SAFETY DATA SHEET

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

Material **HYCAMTIN INJECTABLE**

Synonyms 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

Company Name

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2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
TOPOTECAN	119413-54-6	< 10
NON-HAZARDOUS INGREDIENTS	Unassigned	>90

3. HAZARDS IDENTIFICATION

Fire and Explosion This product is classified as non-flammable.

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	Spread an inert absorbent on the spill and place 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 15-30 °C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT	TOPOTECAN	
GSK Occupational Hazard Category	4	
GSK Occupational Exposure Limit	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

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.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells.
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 mixture to the environment. Local regulations and procedures should be consulted prior to environmental release.

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.

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).
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	Dangerous Goods in Limited Quantities of Class 6.1
IMO Class/Division	6.1
Subsidiary Risk	None
Packing Group	III
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
Marine Pollutant Status	Not listed
US Emergency Response Guide Number	171
Quantity Limitations	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.

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

None.

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 20-Aug-2003 **SDS Version Number** 18

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.