



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** ARRANON INJECTION

**Other means of identification**

**Synonyms**

ARRANON INJECTION 5 MG/ML \* ATRIANCE INFUSION \* 506u78 INJECTION \* GI262250X INJECTION \* NDC 0007-4401-01 \* NDC 0007-4401-06 \* NELARABINE, FORMULATED PRODUCT

**Recommended use**

Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Recommended restrictions**

No other uses are advised.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249  
Email Address: msds@gsk.com  
Website: www.gsk.com  
EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES::  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

**Classified hazards**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Label elements**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Hazard(s) not otherwise classified (HNOC)**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

**Mixtures**

Chemical name	Common name and synonyms	CAS number	%
506U78	NELZARABINE * 2-AMINO-9-BETA-D-ARABINOFURANOSYL -6-METHOXY-9H-PURINE * 2-AMINO-6-METHOXPURINE ARABINOSIDE * GI262250X * 506U78 * BW 506U78 * 1540 (GW ACN)	121032-29-9	0.5
Other components below reportable levels			99.5

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

## 4. First-aid measures

**Inhalation**

Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

**Skin contact**

Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	None known. The following adverse effects have been noted with therapeutic use of this material: temporary decrease in white blood cell counts; abnormal nervous system sensations; gastrointestinal distress . Prolonged exposure may cause chronic effects.
<b>Indication of immediate medical attention and special treatment needed</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
<b>General information</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.  Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.  Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid prolonged exposure. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

GSK Components	Type	Value	Note
NELARABINE (CAS 121032-29-9)	8 HR TWA	10 mcg/m3	
	OHC	4	REPRODUCTIVE HAZARD, CARCINOGEN

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	
<b>Appropriate engineering controls</b>	General ventilation normally adequate.

## Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	For prolonged or repeated skin contact use suitable protective gloves.
<b>Other</b>	Wear suitable protective clothing as protection against splashing or contamination.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.

## General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Liquid.
<b>Form</b>	Vial.
<b>Color</b>	Not available.

**Odor** Not available.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** Not available.

**Flash point** Not available.

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not available.

### Upper/lower flammability or explosive limits

**Flammability limit - lower (%)** Not available.

**Flammability limit - upper (%)** Not available.

**Explosive limit - lower (%)** Not available.

**Explosive limit - upper (%)** Not available.

**Vapor pressure** Not available.

**Vapor density** Not available.

**Relative density** Not available.

### Solubility(ies)

**Solubility (water)** Not available.

**Partition coefficient (n-octanol/water)** Not available.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

### Other information

**Percent volatile** 99 % estimated

## 10. Stability and reactivity

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

### Symptoms related to the physical, chemical and toxicological characteristics

None known.  
The following adverse effects have been noted with therapeutic use of this material: temporary decrease in white blood cell counts; abnormal nervous system sensations; gastrointestinal distress.  
Prolonged exposure may cause chronic effects.

### Information on toxicological effects

**Acute toxicity** Health injuries are not known or expected under normal use. May be harmful if swallowed.

Components	Species	Test Results
506U78 (CAS 121032-29-9)		
<b>Chronic</b>		
<i>Oral</i>		
LOEL	Monkey	10 mg/kg/day Intravenous route

\* Estimates for product may be based on additional component data not shown.

**Skin corrosion/irritation** Health injuries are not known or expected under normal use.  
**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

#### Eye

506U78 Acute ocular irritation, Application of 0.1 mL (61 mg, as a solid) resulted in maximum average score of 6.7 (Draize grade 1)  
Result: Minimal Irritant  
Species: Rabbit

### Respiratory or skin sensitization

**Respiratory sensitization** Not available.  
**Skin sensitization** Health injuries are not known or expected under normal use.

#### Sensitization

506U78 Maximisation assay (Magnusson and Kligman)  
Result: Negative  
Species: Guinea pig

### Germ cell mutagenicity

Health injuries are not known or expected under normal use. Contains a component that produced mutagenicity in laboratory tests.

#### Mutagenicity

506U78 Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay  
Result: Positive  
SAR / QSAR, DEREK, Lhasa, UK  
Result: Plausible (chromosome damage)

### Carcinogenicity

Health injuries are not known or expected under normal use. Contains a component listed as a carcinogen by: (GSK).

506U78 SAR / QSAR  
Result: Plausible

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

**Reproductive toxicity** Health injuries are not known or expected under normal use. Contains components which have been classified as: Suspected of damaging fertility or the unborn child.

**Reproductivity**  
506U78

Embryo-foetal development - Intravenous  
Result: Foetal NOAEL not identified; decreased foetal weight with doses = 300 mg/kg/day (intravenous infusion); delayed foetal skeletal ossification and increased malformations with doses >= 30 mg/kg/day (lowest dose); maternal NOAEL = 100 mg/kg/day  
Species: Rabbit

**Specific target organ toxicity - single exposure** None known.

**Specific target organ toxicity - repeated exposure** May cause damage to organs through prolonged or repeated exposure.

506U78

Repeat dose non-clinical studies; clinical observation  
Organ: bone marrow; blood; central nervous system; gastrointestinal tract

**Aspiration hazard** Not available.

**Chronic effects** Prolonged exposure may cause chronic effects.

**Further information** Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

**12. Ecological information**

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

Components	Species	Test Results
506U78 (CAS 121032-29-9)		
<b>Aquatic</b>		
<i>Acute</i>		
Activated Sludge Respiration	IC50 Residential sludge	> 1000 mg/l, 3 hours
Algae	EC50 Green algae (Selenastrum capricornutum)	> 100 mg/l, 96 hours Static test, OECD 201
	NOEC Green algae (Selenastrum capricornutum)	> 100 mg/l, 96 hours
Crustacea	EC50 Water flea (Daphnia magna)	> 1070 mg/l, 48 hours OECD 202
	NOEC Water flea (Daphnia magna)	260 mg/l, 48 hours
Fish	EC50 Rainbow trout (Adult Oncorhynchus mykiss)	> 100 mg/l, 96 hours Static , OECD 203
	NOEC Rainbow trout (Adult Oncorhynchus mykiss)	> 100 mg/l, 96 hours

\* Estimates for product may be based on additional component data not shown.

**Persistence and degradability**

**Photolysis**

**UV/visible spectrum wavelength**

506U78 294 nm

**Hydrolysis**

**Half-life (Hydrolysis-neutral)**

506U78 > 1 Years Measured

**Biodegradability**

**Percent degradation (Aerobic biodegradation-inherent)**

506U78 40 %, 28 days Modified Zahn-Wellens, Activated sludge

**Percent degradation (Aerobic biodegradation-soil)**

506U78 48 - 67.9 %, 64 days

**Bioaccumulative potential**

**Partition coefficient n-octanol / water (log Kow)**

506U78 < 1

## Mobility in soil

### Adsorption

#### Soil/sediment sorption - log Koc

506U78

1.73 - 1.94 Measured, pH 5.5-7.8

## Mobility in general

### Volatility

#### Henry's law

506U78

0 atm m<sup>3</sup>/mol Estimated

**Other adverse effects** Not available.

## 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as a dangerous good.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

## 15. Regulatory information

### US federal regulations

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

#### SARA 304 Emergency release notification

Not regulated.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### Hazard categories

Immediate Hazard - Yes  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

#### SARA 302 Extremely hazardous substance

Not listed.

#### SARA 311/312 Hazardous chemical

No

#### SARA 313 (TRI reporting)

Not regulated.

## Other federal regulations

### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

### Safe Drinking Water Act (SDWA)

Not regulated.

## US state regulations

### US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

### US. Massachusetts RTK - Substance List

Not regulated.

### US. New Jersey Worker and Community Right-to-Know Act

Not listed.

### US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

### US. Rhode Island RTK

Not regulated.

### US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

## International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

<b>Issue date</b>	11-20-2014
<b>Revision date</b>	11-20-2014
<b>Version #</b>	06
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 1* Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 1 Flammability: 0 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.

**Revision Information**

Product and Company Identification: Business Units  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties:  
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection  
Regulatory Information: United States  
GHS: Classification