SAFETY DATA SHEET

GlaxoSmithKline

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

Material **HYCAMTIN CAPSULES**

Synonyms HYCAMTIN CAPSULES 0.25 MG * HYCAMTIN CAPSULES 1.0 MG * NDC 0007-4205-11 * NDC 0007-4207-11 * TOPOTECAN, FORMULATED PRODUCT

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Brentford, Middlesex TW8 9GS UK

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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
TOPOTECAN	119413-54-6	1
NON-HAZARDOUS INGREDIENTS	Unassigned	99.0

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health 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.

Environment No information is available about the potential of this product to produce adverse environmental effects.

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.
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.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
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 is recommended for fires involving packaging.
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	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.
Environmental Precautions	Do not allow this material to enter surface drainage systems, sewers and poorly ventilated areas.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.

Decontamination Procedures	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 2-8 °C. Keep away from light.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT	TOPOTECAN	
GSK Occupational Hazard Category	5	
GSK Occupational Exposure Limit	0.03 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form	Capsule filled with oil.

10. STABILITY AND REACTIVITY

Stability	This product is expected to be stable.
Conditions to Avoid	Avoid temperatures greater than 30 degrees C.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity	Toxicity 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	Potential for inducing allergic reactions via the dermal or respiratory route is not known.
Genetic Toxicity	Known or probable human mutagen.
Carcinogenicity	Contains a component listed as a carcinogen by: (GSK). No components are listed as carcinogens by: (IARC); (NTP); (US OSHA).
Reproductive Effects	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.
Pharmacological Effects	This preparation contains ingredient(s) with the following activity: a cytotoxic agent.
Other Adverse Effects	Overexposure in the workplace might have the following effects: reduced white blood cell count; nausea; diarrhoea; vomiting; fatigue.

12. ECOLOGICAL INFORMATION

Summary	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 material to the environment. Local regulations and procedures should be consulted prior to environmental release. Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Microtox	Microtox is a general toxicity test which utilizes a sensitive marine photo bacteria as the test species. This material contains an active pharmaceutical ingredient that is not toxic to these microorganisms. EC50: 102 mg/L, 15 Minutes

Daphnid This material contains an active pharmaceutical ingredient that is harmful to daphnids.

EC50: 61.8 mg/L, 48 Hours, Daphnia magna, Static test

Fish This material contains an active pharmaceutical ingredient that is harmful to fish.

Adult Pimephales promelas, fathead minnow

EC50: 45.7 mg/L, 96 Hours, Static test

Adult Pimephales promelas, fathead minnow

NOEL: 25 mg/L, 96 Hours, Static test

MOBILITY

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

Adsorption This material contains an active pharmaceutical ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment.

Sludge Biomass Distribution Coefficient (log Kd): 2.28 Measured

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 stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.

Half-Life, Neutral: 35 Years, Measured

Photolysis This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism.

Half-Life, Aqueous: 2.51 Minutes, Measured

Biodegradation This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines).

Aerobic - Ready

Percent Degradation: 0 %, 28 days, Batch activated sludge (BAS), Residential sludge

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. The recommended method of disposal is incineration.

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

Technical Name	TOPOTECAN CAPSULES
Proper Shipping Name	Medicine, solid, toxic, nos (TOPOTECAN CAPSULES)
UN Number	UN 3249
Class/Division	6.1
Packing Group	III
Risk Label(s)	Class 6.1 Toxic

International Air Transport (IATA Requirements)

UN/ID Number	ID 8000
Proper Shipping Name/Description	Consumer Commodity
ICAO/IATA Class/Division	9
Subsidiary Risk	None
Packing Group	Not applicable (use packing instruction 910).
Hazard Label(s)	Class 9

Limited Quantities	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)

UN Number	UN 3249
Proper Shipping Name/Description	Medicine, solid, toxic, nos
IMO Class/Division	6.1
Subsidiary Risk	None
Packing Group	III
Class Label(s)	Class 6.1 Toxic

Marine Pollutant Status	Not listed
Limited Quantities	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)

Proper Shipping Name	Consumer Commodity, ORM-D
DOT Hazard Class/Division	ORM-D
UN/NA Number	Not applicable.
Packing Group	Not applicable
US Emergency Response Guide Number	151
Limited Quantities	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.

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.

Other US Regulations

TSCA Status	Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 16-Oct-2007 **SDS Version Number** 18

SDS Sections Updated

Sections	Subsections
IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY	

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.