



Cladribine Injection

SAFETY DATA SHEET

Australia and New Zealand GHS

According to The Model Work Health and Safety Regulations and Responsible Care New Zealand (RCNZ) - HSNO CoP 8-1

Section 1: Identification: Product identifier and chemical identity

Product identifier

Product Name: Cladribine Injection

Synonyms: Cladribine Solution for Injection; LITAK® (Cladribine) 2 mg/mL Solution for Injection; LITAK cladribine 10 mg/5mL injection

Pure substance/mixture: Mixture

Recommended use of the chemical and restrictions on use

Recommended Use: Pharmaceutical. Use only as directed.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

Uses advised against: No information available.

Details of manufacturer or importer

Mylan Australia
Level 1, 30 The Bond
30-34 Hickson Road,
Millers Point, NSW, Australia
Phone: (02) 9298 3999
www.mylan.com.au

Mylan New Zealand Ltd.
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Auckland
New Zealand 1060
Phone: +64 9 259 2068
www.mylan.co.nz/

E-mail address:

SDScontact@mylan.com

Emergency telephone number

Emergency telephone number:

24 hr. Emergency Contact ChemTel

International: +1-813-248-0585

Australia: 1-300-954-583

Section 2: Hazard(s) identification

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

GHS Classification:

Carcinogenicity, Category 2 - (H351)

Reproductive toxicity, Category 1A - (H360)

Specific target organ toxicity (repeated exposure), Category 1 - (H372) [Central nervous system, Gastrointestinal system, Bone marrow]

Label elements



Health hazard.

Signal word: Danger

Hazard statements: H351 - Suspected of causing cancer
H360 - May damage fertility or the unborn child
H372 - Causes damage to organs through prolonged or repeated exposure

Precautionary Statements - Prevention: Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Use personal protective equipment as required
Do not breathe dust/fume/gas/mist/vapours/spray

Precautionary Statements - Response: IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage: Store locked up

Precautionary Statements - Disposal: Dispose of contents/container to an approved waste disposal plant

Other hazards which do not result in classification
No information available.

Section 3: Composition and information on ingredients, in accordance with Schedule 8

Mixture

| Chemical name | CAS No | Weight-% | Hazard statements |
|---------------|-----------|----------|--|
| Cladribine | 4291-63-8 | < 0.5 | H301 - Toxic if swallowed H311 - Toxic in contact with skin H331 - Toxic if inhaled H315 - Causes skin irritation H319 - Causes serious eye irritation H351 - Suspected of causing cancer H341 - Suspected of causing genetic defects H360 - May damage fertility or the unborn child H335 - May cause respiratory irritation H372 - Causes damage to organs through prolonged or repeated exposure |

| Chemical name | CAS No | Weight-% |
|---------------------------|-------------|----------|
| Non-hazardous ingredients | Proprietary | Balance |

Section 4: First aid measures

Description of first aid measures

Overdose: Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Centre right away.

General advice: Show this safety data sheet to the doctor in attendance. IF exposed or concerned: Get medical advice/attention.

Poisons Information Centre, Australia: 13 11 26

Poisons Information Centre, New Zealand: 0800 764 766

Inhalation: IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.

Skin contact: Wash off immediately with plenty of water for at least 15 minutes. If skin irritation or rash occurs: Get medical advice/attention.

Eye contact: In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation persists or eye and/or skin remains bonded: Get medical advice/attention.

Ingestion: Rinse mouth thoroughly with water. Get medical attention if symptoms occur.

Self-protection of the first aider: First aider: Pay attention to self-protection. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Most important symptoms and effects, both acute and delayed

Symptoms: Headache. Nausea. Rashes. Fatigue. Anemia.

Chronic symptoms: May cause adverse reproductive effects - such as birth defect, miscarriages, or infertility. May cause cancer. Causes damage to the following organs through prolonged or repeated exposure: Central nervous system, Gastrointestinal system, Bone marrow.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Section 5: Firefighting measures

Suitable Extinguishing Media

Suitable Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: No information available.

Specific hazards arising from the chemical

Hazardous combustion products: Carbon oxides. Nitrogen oxides. Hydrogen chloride.

Special protective actions for fire-fighters

Special protective equipment for fire-fighters: Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Hazchem code

Not applicable

Other information

Refer to Section 9 for flammability properties.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions: Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.

Other Information: Refer to protective measures listed in Sections 7 and 8.

For emergency responders: Use personal protection recommended in Section 8. Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

Environmental precautions

Do not flush into surface water or sanitary sewer system. Should not be released into the environment. See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment: Prevent further leakage or spillage if safe to do so.

Methods for cleaning up: Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust.

Precautions to prevent secondary hazards

Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections

See section 8 for more information. See section 13 for more information.

Section 7: Handling and storage, including how the chemical may be safely used

Precautions for safe handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Ensure adequate ventilation.

General hygiene considerations: Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place. Store under refrigeration at 2°C to 8°C (35.6°F to 46.4°F). Do not freeze. Do not re-use. Once opened, discard. Keep out of reach of children. Store locked up. Store locked up.

Incompatible materials: Strong oxidising agents, strong acids, and strong bases.

Specific end use(s): Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

Section 8: Exposure controls and personal protection

Control parameters

Exposure Limits: No information available

Appropriate engineering controls

Engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Eye/face protection: Wear safety glasses with side shields (or goggles).

Skin and body protection: Wear suitable protective clothing.

Hand protection: Wear suitable gloves.

Respiratory protection: Use appropriate respiratory protection.

Environmental exposure controls: Do not allow into any sewer, on the ground or into any body of water.

Section 9: Physical and chemical properties

Information on basic physical and chemical properties

| | |
|-------------------------|-------------------|
| Physical state: | Liquid |
| Appearance: | solution |
| Colour: | clear, colourless |
| Odour: | No data available |
| Odour threshold: | No data available |

| | |
|--|-------------------|
| pH: | No data available |
| Melting point / freezing point: | No data available |
| Boiling point / boiling range: | No data available |
| Flash point: | No data available |
| Evaporation rate: | No data available |
| Flammability (solid, gas): | No data available |
| Upper flammability limit: | No data available |
| Lower flammability limit | No data available |
| Vapour pressure: | No data available |
| Vapour density: | No data available |
| Relative density: | No data available |
| Water solubility: | No data available |
| Solubility(ies): | No data available |
| Partition coefficient: | No data available |
| Autoignition temperature: | No data available |
| Decomposition temperature: | No data available |
| Kinematic viscosity: | No data available |
| Dynamic viscosity: | No data available |
| Explosive properties: | No data available |
| Oxidising properties | No data available |
| <u>Other Information</u> | |
| VOC Content (%): | No data available |

Section 10: Stability and reactivity

Reactivity

Hazardous reactions will not occur under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Extremes of temperature and direct sunlight.

Incompatible materials

Strong oxidising agents, strong acids, and strong bases.

Hazardous decomposition products

Decomposition will not occur under normal conditions.

Section 11: Toxicological information

Acute toxicity

Information on likely routes of exposure

Product Information

Inhalation: Specific test data for the substance or mixture is not available.

Eye contact: Specific test data for the substance or mixture is not available.

Skin contact: Causes mild skin irritation.

Ingestion: Specific test data for the substance or mixture is not available.

Symptoms: Headache. Nausea. Rashes. Fatigue. Anemia.

Numerical measures of toxicity

Oral LD50: No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: No information available. Contains a known or suspected carcinogen.

Reproductive toxicity: Contains a known or suspected reproductive toxin.

STOT - single exposure: Based on available data, the classification criteria are not met.

STOT - repeated exposure: May cause damage to organs through prolonged or repeated exposure (Central nervous system, Gastrointestinal system, bone marrow).

Aspiration hazard: Based on available data, the classification criteria are not met.

Section 12: Ecological information

Ecotoxicity

No information available.

Persistence and degradability

No information available

Bioaccumulative potential

No information available

Mobility

No information available

Other adverse effects

No information available

Section 13: Disposal considerations**Waste treatment methods**

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

Section 14: Transport information

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

In accordance with ADG / IATA / IMDG**UN Number**

Not regulated

UN proper shipping name

Not regulated

Transport hazard class(es)

Not regulated

Packing group

Not regulated

Environmental hazards

No

Special precautions for user

No information available

Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Hazchem code

Not applicable

Section 15: Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulations****Australia:****Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)**

Classified as a scheduled poison according to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

Poison Schedule Number: 4

See section 8 for national exposure control parameters

New Zealand:

See section 8 for national exposure control parameters

Carcinogenicity: 6.7B

Reproductive toxicity: 6.8A

Specific target organ toxicity (repeated exposure): 6.9A

International Regulations

Ozone-depleting substances (ODS): Not applicable

Persistent Organic Pollutants: Not applicable

The Rotterdam Convention: Not applicable

Section 16: Any other relevant information

Revision Date: 05-June-2020

Classification procedure: In accordance with The Model Work Health and Safety Regulations, and the Globally Harmonized System of Classification and Labelling of Chemicals 3rd Revised Edition.

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Key or legend to abbreviations and acronyms used in the safety data sheet:**Legend, Section 8: Exposure controls and personal protection**

TWA: TWA (time-weighted average)

STEL: STEL (Short Term Exposure Limit)

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