmaceutical agent. May cause cancer. May produce adverse effects on the development of human offspring. Possible effects of overexposure in the workplace include: nausea; vomiting; diarrhoea; bone marrow toxicity. Health effects information is based on hazards of components.

<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.
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#### 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>	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 is recommended for fires involving packaging.
<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>	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. Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	Do not allow this material to enter surface drainage systems, sewers and poorly ventilated areas.

<b>Clean-up Methods</b>	Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination Procedures</b>	Surfaces should be decontaminated so that potential exposures do not exceed the hygiene guide specified in Section 8 of this SDS. The pH of the collected wash waters should be adjusted using base, such as sodium hydroxide, to a pH greater than 8; commercial bleach solution, containing approximately 5% hypochlorite, should then be added to the waste water. Microgram levels of surface contamination can be visualised using ultraviolet light.

## 7. HANDLING AND STORAGE

### HANDLING

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

### STORAGE

The recommended temperature for storage is 15-30 °C.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>INGREDIENT</b>	TOPOTECAN	
<b>GSK Occupational Hazard Category</b>	4	
<b>GSK Occupational Exposure Limit</b>	0.03 MCG/M3 (8 HR TWA)	CARCINOGEN, REPRODUCTIVE HAZARD, HIGHLY POTENT

### ENGINEERING CONTROLS

**Containment** Open handling may result in overexposure. Consider use of enclosures.

**Administrative** Entry to the working area should be controlled.

### PERSONAL PROTECTIVE EQUIPMENT

**Eye Protection** Wear approved safety glasses with side shields if eye contact is possible.

**Gloves** 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. Glove selection must take into account any solvents and other hazards present. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Care must be exercised if no data are available and further guidance should be sought from your local safety department. Glove selection must take into account any solvents and other hazards present.

**Respirators** Respiratory protective equipment (RPE) is not required for normal handling of this material.

**Other Equipment or Procedures** Wear appropriate clothing to avoid skin contact.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Appearance

**Physical Form** Lyophilised powder.

**pH of Aqueous Solutions** 3

## 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

<b>Oral Toxicity</b>	Toxicity 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>Target Organ Effects</b>	Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells.
<b>Sensitisation</b>	Potential for inducing allergic reactions via the dermal or respiratory route is not known.
<b>Genetic Toxicity</b>	Known or probable human mutagen.
<b>Carcinogenicity</b>	Contains a component listed as a carcinogen by: (GSK). No components are listed as carcinogens by: (IARC); (NTP); (US OSHA).
<b>Reproductive Effects</b>	Contains components which have been classified as: Known or presumed to cause toxicity in developing human offspring. Known or presumed to impair fertility in human females.
<b>Pharmacological Effects</b>	This preparation contains ingredient(s) with the following activity: a cytotoxic agent.
<b>Other Adverse Effects</b>	Overexposure in the workplace might have the following effects: reduced white blood cell count; nausea; diarrhoea; vomiting; fatigue.

## 12. ECOLOGICAL INFORMATION

<b>Summary</b>	No information is available about the potential of this product to produce adverse environmental effects. This material contains an active pharmaceutical ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this mixture to the environment. Local regulations and procedures should be consulted prior to environmental release.
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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. The recommended method of disposal is incineration.
<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.

**International Air Transport (IATA Requirements)**

<b>UN/ID Number</b>	ID 8000
<b>Proper Shipping Name/Description</b>	Consumer Commodity
<b>ICAO/IATA Class/Division</b>	9
<b>Subsidiary Risk</b>	None
<b>Packing Group</b>	Not applicable (use packing instruction 910).
<b>Limited Quantities</b>	Quantities equal to or less than 0.5 kg per inner packaging are not subject to the full packaging and labelling requirements, although the appropriate shipping papers will be required.

**International Maritime Transport (IMDG Requirements)**

<b>UN Number</b>	UN 3249
<b>Proper Shipping Name/Description</b>	Dangerous Goods in Limited Quantities of Class 6.1
<b>IMO Class/Division</b>	6.1
<b>Subsidiary Risk</b>	None
<b>Packing Group</b>	III
<b>Marine Pollutant Status</b>	Not listed
<b>Limited Quantities</b>	Quantities equal to or less than 3 kg per inner packaging are not subject to the full packaging and labelling requirements, although the appropriate shipping papers will be required.

**US Domestic Transport (DOT Requirements)**

<b>Proper Shipping Name</b>	Consumer Commodity, ORM-D
<b>DOT Hazard Class/Division</b>	ORM-D
<b>UN/NA Number</b>	Not applicable.
<b>Packing Group</b>	Not applicable
<b>Marine Pollutant Status</b>	Not listed
<b>US Emergency Response Guide Number</b>	171
<b>Quantity Limitations</b>	Quantities equal to or less than 0.25 kg per inner packaging are not subject to the full packaging and labelling requirements, although the appropriate shipping papers will be required.

<b>15. REGULATORY INFORMATION</b>
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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**

None.

**US OSHA Standard (29 CFR Part 1910.1200)**

<b>Classification</b>	This product is classified as hazardous according to the OSHA Hazard Communication Standard.
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**Other US Regulations**

<b>TSCA Status</b>	Exempt
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<b>16. OTHER INFORMATION</b>
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<b>References</b>	GSK Hazard Determination
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<b>Date Approved/Revised</b>	20-Aug-2003
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<b>SDS Version Number</b>	18
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**SDS Sections Updated****Sections****Subsections**

COMPOSITION / INFORMATION ON INGREDIENTS

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.