NordMedica

# MATERIAL SAFETY DATA SHEET



## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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### Material Name: Amsacrine Solution for Injection, 50 mg/ml

**Trade Name:** Amsidyl; Amsidine; Amekrin
**Synonyms:** m-Amsa Solution for Injection
**Chemical Family:** Mixture
**Intended Use:** Pharmaceutical product used as Antineoplastic

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

| Ingredient | CAS Number | EU EINECS List | % |
|---|---|---|---|
| N,N-dimethylacetamide | 127-19-5 | 204-826-4 | 94.8 |
| Amsacrine | 51264-14-3 | 257-094-3 | 5.2 |

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Red-orange solution
**Signal Word:** WARNING

**Statement of Hazard:**
Harmful if swallowed.
May cause allergic skin reaction.
May cause harm to the unborn child.
Possible carcinogen and mutagen

**Additional Hazard Information:**

**Short Term:** May cause allergic skin reaction, May be harmful if swallowed. (Based on components) May be absorbed through the skin and cause systemic effects.

**Known Clinical Effects:** Bone marrow suppression is the most serious adverse effect seen during clinical use. Effects reported during clinical use included vomiting and diarrhea.

| | | |
|---|---|---|
| **EU Indication of danger:** | Toxic to reproduction: | Category 2 |
| | Mutagenic: | Category 2 |
| | Carcinogenic: | Category 2 |

**EU Hazard Symbols:**

**EU Risk Phrases:**

R43 - May cause sensitization by skin contact.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.

**Note:**

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases.
Your needs may vary depending upon the potential for exposure in your workplace.

## 4. FIRST AID MEASURES

**Eye Contact:**

Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:**

Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

**Ingestion:**

Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:**

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:**

Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:**

No data available

**Fire Fighting Procedures:**

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

**Fire / Explosion Hazards:**

Fine particles (such as dust and mists) may fuel fires/explosions.

## 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Eliminate all sources of ignition and ventilate area using explosion-proof equipment. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

**General Handling:** Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use with adequate ventilation.

**Storage Conditions:** Keep in tightly closed containers away from heat and light.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Amsacrine**

**OEL TWA-8 Hr:** 6 ug/m3, Sensitizer, Skin

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Personal Protective Equipment:**

**Hands:** Wear two layers of disposable gloves.
**Eyes:** Safety glasses or goggles
**Skin:** Protective coveralls should be worn. The sleeves should either be taped or have gloves worn over them to prevent material from contacting the skin.
**Respiratory protection:** If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

## 9. PHYSICAL AND CHEMICAL PROPERTIES:

| | | | |
|---|---|---|---|
| **Physical State:** | Solution | **Color:** | Red-orange |
| **Molecular Formula:** | Mixture | **Molecular Weight:** | Mixture |

**Boiling Point (°C):** >100

**Flash Point (Liquid) (°C):** >55

## 10. STABILITY AND REACTIVITY

**Stability:** Stable
**Conditions to Avoid:** Avoid direct sunlight, conditions that might generate heat, and sources of ignition.
**Incompatible Materials:** None known

**Hazardous Decomposition Products:** None known
**Polymerization:** No data available

## 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Acute Toxicity: (Species, Route, End Point, Dose)**

**Amsacrine**

| | | | |
|---|---|---|---|
| Rat | Oral | LD50 | 100 mg/kg |
| Mouse | Oral | LD50 | 243 mg/kg |
| Rat | IV | LD50 | 24.8 mg/kg |
| Mouse | IV | LD50 | 54.1 mg/kg |

**N,N-diethylacetamide**

| | | | |
|---|---|---|---|
| Rat | Oral | LD50 | 1500 mg/kg |

**Irritation / Sensitization: (Study Type, Species, Severity)**

**Amsacrine**

| | | |
|---|---|---|
| Skin Sensitization - GPMT | Guinea Pig | Positive |

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

**Amsacrine**

| | | | | | |
|---|---|---|---|---|---|
| 13 Week(s) | Rat | Intraperitoneal | 0.0975 mg/day | LOAEL | Bone marrow |

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

**Amsacrine**

| | | | | | |
|---|---|---|---|---|---|
| Embryo / Fetal Development | Rat | Intraperitoneal | 0.5 mg/kg/day | LOAEL | Teratogenic |
| Embryo / Fetal Development | Rat | Intraperitoneal | 0.5 mg/kg/day | LOAEL | Fetotoxicity |

**Amsacrine**

| | | |
|---|---|---|
| Bacterial Mutagenicity (Ames) | *Salmonella* | Positive |
| *In Vitro* Chromosome Aberration | Chinese Hamster Ovary (CHO) cells | Positive |
| *In Vivo* Micronucleus | Mouse Bone Marrow | Positive |
| *In Vivo* Chromosome | Aberration Human Lymphocytes | Positive |
| Dominant Lethal Assay | Mouse | Positive |

**Amsacrine**

| | | | | | |
|---|---|---|---|---|---|
| 2 Year(s) | Rat | Intravenous | 1 mg/kg/day | LOAEL | Malignant tumors |

**Carcinogen Status:** See below

**Amsacrine**

**IARC:** Group 2B
**OSHA:** Present

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

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

## 15. REGULATORY INFORMATION

**EU Symbol:** T
**EU Indication of danger:** Toxic to reproduction, Category 2
Mutagenic Category 2
Carcinogenic: Category 2

**EU Risk Phrases:** R43 - May cause sensitization by skin contact.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.4

**EU Safety Phrases:** S24 - Avoid contact with skin.
S37 - Wear suitable gloves.
S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
S53 - Avoid exposure - obtain special instructions before use.

**OSHA Label:**
WARNING
Harmful if swallowed.
May cause allergic skin reaction.
May cause harm to the unborn child.
Possible carcinogen and mutagen

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**
Class D, Division 1, Subdivision B
Class D, Division 2, Subdivision A

**N,N-dimethylacetamide**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **EU EINECS List** | 204-826-4 |

**Amsacrine**

| | |
|---|---|
| **Australia (AICS):** | Present |
| **Standard for the Uniform Scheduling for Drugs and Poisons:** | Schedule 4 |
| **EU EINECS List** | 257-094-3 |

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 1 – Identification of the substance/preparation and the company/undertaking. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information. Updated Section 2 – Correction of excipient from N,N-diethylacetamid to N,N-dimethylacetamid.

**Prepared by:** Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety
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**End of Safety Data Sheet**