

MAYNE CYTARABINE INJECTION



ChemWatch Material Safety Data Sheet
CHEMWATCH 62611
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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

MAYNE CYTARABINE INJECTION

STATEMENT OF HAZARDOUS NATURE


Not considered a hazardous substance according to OSHA 29 CFR 1910.1200.



SUPPLIER

Mayne Pharma (USA) Inc.
Mack Cali Centre II
650 From Rd.
Paramus, NJ 07652
USA
Phone: 1.888.606.2245
E-mail: medicalinformation@us.maynepharma.com

HAZARD RATINGS

Flammability: 0

Toxicity: 2

Body Contact: 0

Reactivity: 0

Chronic: 2

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

PRODUCT USE

Cytarabine is a pyrimidine nucleoside analogue used as a antineoplastic agent to inhibit the synthesis of deoxyribonucleic acid. Also has antiviral and immunosuppressant properties. Used mainly in the treatment of leukaemia, especially acute myeloid leukaemia in adults (in association with thioguanine and doxorubicin or daunorubicin). Also used in the treatment of Herpes infection. Usually given intravenously.

SYNONYMS

C9-H13-N3-O5.HCl	arabinofuranosylcytosine hydrochloride
1-beta-D-arabinofuranosylcytosine hydrochloride	1-beta-D-arabinofuranosylcytosine monohydrochloride
arabinosylcytosine hydrochloride	arabitin hydrochloride
aracytidine hydrochloride	aracytin hydrochloride
cytarabine hydrochloride	cytosar hydrochloride
cytosine, 1-beta-D-arabinofuranosyl-, hydrochloride	CA
ARA-C	AC-1075
Cycolcide	Iretin
NSC-63878	4-amino-1-beta-D-arabinofurosylpyrimidin-2 [1H] one monohydrochloride
spongocytidine hydrochloride	antineoplastic/ viricide/ immunosuppressive

Section 2 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
cytosine arabinose hydrochloride	69-74-9	10
water	7732-18-5	>85

Section 3 - HAZARDS IDENTIFICATION

CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

Ingestion may produce health damage*.
Cumulative effects may result following exposure*.
Exposure may produce irreversible effects*.
May be harmful to the fetus/ embryo*.
* (limited evidence).

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.

EYE

Although the material is not thought to be an irritant, direct contact with the eye may produce transient discomfort characterized by tearing or conjunctival redness (as with windburn).

SKIN

The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

INHALED

The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

CHRONIC HEALTH EFFECTS

Danger of cumulative effects.

There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment.

Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.

Principal routes of exposure are by accidental skin and eye contact and by inhalation of vapours especially at higher temperatures.

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. Digestive system effects may include inflammation of the mouth cavity, mouth ulcers, esophagus inflammation, abdominal pain and bleeds, diarrhea, bowel ulcers and perforation. Reversible hair loss can result and wound healing may be delayed. Long-term effects on the gonads may cause periods to stop and inhibit sperm production. Most anti-cancer drugs can potentially cause mutations and birth defects, and coupled with the effects of the suppression of the immune system, may also cause cancer.

Section 4 - FIRST AID MEASURES

SWALLOWED

If poisoning occurs, contact a doctor or Poisons Information Center.

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

EYE

- If this product comes in contact with the eyes:
- Immediately hold the eyes open and wash continuously for at least 15 minutes with fresh running water.
- Ensure irrigation under eyelids by occasionally lifting the upper and lower lids.
- Transport to hospital or doctor without delay.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

If product comes in contact with the skin:

- Immediately remove all contaminated clothing, including footwear (after rinsing with water).
- Wash affected areas thoroughly with water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- If fumes or combustion products are inhaled:
- Remove to fresh air.
- Lay patient down. Keep warm and rested.
- If breathing is shallow or has stopped, ensure clear airway and apply resuscitation. Transport to hospital, or doctor.

NOTES TO PHYSICIAN

Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

Flash Point (°F): None

Lower Explosive Limit (%): Not applicable

Upper Explosive Limit (%): Not applicable

Autoignition Temp (°F): Not applicable

EXTINGUISHING MEDIA

There is no restriction on the type of extinguisher which may be used.

FIRE FIGHTING

- Use water delivered as a fine spray to control fire and cool adjacent area.
- Avoid spraying water onto liquid pools.
- Do not approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- Non combustible.
- Not considered to be a significant fire risk, however containers may burn.

FIRE INCOMPATIBILITY

Avoid contamination with strong oxidizing agents as ignition may result

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up all spills immediately.
- Avoid breathing vapors and contact with skin and eyes.
- Control personal contact by using protective equipment.
- Contain and absorb spill with sand, earth, inert material or vermiculite.
- Wipe up.
- Place in a suitable labeled container for waste disposal.

MAJOR SPILLS

- Clean up all spills immediately.
- Secure load if safe to do so.
- Bundle/collect recoverable product.
- Collect remaining material in containers with covers for disposal.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area. Avoid contact with moisture.
- Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately.
- Launder contaminated clothing before re-use.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

RECOMMENDED STORAGE METHODS

SUITABLE CONTAINER

STORAGE INCOMPATIBILITY

Avoid reaction with oxidizing agents

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.

- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations.

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- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
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- Observe manufacturer's storing and handling recommendations.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

SUMMARY:

INGREDIENT DATA

DETAILS:

None assigned. Refer to individual constituents.

EXPOSURE STANDARDS FOR MIXTURE

"Worst Case" computer-aided prediction of spray/ mist or fume/ dust components and concentration:

Composite Exposure Standard for Mixture (TWA) :100 mg/m³.

Operations which produce a spray/mist or fume/dust, introduce particulates to the breathing zone. If the breathing zone concentration of ANY of the components listed below is exceeded, "Worst Case" considerations deem the individual to be overexposed. Component Breathing Zone ppm Breathing Zone mg/m³ Mixture Conc (%)

INGREDIENT DATA

For each of the following
CYTOSINE ARABINOSIDE HYDROCHLORIDE:
WATER:

No exposure limits set by NOHSC or ACGIH

PERSONAL PROTECTION



EYE

Safety glasses with side shields

Chemical goggles.

Contact lenses pose a special hazard; soft lenses may absorb irritants and all lenses concentrate them.

HANDS/FEET

Wear general protective gloves, e.g.. light weight rubber gloves.

OTHER

Overalls

- Impervious protective clothing
- Eyewash unit.

ENGINEERING CONTROLS

Local exhaust ventilation usually required. If risk of overexposure exists, wear an approved respirator. Correct fit is essential to obtain adequate protection an approved self contained breathing apparatus (SCBA) may be required in some situations. Provide adequate ventilation in warehouse or closed storage area.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Liquid.

Mixes with water.

Molecular Weight: Not applicable

Boiling Range (°F): >212

Melting Range (°F): <0

Specific Gravity (water=1): 1.03

Solubility in water (g/L): Miscible

pH (as supplied): 7.5-7.9

pH (1% solution): Not available

Vapor Pressure (kPa): As water

Volatile Component (%vol): As water

Evaporation Rate: As water

Relative Vapor Density (air=1): Not available

Flash Point (°F): None

Lower Explosive Limit (%): Not applicable

Upper Explosive Limit (%): Not applicable

Autoignition Temp (°F): Not applicable

Decomposition Temp (°F): Not available

State: Liquid

APPEARANCE

Clear solution; mix with water.

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerization will not occur.

STORAGE INCOMPATIBILITY

Avoid reaction with oxidizing agents

Section 11 - TOXICOLOGICAL INFORMATION

Mayne Cytarabine Injection

Not available. Refer to individual constituents.

Section 12 - ECOLOGICAL INFORMATION

Section 13 - DISPOSAL CONSIDERATIONS

US EPA Waste Number & Descriptions

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

- Consult manufacturer for recycling options and recycle where possible .
- Consult Waste Management Authority for disposal.
- Incinerate residue at an approved site.
- Recycle containers where possible, or dispose of in an authorized landfill.

Section 14 - TRANSPORTATION INFORMATION

DOT Information

Shipping Name:

NONE

Hazard Class: None

UN/NA Number: None

Packing Group: None

Labels Required:

Additional Shipping Information:

International Transport Regulations:

IMO: None

Section 15 - REGULATORY INFORMATION

US Federal Regulations

A. General Product Information

In addition to Federal and State regulation, local regulations may apply. Check with your local regulatory authorities.

B. Component Information

This material contains one or more of the following chemicals required to be identified under SARA Section 302 (40 CFR 455 Appendix A) SARA Section 313 (40 CFR 372.65) and/or CERCLA (40 CFR 302.4):

Component	TSCA
cytosine arabinose hydrochloride	Y
	N

State Regulations

A. General Product Information

No component(s) require labeling under California Proposition 65

B. Component Information

The following components appear on one or more of the following state hazardous substance lists.

Component	CAS No	CA	FL	MA	MN	NJ	PA
cytosine arabinose hydrochloride	69-74-9	N	N	N	N	N	N

Other Regulations

A. General Product Information

All components are listed in the European Inventory of New and Existing Chemical Substances (EINECS)

B. Component Information

CANADA

The following component(s) are identified under the Canadian Hazardous Products Act Ingredient Disclosure List:

All of this product's components are on the Canadian Domestic Substances List.

Section 16 - OTHER INFORMATION

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