MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

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

Trade Name: Amsidyl; Amsidine; AMSA-PD; Amerkin
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-diethylacetamide	685-91-6	211-685-2	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

Pfizer OEL TWA-8 Hr: 6 ug/m^3, 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 Fetotoxicity
Embryo / Fetal Development Rat Intraperitoneal 0.5 mg/kg/day LOAEL Teratogenic

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.

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-diethylacetamide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	211-685-2

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 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.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet