



# 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 - 1,4-DIOXANE

Catalog Number: 1601521

Revision Date:

April 1, 2009

### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

**Common Name:** 1,4-Dioxane

**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

This reference standard contains 1,4-dioxane 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.

1,4-Dioxane is an irritant and possible carcinogen.

**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; and nasal congestion. Effects from exposure to 1,4-dioxane may include seizures, increased blood pressure, cough, drowsiness, headache, nausea, vomiting, liver and kidney damage, dizziness, difficulty breathing, loss of appetite, and stomach pain. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

**Overdose Effects:** Exposure to high levels of 1,4-dioxane has caused stomach pain, loss of appetite, scanty urine, coma, and death.

**Acute:** Eye, skin, gastrointestinal and/or respiratory tract irritation; central nervous system depression.

**Chronic:** Possible hypersensitization; liver and kidney damage; cancer.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to material; skin, eye, respiratory, neurological, liver, or kidney conditions.

**Cross Sensitivity:** n/f

**Target Organs:** Central nervous system, respiratory system, liver, kidneys (1,4-Dioxane)

**For additional information on toxicity, see Section 11.**

### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

**Common Name:** 1,4-Dioxane**Formula:** See Composition**Synonym:** Diethylene dioxide; diethylene ether; p-dioxane**Chemical Name:** 1,4-Dioxane in dimethyl sulfoxide**CAS:** See Composition**RTECS Number:** See Composition**Chemical Family:** Heterocyclic compounds (1,4-Dioxane)**Therapeutic Category:** Residual solvent**Composition:** 1,4-Dioxane (C<sub>4</sub>H<sub>8</sub>O<sub>2</sub>; CAS # 123-91-1; RTECS # JG8225000): 0.19%  
Dimethyl sulfoxide (C<sub>2</sub>H<sub>6</sub>OS; CAS # 67-68-5; RTECS # PV6210000): 99.81%**SECTION 4 - FIRST AID MEASURES****Inhalation:** Causes irritation. Remove to fresh air.**Eye:** Causes irritation. Flush with copious quantities of water for at least 15 minutes.**Skin:** Causes irritation. Flush with copious quantities of soap and water. DMSO readily penetrates the skin and can enhance absorption of other chemicals.**Ingestion:** Causes irritation. 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:** Treatment of overdose should be symptomatic and supportive.**SECTION 5 - FIREFIGHTING MEASURES****Extinguisher Media:** Alcohol foam or other appropriate media.**Fire and Explosion Hazards:** DMSO is combustible and 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.**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. Ventilate spill site. Wipe up spillage. Avoid breathing vapors. Place spillage in appropriately labeled container for disposal. Wash spill site. Place spillage and all contaminated cleanup materials in a thick plastic hazardous waste disposal bag or leakproof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE.**SECTION 7 - HANDLING AND STORAGE****Handling:** As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mist, and/or vapor associated with the material. Wash thoroughly after handling.**Storage:** Store in tight, light-resistant 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**

**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 goggles or glasses

**Protective Clothing:** Protect exposed skin.

**Exposure Limits:** OSHA: TWA 100 ppm (skin)  
NIOSH: CL 1 ppm (30 min.); IDLH 500 ppm  
ACGIH: TWA 20 ppm (skin)

<b>SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES</b>
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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****Conditions to Avoid:** Avoid exposure to light.**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****Oral Rat:** 1,4-Dioxane:  
LD50: 4200 mg/kgDMSO:  
14500 mg/kg**Oral Mouse:** 1,4-Dioxane:  
LD50: 5300 mg/kg  
DMSO:  
7920 mg/kg (DMSO)**Other Toxicity Data:** DMSO:  
Inhalation Rat LC50: >25 mg/L/40 hr  
Skin Mouse LD50: 50 grams/kg  
Skin Rat LD50: 40 grams/kg**Irritancy Data:** 1,4-Dioxane:  
Skin/rabbit: mild  
Eye/rabbit, guinea pig: moderateDMSO:  
Skin/rabbit (Standard Draize, 500 mg/24 hour): mild  
Skin/rabbit (Open Draize, 10 mg/24 hour): mild  
Eye/rabbit (Standard Draize, 500 mg/24 hour): mild**Corrosivity:** n/f**Sensitization Data:** DMSO:  
Guinea Pig Buehler Test: not sensitizing**Listed as a Carcinogen by:**      **NTP:** Yes      **IARC:** Yes      **OSHA:** No**Other Carcinogenicity Data:** 1,4-Dioxane is listed as a carcinogen by NTP and IARC.**Mutagenicity Data:** 1,4-Dioxane:  
No increase in chromosome aberrations was seen in workers with chronic dioxane exposure. Dioxane produced sister chromatid exchange in hamster ovary cells. Dioxane was not mutagenic in five different in vitro assays in mouse peripheral blood, but was mutagenic in the mouse liver micronucleus assay. This could indicate that dioxane might be mutagenic or that it acts by a nongenotoxic mechanism such as errors in repair following cell proliferation. Dioxane produced DNA inhibition in HeLa cells and DNA damage in rat liver cells.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.**Reproductive and Developmental Effects:** 1,4-Dioxane:  
Dioxane has caused birth defects in chicks. In rats, birth defects were not seen, but at high doses (up to 1000 mg/kg/day) producing maternal toxicity, toxic effects and abnormalities of the musculoskeletal system were seen in the fetus.

**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.

<b>SECTION 12 - ECOLOGICAL INFORMATION</b>
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**Ecological Information:** n/f

<b>SECTION 13 - DISPOSAL CONSIDERATIONS</b>
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**Disposal:** Place material in a thick plastic hazardous waste disposal bag or leakproof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE. Dispose of waste in accordance with all applicable Federal, State, and local laws.

<b>SECTION 14 - TRANSPORT INFORMATION</b>
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**Shipping Name:** n/f**Class:** n/f**UN Number:** n/f**Packing Group:** n/f**Additional Transport Information:** n/f

<b>SECTION 15 - REGULATORY INFORMATION</b>
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**U.S. Regulatory Information:** n/f**International Regulatory Information:** n/f

<b>SECTION 16 - OTHER INFORMATION</b>
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**Revision:** 01-Apr-09**Previous Revision Date:** 07-Oct-03