



MSN Laboratories Private Limited
R&D Center, Formulation Division

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Product Name	Decitabine for Injection 50 mg/Vial	

1. Product Information

Product Name : Decitabine for Injection
Strength : 50 mg/Vial

2. Information on Active

C.A.S. No : : 2353-33-5
Molecular Formula : $C_8H_{12}N_4O_4$
Molecular Weight : 228.21 g/mol
Chemical Name : 4-Amino-1-(2-deoxy- β -D-erythro-pentofuranosyl)-1,3,5-triazin2(1H)-one

3. Hazards Identification

Precautionary Statements:

The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: White to almost white powder.

Routes of Exposure:

Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

Inhalation : No data available

Ingestion : No data available

Skin and Eye : No data available

Potential Environmental Effects:

Unknown.

4. First Aid Measures

If Inhaled:

Remove to fresh air. If breathing is irregular or stopped, administer artificial respiration. Call a physician immediately.

In case of skin contact:

Wash off immediately with plenty of water for at least 15 minutes. Take off all contaminated clothing

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immediately. Get medical attention if irritation develops and persists.

In case of eye

In case of contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.

If swallowed:

If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a physician immediately.

5. Fire Fighting Measures

Suitable Extinguishing Media:

Carbon dioxide, dry chemical powder. Water spray. Avoid spill into drains, surface and ground water and soil.

Special protective equipment:

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6. Accidental Release Measures

Personal Precautions:

Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental Precautions:

Prevent further leakage or spillage. Do not let product enter into drains.

Methods and Materials for Containment and Clean-Up:

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

7. Handling and Storage

Precautions for safe handling:

Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

Conditions for safe storage:

Preserve in tight, light-resistant containers and store at 2°C and 8°C .

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8. Exposure Controls/Personal Protection

Personal protective equipment:

Glasses, Gloves, Respiratory, Particulate etc.

Respiratory protection:

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N99 (US) or type P2 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection:

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Handle with gloves.

Eye Protection:

Wear protective chemical safety goggles.

Skin and body protection:

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Skin: Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Hygiene measures:

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

9. Physical and Chemical Properties
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Appearance: White to almost white powder.

Melting point : 198 – 199°C.

Boiling Point : No data available.

Flash Point : No data available.

Ignition temperature : No data available.

Internal explosion limit : No data available.

Upper explosion limit : No data available.

Solubility : Sparingly soluble in water.



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Dissociation Constant (pKa) : No data available.

10. Stability and Reactivity

Chemical Stability:

Stable under recommended storage conditions.

Conditions to avoid:

Heat, open flame and moisture.

Incompatible materials:

Strong oxidizing agents.

Hazardous decomposition products:

Hazardous decomposition products formed under fire conditions. Carbon oxides, nitrogen oxides (Nox).

11. Toxicological Information

Acute toxicity : LD₅₀ I.v (mouse) : 200 mg/kg

Skin corrosion/irritation : Toxic in contact with skin.

Serious eye damage/eye irritation : Toxic in contact with eye.

Respiratory or skin sensitization : Toxic if inhaled.

Mutagenicity : Decitabine was not mutagenic.

Carcinogenicity : No conventional carcinogenicity studies were conducted with Decitabine.

Reproductive toxicology & Teratology : Decitabine has been shown to be teratogenic and shows effect on fertility and reproductive function.

Specific target organ toxicity – repeated exposure : Kidney, liver and salivary glands.

Aspiration hazard : No data available.

12. Ecological Information

Toxicity : No data available.

Persistence and Degradability : No data available.

Bioaccumulative Potential (log Kow) : No potential PBT.

Mobility in soil : No data available.

PBT and vPvB assessment : No data available.

Other adverse effects : No data available.

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13. Disposal Considerations

Waste treatment method : Disposal by incineration is recommended. Dispose in according with applicable federal, state and local regulations. Local regulation may be more stringent than regional and national requirements.

14. Transport Information

Not regulated for transport under USDOT, EUDAR, IATA or IMDG regulations.

15. Regulatory Information

This safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008/EC.

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

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