Epirubicin Hydrochloride

sc-203041

Material Safety Data Sheet

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Epirubicin Hydrochloride

STATEMENT OF HAZARDOUS NATURE
CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA


SUPPLIER
Santa Cruz Biotechnology, Inc.
2145 Delaware Avenue
Santa Cruz, California 95060
800.457.3801 or 831.457.3800
EMERGENCY:
ChemWatch
Within the US & Canada: 877-715-9305
Outside the US & Canada: +800 2436 2255
(1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS
C27-H29-N-O11.HCl, "5, 12-naphthacenedione, ", "10-[(3-amino-2, 3, 6-trideoxy-alpha-L-arabinohexopyr", "anosyloxy)-7, 8, 9, 10-tetrahydro-6, 8, 11-trihydroxy-8", "-(hydroxyacetyl)-1-methoxy-, hydrochloride, (8S-ci", s), "(8S-cis)-10-[(3-amino-2, 3, 6-trideoxy-alpha-L-arabi", "no-hexopyranosyl)oxy]-7, 8, 9, 10-tetrahydro6, 8, 11-tr", "ihydroxy-8-(hydroxyacetyl)-1-methoxy-5, 12-naphthac", "enedione hydrochloride", "4' -epi-adriamycin hydrochloride", "4-epidoxorubicin hydrochloride", IMI-28, "pidorubicin hydrochloride", Pharmorubicin, Farmarubicine, Farmorubicin, Farmorubicina, Farmorubicine, Ellence, "antineoplastic/ immunosuppressive", anthracycline, "derivative of doxorubicin"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

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

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4

CANADIAN WHMIS SYMBOLS

EMERGENCY OVERVIEW

RISK

May cause CANCER.
May cause heritable genetic damage.
May impair fertility.
May cause harm to the unborn child.
Harmful by inhalation, in contact with skin and if swallowed.
Irritating to eyes, respiratory system and skin.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
■ 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.
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■ May cause irreversible, partial or total deafness when aminoglycoside antibiotics are given by injection, by mouth or when applied as an aerosol to open wounds, or damaged skin. Effects are dose related. Large doses may cause nausea, vomiting and diarrhoea. Prolonged oral therapy may cause malabsorption syndrome with steatorrhoea and diarrhoea which may be severe. Supra-infection may occur. Neuromuscular blockade and respiratory depression and arrest may follow intraperitoneal injection.

EYE

■ This material can cause eye irritation and damage in some persons.

SKIN

■ Skin contact with the material may be harmful; systemic effects may resultfollowing absorption.
■ This material can cause inflammation of the skin oncontact in some persons.
■ The material may accentuate any pre-existing dermatitis condition.
■ Open cuts, abraded or irritated skin should not be exposed to this material.
■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

■ Inhalation of dusts, generated by the material, during the course of normalhandling, may be harmful.
■ The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

■ Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.
There is ample evidence that this material can be regarded as being able to cause cancer in humans based on experiments and other information.
Based on experiments and other information, there is ample evidence to presume that exposure to this material can cause genetic defects that can be inherited.
Ample evidence exists from experimentation that reduced human fertility is directly caused by exposure to the material.
Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.
Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.
There is limited evidence that, skin contact with this product is more likely to cause a sensitization reaction in some persons compared to the general population.
Long-term exposure to aminoglycoside antibiotics (such as gentamicin) can damage the kidneys and malabsorption with a fatty, foul-smelling diarrhea. In some patients, there may be hearing loss and damage to the balancing system, after topical application or injection.
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The inhibitory effects of the aminoglycoside antibiotics on calcium ion homeostasis in peripheral neurones, vascular smooth muscle and the myocardium are thought to be the cause of disruption to haemodynamic control mechanisms. Therefore the adverse effect of aminoglycosides on blood circulation does not seem to be due to cytotoxic damage of cardiovascular tissues but is related to a reversible interaction with calcium ion binding sites of excitable membranes. Many of the biological actions of aminoglycosides in mammals, including cellular damage of the kidney an inner ear tissues, are also associated with disturbance of membrane phospholipids where calcium ion is normally distributed. Kerzee, J. Kevin et al: Cardiovascular Toxicology, Part 7, Third Edition; Edited Daniel Acosta Jr.; Published Taylor and Francis 2001.
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.
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Anthracycline therapies may produce a range of long-term effects.
Allergic reactions to mitoxantrone have been reported (rarely); these include vasculitis, facial oedema, skin rashes, breathlessness, tachypnoea, cyanosis, unrecordable pulse and blood pressure. Two patients developed selective alopecia of white but not dark hair.

Transient blue-green discoloration of the urine, and occasionally the sclerae, may occur with mitoxantrone; daunorubicin therapies may produce a transient red discolouration of the urine.
Daunorubicin and doxorubicin therapies produce alopecia, impaired wound healing, and enhanced toxic effects of radiotherapy. Both also produce a unique chronic effect on the heart. Cardiotoxicity is characterised by a clinically insignificant arrhythmia and late reversible cardiomyopathy. Most patients show cardiac damage though the incidence of congestive heart failure is low if treatment is stopped after a cumulative dose of 450 mg/m2 (doxorubicin) to 550 mg/m2 body-surface (daunorubicin).
Evidence suggest that the semiquinoline metabolite of doxorubicin (and other anthracyclines) produces a superoxide anion and superhydroxide free radicals with iron as a cofactor. The heart muscle has only a low concentration of protective enzymes, so the free radicals cause lipid peroxidation, destroying the mitochondria in myocardial cells.
Intravesical instillation of doxorubicin into 4-week female rats induced an increase in DNA synthesis associated with abnormal cell division in the bladder (epithelial hyperplasia characterised by elevated nuclear cytoplasmic ratios, cytomegaly and pleomorphism).
This indicates that chemotherapy may itself play a role in the promotion of bladder carcinogenicity. Doxorubicin produces mammary tumours, in rats, after a single intravenous injection and local sarcomas after single or repeated subcutaneous injections.
Intravenous injection of a single dose of daunorubicin, in rats, produced mammary and kidney tumours; repeated subcutaneous injections in mice produce local sarcomas.
· CAUTION: May produce immunosuppression in individuals occupationally exposed to the material.
Exposure to immunosuppressives may aggravate infectious diseases.
Chronic exposure to therapeutic doses of compounds which produce immunosuppression has been associated with development of lymphomas (occasionally malignant) and mammary tumours. These may be secondary effects induced by activation of endogenous retroviruses.
Patients on immunosuppressive medications have a 10- to 100-fold increased risk of cancer compared to the general population. Furthermore, people who currently have or have already been treated for cancer have a higher rate of tumor progression and recurrence than patients with an intact immune system.
Patients receiving immunosuppressive regimens involving combinations of drugs, as part of an immunosuppressive regimen are at increased risk of developing lymphomas and other malignancies, particularly of the skin. The risk appears to be related to the intensity and duration of immunosuppression rather than to the use of any specific agent
Increased incidences of neoplasms, in mice and humans, have been reported after long-term immunosuppression by azathioprine and cyclosporin. Cyclosporin has been classified as a human carcinogen, by IARC, based on development of lymphomas after repeated and prolonged exposures to therapeutic doses.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
epirubicin hydrochloride	56390-09-1	>98

Section 4 - FIRST AID MEASURES

SWALLOWED
· IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. · Where Medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:

EYE
■ If this product comes in contact with the eyes: · 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.

SKIN
■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED
· If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

NOTES TO PHYSICIAN
■ 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.
Dexrazoxane chelates iron and copper ions before they can form a complex with the anthracycline, which decreases free radical formation and is thus cardioprotective. When dexrazoxane is given with doxorubicin in dose ratios between 10 and 20:1, patients are able to tolerate larger cumulative doses of doxorubicin without increased risks of cardiac effects.
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Aminoglycoside antibiotics may be removed by hemodialysis or to a lesser extent by peritoneal dialysis. Calcium salts given intravenously have been used to counter neuromuscular blockade; the effectiveness of neostigmine has been variable.
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Epirubicin is extensively distributed through the body after administration and undergoes metabolism in the liver to epirubicinol (13-hydroxy-epirubicin) which also exhibits antineoplastic activity. Epirubicin is reported to have a plasma half-life of about 40 hours.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible

Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

EXTINGUISHING MEDIA
· Water spray or fog.
· Foam.

FIRE FIGHTING
· Alert Emergency Responders and tell them location and nature of hazard.
· Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS
· Combustible solid which burns but propagates flame with difficulty.
· Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), hydrogen chloride, phosgene, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.
May emit poisonous fumes.
May emit corrosive fumes.

FIRE INCOMPATIBILITY
■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids,chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION
Glasses:
Gloves:
Respirator:
Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS
· Clean up waste regularly and abnormal spills immediately.
· Avoid breathing dust and contact with skin and eyes.
· Wear protective clothing, gloves, safety glasses and dust respirator.
· Use dry clean up procedures and avoid generating dust.
· Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
· Dampen with water to prevent dusting before sweeping.
· Place in suitable containers for disposal.
It is recommended that areas handling final finished product have cytotoxic spill kits available.
Spill kits should include:
· impermeable body covering,
· shoe covers,
· latex and utility latex gloves,
· goggles,
· approved HEPA respirator,
· disposable dust pan and scoop,
· absorbent towels,
· spill control pillows,
· disposable sponges,
· sharps container,
· disposable garbage bag and
· hazardous waste label.
To avoid accidental exposure due to waste handling of cytotoxics:
· 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.
All personnel likely to involved in a antineoplastic (cytotoxic) spill must receive practical training in:
· the correct procedures for handling cytotoxic drugs or waste in order to prevent and minimize the risk of spills
· the location of the skill kit in the area.
MAJOR SPILLS
· Clear area of personnel and move upwind.
· Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING
■ 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.

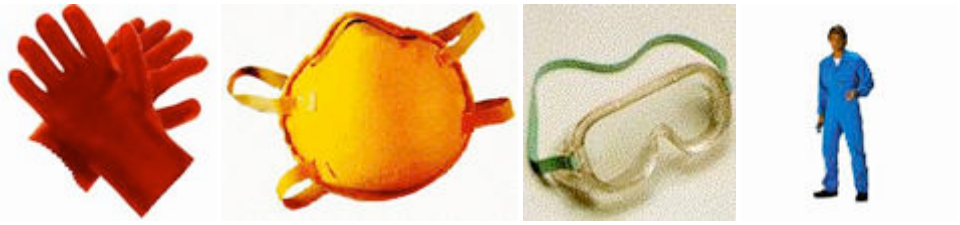
Emphasise controls on containment.
· Avoid all personal contact, including inhalation.
· Wear protective clothing when risk of exposure occurs.
Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
· Do NOT cut, drill, grind or weld such containers.
· In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS
■ Glass container.
· Polyethylene or polypropylene container.
· Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS
■ Antineoplastics (cytotoxics):
· should be clearly identifiable to all personnel involved in their handling
· should be stored in impervious break-resistant containers.
Observe manufacturer's storing and handling recommendations.
Solutions should be protected from sunlight.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS
The following materials had no OELs on our records
• epirubicin hydrochloride: CAS:56390-09-1

PERSONAL PROTECTION


RESPIRATOR
Particulate
Consult your EHS staff for recommendations

EYE
· 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 lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET
■ NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.
Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
· frequency and duration of contact,
· chemical resistance of glove material,
· glove thickness and
· dexterity
Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).
· When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
· When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
· Contaminated gloves should be replaced.
Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
· Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
· Double gloving should be considered.
· PVC gloves.
· Protective shoe covers.
· Head covering.
Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

· polychloroprene
· nitrile rubber
· butyl rubber
· fluorocaoutchouc
· polyvinyl chloride
Gloves should be examined for wear and/ or degradation constantly.

OTHER

· Employees working with confirmed human carcinogens should be provided with, and be required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), shoe covers and gloves prior to entering the regulated area.
· Employees engaged in handling operations involving carcinogens should be provided with, and required to wear and use half-face filter-type respirators with filters for dusts, mists and fumes, or air purifying canisters or cartridges. A respirator affording higher levels of protection may be substituted.
· Emergency deluge showers and eyewash fountains, supplied with potable water, should be located near, within sight of, and on the same level with locations where direct exposure is likely.
· Prior to each exit from an area containing confirmed human carcinogens, employees should be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers must be identified with suitable labels. For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood.
· Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood.
· When handling antineoplastic materials, it is recommended that a disposal work-uniform (such as Tyvek or closed front surgical-type gown with knit cuffs) is worn.
· For quantities up to 500 grams a laboratory coat may be suitable.
· For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
· For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
· For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
· Eye wash unit.
· Ensure there is ready access to an emergency shower.
· For Emergencies: Vinyl suit.

ENGINEERING CONTROLS

· Employees exposed to confirmed human carcinogens should be authorized to do so by the employer, and work in a regulated area.
· Work should be undertaken in an isolated system such as a "glove-box" . Employees should wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.
· Within regulated areas, the carcinogen should be stored in sealed containers, or enclosed in a closed system, including piping systems, with any sample ports or openings closed while the carcinogens are contained within.
· Open-vessel systems are prohibited.
· Each operation should be provided with continuous local exhaust ventilation so that air movement is always from ordinary work areas to the operation.
· Exhaust air should not be discharged to regulated areas, non-regulated areas or the external environment unless decontaminated. Clean make-up air should be introduced in sufficient volume to maintain correct operation of the local exhaust system.
· For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood. Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood.
· Except for outdoor systems, regulated areas should be maintained under negative pressure (with respect to non-regulated areas).
· Local exhaust ventilation requires make-up air be supplied in equal volumes to replaced air.
· Laboratory hoods must be designed and maintained so as to draw air inward at an average linear face velocity of 150 feet/ min. with a minimum of 125 feet/ min. Design and construction of the fume hood requires that insertion of any portion of the employees body, other than hands and arms, be disallowed.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.
Mixes with water.

State	Divided solid	Molecular Weight	580.03
Melting Range (°F)	365 (decomposes)	Viscosity	Not Applicable
Boiling Range (°F)	Not applicable	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	Not available
Decomposition Temp (°F)	365	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	>1
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE

Orange-red, hygroscopic powder; mixes with water.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

· Presence of incompatible materials.
· Product is considered stable.

STORAGE INCOMPATIBILITY

■ Avoid reaction with oxidizing agents.
Incompatible with heparin and, possibly, aminophylline, cephalothin sodium, dexamethasone, fluorouracil, or hydrocortisone.
Prolonged contact with any solution of an alkaline pH should be avoided as it will result in hydrolysis of the drug.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

EPIRUBICIN HYDROCHLORIDE

TOXICITY AND IRRITATION

EPIRUBICIN HYDROCHLORIDE:
■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Intravenous (woman) TDLo: 1622 mg/kg	Nil Reported
Oral (rat) LD50: 1350 mg/kg	
Intraperitoneal (rat) LD50: 10.8 mg/kg	
Subcutaneous (rat) LD50: 17.6 mg/kg	
Oral (mouse) LD50: >2000 mg/kg	
Subcutaneous (mouse) LD50: 37.5 mg/kg	
Intravenous (mouse) LD50: 31.5 mg/kg	
Intravenous (Human) TDLo: 1622 mg/kg	
Intravenous (Rat) LD50: 17 mg/kg	
Intravenous (Dog) LD50: 2.25 mg/kg	
Intravenous (Rat) TDLo: 7.5 mg/kg	

■ 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. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.
Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).
Category D Drug: ie drugs which have caused, or may be suspected to cause an increased incidence of human foetal malformations or irreversible damage.

Section 12 - ECOLOGICAL INFORMATION

No data

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
epirubicin hydrochloride	HIGH		LOW	HIGH

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.
¦ 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.
A Hierarchy of Controls seems to be common - the user should investigate:

· Reduction
· Reuse
· Recycling
· Disposal (if all else fails)
This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.
DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.
· Antineoplastic (cytotoxic) wastes must be packed directly, ready for incineration, into color-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.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

epirubicin hydrochloride (CAS: 56390-09-1) is found on the following regulatory lists;
"US - California Proposition 65 - Priority List for the Development of MADLs for Chemicals Causing Reproductive Toxicity","US - California Proposition 65 - Reproductive Toxicity","US - Maine Chemicals of High Concern List"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE
■ Cumulative effects may result following exposure*.
■ Possible skin sensitiser*.
* (limited evidence).

Reasonable care has been taken in the preparation of this information, but the author makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The author makes no representations and assumes no liability for any direct, incidental or consequential damages resulting from its use. For additional technical information please call our toxicology department on +800 CHEMCALL.

■ 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/references.

■ The (M)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.

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