



SAFETY DATA SHEET

1. Identification

Product identifier	Daunorubicin Hydrochloride	
Other means of identification		
Catalog number	1164700	
CAS number	23541-50-6	
Chemical name	5,12-Naphthacenedione, 8-acetyl-10-[(3-amino-2,3,6-trideoxy-alpha-L-lyxo-hexopyranosyl)]oxy]-7,8,9,10-tetrahydro- 6,8,11-trihydroxy-1-methoxy-, (8S-cis)-, hydrochloride	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 3
	Germ cell mutagenicity	Category 1
	Carcinogenicity	Category 1A
	Reproductive toxicity	Category 1
	Specific target organ toxicity, repeated exposure	Category 1 (heart, bone marrow)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Toxic if swallowed. May cause genetic defects. May cause cancer. May damage fertility or the unborn child. Causes damage to organs (heart, bone marrow) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.
Storage	Store locked up.

Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Daunorubicin Hydrochloride		23541-50-6	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Bone marrow suppression. Cardiac toxicity. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment of anthracycline antineoplastic overdose should be symptomatic and supportive and may include the following: Filgrastim may be useful in treating severe granulocytopenia. For fever or infection, take cultures and administer appropriate antibiotics. Treat bleeding from bone marrow suppression with transfusions of packed red blood cells and platelets. Cardiac monitoring is recommended. Dexrazoxane may prevent cardiomyopathy. Treatment of cardiomyopathy consists of vigorous management of congestive heart failure with digitalis preparations, diuretics, and after-load reducers such as ACE inhibitors. Hemodialysis is not likely to be effective, however hemoperfusion initiated within minutes of overdose may reduce serum levels.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

Exposure limit values

Industrial Use Material

Type

Value

Daunorubicin Hydrochloride
(CAS 23541-50-6)

TWA

0.1 micrograms/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Needles. Crystalline powder.

Color

Red. Orange.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

370.4 - 374 °F (188 - 190 °C) (decomposes)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Freely soluble.

Solubility (other) Methanol: Freely soluble.
Alcohol: Slightly soluble.
Chloroform: Very slightly soluble.
Acetone: Practically insoluble.
Ether: Practically insoluble.
Benzene: Practically insoluble.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Chemical family Anthracycline glycoside.

Molecular formula C₂₇H₂₉NO₁₀ . HCl

Molecular weight 563.98 g/mol

pH in aqueous solution 4.5 - 6.5 Solution: 0.5%

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NO_x. HCl.

11. Toxicological information**Information on likely routes of exposure**

Inhalation Knowledge about health hazard is incomplete.

Skin contact Knowledge about health hazard is incomplete.

Eye contact Knowledge about health hazard is incomplete.

Ingestion Toxic if swallowed.

Symptoms related to the physical, chemical, and toxicological characteristics Anthracycline antineoplastics: Fainting. Tiredness. Gastrointestinal disturbances. Hair loss. Reddish discoloration of urine. Fever. Chills. Cough. Hoarseness. Joint, stomach, lower back, or side pain. Painful or difficult urination. Darkening of soles, palms or nails. Unusual bleeding or bruising. Pinpoint red spots on skin. Sores in mouth and throat. Swelling of feet or legs. Weakness. Shortness of breath. Fast, slow or irregular heartbeat. Absence of menstruation.

Information on toxicological effects

Acute toxicity Toxic if swallowed.

Product	Species	Test Results
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Daunorubicin Hydrochloride (CAS 23541-50-6)		
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Oral		
LD50	Mouse	205 mg/kg

Product	Species	Test Results
	Rat	290 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about sensitization hazard is incomplete.	
Skin sensitization	Knowledge about sensitization hazard is incomplete.	
Germ cell mutagenicity	May cause genetic defects.	
Mutagenicity		
Ames test		
Result: Positive		
Mutagenicity: In vitro V79 hamster cell assay		
Result: Positive		
Mutagenicity: In vitro human lymphoblasts		
Result: Positive		
Sister chromatid exchange: In vivo assay in bone marrow		
Result: Positive		
Carcinogenicity	May cause cancer. Secondary malignancies are potential delayed effects of many antineoplastic agents, although it is not clear whether the effect is related to their mutagenic or immunosuppressive action. The effect of dose and duration of therapy is also unknown, although risk seems to increase with long-term use.	
	Carcinogenicity: Oral dose	
	Result: Negative for carcinogenicity.	
	Species: Mouse	
	Carcinogenicity: Repeated subcutaneous doses	
	Result: Increased local sarcomas.	
	Species: Mouse	
	Carcinogenicity: Single IV dose	
	Result: Increased mammary and kidney tumors.	
	Species: Rat	
IARC Monographs. Overall Evaluation of Carcinogenicity	Not listed.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)	Not regulated.	
US. National Toxicology Program (NTP) Report on Carcinogens	Not listed.	
Reproductive toxicity	May damage fertility or the unborn child. Antineoplastic therapy can adversely affect fertility through gonadal suppression. These effects appear to be related to dose and length of therapy and may be irreversible. In general, antineoplastic agents administered during the first trimester of pregnancy may increase the risk of birth defects, but when given during the second or third trimester, may only increase the risk of growth retardation.	
Reproductivity		
0.05 mg/kg/day Gestational study		
Result: Increased fetal abnormalities and miscarriage.		
Species: Rabbit		
0.25 mg/kg Fertility study		
Result: Testicular atrophy and aspermatogenesis.		
Species: Dog		
4 mg/kg/day Gestational study		
Result: Increased incidence of malformations.		
Species: Rat		
Specific target organ toxicity - single exposure	Knowledge about health hazard is incomplete.	
Specific target organ toxicity - repeated exposure	Causes damage to organs (heart, bone marrow) through prolonged or repeated exposure.	
Aspiration hazard	Based on available data, the classification criteria are not met.	
Further information	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.	

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data is available on the degradability of this substance.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT	
UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Daunomycin hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	III
IATA	
UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Daunomycin hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	III
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

DOT; IATA



General information	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.
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15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
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TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Daunorubicin Hydrochloride (CAS 23541-50-6) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical

Classified hazard categories	Yes Acute toxicity (any route of exposure) Germ cell mutagenicity Carcinogenicity Reproductive toxicity Specific target organ toxicity (single or repeated exposure)
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SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Daunorubicin Hydrochloride (CAS 23541-50-6)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations**California Proposition 65**

WARNING: This product can expose you to Daunorubicin Hydrochloride, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Developmental toxin

Daunorubicin Hydrochloride (CAS 23541-50-6) Listed: July 1, 1990

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Daunorubicin Hydrochloride (CAS 23541-50-6)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	11-24-2008
Revision date	01-31-2019
Version #	04
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