

Doxorubicin • HCl (Adriamycin)

sc-200923



The Power is Question

Material Safety Data Sheet

Hazard Alert Code Key: **EXTREME** **HIGH** **MODERATE** **LOW**

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

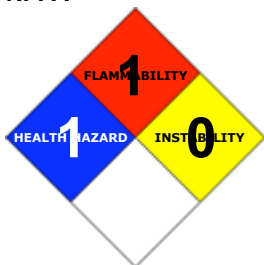
PRODUCT NAME

Doxorubicin • HCl (Adriamycin)

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

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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, "hydroxydaunorubicin hydrochloride", "5, 12-naphthacenedione, ", "10-[(3-amino-2, 3, 6-trideoxy-alpha-L-lyxohexopyranosyl)oxy]-7, 8, 9, ", "10-tetrahydro-6, 8, 11-trihydroxy-8-(hydroxyacetyl)-1-methoxy-, ", "hydrochloride, (8S-cis)-", "ADM hydrochloride", ADR, Adriacin, Adriamycin, "Adriamycin hydrochloride", Adriblastina, Adriblastin, Dox, "Dox hydrochloride", FI-106, FI-6804, "antineoplastic/ immunosuppressive", "anthracycline antibiotic"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

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

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



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

Harmful if swallowed.
May cause CANCER.
May cause heritable genetic damage.
May cause harm to the unborn child.

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.

EYE

- Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn).
- Slight abrasive damage may also result.

SKIN

- Skin contact is not thought to produce harmful health effects (as classified using animal models). Systemic harm, however, has been identified following exposure of animals by at least one other route and the material may still produce health damage following entry through wounds, lesions or abrasions.
 - 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

- The material is not thought to produce respiratory irritation (as classified using animal models). Nevertheless inhalation of dusts, or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.
 - Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.
 - Anthracyclines, which are used in chemotherapy, has been shown to cause nausea and vomiting, suppression of bone marrow, inflammation of the oral cavity, hair loss and leukemia.
- It is also toxic to the heart, causing changes in the ECG and heart failure can result later, after months of treatment.

CHRONIC HEALTH EFFECTS

- 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 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.

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 and 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.

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 discoloration 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.

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.

· 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	%
doxorubicin hydrochloride	25316-40-9	>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.

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.

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.

Myelosuppression and cardiotoxicity are life threatening. Symptomatic supportive measures should be instituted with particular attention paid to prevention and treatment of severe haemorrhage or infection secondary to severe, persistent bone marrow suppression.

[Australian Prescription Products Guide 1994].

Doxorubicin shows rapid plasma clearance and significant tissue binding. It does not cross the blood brain barrier.

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 (NO_x), 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:

1. NEOPRENE

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 be involved in an 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 spill 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.

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.

- Store in original containers.
- Keep containers securely sealed.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- doxorubicin hydrochloride: CAS:25316-40-9

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
- fluorocautchouc
- polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

OTHER

- 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.
- 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.

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	579.99
Melting Range (°F)	399- 401 (decomp)	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	3.8-6.5 (0.5%)
Decomposition Temp (°F)	Not available	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 (thin needles); mixes with water (2%). Aqueous solutions are yellow-orange in acid, orange-red when neutral, and violet-blue at pHs exceeding 9.0.

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.

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

Section 11 - TOXICOLOGICAL INFORMATION

doxorubicin hydrochloride

TOXICITY AND IRRITATION

DOXORUBICIN HYDROCHLORIDE:

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

TOXICITY	IRRITATION
Intravenous (man) LDLo: 2.57 mg/kg/3w -I	Nil Reported
Intraperitoneal (rat) LD50: 16.03 mg/kg	
Subcutaneous (rat) LD50: 21.84 mg/kg	
Intravenous (rat) LD50: 12.5 mg/kg	
Intramuscular (rat) LD50: 16 mg/kg	

Oral (mouse) LD50: 698 mg/kg

Intraperitoneal (mouse) LD50: 11.16 mg/kg

Subcutaneous (mouse) LD50: 7.68 mg/kg

Intravenous (mouse) LD50: 1.245 mg/kg

Intramuscular (mouse) LD50: 13.7 mg/kg

Intravenous (rabbit) LD50: 5.98 mg/kg

■ Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Lachrymation, muscle weakness, cardiomyopathy including infarction, acute pulmonary oedema, diarrhoea, changes in kidney tubules, leukaemia, allergic dermatitis after topical application, paternal effects, maternal effects recorded.

Equivocal tumourigen by RTECS criteria.

Category D Drug: ie drugs which have caused, or may be suspected to cause an increased incidence of human foetal malformations or irreversible damage.

CARCINOGEN

Adriamycin (Doxorubicin hydrochloride)	US Environmental Defense Scorecard Suspected Carcinogens	Reference(s)	NTP-C
VPVB_(VERY~	US - Maine Chemicals of High Concern List	Carcinogen	CA Prop 65
VPVB_(VERY~	US - Maine Chemicals of High Concern List	Carcinogen	

Section 12 - ECOLOGICAL INFORMATION

No data

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
doxorubicin 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

doxorubicin hydrochloride (CAS: 25316-40-9) is found on the following regulatory lists;

"US - California Proposition 65 - Carcinogens", "US - California Proposition 65 - Priority List for the Development of MADLs for Chemicals Causing Reproductive Toxicity", "US - California Proposition 65 - Priority List for the Development of NSRLs for Carcinogens", "US - California Proposition 65 - Reproductive Toxicity", "US - Maine Chemicals of High Concern List", "US - Pennsylvania - Hazardous Substance List", "US National Toxicology Program (NTP) 11th Report Part B. Reasonably Anticipated to be a Human Carcinogen"

Section 16 - OTHER INFORMATION

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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