

## SAFETY DATA SHEET



GlaxoSmithKline

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

<b>Material</b>	<b>ARRANON INJECTION</b>
<b>Synonyms</b>	ARRANON INJECTION 5 MG/ML * ATRIANCE INFUSION * 506u78 INJECTION * GI262250X INJECTION * NDC 0007-4401-01 * NDC 0007-4401-06 * NELARABINE, FORMULATED PRODUCT
<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 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
506U78	121032-29-9	0.5
NON-HAZARDOUS INGREDIENTS	Unassigned	99.5

### 3. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	This product is classified as non-flammable.
<b>Health</b>	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.
<b>Environment</b>	There is insufficient information to determine the scope of the environmental effects this material may cause.

### 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. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
<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, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
<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>	Prevent entry into waterways, sewers, surface drainage systems 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.

**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

**GSK Occupational Exposure Limit** 10 mcg/m<sup>3</sup>

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.

<b>Carcinogenicity</b>	Contains a component listed as a carcinogen by: (GSK) Possible human carcinogen. No components are listed as carcinogens by: (IARC); (NTP); (US OSHA); (EU).
<b>Reproductive Effects</b>	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.
<b>Pharmacological Effects</b>	This product contains active ingredient(s) with the following activity: a cytotoxic agent.

## 12. ECOLOGICAL INFORMATION

**Summary** There is insufficient information to determine the scope of the environmental effects this material may cause. Local regulations and procedures should be consulted prior to environmental release. Specific information on the active pharmaceutical ingredient is provided below.

### ECOTOXICITY

#### Aquatic

**Activated Sludge Respiration** This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

IC50: > 1000 mg/l, 3 Hours, Activated sludge

**Algal** This material contains an active pharmaceutical ingredient that is not toxic to algae.

IC50: > 100 mg/l, 96 Hours, Selenastrum capricornutum, green algae, Static test

NOEL: > 100 mg/l, 96 Hours, Selenastrum capricornutum, green algae, Static test

**Daphnid** This material contains an active pharmaceutical ingredient that is not toxic to daphnids.

EC50: > 1070 mg/l, 48 Hours, Daphnia magna

NOEL: 260 mg/l, 48 Hours, Daphnia magna

**Fish** This mixture contains an active pharmaceutical ingredient that is not toxic to fish.

Adult Oncorhynchus mykiss, rainbow trout

EC50: > 100 mg/l, 96 Hours, Static test

Adult Oncorhynchus mykiss, rainbow trout

NOEL: > 100 mg/l, 96 Hours, Static test

#### MOBILITY

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

**Volatility** This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant 4.91E-12 atm m<sup>3</sup>/mol, Estimated

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

Soil Sediment Sorption 1.73 to 1.94, Measured at pH 5.5 to 7.8 (log Koc):

**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

<b>Hydrolysis</b>	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: > 1 Years, Measured
<b>Photolysis</b>	This material contains an active pharmaceutical ingredient that is likely to undergo photodegradation. UV/Visible Spectrum: 294 nm
<b>Biodegradation</b>	This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines). This mixture contains an active pharmaceutical ingredient that slowly undergoes biodegradation in soil. It is not expected to persist in the environment. Aerobic - Inherent Percent Degradation: 40 %, 28 days, Modified Zahn-Wellens, Activated sludge Aerobic - Soil Percent Degradation: 48 to 67.9 %, 64 days
<b>BIOACCUMULATION</b>	This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

### 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.

#### UN Classification and Labelling

<b>Transport Information</b>	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)

<b>Classification</b>	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

<b>TSCA Status</b>	Exempt
--------------------	--------

### 16. OTHER INFORMATION

**References** GSK Hazard Determination

**Date Approved/Revised** 29-Aug-2007

**SDS Version Number** 5

## 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.