



<b>1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING</b>	
<b>1.1 Product Identifier</b>	
Product name	ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension)(albumin-bound)
Version	4.0, 09.02.2024
Jurisdiction	This Safety Data Sheet was prepared for the European Union (EU) (EC 1272/2008).
Chemical Name	Trade Secret
Synonyms	ABRAXANE® for Injectable Suspension, for intravenous use; Abraxane® Powder for Suspension for Infusion; ABI-007; Albumin-bound paclitaxel; nab-paclitaxel; 5b,20-epoxy-1,2a,4,7b,10b,13a-hexahydroxytax-11-en-9-one 4,10-diacetate 2-benzoate 13-ester with (2R, 3S)-N-benzoyl-3-phenylisoserine.
<b>1.2 Relevant identified uses of the substance or mixture and uses advised against</b>	
Intended Uses	This material is a finished drug product for patient use. It is used in the treatment of cancer. It is a protein nanoparticle formulation.
<b>1.3 Details of the supplier of the safety data sheet</b>	
Address	<b>Celgene Corporation</b> E-mail: MG-GBS-MSDS-Request@bms.com 86 Morris Avenue, Summit, NJ 07901  Ireland + 353.1.8854000
<b>1.4 Emergency Phone No.</b>	
	In the EU, call 353-1813-9456. Other Countries: See "Section 16" for country-specific emergency phone numbers from CHEMTREC.

<b>2. HAZARDS IDENTIFICATION</b>	
<b>2.1 Classification of the substance or mixture</b>	
Classification	Germ Cell Mutagenicity - Category 2 Toxic To Reproduction - Reproductive Toxicity - Category 1B Toxic To Reproduction - Developmental Toxicity - Category 1B Specific Target Organ Systemic Toxicity (Repeated Exposure) - Category 1 Hazardous To The Aquatic Environment - Chronic Hazard - Category 2
<b>2.2 Label Elements</b>	
Hazard pictogram(s)	 
Signal Word	Danger
Hazard Statements	Suspected of causing genetic defects. May damage fertility (male/female fertility) . May damage the unborn child (developmental toxicity) .

## **2. HAZARDS IDENTIFICATION**

	Causes damage to organs (hematopoietic system, cardiovascular system, nervous system, gastrointestinal tract, liver, kidney, skin, reproductive organs) through prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.
Precautionary Statements	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Do not breathe dust. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment. Collect spillage.
<b>2.3 Other Hazards</b>	Cytotoxic, See section 16 for additional information. 100% of the mixture consists of ingredients(s) of unknown hazards to the aquatic environment.

## **3. COMPOSITION/INFORMATION ON INGREDIENTS**

### **3.1 Substances**

Components	Concentration	CAS No.	EC No./REACH Reg no./Index No.	Classification/Specific Conc. Limit/ATE/Particle Charac.	H- code(s)/M- Factor
<i>Hazardous components</i> ABRAXANE ® for Injectable Suspension	100 %	Not available	--	Muta:CAT 2 Repro:CAT 1B Dev:CAT 1B STOT RE:CAT 1 Aquatic Chronic:CAT 2	H341 H360F H360D H372 H411

See section 16 for H-code text.

### **3.2 Mixtures**

Not applicable

## **4. FIRST AID MEASURES**

### **4.1 Description of first aid measures**

Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. If exposed or concerned: Get medical attention/advice.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Discard contaminated clothing or wash before re-use. If exposed or concerned: Get medical attention/advice.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. If exposed or concerned: Get medical attention/advice.

Ingestion	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. If exposed or concerned: Get medical attention/advice.
Self-protection of the first aider	Personal protective equipment for first aid responders is recommended.
<b>4.2 Most important symptoms and effects, both acute and delayed</b>	
Notes to Physician	Medical conditions aggravated include: bone marrow suppression, cardiac irregularities, liver disease. This product has been reported to interact with the following medications: drugs that inhibit cytochrome P-450, drugs that induce cytochrome P-450. Material not fully tested. Refer to Section 11.
<b>4.3 Indication of any immediate medical attention and special treatment needed</b>	
Medical Surveillance	Employees who are planning pregnancy, pregnant, breast-feeding, or concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

<b>5. FIRE-FIGHTING MEASURES</b>	
<b>5.1 Extinguishing Media</b>	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
<b>5.2 Special hazards arising from the substance or mixture</b>	Specific hazards: Not available Flammable Properties: Not available Hazardous Combustion Products: carbon oxides (COx), nitrogen oxides (NOx) Other information: Decontaminate protective clothing and equipment before reuse.
<b>5.3 Advice for firefighters</b>	Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.

<b>6. ACCIDENTAL RELEASE MEASURES</b>	
<b>6.1 Personal precautions, protective equipment and emergency procedures</b>	
Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, disposable lab coat of low permeability with cuffs, double gloves and shoe covers. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.	
<b>6.2 Environmental precautions</b>	
Prevent release to drains and waterways. Prevent release to the environment.	
<b>6.3 Methods and material for containment and cleaning up</b>	
Containment Methods	Wet down any dust to prevent generation of aerosols, if appropriate. Cover with suitable material.
Cleanup Methods	Spill prevention procedures and a spill response procedure should be implemented. Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Clean spill area with a deactivating solution (if available) followed by detergent and water after spill pick-up. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

## **6. ACCIDENTAL RELEASE MEASURES**

**6.4 Reference to other sections** Not available

## **7. HANDLING AND STORAGE**

### **7.1 Precautions for safe handling**

Avoid exposure - obtain special instructions before use. Avoid inhalation of vapour or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways.

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

Container Requirements Store in the original primary packaging as provided.

Storage Conditions Store at controlled room temperature. ( 20 - 25°C ) Do not store near incompatible substances. Excursions permitted to 15° - 30°C. Keep away from direct sunlight. Protect against light. Store in the dark. Keep in a dry place. Keep away from heat, sparks and flames. Store locked up.

**7.3 Specific end use(s)** Refer to Section 1

## **8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

### **8.1 Control parameters**

Exposure limit(s)	Company Guideline	ACGIH	Germany OEL	UK MEL
ABRAXANE® for Injectable Suspension	2 µg/m3 8 hour-TWA	--	--	--

Recommended Industrial Hygiene Monitoring Methods General - The health hazard risk of handling this material is dependent on many factors, including physical form, % API in material being handled, duration and frequency of process task, and effectiveness of controls. If it is necessary to handle this compound outside of engineering controls, an exposure risk assessment should be conducted and procedures documented by a qualified EHS professional.

### **8.2 EXPOSURE CONTROLS**

Engineering Controls and Ventilation	<p>LABORATORIES: When handling quantities up to 1 grams Total Weight (lyophilized materials), a standard laboratory with general laboratory dilution ventilation (e.g. 6-12 air changes per hour) is appropriate. Refer to HVAC standard DS-4301 for exact requirements. When handling quantities &gt;1 gram - 100 grams Total Weight (lyophilized materials), work in a standard laboratory when manipulating materials, fume hood; biological safety cabinet (Class II Type A2 with thimble connection, B1, or B2); approved vented enclosure and closed processes for high energy biologic processes. When handling quantities &gt;100 grams Total Weight (lyophilized materials), work in Development Laboratory or Biologic Pilot Plant Area using Biological safety cabinet (Class II Type A2 with thimble connection, B1, or B2), glove box, or approved vented enclosure required. Closed processes for high energy biologic processes. Appropriate containment isolation technology. For low energy operations, use protective shielding (shields, absorbent lined trays or work surfaces) to limit spread of splash or splatter. Local exhaust ventilation is required. For high energy operations must be performed in closed or contained systems. Eliminate the use of all sharps, if possible. A documented risk assessment is required to support sharp usage.</p> <p>For all quantities noted - For low energy operations, use protective shielding (shields, absorbent lined trays or work surfaces) to limit spread of splash or splatter. Local exhaust ventilation is required. High-energy operations must be performed in closed or contained systems. Eliminate the use of all sharps, if possible. A documented risk assessment is required to support sharp usage.</p> <p>MANUFACTURING: Perform closed transfers when feasible. Avoid generation of dust. Control total dust levels to recommended control limits for material as supplied (based on concentration of API in material being handled). Establish a spill/leak procedure as outlined in Section 6 to address equipment failures/leaks. Exposures are typically controlled by GMP design specifications under normal operations.</p> <p>CLINICAL: When preparing drug in a clinical setting, use good clinical practice for drug preparation. If the potential for personal exposure exists, use an approved vented enclosure such as a fume hood or biological safety cabinet if available. Please refer to the general guidance at the beginning of this section.</p>
Respiratory protection	Use and selection of respiratory protection is based upon an exposure risk assessment and potential for aerosol generation. When engineering controls are not sufficient to control exposure, wear an approved respiratory protection device that is adequate to control exposure based on measured or estimated airborne, and the rating for the device. Follow local regulatory requirements.
Eye protection	Wear safety glasses with side-shields. Face shields or chemical safety goggles may be required if contact potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected.
Hand protection	When handling solutions wear impermeable gloves (e.g. latex or nitrile). Persons who are allergic to natural rubber latex should select gloves made from one of the other materials.
Skin and body protection	<p>LABORATORIES: Wear a laboratory coat (EN 340).</p> <p>MANUFACTURING: Wear laboratory coat or full coverall of low permeability. Wear wrist gauntlets/sleeves and shoe covers as appropriate.</p> <p>CLINICAL: When preparing drug in clinical setting wear lab coat.</p>
Hygiene	Wash hands and face before breaks and immediately after handling the product.
Environmental exposure controls	Prevent release to drains and waterways.

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>	
<b>9.1 Information on basic physical and chemical properties</b>	
<i>General Information</i>	
<i>Appearance</i>	
Physical State	solid
Colour	white to yellow
Form	(lyophilized), powder
<i>Odour</i>	
Odour	odorless
Odor Threshold	Not available
<i>Important health safety and environmental information</i>	
pH	6 - 7.5 (reconstituted)
<i>Other information</i>	
Bulk density	Not available
Chemical Name	Trade Secret
Evaporation rate	Not available
Molecular formula	Trade Secret
Hydrolysis/Photolysis	Low rate of hydrolysis in water (This result is from a study on paclitaxel.) Refer to Section 12
Hygroscopicity	Not available
Molecular Weight	Not applicable
Log Octanol/Water Partition Coefficient [log Kow]	3.69 This result is from a study on a structurally-and/or pharmacologically-related substance.
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	insoluble
Specific Gravity/ Relative density	Not available
Viscosity, dynamic	Not available
Viscosity, kinematic	Not available
% Volatile	Not available
<i>Thermal/Stability properties</i>	
Autoignition temperature	Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Non-explosive based on chemical structure.
Flammability	Not available
Flash point	Not available
Melting Point	216 °C approximately
Oxidizing Potential	Non-oxidizer based on chemical structure.
<i>Vapor Properties</i>	
Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available
<b>9.2 Other information</b>	Not available

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>	
Other Safety Characteristics	Not available
<i>Sensitivity to static discharge/Dust exp.</i>	
Summary Statements	Although material has not been specifically tested, fine dust suspended in air in sufficient concentration and in the presence of an ignition source may pose a potential explosion hazard. Provide appropriate bonding and grounding protection to control static charge. Powder handling equipment such as dust collectors, dryers, and mills may require additional protective measures (e.g. explosion venting, inerting, etc.).

<b>10. STABILITY AND REACTIVITY</b>	
<b>10.1 Reactivity</b>	Not available
<b>10.2 Chemical Stability</b>	Stable under normal conditions.
<b>10.3 Possibility of Hazardous Reactions</b>	None known.
<b>10.4 Conditions to avoid</b>	light
<b>10.5 Incompatible materials</b>	strong oxidizing agents , strong acids and strong bases
<b>10.6 Hazardous decomposition products</b>	Hazardous decomposition products formed under fire conditions.: carbon oxides (COx), nitrogen oxides (NOx)

<b>11. TOXICOLOGICAL INFORMATION</b>	
<b>11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008</b>	
Routes of Entry	Ingestion, inhalation, Eye contact, Skin contact
Eye Irritation	Not available
Skin Irritation	Not available
Respiratory Irritation	Not available
Sensitization	Not available
Acute Toxicity Study	<b>Acute toxicity (other routes of administration)</b> LD50 (rat, intravenous): > 120 mg/kg low exposure effects include (<= 300 mg/kg): mortality, Microscopic changes were observed in the following organs:, male reproductive organs. LD50 (mouse, intravenous): 447 mg/kg LD50 (dog, intravenous): > 8.4 mg/kg low exposure effects include (<= 300 mg/kg): hypoactivity, gastrointestinal effects , oedema, Microscopic changes were observed in the following organs:, male reproductive organs. LD50 (Pig, intravenous): > 6 mg/kg low exposure effects include (<= 300

## 11. TOXICOLOGICAL INFORMATION

mg/kg): decreased body weight, decreased appetite, vomiting, diarrhoea, decreased white blood cell count.

Repeated Dose Toxicity	3 - 4 Weeks intravenous (Once per 5-7 days) rat, monkey study with recovery period (4 Weeks) (males and females): LOAEL (4 week, rat) = 10 mg/kg; Low dose effects include (< = 100 mg/kg): decreased body weight, decreased food consumption, vomiting, abnormal posture, fecal changes, changes in red blood cell parameters, decreased white blood cell count, changes in urine chemistry, changes in clinical chemistry parameters, mortality, increased organ weights included:, spleen, decreased organ weights included:, thymus, pituitary gland, testes, liver, thyroid gland, parathyroid gland. Low dose microscopic effects include: lymphoid tissue, heart, male reproductive organs, liver, nervous system, skin, eyes. Effects still present after recovery include: Microscopic changes were observed in the following organs:, male reproductive organs, nervous system, eyes.
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Genetic Toxicity	<b>Mutagenicity Assessment</b> This material was positive in genotoxicity assays in animals. (This result is from a study on a structurally-and/or pharmacologically-related substance.)
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Carcinogenicity	Not available
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Carcinogenicity	ACGIH	IARC	NTP
ABRAXANE® for Injectable Suspension	--	--	--

Reproductive Toxicity	12 Weeks intravenous (1/week) male reproductive toxicity (rat) (parent, males) NOAEL = 2 mg/kg Effects on offspring include: reduction in litter size. Paternal effects include: impaired spermatogenesis, mortality. Effects occurred in male fertility. <b>Assessment Reproductive Toxicity</b> Reproductive toxicant See also "Repeated Dose Toxicity" for information on reproductive effects.
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Developmental Toxicity	intravenous (daily) Study of Embryo-Fetal Development (rat) (parent, females) NOAEL = 0.5 mg/kg (embryo/fetus) NOAEL = 0.5 mg/kg Fetal effects include: decreased body weight, skeletal variation, malformations, mortality. Maternal effects include: decreased weight gain, decreased body weight, decreased food consumption, increased resorption incidence, mortality. <b>Developmental Toxicity Assessment</b> Compound produced effects on the fetus at doses similar to those which produced effects on the maternal animal. However, the effects noted in the fetus are consistent with those expected based on the mechanism of action of this
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## 11. TOXICOLOGICAL INFORMATION

substance.

### Human experience

#### Experiences with Human Exposure

intravenous patient population (1/week-1/3 weeks) low exposure - acute effects include: decreased appetite, nausea, vomiting, diarrhea, constipation, dehydration, mouth effects, fatigue, chills, fever, cough, oedema, headache, dizziness, depression, insomnia, rash, skin effects, changes in electrolytes, hyperglycemia, increased liver enzymes, changes in clinical chemistry parameters, anemia, neutropenia, thrombocytopenia, increase in heart rate, congestive heart failure, changes in blood pressure, peripheral neuropathies, kidney effects, liver effects, eye effects, musculoskeletal pain, joint pain, infection.

### Target Organs

hematopoietic system, cardiovascular system, nervous system, gastrointestinal tract, liver, kidney, skin, reproductive organs

### Aspiration Toxicity

Not available

### Symptoms

Not available

### Pharmacokinetics/ Toxicokinetics

Absorption: Data available upon request.  
Distribution: Data available upon request.  
Metabolism: Data available upon request.  
Elimination: Half-life = 13 - 27 Hour(s) (Human).

## 11.2 Information on other hazards

### Other Toxicity Information

Not available

### Other Information:

Some of the toxicological data presented is derived from a structurally or pharmacologically similar compound.

### Endocrine Disruptor Properties

Not available

## **12. ECOLOGICAL INFORMATION**

### **12.1 Ecotoxicity**

#### **Acute Toxicity to Fish**

LC50 (Pimephales promelas (fathead minnow), 96 H): > 7.1 mg/l. Highest dose tested (This result is from a study on paclitaxel.)

#### **Acute Toxicity to Aquatic Invertebrates**

NOEC (Daphnia magna (Water flea), 48 H): 0.74 mg/l. Highest dose tested (This result is from a study on paclitaxel.)

EC50 (Daphnia magna (Water flea), 48 H): > 0.74 mg/l. Highest dose tested (This result is from a study on paclitaxel.)

#### **Toxicity to aquatic plants**

EC50 (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Growth rate, 72 H): > 0.16 mg/l Highest dose tested, (This result is from a study on paclitaxel.)

EC50 (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Growth rate, 72 H): > 0.55 mg/l (limit of solubility)

#### **Toxicity to microorganisms**

Respiration inhibition, EC50 (Activated Sludge, 3 H): > 1,000 mg/l (This result is from a study on paclitaxel.)

Respiration inhibition, NOEC (Activated Sludge, 3 H): 1,000 mg/l (This result is from a study on paclitaxel.)

#### **Chronic toxicity to fish**

Early-life Stage LOEC (Pimephales promelas (fathead minnow), 33 Days): 0.1 mg/l., growth, (This result is from a study on paclitaxel.)

Early-life Stage NOEC (Pimephales promelas (fathead minnow), 33 Days): 0.05 mg/l., growth, (This result is from a study on paclitaxel.)

#### **Chronic toxicity to aquatic invertebrates**

EC10 (Daphnia magna (Water flea), 21 Days): 0.036 mg/l reproduction, (This result is from a study on paclitaxel.)

NOEC (Daphnia magna (Water flea), 21 Days): 0.023 mg/l reproduction, (This result is from a study on paclitaxel.)

#### **Mobility**

Not available

### **12.2 Persistence and degradability**

#### **Biodegradation**

Biodegradation: Inherently biodegradable. (This result is from a study on paclitaxel.)

#### **Stability in water**

Hydrolysis ( pH 5): Half-life - 65.6 Days; Degree of hydrolysis - 28 Days; Low rate of hydrolysis in water (This result is from a study on paclitaxel.)

Hydrolysis ( pH 7): Half-life - 18.6 Days; Degree of hydrolysis - 28 Days; Low rate of hydrolysis in water (This result is from a study on paclitaxel.)

Hydrolysis ( pH 9): Half-life - 13.9 Days; Degree of hydrolysis - 28 Days; Low rate of hydrolysis in water (This result is from a study on paclitaxel.)

#### **sorption/desorption**

Kfoc (soil) : 341 - 661

(This result is from a study on paclitaxel.)

Kfoc (Sludge) : 508 - 877

(This result is from a study on paclitaxel.)

### **12.3 Bioaccumulative potential**

Bioconcentration factor (BCF): 2.4 - 3.5 (Cyprinus carpio (Carp))

steady state lipid adjusted (This result is from a study on paclitaxel.)

## **12. ECOLOGICAL INFORMATION**

**12.4 Mobility in soil** Not available

### **12.5 Results of PBT and vPvB assessment**

Does not fulfill PBT or vPvB criteria (This result is from a study on paclitaxel.)

**12.6 Endocrine Disruptor Properties** Not available

**12.7 Other adverse effects** Not available

## **13. DISPOSAL CONSIDERATIONS**

### ***13.1 Waste treatment methods***

Advice On Disposal And Packaging Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.

Other information Disposal by incineration is recommended.

## **14. TRANSPORT INFORMATION**

### **IMDG**

<b>14.1 UN/ID No.</b>	UN3077
<b>14.2 Proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (abraxane)
<b>14.3 Class</b>	9
<b>14.4 Packing group</b>	III
Labelling	9
EmS	F-A, S-F

### **ICAO/IATA-DGR**

<b>14.1 UN/ID No.</b>	UN3077
<b>14.2 Proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (abraxane)
<b>14.3 Class</b>	9
<b>14.4 Packing group</b>	III
Labelling	9

### **ADR**

<b>14.1 UN/ID No.</b>	UN3077
<b>14.2 Proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (abraxane)
<b>14.3 Class</b>	9
<b>14.4 Packaging group</b>	III
Labelling	9

### **RID**

<b>14.1 UN/ID No.</b>	UN3077
<b>14.2 Proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (abraxane)
<b>14.3 Class</b>	9
<b>14.4 Packaging group</b>	III
Labelling	9

### **US DOT**

<b>14.1 UN/ID No.</b>	UN3077
<b>14.2 Proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (abraxane)
<b>14.3 Class</b>	9
<b>14.4 Packing group</b>	III

#### 14. TRANSPORT INFORMATION

Labelling 9

##### Transportation Classification for All Modes:

Marine pollutant

**14.5 Environmental hazards** Marine pollutant

**14.6. Special precautions for user** Not available

**14.7 Maritime transport in bulk according to IMO instrument** Not applicable

#### 15. REGULATORY INFORMATION

##### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulatory Authorizations and Restrictions: Not available

##### United States of America

313 Toxic Release Inventory No components listed on the SARA 313 inventory.

TSCA Inventory Not listed. Food, drug and cosmetic products are exempt from TSCA.

California Prop. 65	Developmental toxicant	Paclitaxel
	Reproductive toxicant (male)	Paclitaxel
	Reproductive toxicant (female)	Paclitaxel

##### 15.2 Chemical Safety Assessment

Not available

#### 16. OTHER INFORMATION

##### Text of H-code(s) mentioned in Section 3.

H341	Suspected of causing genetic defects.
H360D	May damage the unborn child
H360F	May damage fertility
H372	Causes damage to organs through prolonged or repeated exposure.
H411	Toxic to aquatic life with long lasting effects.

##### Recommended Restrictions for Use:

Not available

##### SDS preparation information

Prepared by Global Environment, Health, Safety, and Sustainability 1-732-227-7380

Prepared on 09.02.2024 DD/MM/YYYY

This Safety Data Sheet has been revised. This data sheet contains changes from the previous version in section(s): 1, 2, 7, 9, 12, and 16. This Safety Data Sheet was prepared for the European Union (EU) (EC 1272/2008).

*Country- Specific Emergency  
Phone Numbers*

Country	Local # or Toll Free in Country*	Greeting Language	Country	Local # or Toll Free in Country*	Greeting Language
<b>AMERICAS</b>			Latvia (Riga)	+371-66165504	Latvian
Argentina (Buenos Aires)	+54- 1159839431	Latin American Spanish	Lithuania (Vilnius)	+370-52140238	Lithuanian
Brazil (Rio De Janeiro)	+55- 2139581449	Portuguese	Luxembourg	+352-20202416	French, German, Luxembourgish
Cayman Islands	+1-345-749- 8392	English	Netherlands	+31-858880596	Dutch
Chile (Santiago)	+56-225814934	Latin American Spanish	Norway (Oslo)	+47-21930678	Norwegian
Colombia *	01800-710-2151	Latin American Spanish	Poland (Warsaw)	+48-223988029	Polish
Costa Rica*	+506-40003869	Latin American Spanish	Portugal	+351- 308801773	Portuguese
Mexico*	01-800-681-9531	Latin American Spanish	Romania	+40-37- 6300026	Romanian
Panama	+507-8322475	Latin American Spanish	Russia*	8-800-100-6346	Russian
Peru (Lima)	+51-17071295	Latin American Spanish	Slovakia (Bratislava)	+421- 233057972	Slovak
Trinidad and Tobago*	+1-868-224- 5716	English	Slovenia (Ljubljana)	+386-18888016	Slovene/Slovenian
<b>EUROPE</b>			Spain (Barcelona)	+34-931768545	European Spanish
			Spain*	900-868538	European Spanish
Austria (Vienna)	+43-13649237	German	Sweden (Stockholm)	+46-852503403	Swedish
Belgium (Brussels)	+32-28083237	French, Flemish, German	Switzerland (Zurich)	+41- 435082011	Swiss German, French and Italian
Bulgaria (Plovdiv)	+359-32570104	Bulgarian	Turkey (Istanbul)	+90-212- 7055340	Turkish
Croatia (Zagreb)	+385-17776920	Croatian	Ukraine	+380- 947101374	Ukrainian
Czech Republic (Prague)	+420- 228880039	Czech	UK (London)	+44-870- 8200418	English
Finland (Helsinki)	+358- 942419014	Finnish	<b>EAST ASIA</b>		
France	+33-975181407	French	China	86-21-33235036	Mandarin
Germany *	0800-181-7059	German	Hong Kong*	800-968-793	Cantonese
Denmark	+45-69918573	Danish	Japan	+81-345209637	Japanese
Estonia	+372-6681294	Estonian	Singapore	+65-31581349	English and Mandarin
Germany (Frankfurt)	+49- 69643508409	German	South Korea	+82 070-7686- 0086	Korean
Greece (Athens)	+30- 2111768478	Greek	<b>AUSTRALIA &amp; OCEANIA</b>		
Hungary (Budapest)	+36-18088425	Hungarian	Australia (Sydney)	+61-290372994	English
Italy *	800-789-767	Italian	New Zealand*	+64-98010034	English
Italy (Milan)	+39- 245557031	Italian	India *	000-800-100- 7141	Hindi
*Phone numbers for countries marked with an asterisk must be dialed within the country.					

The information contained in this SDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information. and we assume no liability from its use.

Other information: Cytotoxic - A compound is considered cytotoxic if it possesses the ability to cause mammalian cell death by interacting directly with DNA or DNA-associated macromolecules. In addition, a cytotoxic agent causes such damage in an indiscriminate manner, affecting healthy cells in addition to abnormal (e.g., tumor) cells and causing serious systemic toxicity. For active pharmaceutical ingredients, these effects are expected to occur at or below the therapeutic dose.