

	Sagent Pharmaceuticals, Inc.		
	Document Type SDS	Document Title Docetaxel Inj, USP	
	Document No. MSDS-0087	Version 1.0	Effective Date 9/26/2017

Section 1 - Identification

- (a) **Product Identifier:** Docetaxel Injection, USP
- (b) **Product Code:** 25021-245
- Common/Trade Name:** Taxotere
- Chemical Name:** (2R,3 S)-N-carboxy-3-phenylisoserine,N-*tert*-butyl ester, 13-ester with 5 β -20-epoxy-1 ,2 α ,4, 7 β , 10 β , 13 α -hexahydroxytax-11-en-9-one 4-acetate 2-benzoate, trihydrate
- Chemical Family:** Mixture
- (c) **Product Use:** Indicated for the treatment of certain types of cancer
- Product Type:** Regulated Prescription Drug
- Container Information:** Vials
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 450, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:**
- Flammable liquid (category 2)
 - Skin corrosion / irritation (Category 2)
 - Serious eye damage / eye irritation (category 2A)
 - Reproductive toxicity (Category 1A)
 - Specific target organ toxicity - single exposure (Category 3, narcotic effects, respiratory tract irritation)
 - Specific target organ toxicity - repeated exposure (category 1-liver)
 - Specific target organ toxicity - repeat exposure (Category 2-central nervous system)

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Section 4 - First Aid Measures

- Eye Exposure:** Flush immediately with copious amounts of water for at least 15 minutes. If irritation persists, call a physician.
- Skin Exposure:** Wash with copious amounts of water for at least 15 minutes. If irritation persists, call a physician.
- Ingestion:** If ingestion occurs, flush mouth with water and seek medical attention immediately. Never give anything by mouth to an unconscious person.
- Injection:** N/A
- Inhalation:** If difficulty with breathing, remove from exposure to fresh air. Administer oxygen if breathing is difficult. If irritation persists, seek medical attention.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Water spray, dry chemical., carbon dioxide or appropriate foam
- (b) **Hazardous Combustion Products:** May produce carbon oxides and nitrogen oxides
- (c) **Special Protective Equipment / Precautions:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus and protective clothing/shields to prevent skin and eye contact and to avoid inhalation of smoke and fumes.

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Section 6 - Accidental Release Measures

Spill:	<p>Use PPE. Remove all sources of ignition and heat. Avoid breathing vapors and mist. Keep people away from the spill and ensure adequate ventilation. Do not let product enter drains. Avoid release into environment.</p> <p>To clean, mix with inert material (i.e. sand, vermiculite) and move to dry, clean lidded container for disposal. Avoid inhalation. Ventilate area and wash spill site after material pick up is finished.</p>
Release to Air:	Not available
Release to Water:	Not available

Section 7 - Handling and Storage

- General Handling:** Avoid contact with eyes, skin and clothing. Do not inhale. Wear anti-electrostatic clothing and chemical safety gloves. Keep container tightly closed. Do not expose empty containers to heat or ignition sources. Use only with adequate ventilation. Ensure electrical continuity by bonding all equipment. Wash hands and face thoroughly after handling.
- Storage Conditions:** Store in a cool environment. Keep container closed tightly in dry and well-ventilated place. Keep away from heat and ignition sources and incompatible materials (see section 10).

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Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Docetaxel	OSHA	PEL	Not available
	ACGIH	TLV	Not available
Polysorbate 80	OSHA	PEL	Not available
	ACGIH	TLV	Not available
Dehydrated alcohol	OSHA	PEL	Not available
	ACGIH	TLV	Not available
Anhydrous citric acid	OSHA	PEL	Not available
	ACGIH	TLV	Not available

(b) Engineering Controls

Ventilation: Mechanical exhaust required.

(c) Individual Protection Measures

Respiratory Protection:	Wear government approved respirator
Eye Protection:	Chemical safety glasses
Skin Protection:	Anti-electrostatic clothing
Other Protective Equipment:	Compatible chemical-resistant gloves
Additional Exposure Precautions:	Wash hands following use. No eating, drinking, or smoking while handling this product.

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Section 9 - Physical and Chemical Properties

(a)	Appearance	Pale yellow transparent viscous liquid
(b)	Odor	Weak
(c)	Odor Threshold	Not available
(d)	pH	6.3-6.4 (50 g/L)
(e)	Melting Point:	Approx. 234 °C
(f)	Initial Boiling Point:	79.5°C
(g)	Flash Point	12.5°C
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	0.949 g/cm ³
(n)	Solubility(ies)	Miscible in water
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	19.89 mm ² /s (kinetic viscosity)

Section 10 - Stability and Reactivity

(a)	Reactivity	Not available
(b)	Chemical Stability	Stable under normal conditions
(c)	Possibility of Hazardous Reactions	Not available
(d)	Conditions to Avoid	Heat, ignition sources, extreme temperature and direct sunlight
(e)	Incompatible Materials	Alkali metals, oxidizing agents, reducing agents, peroxides, heavy metal salts, nitrates, combustible materials.
(f)	Hazardous Decomposition Products	Carbon oxides, Nitrogen Oxides

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Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Injection, Ingestion, Inhalation, skin, eye
(b)	Symptoms related to the physical, chemical and toxicological characteristics	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Occupational exposure has not been fully investigated.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	May damage fertility or fetus. May cause damage to organs through prolonged or repeat exposure (liver, central nervous system).

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Dehydrated alcohol	LD ₅₀	Oral	Rat	7060 mg/ kg
Dehydrated alcohol	LC ₅₀	Inhalation	Rat	20000 ppm/10H
Polysorbate 80	LD ₅₀	Oral	Rat	34500 uL/kg
Polysorbate 80	LD ₅₀	Oral	Mouse	25000 mg/kg
Anhydrous citric acid	LD ₅₀	Oral	Rat	3000 mg/ kg
Anhydrous citric acid	LD ₅₀	Oral	Mouse	5040 mg/kg

(e) Hazardous Chemical Listings

NTP: Not available IARC: Not available OSHA: Not available

Section 12 - Ecological Information

(a)	Ecotoxicity	<i>Toxicity to fish</i> LC ₅₀ : 14,2000 mg/1-96 <i>Toxicity to aquatic invertebrates</i> LC ₅₀ : 5,012 mg/1-48 h
(b)	Persistence and degradability	95%- Readily biodegradable
(c)	Bioaccumulative potential	Not available

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(d)	Mobility in soil	Not available
(e)	Other Adverse Effects	Not available

Section 13 - Disposal Considerations

Contact a licensed professional waste disposal service to dispose of material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with and afterburner and scrubber. Observe all federal, state and local environmental regulations.

Section 14 - Transport Information

(a)	UN Number	UN1170
(b)	UN Proper Shipping Name	Ethanol Solution
(c)	Transport Hazard Class(es)	3
(d)	Packing Group	II
(e)	Environmental Hazards	Not available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
(g)	Special Precautions	Not available

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA: No

CERCLA: Not on this list

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302. Polysorbate 80: SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302. Anhydrous citric acid: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313: Dehydrated alcohol: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313. Polysorbate 80: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels

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established by SARA Title III, Section 313. Anhydrous citric acid: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

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Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
 Sagent Pharmaceuticals, Inc.
 1901 N. Roselle Rd, Suite 450
 Schaumburg, IL 60195
 847-908-1600

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration

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NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System