SAFETY DATA SHEET

1. Identification

Product identifier: Dapsone

Other means of identification:

- Catalog number: 1164008
- Chemical name: Benzenamine, 4,4'-sulfonylbis-
- Synonym(s): 4,4'-Sulfonyldianiline * Diaminodiphenylsulfone

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information:

- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway Rockville MD 20852-1790 US
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Emergency phone number: CHEMTREC within US & Canada 1-800-424-9300 CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards:

- Acute toxicity, oral Category 4

OSHA hazard(s): Not classified.

Label elements:

Signal word: Warning

Hazard statement: Harmful if swallowed.

Precautionary statement:

- Prevention: Wash thoroughly after handling.
- Response: If swallowed: Call a physician if you feel unwell. Rinse mouth.
- Storage: Not available.
- Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): Not classified.

3. Composition/information on ingredients

Substance: Dapsone

Hazardous components:

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dapsone</td>
<td>4,4'-Sulfonyldianiline</td>
<td>80-08-0</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Diaminodiphenylsulfone</td>
<td></td>
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</tr>
</tbody>
</table>

4. First-aid measures

Inhalation: Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact: Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact: Rinse with water. Get medical attention if irritation develops and persists.
Ingestion

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. Gastrointestinal disturbances. Cyanosis (blue tissue condition, nails, lips, and/or skin).

Most important symptoms/effects, acute and delayed

Treatment for dapsone overdose should be supportive and symptomatic and may include the following: For methemoglobinemia, administer slow intravenous methylene blue (1 to 2 mg/kg of body weight). Repeat if methemoglobin reaccumulates. For non-emergencies, methylene blue may be given orally in doses of 3 - 5 mg/kg of body weight every 4 to 12 hours. In severe overdose, repeated oral doses of activated charcoal should be given to prevent absorption and aid elimination. Gastric lavage may be effective for up to 12 hours. Hemolysis has been treated with infusion of concentrated human red blood cells to replace the damaged cells. Supportive therapy includes administration of oxygen and fluids. [USP DI]

Indication of immediate medical attention and special treatment needed

General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media

Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire-fighting equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe 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. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for safe storage, including any incompatibilities

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

8. Exposure controls/personal protection

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

No exposure standards allocated.

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection
   Hand protection
   Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other
   For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection
   Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards
   Not available.

General hygiene considerations
   Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance
   White or creamy-white to light yellow crystalline powder.

Physical state
   Solid.

Form
   Powder.

Odor
   Odorless.

Odor threshold
   Not available.

pH
   Not available.

Melting point/freezing point
   347 - 348.8 °F (175 - 176 °C)

Initial boiling point and boiling range
   Not available.

Flash point
   > 320.00 °F (> 160.00 °C)

Evaporation rate
   Not available.

Flammability (solid, gas)
   Not applicable.

Upper/lower flammability or explosive limits
   Flammability limit - lower (%)
      Not available.

   Flammability limit - upper (%)
      Not available.

   Explosive limit - lower (%)
      Not available.

   Explosive limit - upper (%)
      Not available.

Vapor pressure
   < 0.0000001 kPa at 25 °C

Vapor density
   8.3

Relative density
   Not available.

Solubility in water
   Practically insoluble.

Partition coefficient (n-octanol/water)
   0.97

Auto-ignition temperature
   Not available.

Decomposition temperature
   Not available.

Viscosity
   Not available.

Other information
   Chemical family
      Sulfone.

   Molecular formula
      C12-H12-N2-O2-S

   Molecular weight
      248.31 g/mol

   Solubility (other)
      Soluble in acetone, in methanol, in ethanol, and in dilute mineral acids.

10. Stability and reactivity

Reactivity
   No reactivity hazards known.

Chemical stability
   Material is stable under normal conditions.

Possibility of hazardous reactions
   No dangerous reaction known under conditions of normal use.

Conditions to avoid
   None known.

Incompatible materials

Hazardous decomposition products
   Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. SOx. NOx.
11. Toxicological information

Information on likely routes of exposure

Ingestion: Harmful if swallowed.
Inhalation: Due to lack of data the classification is not possible.
Skin contact: Due to lack of data the classification is not possible.
Eye contact: Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics


Delayed and immediate effects of exposure


Cross sensitivity

Persons sensitive to sulfonamides may be sensitive to this material also.

Medical conditions aggravated by exposure


Acute toxicity

Harmful if swallowed.

Skin corrosion/irritation: Due to lack of data the classification is not possible.
Serious eye damage/eye irritation: Due to lack of data the classification is not possible.
Respiratory sensitization: Due to lack of data the classification is not possible.
Skin sensitization: Due to lack of data the classification is not possible.
Germ cell mutagenicity: Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity

Ames test (E. coli and Salmonella)
Result: Negative with and without activation.
Chromosome aberration assay (Chinese hamster ovary cells)
Result: Positive.
In vivo micronucleus assay (mouse)
Result: Negative.

Carcinogenicity

Based on available data, the classification criteria are not met. IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans. NTP Not Listed. OSHA Not Regulated. Epidemiological studies have not shown a causal relationship between this material and cancer in humans.

15 mg/kg/day 92-100 Week study (oral, 5% gel)
Result: No evidence of carcinogenicity in males (160x human exposure) or females (300x human exposure).
Species: Rat
26-Week study (dermal, 3% to 10% gel)
Result: No evidence of carcinogenicity.
Species: Mouse

Reproductive toxicity

Due to lack of data the classification is not possible. Hemolytic anemia has been reported in human mothers and their offspring after therapeutic use of dapsone.

Reproductivity

30 mg/kg/day Reproductive study (oral)
Result: Maternal toxicity and developmental toxicity
Species: Rat
Reproductive study (topical exposure)
Result: Treatment of males significantly reduced embryo implantations and viability when mated with untreated females.
Species: Rat

Specific target organ toxicity - single exposure

Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure

Due to lack of data the classification is not possible.

Aspiration hazard

Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

No ecotoxicity data noted for the ingredient(s).

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

Not available.

Mobility in soil

Not available.
Other adverse effects  Not available.

13. Disposal considerations

Disposal instructions  Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations  Not available.

Hazardous waste code  Not available.

Waste from residues / unused products  Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging  Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT  Not regulated as a hazardous material by DOT.

IATA  Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code  No information available.

15. Regulatory information

US federal regulations  CERCLA/SARA Hazardous Substances - Not applicable.

All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories  Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance  No
SARA 311/312 Hazardous chemical  No

Other federal regulations

Safe Drinking Water Act (SDWA)  Not regulated.

Food and Drug Administration (FDA)  Not regulated.

US state regulations  California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>Yes</td>
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<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>Yes</td>
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<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*A “Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
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Revision Information

This document has undergone significant changes and should be reviewed in its entirety.