

1. Identification

| | | |
|---|--|-----------------|
| Product identifier | Amikacin Sulfate | |
| Other means of identification | | |
| Catalog number | 1019494 | |
| CAS number | 39831-55-5 | |
| Chemical name | D-streptomine, O-3-amino-3-deoxy-alpha-D-glycopyranosyl-(1-6)-O-(6-amino-6-deoxyalpha-D-glycopyranosyl-(1-4))-N(supl)-(4-amino-2-hydroxy-1-oxobutyl)-2-deoxy-, (S)-, sulfate (1:2)(salt) | |
| 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 | | |
| Manufacturer | | |
| Company name | U. S. Pharmacopeia | |
| Address | 12601 Twinbrook Parkway Rockville MD 20852-1790 United States | |
| 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 | Sensitization, skin | Category 1 |
| | Reproductive toxicity | Category 1B |
| Environmental hazards | Not classified. | |
| OSHA defined hazards | Not classified. | |

Label elements



| | | |
|--|---|--|
| Signal word | Danger | |
| Hazard statement | May cause an allergic skin reaction. May damage fertility or the unborn child. | |
| Precautionary statement | | |
| Prevention | Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Contaminated work clothing must not be allowed out of the workplace. Avoid breathing dust. Wear protective gloves/protective clothing/eye protection/face protection. | |
| Response | If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If exposed or concerned: Get medical advice/attention. | |
| Storage | Store locked up. | |
| Disposal | Dispose of contents/container in accordance with local/regional/national/international regulations. | |
| Hazard(s) not otherwise classified (HNOC) | None known. | |
| Supplemental information | Pharmacologically active material. | |

3. Composition/information on ingredients

Substance

| Chemical name | Common name and synonyms | CAS number | % |
|------------------|--------------------------|------------|-----|
| Amikacin Sulfate | | 39831-55-5 | 100 |

4. First-aid measures

| | |
|---|---|
| Inhalation | Move to fresh air. Call a physician if symptoms develop or persist. |
| Skin contact | Remove contaminated clothing immediately and wash skin with soap and water. Rinse skin with water/shower. Get medical attention if irritation develops and persists. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. |
| Eye contact | Rinse with water. Get medical attention if irritation develops and persists. |
| Ingestion | Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Get medical attention if symptoms occur. |
| Most important symptoms/effects, acute and delayed | Reproductive system effects. Pharmacologically active material. Occupational exposure may cause physiological effects. |
| Indication of immediate medical attention and special treatment needed | Treat symptomatically. Treatment of aminoglycoside overdose may include: Administer activated charcoal as a slurry. For mild/moderate allergic reactions, administer antihistamines with or without inhaled beta agonists, corticosteroids or epinephrine; for severe reactions add aggressive airway management, oxygen, ECG monitoring, and intravenous fluids. Maintain urine output with IV fluids in patients with normal renal function. Consider dialysis in patients with renal failure. Complexation with intravenous ticarcillin may be effective. (Meditext) |
| 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

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|--|--|
| Suitable extinguishing media | Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding 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 | 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. |
| General fire hazards | No unusual fire or explosion hazards noted. |

6. Accidental release measures

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|--|--|
| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. |
| Methods and materials for containment and cleaning up | For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. |
| Environmental precautions | Avoid discharge into drains, water courses or onto the ground. Prevent further leakage or spillage if safe to do so. No special environmental precautions required. |

7. Handling and storage

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|---|---|
| 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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. |
| 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

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use Material

Type

Value

Amikacin Sulfate (CAS
39831-55-5)

TWA

0.3 mg/m³

Biological limit values

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

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Powder.

Color

White.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

428 - 446 °F (220 - 230 °C) (decomposes)

Initial boiling point and boiling range

650.66 °F (343.7 °C) at 760 mmHg

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

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

Not available.

Vapor density

Not available.

Relative density

Not available.

Solubility(ies)

Solubility (water)

Soluble.

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.

Other information

| | |
|------------------------|--|
| Chemical family | Aminoglycoside. |
| Molecular formula | C ₂₂ H ₄₃ N ₅ O ₁₃ · 2H ₂ SO ₄ |
| Molecular weight | 781.76 |
| pH in aqueous solution | 2 - 4 |

10. Stability and reactivity

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|------------------------------------|--|
| Reactivity | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| Chemical stability | Material is stable under normal conditions. |
| Possibility of hazardous reactions | No dangerous reaction known under conditions of normal use. |
| Conditions to avoid | Contact with incompatible materials. |
| Incompatible materials | Oxidizing agents. Strong acids. |
| Hazardous decomposition products | NO _x . SO _x . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. |

11. Toxicological information

Information on likely routes of exposure

| | |
|---|--|
| Inhalation | Knowledge about health hazard is incomplete. |
| Skin contact | May cause an allergic skin reaction. |
| Eye contact | Knowledge about health hazard is incomplete. |
| Ingestion | Knowledge about health hazard is incomplete. |
| Symptoms related to the physical, chemical, and toxicological characteristics | Aminoglycosides: Hearing problems. Clumsiness. Dizziness. Change in frequency or amount of urination. Thirst. Loss of appetite. Numbness or tingling of skin. Gastrointestinal disturbances. |

Information on toxicological effects

Acute toxicity

| Product | Species | Test Results |
|-----------------------------------|---------|---------------|
| Amikacin Sulfate (CAS 39831-55-5) | | |
| Acute | | |
| Oral | | |
| LD50 | Mouse | > 10679 mg/kg |
| | Rabbit | > 3000 mg/kg |
| | Rat | > 4000 mg/kg |

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye irritation Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization May cause an allergic skin reaction. Contact dermatitis has been reported in literature following the therapeutic use of aminoglycosides.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity May damage fertility or the unborn child. Therapeutic use of aminoglycosides during pregnancy has been reported to cause kidney damage and deafness in the human fetus.

Reproductivity

200 mg/kg Reproductivity, No evidence of hearing damage in the offspring.

Result: Negative.

Species: Guinea pig

Reproductivity

200 mg/kg/day Reproductivity, Maternal toxicity and fetotoxicity (kidney problems, skeletal anomalies, increased fetal death rate).

Result: Positive.

Species: Rat

Reproductivity, Decreased fetal weights.

Result: Positive.

Species: Mouse

Reproductivity, Increased fetal death rate.

Result: Positive.

Species: Rabbit

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

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

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

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 Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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 Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US - California Proposition 65 - CRT: Listed date/Developmental toxin

Amikacin Sulfate (CAS 39831-55-5)

Listed: July 1, 1990

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) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| 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) | Yes |
| New Zealand | New Zealand Inventory | No |
| 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)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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

Issue date 07-23-2012

Revision date 12-12-2017

Version # 04

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