

Safety Data Sheet acc. to OSHA HCS

Printing date 10/06/2023

Revision date 10/06/2023

1 Identification

- **Product identifier**
- **Trade name:** Docetaxel Polymeric Nanoparticles
- **Synonym**
- **Article number:** 39769
- **Application of the substance / the mixture**
This product is for research use - Not for human or veterinary diagnostic or therapeutic use.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Cayman Chemical Co.
1180 E. Ellsworth Rd.
Ann Arbor, MI 48108
USA
- **Information department:** Product safety department
- **Emergency telephone number:**
During normal opening times: +1 (734) 971-3335
US/CANADA: 800-424-9300
Outside US/CANADA: 703-741-5970

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS08 Health hazard

Toxic to Reproduction 2

H361 Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity - Repeated Exposure 2
H373 May cause damage to organs through prolonged or repeated exposure.



GHS07

Skin Irritation 2

H315 Causes skin irritation.

Eye Irritation 2A

H319 Causes serious eye irritation.

- **Label elements**
- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

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- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Warning

- **Hazard-determining components of labeling:**

Sodium chloride
Docetaxel (hydrate)

- **Hazard statements**

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H361 Suspected of damaging fertility or the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.

- **Precautionary statements**

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.
P264 Wash thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 If on skin: Wash with plenty of water.
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.
P321 Specific treatment (see on this label).
P314 Get medical advice/attention if you feel unwell.
P362+P364 Take off contaminated clothing and wash it before reuse.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 2
Fire = 0
Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



HEALTH 2 Health = 2
FIRE 0 Fire = 0
REACTIVITY 0 Reactivity = 0

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 77-86-1 RTECS: TY2900000	Tris base	6.61%
CAS: 7647-14-5 RTECS: VZ4725000	Sodium chloride	4.37%
CAS: 114977-28-5 RTECS: DA4172750	Docetaxel (hydrate)	1.1%

- **Other ingredients**

CAS: 9003-11-6 RTECS: TP6000000	Poloxanlene	45.39%
CAS: 6138-23-4 RTECS: LZ5776547	Trehalose (hydrate)	27.34%
CAS: 9002-96-4 RTECS: TR1581200	Tocofersolan	15.03%
CAS: 7558-80-7 RTECS: WA1900000	Sodium phosphate, Monobasic	0.109%
CAS: 67-68-5 RTECS: PV6210000	Dimethyl sulfoxide	0.03%

4 First-aid measures

- **Description of first aid measures**
- **General information:**
Immediately remove any clothing soiled by the product.
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:** In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Use fire fighting measures that suit the environment.
A solid water stream may be inefficient.
- **Special hazards arising from the substance or mixture**
67-56-1 During heating or in case of fire poisonous gases are produced.

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- **Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**

- **PAC-1:**

9003-11-6	Poloxanlene	6.9 mg/m ³
77-86-1	Tris base	18 mg/m ³
67-68-5	Dimethyl sulfoxide	150 ppm

- **PAC-2:**

9003-11-6	Poloxanlene	76 mg/m ³
77-86-1	Tris base	190 mg/m ³
67-68-5	Dimethyl sulfoxide	290 ppm

- **PAC-3:**

9003-11-6	Poloxanlene	460 mg/m ³
77-86-1	Tris base	1,200 mg/m ³
67-68-5	Dimethyl sulfoxide	1,800 ppm

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
- **Information about protection against explosions and fires:**
Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:** Store in accordance with information listed on the product insert.
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.

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- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Store protective clothing separately.
Avoid contact with the eyes and skin.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product 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.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**



Tightly sealed goggles

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Dry Powder
Color:	White
- **Odor:** Characteristic
- **Odor threshold:** Not determined.

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· pH-value at 20 °C (68 °F):	7.2
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not determined.
· Decomposition temperature:	Not determined.
· Ignition temperature:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Soluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Organic solvents:	0.0 %
VOC content:	0.03 %
Solids content:	100.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

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11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

77-86-1 Tris base

Oral	TDLO	3,000 ml/kg (mouse)
	LD50	5,500 mg/kg (mouse)
		5,900 mg/kg (rat)
	Intraperitoneal LD50	3,350 mg/kg (mouse)
	Intrapritoneal LD50	3,350 mg/kg (mouse)

7647-14-5 Sodium chloride

Oral	LDLO	1,000 mg/kg (man)
	TDLO	650 ml/kg (man)
	LD50	4,000 mg/kg (mouse)
Inhalative		3,000 mg/kg (rat)
	LD50	4 g/kg (mouse)
	LC50	320 mg/m ³ (mouse)
	TCLO	0.63 mg/m ³ (human)
Irritation of skin	LCLO	29,300 mg/m ³ /7h (mouse)
	Irritation	500 mg/24h (rabbit) mild
Irritation of eyes	Irritation	100 mg/24h (rabbit) moderate
	Intraperitoneal LD50	2,602 mg/kg (mouse)
	Subcutaneous LD50	31.6 mg/kg (rat)
	Intravenous LD50	59.5 mg/kg (rat)
	Data	15 mg/3D (human) mild
	Subcutaneous LD50	3 g/kg (mouse)

- **Primary irritant effect:**

- **on the skin:** Irritant to skin and mucous membranes.

- **on the eye:** Irritating effect.

- **Sensitization:** No sensitizing effects known.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- | | |
|---------------------------------------|-----------------|
| · UN-Number | |
| · DOT, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · DOT, IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · DOT, ADN, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · DOT, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |

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- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":** not regulated

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

9003-11-6	Poloxanlene	ACTIVE
77-86-1	Tris base	ACTIVE
7647-14-5	Sodium chloride	ACTIVE
7558-80-7	Sodium phosphate, Monobasic	ACTIVE
67-68-5	Dimethyl sulfoxide	ACTIVE

- **Hazardous Air Pollutants**

None of the ingredients is listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value)**

None of the ingredients is listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

All chemicals may pose unknown hazards and should be used with caution. This SDS applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. Cayman Chemical Company assumes

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no responsibility for incidental or consequential damages, including lost profits, arising from the use of these data. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Cayman Chemical Company assumes no responsibility for the completeness or accuracy of the information contained herein.

· **Department issuing SDS:** Environment protection department.

· **Contact:** -

· **Date of preparation / last revision** 10/06/2023

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Irritation 2: Skin corrosion/irritation – Category 2

Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

Toxic to Reproduction 2: Reproductive toxicity – Category 2

Specific Target Organ Toxicity - Repeated Exposure 2: Specific target organ toxicity (repeated exposure) – Category 2

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