SAFETY DATA SHEET

1. Identification

Product identifier **Dextroamphetamine Sulfate**

Other means of identification

Catalog number 1180004

Chemical name Benzeneethanamine, alpha-methyl-, (S)-, sulfate (2:1)

Synonym(s) Dexamphetamine sulfate

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 2
Reproductive toxicity	Effects on or via lactation
Specific target organ toxicity, single exposure	Category 1 (Central Nervous System, Cardiovascular system)

OSHA hazard(s) Not classified.

Label elements

Signal word Danger

Hazard statement Fatal if swallowed. May cause harm to breast-fed children. Causes damage to organs (Central Nervous System, Cardiovascular system).

Precautionary statement

Prevention Avoid contact during pregnancy/while nursing. Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

Response If exposed: Call a poison center/doctor/medical professional. Rinse mouth.

Storage Store locked up.

Disposal Dispose of contents/container to an approved disposal site.

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

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Dextroamphetamine Sulfate	Dexamphetamine sulfate	51-63-8	100

4. First-aid measures

Inhalation Remove 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 Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

Most important symptoms/effects, acute and delayed Narcosis. Decrease in motor functions. Behavioral changes.

Indication of immediate medical attention and special treatment needed Do not induce vomiting. Administer activated charcoal as a slurry. For seizures, administer diazepam intravenously. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. For severe hypertension, treat with intravenous benzodiazepines. If unresponsive to sedation, administer intravenous nitroprusside. For arterial spasms, administer heparinization and intravenous or intra-arterial nitroprusside. For delirium, administer benzodiazepines. For hypothermia, administer intravenous diazepam and external cooling. For rhabdomyolosis, administer saline or diuretics to maintain urine output. Urinary alkalinization is NOT recommended. For ventricular arrhythmia, obtain ECG, institute continuous cardiac monitoring, and administer oxygen. Evaluate for hypoxia, acidosis, and electrolyte disorders. For monomorphic ventricular tachycardia, administer lidocaine and amiodarone or sotalol. (Meditext) Provide general supportive measures and treat symptomatically.

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 Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

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

Specific methods Cool containers exposed to flames with water until well after the fire is out.

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. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. 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. Wash spill site.

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. Use of a designated area is recommended for handling of potent materials.

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

Exposure limit values

Industrial Use

Material	Type	Value
Dextroamphetamine Sulfate (CAS 51-63-8)	TWA	8 micrograms/m3

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

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. Avoid any open handling of this material, particularly for grinding, crushing, weighing or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

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. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
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 crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless.
Odor threshold	Not available.
pH	5 - 6 (5% solution)
Melting point/freezing point	> 572 °F (> 300 °C)
Initial boiling point and boiling range	Not available.
Flash point	> 199.94 °F (> 93.30 °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	Not available.
Relative density	Not available.
Solubility in water	Soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

Other information

Chemical family	Phenethylamine derivative.
Molecular formula	C9H13N.1/2H2O4S
Molecular weight	368.49
Solubility (other)	Slightly soluble in alcohol; insoluble in ether.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None under normal conditions.
Incompatible materials	Strong alkalis. Calcium salts.
Hazardous decomposition products	NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Fatal 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	Decrease in motor functions. Bitter or metallic taste. Nervousness. Tiredness. Weakness. Trembling. Depression. Change in heart rhythm. Blurred vision. Constipation. Diarrhea. Loss of appetite. Nausea. Vomiting. Stomach pain. Fever. Dizziness. Headache. Dry mouth. Sweating. Chest pain. Difficulty breathing.
Delayed and immediate effects of exposure	High blood pressure. Hallucinations. Circulatory collapse. Convulsions. Coma. Death.
Chronic effects	Weight loss. Psychological dependence.
Cross sensitivity	Persons sensitive to one sympathomimetic may be sensitive to this material also.
Medical conditions aggravated by exposure	Drug abuse. Impaired kidney function. Epilepsy. Glaucoma. Arteriosclerosis. Extrapyramidal disorders. Cardiovascular disease. Hypertension. Hyperthyroidism
Acute toxicity	Fatal if swallowed.

Product	Species	Test Results
Dextroamphetamine Sulfate (CAS 51-63-8)		
Oral		
LD50	Mouse	10 mg/kg
	Rat	32 mg/kg

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

Mutagenicity

25 mg/kg In vivo micronucleus test
Result: Positive.
Species: Mouse
In vitro DNA adduct test (E. coli - 40 micromoles)
Result: Positive.

Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Reproductive toxicity	May cause harm to breastfed babies. The use of amphetamines during early pregnancy may be associated with an increased risk of birth defects in the fetus, such as cardiac deformity, exencephaly, and limb reduction defects. Infants born to mothers dependent on amphetamines have an increased risk of premature delivery and low birth weight, and may also experience symptoms of withdrawal.

Reproductivity

Reproductivity test
Result: Behavioral alterations occurred.

Reproductivity

Reproductivity test
Result: Fetotoxicity and maternal toxicity observed.
Species: Mouse

Specific target organ toxicity - single exposure	Causes damage to organs (Central Nervous System, Cardiovascular system).
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	This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose in accordance with all applicable regulations.
Local disposal regulations	Not available.
Hazardous waste code	Not regulated.
Waste from residues / unused products	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

UN number	UN2811
UN proper shipping name	Toxic, solid, organic, n.o.s. (Dextroamphetamine Sulfate)
Transport hazard class(es)	6.1
Subsidiary class(es)	Not available.
Packing group	II

IATA

UN number	UN2811
UN proper shipping name	Toxic, solid, organic, n.o.s. (Dextroamphetamine Sulfate)
Transport hazard class(es)	6.1
Subsidiary class(es)	-
Packaging group	II
Environmental hazards	No

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No information available.

DOT; IATA

15. Regulatory information

US federal regulations

DEA Schedule II Controlled Substance
CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

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.
Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)	Schedule II - 1100
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

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

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

16. Other information, including date of preparation or last revision

Issue date	04-12-2006
Revision date	11-16-2012
Version #	02
Further information	Not available.
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Revision Information	This document has undergone significant changes and should be reviewed in its entirety.