

Docetaxel Injection 20mg/ml

Hospira Australia

Chemwatch: 41-4669

Version No: 2.1.1.1

Material Safety Data Sheet according to NOHSC and ADG requirements

Chemwatch Hazard Alert Code: 3

Issue Date: 25/03/2014

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Initial Date: Not Available

S.Local.AUS.EN

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Product Identifier

Product name	Docetaxel Injection 20mg/ml
Synonyms	Not Available
Proper shipping name	ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Other means of identification	Not Available

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Docetaxel is a semi-synthetic taxane produced from a precursor, 10-deacetyl baccatin III, obtained from the leaves of the European yew tree, <i>Taxus baccata</i> , and has been shown to have significant activity against many solid tumours. Docataxel is indicated for the treatment of locally advanced or metastatic breast cancer that has progressed or relapsed despite anthracycline-based chemotherapy. In addition it may be indicated in first-line non-small cell lung carcinoma, locally advanced or metastatic non-small cell carcinoma after platinum-based chemotherapy has failed, small-cell lung carcinoma after first-line chemotherapy has failed, ovarian carcinoma after prior platinum-based therapy has failed, melanoma, colorectal cancers. Normally given by infusion.
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Details of the supplier of the safety data sheet

Registered company name	Hospira Australia
Address	1 Lexia Place VIC Mulgrave North 3170 Australia
Telephone	+61 3 8541 5200
Fax	+61 3 8541 5300
Website	www.hospira.com
Email	Not Available

Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	(within Australia) +61 2 9037 2994 - (within UK) +44 870 820 0418, (within USA) +1 800 424 9300 - (outside USA) +1 703 527 3887
Other emergency telephone numbers	Not Available

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

HAZARDOUS SUBSTANCE. DANGEROUS GOODS. According to the Criteria of NOHSC, and the ADG Code.

CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability	3	
Toxicity	0	
Body Contact	2	
Reactivity	1	
Chronic	2	

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme

Poisons Schedule	S4								
Risk Phrases [1]	<table><tr><td>R11</td><td>Highly flammable.</td></tr><tr><td>R36</td><td>Irritating to eyes.</td></tr><tr><td>R40(3)</td><td>Limited evidence of a carcinogenic effect.</td></tr><tr><td>R67</td><td>Vapours may cause drowsiness and dizziness.</td></tr></table>	R11	Highly flammable.	R36	Irritating to eyes.	R40(3)	Limited evidence of a carcinogenic effect.	R67	Vapours may cause drowsiness and dizziness.
R11	Highly flammable.								
R36	Irritating to eyes.								
R40(3)	Limited evidence of a carcinogenic effect.								
R67	Vapours may cause drowsiness and dizziness.								

Legend: 1. Classified by Chemwatch; 2. Classification drawn from HSIS; 3. Classification drawn from EC Directive 1272/2008 - Annex VI



Continued...

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Relevant risk statements are found in section 2

Indication(s) of danger	Xn
SAFETY ADVICE	
S02	Keep out of reach of children.
S09	Keep container in a well ventilated place.
S16	Keep away from sources of ignition. No smoking.
S23	Do not breathe gas/fumes/vapour/spray.
S26	In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.
S29	Do not empty into drains.
S33	Take precautionary measures against static discharges.
S35	This material and its container must be disposed of in a safe way.
S36	Wear suitable protective clothing.
S37	Wear suitable gloves.
S39	Wear eye/face protection.
S40	To clean the floor and all objects contaminated by this material, use water and detergent.
S41	In case of fire and/or explosion, DO NOT BREATHE FUMES.
S43	In case of fire use the extinguishing media detailed in section 5 of this SDS.
S46	If swallowed, seek medical advice immediately and show this container or label.
S51	Use only in well ventilated areas.
S53	Avoid exposure - obtain special instructions before use.
S56	Dispose of this material and its container at hazardous or special waste collection point.
S64	If swallowed, rinse mouth with water (only if the person is conscious).

Other hazards

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
9005-65-6	>50	<u>sorbitan monooleate, ethoxylated</u>
64-17-5	39.5	<u>Ethanol</u>
5949-29-1	<1	<u>citric acid, monohydrate</u>
114977-28-5	2	<u>docetaxel</u>

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with fresh running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	<p>If poisoning occurs, contact a doctor or Poisons Information Centre.</p> <ul style="list-style-type: none"> ▶ If swallowed do NOT induce vomiting. ▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. ▶ Observe the patient carefully. ▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. ▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. ▶ Seek medical advice.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

For employees potentially exposed to antineoplastic and/ or cytotoxic agents on a regular basis, a preplacement physical examination and history (noting risk factors) is recommended. Periodic follow-up examinations should also be undertaken and should be overseen by a physician familiar with the toxic effects of the substance and full details of the nature of work undertaken by the employee.

Following administration of antineoplastics, control of nausea and vomiting may be attempted by giving phenothiazines such as perphenazine, prochlorperazine, promethazine or thiethylperazine. In bone-marrow depression, transfusion of blood or platelets reduces the risk of life-threatening haemorrhage. Granulocyte transfusions and injection of antibiotics may be necessary to combat infection in the neutropenic patient. Hyperuricaemia is avoided by the addition of allopurinol to treatment schedules and measures such as alkalinisation of the urine and hydration may be adopted.

MARTINDALE: The Extra Pharmacopoeia, 28th Edition.

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media

- ▶ Alcohol stable foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ May be violently or explosively reactive. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water course.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ Liquid and vapour are highly flammable. ▶ Severe fire hazard when exposed to heat, flame and/or oxidisers. ▶ Vapour may travel a considerable distance to source of ignition. ▶ Heating may cause expansion or decomposition leading to violent rupture of containers. <p>Combustion products include; carbon dioxide (CO₂) other pyrolysis products typical of burning organic material May emit poisonous fumes.</p>

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Minor Spills	<p>It is recommended that areas handling final finished product have cytotoxic spill kits available.</p> <p>Spill kits should include:</p> <ul style="list-style-type: none"> ▶ impermeable body covering, ▶ shoe covers, ▶ latex and utility latex gloves, ▶ goggles, ▶ approved respirator (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent), see Section 8, ▶ disposable dust pan and scoop, ▶ absorbent towels, ▶ spill control pillows, ▶ disposable sponges, ▶ sharps container, ▶ disposable garbage bag and ▶ hazardous waste label <p>Where spills are treated with loose absorbents, such as vermiculite, ensure dust exposure is strictly avoided.</p> <p>To avoid accidental exposure due to waste handling of cytotoxics:</p> <ul style="list-style-type: none"> ▶ Place waste residue in a segregated sealed plastic container. ▶ Used syringes, needles and sharps should not be crushed, clipped, recapped, but placed directly into an approved sharps container. ▶ Dispose of any cleanup materials and waste residue according to all applicable laws and regulations e.g. secure chemical landfill disposal. <p>Slippery when spilt.</p> <p>All personnel likely to be involved in a antineoplastic (cytotoxic) spill must receive practical training in:</p> <ul style="list-style-type: none"> ▶ the correct procedures for handling cytotoxic drugs or waste in order to prevent and minimise the risk of spills ▶ the location of the spill kit in the area ▶ the arrangements for medical treatment of any affected personnel ▶ the procedure for containment of the spill, and decontamination of personnel and the environment, including the different procedures for major and minor spills ▶ the procedure for waste disposal according to the nature and extent of the spill
Major Spills	<p>Slippery when spilt.</p> <ul style="list-style-type: none"> ▶ Clear area of personnel and move upwind. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ May be violently or explosively reactive. ▶ Wear breathing apparatus plus protective gloves.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ DO NOT allow clothing wet with material to stay in contact with skin <p>Australian Standard (AS2639) and the National Institute of Health (USA) recommends that the preparation of injectable antineoplastic drugs should be performed in a Class II laminar flow biological safety cabinet and that personnel preparing drugs of this class should wear appropriate personal protective gear. Emphasise controls on containment.</p> <ul style="list-style-type: none"> ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sumps.
Other information	<p>Antineoplastics (cytotoxics):</p> <ul style="list-style-type: none"> ▶ should be clearly identifiable to all personnel involved in their handling ▶ should be stored in impervious break-resistant containers ▶ should be stored in separate, clearly marked storage areas to minimise the risk of breakage, and to limit contamination in the event of leakage. <p>Spill kits should be available in storage areas.</p> <ul style="list-style-type: none"> ▶ Store in original containers in approved flame-proof area.

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- ▶ No smoking, naked lights, heat or ignition sources.
- ▶ **DO NOT store in pits, depressions, basements or areas where vapours may be trapped.**
- ▶ Keep containers securely sealed.

Conditions for safe storage, including any incompatibilities

Suitable container	Vials
Storage incompatibility	<ul style="list-style-type: none"> ▶ Avoid strong bases. ▶ Avoid reaction with oxidising agents

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	Ethanol	Ethyl alcohol	1880 mg/m ³ / 1000 ppm	Not Available	Not Available	Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
sorbitan monooleate, ethoxylated	Sorbitan, monooleate polyoxyethylene; (Polyethylene sorbitan monooleate; Tween 80)	41 mg/m ³	450 mg/m ³	2700 mg/m ³
Ethanol	Ethyl alcohol; (Ethanol)	Not Available	Not Available	Not Available
citric acid, monohydrate	Citric acid monohydrate	2.3 mg/m ³	25 mg/m ³	150 mg/m ³
citric acid, monohydrate	Citric acid	0.37 mg/m ³	4 mg/m ³	590 mg/m ³

Ingredient	Original IDLH	Revised IDLH
sorbitan monooleate, ethoxylated	Not Available	Not Available
Ethanol	15,000 ppm	3,300 [LEL] ppm
citric acid, monohydrate	Not Available	Not Available
docetaxel	Not Available	Not Available

Exposure controls

Appropriate engineering controls	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.</p>
Personal protection	
Eye and face protection	<ul style="list-style-type: none"> ▶ Chemical protective goggles with full seal. ▶ Shielded mask (gas-type). ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task.
Skin protection	See Hand protection below
Hands/feet protection	<p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Suitability and durability of glove type is dependent on usage.</p> <ul style="list-style-type: none"> ▶ Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. ▶ Double gloving should be considered. ▶ PVC gloves.
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▶ When handling antineoplastic materials, it is recommended that a disposable work-uniform (such as Tyvek or closed front surgical-type gown with knit cuffs) is worn. ▶ Potentially contaminated bodily fluids should be handled in accordance with local standards or codes of practice (appendix 10 of 'Cytotoxic Drugs and Related Waste' - Workcover New South Wales, HSE Information Sheet MISC615, OSHA Technical Manual (OTM) Section VI: Chapter 2) ▶ Overalls. ▶ PVC Apron. ▶ PVC protective suit may be required if exposure severe. ▶ Eyewash unit. <p>Some plastic personal protective equipment (PPE) (e.g. gloves, aprons, overshoes) are not recommended as they may produce static electricity.</p> <p>For large scale or continuous use wear tight-weave non-static clothing (no metallic fasteners, cuffs or pockets).</p> <p>Non sparking safety or conductive footwear should be considered. Conductive footwear describes a boot or shoe with a sole made from a conductive compound chemically bound to the bottom components, for permanent control to electrically ground the foot and shall dissipate static electricity from the body to reduce the possibility of ignition of volatile compounds.</p>
Thermal hazards	Not Available

Recommended material(s)**GLOVE SELECTION INDEX**

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

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Material	CPI
BUTYL	A
NEOPRENE	A
NITRILE	A
NITRILE+PVC	A
PE/EVAL/PE	A
PVC	B
NATURAL RUBBER	C
NATURAL+NEOPRENE	C

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Respiratory protection

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

Required minimum protection factor	Maximum gas/vapour concentration present in air p.p.m. (by volume)	Half-face Respirator	Full-Face Respirator
up to 10	1000	A-AUS / Class1 P2	-
up to 50	1000	-	A-AUS / Class 1 P2
up to 50	5000	Airline *	-
up to 100	5000	-	A-2 P2
up to 100	10000	-	A-3 P2
100+			Airline**

* - Continuous Flow ** - Continuous-flow or positive pressure demand

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties**

Appearance	Clear yellow to brownish-yellow viscous liquid; partly mixes with water.		
Physical state	Liquid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	<21	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	HIGHLY FLAMMABLE.	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water (g/L)	Partly Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 TOXICOLOGICAL INFORMATION

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Information on toxicological effects

Inhaled	Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by sleepiness, reduced alertness, loss of reflexes, lack of co-ordination, and vertigo. Poisoning caused by taxoids show their signs 1 to 3 hours after exposure. These include nausea, a widespread abdominal pain, shallow breathing and heart disturbances similar to those seen in potassium overdose. Inhalation of high concentrations of gas/vapour causes lung irritation with coughing and nausea, central nervous depression with headache and dizziness, slowing of reflexes, fatigue and inco-ordination. Side effects of topoisomerase I and II inhibitors (used to treat cancer) include early diarrhoea with runny nose, increased production of saliva, watery eyes, sweating, flushing and abdominal cramps. Late diarrhoea may also occur, up to 11 days after treatment. Other common side-effects include nausea, vomiting, low white cell count, and anaemia.
Ingestion	The killing action of antineoplastic drugs used for cancer chemotherapy is not selective for cancerous cells alone but affect all dividing cells. Acute side effects include loss of appetite, nausea and vomiting, allergic reaction (skin rash, itch, redness, low blood pressure, unwellness and anaphylactic shock) and local irritation.
Skin Contact	One of the mechanisms of skin irritation caused by surfactants is considered to be denaturation of the proteins of skin. It has also been established that there is a connection between the potential of surfactants to denature protein in vitro and their effect on the skin. Nonionic surfactants do not carry any net charge and, therefore, they can only form hydrophobic bonds with proteins. For this reason, proteins are not deactivated by nonionic surfactants, and proteins with poor solubility are not solubilized by nonionic surfactants Open cuts, abraded or irritated skin should not be exposed to this material
Eye	There is evidence that material may produce eye irritation in some persons and produce eye damage 24 hours or more after instillation. Severe inflammation may be expected with pain.
Chronic	There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment. Anti-cancer drugs used for chemotherapy can depress the bone marrow with reduction in the number of white blood cells and platelets and bleeding. Susceptibility to infections and bleeding is increased, which can be life-threatening. Large doses of taxoid result in nerve damage, characterised by weakness, numbness and paralysis of the hands and feet.

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	Not Available	Not Available
sorbitan monooleate, ethoxylated	TOXICITY	IRRITATION
	Oral (rat) LD50: 37260 mg/kg ^[2]	Eye (rabbit): 150 mg - mild Skin (rabbit): - slight
Ethanol	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: 17100 mg/kg ^[1]	Eye (rabbit): 500 mg SEVERE
	Inhalation (rat) LC50: 64000 ppm/4h ^[2]	Eye (rabbit):100mg/24hr-moderate
	Oral (rat) LD50: >1187-2769 mg/kg ^[1]	Skin (rabbit):20 mg/24hr-moderate Skin (rabbit):400 mg (open)-mild
citric acid, monohydrate	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1] Oral (rat) LD50: 3000 mg/kg ^[2]	Eye (rabbit): 5 mg/30s mild
docetaxel	TOXICITY	IRRITATION
	Oral (rat) LD50: 300 mg/kg ^[2]	Not Available

Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. * Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

SORBITAN MONOOLEATE, ETHOXYLATED	<p>Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS.</p> <p>No significant acute toxicological data identified in literature search.</p> <p>The sorbitan esters are agents that typically find use as emulsifiers, stabilizers, and thickeners in foods, cosmetics and medical products. They do not represent a toxicological concern since they are derived from naturally occurring materials and are ultimately metabolised back to these same natural constituents.</p> <p>The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.</p> <p>Polyoxyethylene sorbitan monooleate (TW80) is widely used as an emulsifier or solubilizer in a variety of foods, cosmetics and other commercial Products. In addition, TW80 in water has been used as a vehicle for the delivery of other chemical agents to pregnant laboratory animals by the oral route of administration (eg. by gavage or in the drinking water). Based upon the large population of pregnant women potentially exposed to TW80, and because of its use as a vehicle in laboratory animal studies, TW80 was evaluated for potential developmental toxicity. Timed-mated Sprague-Dawley-derived (CD®) rats (25 per group) were exposed to 0, 500 or 5000 mg/kg/day of TW80. Aqueous solutions were delivered by gavage in a volume of 5 ml/kg of body weight on gestational days (gd) 6 through 15. At termination (gd 20), the uterus was removed and examined to determine pregnancy status, and to evaluate the number of resorptions, and dead or live foetuses. Dead or live foetuses were weighed, and live foetuses were examined for external, visceral and skeletal defects. All treated females survived to scheduled necropsy and 19-23 pregnancies per group were confirmed. No dose-related signs of toxicity were observed for individual animals during the in-life phase of the study or at scheduled necropsy. Average maternal body weight (gd 0, 3, 6, 9, 12, 15, 18, or 20) did not differ among treatment groups, nor was there a treatment related change in maternal weight gain during treatment or gestation (absolute or corrected). There were no treatment-related effects upon the following maternal organ weights: gravid weight (absolute), kidney weight (absolute or relative), and heart weight (absolute or relative). Relative maternal</p>
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	liver weight (% body weight on gd 20 or % corrected body weight) was elevated in both TW80 groups and absolute liver weight was elevated at 500 mg/kg/day. Maternal food intake was comparable across groups during the pre- and post-treatment periods, but was decreased by 14% during the first 3 days of treatment at 5000 mg/kg/day relative to the vehicle control group. No differences among groups were noted for the number of corpora lutea per dam, the number of implantation sites per dam or the percent preimplantation loss per litter. No adverse effects were noted on the growth, viability or morphological development of the conceptuses. In conclusion, the maternal LOAEL was 500 mg/kg/day (based upon an increase in maternal relative liver weight). No definitive adverse effects of TW80 upon prenatal development were noted in this study. Thus, the developmental NOAEL was greater than 5000 mg/kg/day .
ETHANOL	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
CITRIC ACID, MONOHYDRATE	Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.
DOCETAXEL	Leukopenia recorded. * Rhone-Poulenc

Acute Toxicity	☒	Carcinogenicity	✔
Skin Irritation/Corrosion	☒	Reproductivity	☒
Serious Eye Damage/Irritation	✔	STOT - Single Exposure	✔
Respiratory or Skin sensitisation	☒	STOT - Repeated Exposure	☒
Mutagenicity	☒	Aspiration Hazard	☒

Legend: ✖ – Data available but does not fill the criteria for classification
✔ – Data required to make classification available
☒ – Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

Ingredient	Endpoint	Test Duration (hr)	Species	Value	Source
Ethanol	EC50	24	Algae or other aquatic plants	0.0129024mg/L	4
Ethanol	EC50	48	Crustacea	2mg/L	4
Ethanol	LC50	96	Fish	42mg/L	4
Ethanol	NOEC	2016	Fish	0.000375mg/L	4
Ethanol	EC50	72	Algae or other aquatic plants	275mg/L	2
citric acid, monohydrate	EC10	24	Algae or other aquatic plants	>1000mg/L	4
docetaxel	EC50	96	Algae or other aquatic plants	3.719mg/L	3
docetaxel	EC50	96	Algae or other aquatic plants	40.082mg/L	3
docetaxel	LC50	96	Fish	3.129mg/L	3

Legend: *Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data*

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Ethanol	LOW (Half-life = 2.17 days)	LOW (Half-life = 5.08 days)
citric acid, monohydrate	LOW	LOW
docetaxel	HIGH	HIGH

Bioaccumulative potential

Ingredient	Bioaccumulation
Ethanol	LOW (LogKOW = -0.31)
citric acid, monohydrate	LOW (LogKOW = -1.64)
docetaxel	LOW (LogKOW = 2.7813)

Mobility in soil

Ingredient	Mobility
Ethanol	HIGH (KOC = 1)
citric acid, monohydrate	LOW (KOC = 10)
docetaxel	LOW (KOC = 14940)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	<p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> ▶ Reduction ▶ Reuse ▶ Recycling ▶ Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.</p> <ul style="list-style-type: none"> ▶ Antineoplastic (cytotoxic) wastes must be packed directly, ready for incineration, into colour-coded, secure, labelled, leak-proof containers sufficiently robust to withstand handling without breaking, bursting or leaking. ▶ Containers of special design are available for particular needs (such as disposal of sharps) and should be used. ▶ Once filled and closed, such containers must never be re-opened. ▶ Immediate containers must bear a nationally accepted symbol or device depicting cytotoxic substances and be labelled with the words: CYTOTOXIC WASTE - INCINERATE in a style of lettering approved by the national/ state authority. ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority.
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SECTION 14 TRANSPORT INFORMATION

Labels Required

	
Marine Pollutant	NO
HAZCHEM	•2YE

Land transport (ADG)

UN number	1170				
Packing group	II				
UN proper shipping name	ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)				
Environmental hazard	Not Applicable				
Transport hazard class(es)	<table border="0"> <tr> <td>Class</td> <td>3</td> </tr> <tr> <td>Subrisk</td> <td>Not Applicable</td> </tr> </table>	Class	3	Subrisk	Not Applicable
Class	3				
Subrisk	Not Applicable				
Special precautions for user	<table border="0"> <tr> <td>Special provisions</td> <td>144</td> </tr> <tr> <td>Limited quantity</td> <td>1 L</td> </tr> </table>	Special provisions	144	Limited quantity	1 L
Special provisions	144				
Limited quantity	1 L				

Air transport (ICAO-IATA / DGR)

UN number	1170														
Packing group	II														
UN proper shipping name	Ethanol or Ethanol. Solution														
Environmental hazard	Not Applicable														
Transport hazard class(es)	<table border="0"> <tr> <td>ICAO/IATA Class</td> <td>3</td> </tr> <tr> <td>ICAO / IATA Subrisk</td> <td>Not Applicable</td> </tr> <tr> <td>ERG Code</td> <td>3L</td> </tr> </table>	ICAO/IATA Class	3	ICAO / IATA Subrisk	Not Applicable	ERG Code	3L								
ICAO/IATA Class	3														
ICAO / IATA Subrisk	Not Applicable														
ERG Code	3L														
Special precautions for user	<table border="0"> <tr> <td>Special provisions</td> <td>A3A58A180</td> </tr> <tr> <td>Cargo Only Packing Instructions</td> <td>364</td> </tr> <tr> <td>Cargo Only Maximum Qty / Pack</td> <td>60 L</td> </tr> <tr> <td>Passenger and Cargo Packing Instructions</td> <td>353</td> </tr> <tr> <td>Passenger and Cargo Maximum Qty / Pack</td> <td>5 L</td> </tr> <tr> <td>Passenger and Cargo Limited Quantity Packing Instructions</td> <td>Y341</td> </tr> <tr> <td>Passenger and Cargo Limited Maximum Qty / Pack</td> <td>1 L</td> </tr> </table>	Special provisions	A3A58A180	Cargo Only Packing Instructions	364	Cargo Only Maximum Qty / Pack	60 L	Passenger and Cargo Packing Instructions	353	Passenger and Cargo Maximum Qty / Pack	5 L	Passenger and Cargo Limited Quantity Packing Instructions	Y341	Passenger and Cargo Limited Maximum Qty / Pack	1 L
Special provisions	A3A58A180														
Cargo Only Packing Instructions	364														
Cargo Only Maximum Qty / Pack	60 L														
Passenger and Cargo Packing Instructions	353														
Passenger and Cargo Maximum Qty / Pack	5 L														
Passenger and Cargo Limited Quantity Packing Instructions	Y341														
Passenger and Cargo Limited Maximum Qty / Pack	1 L														

Sea transport (IMDG-Code / GGVSee)

UN number	1170
Packing group	II
UN proper shipping name	ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Environmental hazard	Not Applicable

Transport hazard class(es)	IMDG Class	3
	IMDG Subrisk	Not Applicable
Special precautions for user	EMS Number	F-E, S-D
	Special provisions	144
	Limited Quantities	1 L

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15 REGULATORY INFORMATION**Safety, health and environmental regulations / legislation specific for the substance or mixture****SORBITAN MONOOLEATE, ETHOXYLATED(9005-65-6) IS FOUND ON THE FOLLOWING REGULATORY LISTS**

Australia Inventory of Chemical Substances (AICS)

ETHANOL(64-17-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

Australia Hazardous Substances Information System - Consolidated Lists

CITRIC ACID, MONOHYDRATE(5949-29-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Hazardous Substances Information System - Consolidated Lists

Australia Inventory of Chemical Substances (AICS)

DOCETAXEL(114977-28-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Not Applicable

National Inventory	Status
Australia - AICS	N (docetaxel)
Canada - DSL	N (docetaxel)
Canada - NDSL	N (citric acid, monohydrate; docetaxel; Ethanol; sorbitan monooleate, ethoxylated)
China - IECSC	N (docetaxel)
Europe - EINEC / ELINCS / NLP	N (docetaxel)
Japan - ENCS	N (citric acid, monohydrate; docetaxel; sorbitan monooleate, ethoxylated)
Korea - KECI	N (docetaxel)
New Zealand - NZIoC	N (docetaxel)
Philippines - PICCS	N (docetaxel)
USA - TSCA	N (docetaxel)
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION**Other information****Ingredients with multiple cas numbers**

Name	CAS No
sorbitan monooleate, ethoxylated	1340-85-8, 141927-23-3, 178631-96-4, 209796-63-4, 253447-34-6, 361534-35-2, 37199-23-8, 37280-84-5, 51377-27-6, 541509-66-4, 61723-75-9, 8050-83-7, 9005-65-6, 9015-07-0, 9050-49-1, 9050-57-1

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:

www.chemwatch.net

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average

PC – STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit.

IDLH: Immediately Dangerous to Life or Health Concentrations

OSF: Odour Safety Factor

NOAEL: No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit Of Detection

OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index

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