

# Docetaxel Injection

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Docetaxel Injection  
Other means of identification : 20 mg per 2 mL single dose vial, NDC 55150-378-01  
80 mg per 8 mL multiple dose vial, NDC 55150-379-01  
160 mg per 16 mL multiple dose vial, NDC 55150-380-01

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

#### 1.3. Details of the supplier of the safety data sheet

AuroMedics  
279 Princeton Highstown Road  
East Windsor, NJ 08520

#### 1.4. Emergency telephone number

Emergency number : 1-888-238-7880

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### GHS US classification

Eye Irrit. 2 H319  
Muta. 2 H341  
Carc. 1A H350  
Repr. 1B H360  
Lact. H362

Full text of hazard classes and H-statements : see section 16

#### 2.2. Label elements

##### GHS US labeling

Hazard pictograms (GHS US) :



GHS07

GHS08

Signal word (GHS US) :

Danger

Hazard statements (GHS US) :

H319 - Causes serious eye irritation  
H341 - Suspected of causing genetic defects  
H350 - May cause cancer  
H360 - May damage fertility or the unborn child  
H362 - May cause harm to breast-fed children

Precautionary statements (GHS US) :

P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P260 - Do not breathe dust/fume/gas/mist/vapors/spray.  
P263 - Avoid contact during pregnancy/while nursing.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308+P313 - If exposed or concerned: Get medical advice/attention.  
P337+P313 - If eye irritation persists: Get medical advice/attention.  
P405 - Store locked up.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

#### 2.3. Other hazards

No additional information available

# Docetaxel Injection

## Safety Data Sheet

### 2.4. Unknown acute toxicity (GHS US)

Not applicable

## SECTION 3: Composition/Information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	GHS US classification
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives	(CAS-No.) 9005-65-6	26	Not classified
Ethyl alcohol	(CAS-No.) 64-17-5	23	Flam. Liq. 2, H225 Carc. 1A, H350
Citric acid	(CAS-No.) 77-92-9	≤ 1	Not classified
Docetaxel	(CAS-No.) 114977-28-5	≤ 1	Eye Irrit. 2A, H319 Muta. 2, H341 Repr. 1B, H360 Lact., H362
Polyethylene glycol	(CAS-No.) 25322-68-3	≤ 1	Not classified

Full text of hazard classes and H-statements : see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation : Remove to fresh air and keep patient at rest. Seek medical attention immediately.

First-aid measures after skin contact : Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

First-aid measures after eye contact : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : None anticipated during normal product use.

Symptoms/effects after skin contact : May cause skin irritation.

Symptoms/effects after eye contact : Causes serious eye irritation.

Symptoms/effects after ingestion : May be harmful if swallowed.

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

### 5.3. Advice for firefighters

Protection during firefighting : During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

#### 6.1.1. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

# Docetaxel Injection

## Safety Data Sheet

### 6.3. Methods and material for containment and cleaning up

For containment	: Stop the flow of material, if this is without risk.
Methods for cleaning up	: Absorb spillage with suitable absorbent material. Place in a suitable container and dispose according to local, state and federal regulations.

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling	: Avoid prolonged and repeated contact. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
-------------------------------	--

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store at 20° to 25°C (68° to 77°F).
--------------------	---------------------------------------

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Polyethylene glycol (25322-68-3)		
AIHA	WEEL TWA	10 mg/m <sup>3</sup> (MW>200-aerosol)
Ethyl alcohol (64-17-5)		
ACGIH	ACGIH OEL STEL [ppm]	1000 ppm
OSHA	OSHA PEL (TWA) [1]	1900 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) [2]	1000 ppm
IDLH	IDLH [ppm]	3300 ppm (10% LEL)
NIOSH	NIOSH REL (TWA)	1900 mg/m <sup>3</sup>
NIOSH	NIOSH REL TWA [ppm]	1000 ppm
Docetaxel (114977-28-5)		
Not applicable		
Citric acid (77-92-9)		
Not applicable		
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)		
Not applicable		

### 8.2. Exposure controls

Appropriate engineering controls	: Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection	: No protection is ordinarily required under normal conditions of use.
Eye protection	: Wear safety glasses or goggles.
Skin and body protection	: Wear suitable working clothes.
Respiratory protection	: No protection is ordinarily required under normal conditions of use.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear.
Color	: Colorless to pale yellow
Odor	: Odorless
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available

# Docetaxel Injection

## Safety Data Sheet

Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: completely soluble.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

### 10.3. Possibility of hazardous reactions

Will not occur.

### 10.4. Conditions to avoid

Air contact.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

None known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

<b>Polyethylene glycol (25322-68-3)</b>	
LD50 oral rat	22 g/kg
LD50 dermal rabbit	> 20 g/kg
ATE US (oral)	28000000 mg/kg
<b>Ethyl alcohol (64-17-5)</b>	
LD50 oral rat	7060 mg/kg
LC50 Inhalation - Rat	124.7 mg/l/4h
ATE US (oral)	7060 mg/kg
<b>Citric acid (77-92-9)</b>	
LD50 oral rat	3 g/kg
ATE US (oral)	3000 mg/kg
<b>Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)</b>	
LD50 oral rat	34500 µl/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: Not classified

# Docetaxel Injection

## Safety Data Sheet

Germ cell mutagenicity : Suspected of causing genetic defects.  
Carcinogenicity : May cause cancer.

Ethyl alcohol (64-17-5)	
IARC group	1 - Carcinogenic to humans
In OSHA Hazard Communication Carcinogen list	Yes

Reproductive toxicity : May damage fertility or the unborn child. May cause harm to breast-fed children.  
STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

Ethyl alcohol (64-17-5)	
LC50 - Fish [1]	12 – 16 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	9268 – 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 - Fish [2]	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [2]	2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

  

Citric acid (77-92-9)	
LC50 - Fish [1]	1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

Ethyl alcohol (64-17-5)	
Partition coefficient n-octanol/water (Log Pow)	-0.32

  

Citric acid (77-92-9)	
Partition coefficient n-octanol/water (Log Pow)	-1.72 (at 20 °C)

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

## SECTION 14: Transport information

### Department of Transportation (DOT)

In accordance with DOT

Transport document description (DOT) : UN1170 Ethanol solutions, 3, II

UN-No.(DOT) : UN1170

Proper Shipping Name (DOT) : Ethanol solutions

Class (DOT) : 3 - Class 3 - Flammable and combustible liquid 49 CFR 173.120

# Docetaxel Injection

## Safety Data Sheet

Packing group (DOT) : II - Medium Danger  
 Hazard labels (DOT) : 3 - Flammable liquid



DOT Packaging Non Bulk (49 CFR 173.xxx) : 202  
 DOT Packaging Bulk (49 CFR 173.xxx) : 242  
 DOT Special Provisions (49 CFR 172.102) : 24 - Alcoholic beverages containing more than 70 percent alcohol by volume must be transported as materials in Packing Group II. Alcoholic beverages containing more than 24 percent but not more than 70 percent alcohol by volume must be transported as materials in Packing Group III.  
 IB2 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized.  
 T4 - 2.65 178.274(d)(2) Normal..... 178.275(d)(3)  
 TP1 - The maximum degree of filling must not exceed the degree of filling determined by the following: Degree of filling =  $97 / 1 + a (tr - tf)$  Where: tr is the maximum mean bulk temperature during transport, and tf is the temperature in degrees celsius of the liquid during filling.

DOT Packaging Exceptions (49 CFR 173.xxx) : 4b, 150  
 DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) : 5 L  
 DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) : 60 L  
 DOT Vessel Stowage Location : A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel.  
 Emergency Response Guide (ERG) Number : 127  
 Other information : No supplementary information available.

## SECTION 15: Regulatory information

### 15.1. US Federal regulations

<b>Polyethylene glycol (25322-68-3)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
<b>Ethyl alcohol (64-17-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Citric acid (77-92-9)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).

### 15.2. US State regulations

<b>Ethyl alcohol (64-17-5)</b>				
U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significant risk level (NSRL)
Yes	Yes	No	No	

<b>Polyethylene glycol (25322-68-3)</b>
U.S. - Minnesota - Hazardous Substance List

# Docetaxel Injection

## Safety Data Sheet

### Ethyl alcohol (64-17-5)

U.S. - Massachusetts - Right To Know List  
U.S. - Minnesota - Hazardous Substance List  
U.S. - New Jersey - Right to Know Hazardous Substance List  
U.S. - Pennsylvania - RTK (Right to Know) List

## SECTION 16: Other information

Full text of H-phrases:

Carc. 1A	Carcinogenicity Category 1A
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 2	Flammable liquids Category 2
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation
Muta. 2	Germ cell mutagenicity Category 2
Repr. 1B	Reproductive toxicity Category 1B
H225	Highly flammable liquid and vapor
H319	Causes serious eye irritation
H341	Suspected of causing genetic defects
H350	May cause cancer
H360	May damage fertility or the unborn child
H362	May cause harm to breast-fed children

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*