



Material Safety Data Sheet

12601 Twinbrook Parkway,
Rockville, MD 20852 USA

Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

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RESIDUAL SOLVENT CLASS 2 - N-METHYLPYRROLIDONE

Catalog Number: 1601703

Revision Date:

November 3, 2008

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: N-methylpyrrolidone

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA

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Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

EMERGENCY OVERVIEW: Irritant. Combustible.

This reference standard contains N-methylpyrrolidone in dimethyl sulfoxide (DMSO). The mixture has not been tested to determine specific physical hazards, but it is considered potentially combustible.

DMSO is an irritant and is rapidly absorbed through the skin. It may carry dissolved chemicals into the body through this route.

N-methylpyrrolidone is an irritant.

Adverse Effects: Adverse effects of DMSO may include redness, itching, or rash on skin; garlic-like taste or odor on breath and skin; swelling of face; troubled breathing; shortness of breath; nasal congestion; gastrointestinal disturbances; drowsiness; and headache. N-methylpyrrolidone exposure may cause chronic eye irritation, and headaches. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: n/f

Acute: Eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material.

Cross Sensitivity: n/f

Target Organs: n/f

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

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Common Name: N-methylpyrrolidone

Formula: See Composition

Synonym: N-methylpyrrolidinone

Chemical Name: N-methyl-2-pyrrolidone in dimethyl sulfoxide

CAS: See Composition

RTECS Number: See Composition

Chemical Family: Cyclic amide (N-methylpyrrolidone)

Therapeutic Category: Residual solvent

Composition: N-Methylpyrrolidone (C₅H₉NO; CAS # 872-50-4; RTECS # UY5790000): 0.265%
Dimethyl sulfoxide (C₂H₆OS; CAS # 67-68-5; RTECS # PV6210000): 99.735%

SECTION 4 - FIRST AID MEASURES

Inhalation: Causes irritation. Avoid inhalation. Remove to fresh air.

Eye: Causes irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes.

Skin: Causes irritation. Avoid contact. Flush with copious quantities of soap and water. DMSO readily penetrates the skin and can enhance absorption of other chemicals.

Ingestion: Causes irritation. Avoid ingestion. Flush out mouth with water.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.

SECTION 5 - FIREFIGHTING MEASURES

Extinguisher Media: Alcohol foam or other appropriate media.

Fire and Explosion Hazards: N-Methylpyrrolidone and DMSO are combustible, and DMSO reacts violently with many acyl, aryl and non-metal halides, boron compounds and metal salts of oxoacids. Vapors may form explosive mixtures with air. Vapors may travel to sources of ignition and flash back. This mixture has not been tested.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Remove ignition sources. Ventilate enclosed spaces. Absorb with suitable material. Do not flush into a confined space such as a sewer. Avoid breathing vapors. Place spillage and all contaminated cleanup materials in an appropriately-labelled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

Handling: As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

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Engineering Controls: Engineering controls such as exhaust ventilation are recommended.**Respiratory Protection:** Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring.**Gloves:** Chemically compatible**Eye Protection:** Safety glasses or goggles**Protective Clothing:** Protect exposed skin.**Exposure Limits:** N-methylpyrrolidone:
AIHA: 10 ppm

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.**Appearance and Odor:** Clear liquid.**Odor Threshold:** n/f**pH:** n/f**Melting Range:** n/f**Boiling Point:** n/f**Flash Point:** n/f**Autoignition Temperature:** n/f**Evaporation Rate:** n/f**Upper Flammability Limit:** n/f**Lower Flammability Limit:** n/f**Vapor Pressure:** n/f**Vapor Density:** n/f**Specific Gravity:** n/f**Solubility in Water:** n/f**Fat Solubility:** n/f**Other Solubility:** n/f**Partition Coefficient: n-octanol/water:** n/f**Percent Volatile:** n/f**Reactivity in Water:** n/f**Explosive Properties:** n/f**Oxidizing Properties:** n/f**Formula:** See Composition**Molecular Weight:** n/f

SECTION 10 - STABILITY AND REACTIVITY
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Conditions to Avoid: n/f**Incompatibilities:** n/f**Decomposition Products:** When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions.**Stable?** Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES
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Oral Rat: N-methylpyrrolidone:
LD50: 3914 mg/kgDMSO:
LD50: 14500 mg/kg**Oral Mouse:** N-methylpyrrolidone:
LD50: 5130 mg/kgDMSO:
LD50: 7920 mg/kg**Other Toxicity Data:** N-methylpyrrolidone:
Inhalation Rat LC50: >400ppm, 3.1 mg/L/4hr
Skin Rabbit LD50: 2000 mg/kg, 8000 mg/kg
Skin Rat LD50: 2500 mg/kgDMSO:
Inhalation Rat LC50: >25 mg/L/40 hour
Skin Mouse LD50: 50 grams/kg
Skin Rat LD50: 40 grams/kg**Irritancy Data:** N-methylpyrrolidone:
Rabbit/eye (Standard Draize, 100 mg): moderate
Human/skin (Repeat Insult Patch Test): non-irritant
Rabbit/skin (50% solution): mildDMSO:
Rabbit/skin (Standard Draize, 500 mg/24 hour): mild
Rabbit/skin (Open Draize, 10 mg/24 hour): mild
Rabbit/eye (Standard Draize, 500 mg/24 hour): mild**Corrosivity:** n/f**Sensitization Data:** N-methylpyrrolidone:
Human (Repeat Insult Patch Test): non-sensitizing
Guinea Pig (1% solution): non-sensitizingDMSO:
Guinea Pig (Buehler Test): non-sensitizing**Listed as a Carcinogen by:** **NTP:** No **IARC:** No **OSHA:** No**Other Carcinogenicity Data:** N-methylpyrrolidone:
Methylpyrrolidone was not carcinogenic in rats in a 2-year inhalation study at concentrations up to 0.4 mg/L. There was no increase in tumors in mice receiving subcutaneous injections over a 17-month period. Hepatocellular adenomas and carcinomas occurred in mice administered oral doses up to 7200 ppm in diet for 18 months.**Mutagenicity Data:** N-methylpyrrolidone:
Methylpyrrolidone tested negative in the *S. typhimurium* assay (with and without activation), the Chinese hamster

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ovary HGPRT forward mutation assay, the mouse lymphoma assay, the rat primary hepatocyte unscheduled DNA synthesis (UDS) assay, the in vivo mouse micronucleus test, the in vivo mouse dominant lethal test, and the in vivo Chinese hamster inhalation test. It tested positive without activation in the yeast aneuploidy test.

DMSO:

Dimethyl sulfoxide did not show a potential to induce gene mutations in bacterial or yeast cells, and was not mutagenic in in vivo studies in *Drosophila*. Dimethyl sulfoxide did not induce micronuclei or sister-chromatid exchange in mice or chromosomal aberrations or sister chromatid exchange in mammalian cells, but did induce an increase in chromosomal aberrations in rats. [EPA 2007]

Reproductive and Developmental Effects: N-methylpyrrolidone:

In pregnant rats administered methylpyrrolidone at dermal doses of 270 mg/kg, pregnant rats administered oral doses of 997 mg/kg, and pregnant mice administered oral doses of 2637 mg/kg, fetotoxicity, embryotoxicity, and/or an increase in birth defects occurred in the presence of maternal toxicity. It is not clear if effects on the fetus could occur in the absence of maternal toxicity.

Increased preimplantation losses and skeletal abnormalities occurred, without maternal toxicity, in the offspring of pregnant rats given inhalation doses of 150 and 165 ppm, and embryonic loss and fetal malformations occurred at inhalation doses of 500 mg/kg/day.

DMSO:

Examination of the reproductive system during a 13-week inhalation repeated-dose toxicity study in rats revealed no abnormalities on estrus cycle in females, sperm count, motility or morphology in males, or on the reproductive organs of both sexes. In two oral developmental toxicity studies in rats, maternal effects included decreased food consumption and decreased body weight gain. Developmental effects included decreased fetal weights, higher rates of early resorptions per animal, increased total post-implantation loss, dilated renal pelvis, dilated ureters and reduced or delayed ossification of ribs. All of the fetal effects except dilated renal pelvis occurred at levels that demonstrated maternal toxicity. [EPA 2007]

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: N-methylpyrrolidone:
California Proposition 65: Developmental Toxicity

International Regulatory Information: N-methylpyrrolidone:
EINCES # 212-828-1

DMSO:

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EINECS # 200-664-3

SECTION 16 - OTHER INFORMATION

Revision: 03-Nov-08

Previous Revision Date: 13-Oct-03