

MATERIAL SAFETY DATA SHEET

Version 001 – 04. April 2016
Supersedes: new

1. COMPOUND IDENTITY/FORMULATION AND COMPANY INFORMATION

Description of compound or formulation

Article number: CDA-25-S.10
Common/Trade Name: Litak® 10 (solution for subcutaneous injection or intravenous infusion: vials containing 10 mg/5 ml)
Chemical Names: 2-chloro-2'-deoxyadenosine

Synonyms

Cladribinum, 2-Chloro-2'-deoxy-b-D-adenosinum, 2-CdA, 2-chloro-2'-deoxyadenosine, Cladribine

Manufacturer's/Supplier's information

Manufacturer's Name: Lipomed AG
Address: Fabrikmattenweg 4
CH-4144 Arlesheim
Tel: 0041 61 702 02 00
E-Mail: save@lipomed.com

Emergency Telefax Number: 0041 61 702 02 20

Address for detailed scientific information

LIPOMED AG
Fabrikmattenweg 4
CH-4144 Arlesheim
Switzerland
Tel.: 0041 61 702 02 00
Fax: 0041 61 702 02 20
E-Mail: save@lipomed.com

2. HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>
2-CdA	0.2	4291-63-8

3. HEALTH HAZARD DATA

Routes of Entry: Product may be absorbed via ingestion or skin contact.

Date: 04.04.2016
Issued: S. Lombardi Borgia

Date: 04.04.2016
Checked: P. Wolff

Date: 04.04.2016
QA-approved: D. Foechterlen





Health Hazard (Acute & Chronic): It is a possible human teratogen. LITAK® may affect the digestive and central nervous systems. Product affects the blood forming systems, liver, and kidneys. LITAK® is fetotoxic.

Carcinogenicity: NTP? NO

IARC Monographs? NONE

OSHA Regulated? NO

Signs & Symptoms of Exposure:

May cause irritation to eyes, skin and respiratory system or skin rash. May cause fatigue, headache, nausea, vomiting and dizziness and a variety of other systemic effects.

4. FIRST AID MEASURES

Inhalation: Not applicable (water solution)

Skin Exposure: Wash skin with copious amounts of soapy water.

Eye Exposure: Flush eyes with large amounts of water for 15 minutes. Seek attention of a physician.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious and medical assistance is not available, induce vomiting.

5. FIRE AND EXPLOSION HAZARD DATA

Flash point (Method Used): Not applicable (water solution)

Flammable Limits: Not applicable **LEL:** Not applicable **UEL:** Not applicable

Unusual Fire/Explosion Hazards: None

6. ACCIDENTAL RELEASE INFORMATION

Release to Land: Absorb LITAK® with towels or absorbents and dispose of with 0.1 N HCl solution according to local, state and federal regulations. Wear appropriate protective equipment. Prevent spills from entering drains or sewers. Wash area with 0.1 N HCl solution.

Release to Water: Refer to local water authority. Drain disposal is not recommended.

7. PRECAUTIONS FOR SAFE HANDLING AND USE

Instructions for proper handling and disposal of antineoplastic drugs should be considered according to the guidelines for the handling with and disposal of cytotoxic drugs.

Cautions handling with LITAK® and with the prepared infusion is required.

The use of disposable gloves, protective glasses and garments are recommended to avoid the direct contact with the drug.

Date: 04.04.2016
Issued: S. Lombardi Borgia

Date: 04.04.16
Checked: P. Wolff

Date: 04.04.2016
QA-approved: D. Foechterlen





8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Protective Gloves: Latex or nitrile

Eye Protection: Safety glasses

Other Protective Clothing or Equipment:

Necessary clothing to prevent skin contact such as a lab coat with a closed front, long sleeves, or elastic cuffs.

Work/Hygienic Practices:

Wash hands following use. No eating, drinking or smoking while handling this product.

9. PHYSICAL/CHEMICAL CHARACTERISTICS

Physical state:	Aqueous solution (2 mg/ml in 0.9% NaCl solution)
Appearance and Odour:	Clear, colourless solution with no odour
pH:	6.5-7.5
Melting Point:	Not applicable
Boiling point:	100 °C
Vapour Pressure:	Not applicable
Relative Density: (Specific Gravity)	1,0059
Vapour Density:	Not applicable
Evaporation Rate:	Not applicable
Solubility in Water:	Soluble

10. STABILITY AND REACTIVITY DATA

Stability

Stable. Product is decomposed to 2-Chloro-6-aminopurine and 2-Deoxy-D-ribose by acidic pH
1. Avoid strong oxidizers or water reactive materials.

11. TOXICOLOGICAL INFORMATION

Acute toxicity (single dose toxicity)

Mouse, intraperitoneal	MTD = 120 mg/kg (360 mg/m ²)
	LD ₅₀ = 150 mg/kg (450 mg/m ²)
	LD ₉₀ = 180 mg/kg (540 mg/m ²)

Chronic toxicity (repeated dose toxicity)

Mouse, intraperitoneal	MTD = 50 mg/kg/day
	LD ₅₀ = 75 mg/kg/day
	LD ₉₀ = 100 mg/kg/day

Human, man	TD _{Lo} = 700 µg/kg/7D-C
------------	-----------------------------------

Date: 04.04.2016
Issued: S. Lombardi Borgia

Date: 04.04.16
Checked: P. Wolff

Date: 04.04.2016
QA-approved: D. Foechterlen

12. ENVIRONMENTAL IMPACT INFORMATION

N-Octanol/water partition coefficient: 0.551

LITAK® does not present a risk for the environment.

Therefore no others detailed environmental effect analysis and further testing are available.

13. DISPOSAL INFORMATION

Dispose of via incineration at an approved/permitted waste disposal facility according to federal, state and local guidelines or decompose with 0.1 N HCl solution.

14. TRANSPORTATION INFORMATION

LITAK® is not a hazardous material.

Storage: cooled +2°C up to +8°C
Dispatch: feasible at room temperature
interim storage for max. 2 weeks

15. REGULATORY INFORMATION

R-Phrases

- R-45 May cause cancer.
- R-46 May cause heritable genetic damage.
- R-60 May impair fertility.
- R-61 May cause harm to the unborn child.

S-Phrases

- S-45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
- S-53 Avoid exposure - obtain special instructions before use.

16. OTHER DATA

Aseptic conditions must be observed while handling with LITAK® and preparing the infusions. LITAK® should be administered under the supervision of a qualified physician with experience in cancer chemotherapy.

This information is given without any warranty or representation. It is believed to be correct but does not claim to be all inclusive and shall be used only as a guide. Lipomed AG shall not be held liable for any damage resulting from handling or contact with the above products. It is offered solely for your consideration, investigation and verification.

Date: 04.04.2016
Issued: S. Lombardi Borgia

Date: 04.04.16
Checked: P. Wolff

Date: 04.04.2016
QA-approved: D. Foechterlen



