SAFETY DATA SHEET

GlaxoSmithKline

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

Material **NAVELBINE INJECTION**

Synonyms NAVELBINE 10 MG/1 ML SINGLE-USE VIAL * NAVELBINE 50 MG/5 ML SINGLE-USE VIAL * NAVELBINE INJECTION 10 MG/ML * VINORELBINE TARTRATE, FORMULATED PRODUCT

Company Name

GlaxoSmithKline, Corporate Environment, Health & Safety
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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

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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
VINORELBINE TARTRATE	125317-39-7	1
NON-HAZARDOUS INGREDIENTS	Unassigned	99

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health Caution - Potent pharmaceutical agent.
Exposure might occur via skin; eyes; ingestion.
May cause cancer. May produce adverse effects on human fertility. May produce adverse effects on the development of human offspring. May impair the quantity or quality of human milk production.
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. 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	None for occupational exposure.
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 or foam extinguishers are recommended. Carbon dioxide or dry powder 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.
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	No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
STORAGE	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT	VINORELBINE TARTRATE	
GSK Occupational Hazard Category	5	
GSK Occupational Exposure Limit	0.5 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

Clarity	Clear.
Colour	Colourless/light yellow.
Physical Form	Solution.
pH of Aqueous Solutions	3.5

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 might occur following direct contact with eyes.

Target Organ Effects Adverse effects might occur in the following organ(s) following overexposure: toxicity to rapidly dividing cells.

Sensitisation Allergic skin reactions might occur following dermal exposure.

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); (EU).

Reproductive Effects Contains components which have been classified as: Possible risk of toxicity in developing human offspring. Known or presumed to impair fertility in humans. Known or presumed to affect the quantity and quality of breast milk in humans.

Pharmacological Effects This preparation contains ingredient(s) with the following activity: a cytotoxic agent.

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 no environmental effects have been identified. 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.

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.
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

Date Approved/Revised 01-Aug-2006 **SDS Version Number** 9

SDS Sections Updated

Sections	Subsections
EXPOSURE CONTROLS / PERSONAL PROTECTION	Administrative Containment Exposure Controls Eye Protection Gloves Occupational Hygiene Air Monitoring Methods Occupational Hygiene Surface Monitoring Metho Other Equipment or Procedures Other Exposure Limits Other Information Other Protective Equipment Respirators Surface Exposure Target Ventilation
REGULATORY INFORMATION	US OSHA Standard (29 CFR Part 1910.1200) - Classification

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.