SAFETY DATA SHEET

GlaxoSmithKline

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

Material **NELARABINE INJECTION 5 MG/ML**

Synonyms 506u78 INJECTION * GI262250X INJECTION * NELARABINE, FORMULATED PRODUCT

Company Name

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Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
506U78	121032-29-9	0.5
NON-HAZARDOUS INGREDIENTS	Unassigned	99.5

3. HAZARDS IDENTIFICATION

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

Health 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. Health effects information is based on hazards of components.

Environment No environmental hazards have been identified for this material.

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.
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, dry powder or foam extinguishers are recommended. Carbon dioxide 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	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	Prevent entry into waterways, sewers, surface drainage systems 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	Water can be used for clean-up and decontamination operations.

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	506U78	
GSK Occupational Hazard Category	4	CARCINOGEN, REPRODUCTIVE HAZARD

ENGINEERING CONTROLS

Containment	Open handling may result in overexposure. Consider use of enclosures.
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. Restrict access to authorised personnel.
Other Equipment or Procedures	Wear appropriate clothing to avoid skin contact. When isolation is not possible in production areas, appropriate personal protective equipment must be used. Consider additional control procedures for maintenance, cleaning and emergencies.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Clarity	Clear.
Colour	Colourless.
Physical Form	Solution.

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	Adverse effects 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; dividing cells; gastro-intestinal tract.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Known or probable human mutagen.
Carcinogenicity	Contains a component listed as a carcinogen by: (GSK) Possible human carcinogen. No components are listed as carcinogens by: (IARC); (NTP); (US OSHA); (EU).
Reproductive Effects	Contains components which have been classified as: Known or presumed to impair fertility in humans. Known or presumed to cause toxicity in developing human offspring.

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

12. ECOLOGICAL INFORMATION

Summary 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.
For waste disposal purpose, this product should be classified in line with the European Waste Catalogue criteria.

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 09-Mar-2004 **SDS Version Number** 2

SDS Sections Updated

Sections	Subsections
FIRST-AID MEASURES	Inhalation
REGULATORY INFORMATION	European Union Classification and Labelling
	Other Regulations
	Other US Regulations - California Proposition 65
	Other US Regulations - TSCA Status
	State Regulations
	Summary
	US Environmental (EPA) Requirements

SDS Sections Updated

Sections	Subsections
REGULATORY INFORMATION	US OSHA Standard (29 CFR Part 1910.1200) -
	US OSHA Standard (29 CFR Part 1910.1200) -

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.