



SAFETY DATA SHEET

1. Identification

Product identifier	Dalfampridine
Other means of identification	
Catalog number	1162454
CAS number	504-24-5
Synonyms	Fampridine * 4-Pyridinamine
Chemical name	4-Aminopyridine
Recommended use	For analytical laboratory 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	Technical Services 301-816-8129
Website	www.usp.org
E-mail	RSTECH@usp.org
Emergency phone number	CHEMTREC within US & 1-800-424-9300 Canada CHEMTREC outside US & +1 703-527-3887 Canada

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Acute toxicity, oral Category 2 Acute toxicity, dermal Category 3 Specific target organ toxicity, single exposure Category 1 (nervous system)
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	



Signal word	Danger
Hazard statement	Fatal if swallowed. Toxic in contact with skin. Causes damage to organs (nervous system).
Precautionary statement	
Prevention	Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. Call a poison center/doctor if you feel unwell. Take off immediately all contaminated clothing and wash it before reuse. If exposed: Call a poison center/doctor.
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	%
Dalfampridine	Fampridine 4-Pyridinamine	504-24-5	100

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	IF ON SKIN: Rinse with water. Call a POISON CENTER or doctor/physician if you feel unwell. Take off contaminated clothing and wash before reuse.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	If swallowed: Immediately call a poison center or doctor/physician. Rinse mouth. 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	Behavioral changes. Nervous system stimulation. Pharmacologically active material. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	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. 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	Cool containers exposed to flames with water until well after the fire is out.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

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	Avoid the generation of dusts during clean-up. This product is miscible in water. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP materials, 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.
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Conditions for safe storage, including any incompatibilities	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.
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8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
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	Handle in accordance with good industrial hygiene and safety practice. Handling practices in this SDS are recommendations for laboratory use of USP materials.
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9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Crystalline powder.
Color	White. Cream. Light yellow.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	317.3 °F (158.5 °C)
Initial boiling point and boiling range	523.4 °F (273 °C)
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	0.00005 kPa (77 °F (25 °C))
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble.
Solubility (other)	Ethanol: Very soluble. Methanol: Freely soluble.

	Ethyl ether: Soluble. Benzene: Soluble.
Partition coefficient (n-octanol/water)	0.32
Auto-ignition temperature	1184 °F (640 °C)
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Pyridine.
Molecular formula	C5H6N2
Molecular weight	94.12 g/mol

10. Stability and reactivity

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	Strong acids. Strong oxidizing agents. Peroxides. Phenols. Acid chlorides. Acid anhydrides.
Hazardous decomposition products	NOx. 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	Toxic in contact with skin. This material may cause: Central nervous system effects.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Fatal if swallowed. This material may cause: Central nervous system effects.

Symptoms related to the physical, chemical and toxicological characteristics	Central nervous system stimulation. Behavior, mood, or mental changes. Headache. Back pain. Seizures. Gastrointestinal disturbances.
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Information on toxicological effects

Acute toxicity	Fatal if swallowed. Toxic in contact with skin.
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Product	Species	Test Results
Dalfampridine (CAS 504-24-5)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	326 mg/kg
Oral		
LD50	Mouse	19 mg/kg
	Rat	21 mg/kg
		20 mg/kg

Skin corrosion/irritation	Knowledge about health hazard is incomplete.
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Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.
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Respiratory or skin sensitization

Respiratory sensitization	Knowledge about sensitization hazard is incomplete.
Skin sensitization	Knowledge about sensitization hazard is incomplete.

Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.
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Mutagenicity

Chromosome aberration assay
Result: Negative.
Mouse bone marrow assay
Result: Negative.

Mutagenicity

Mouse lymphoma assay
Result: Negative.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

2 - 80 mg/kg/day Two year carcinogenicity study
Result: No evidence of drug related carcinogenicity.
Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

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

Reproductivity

> 10 mg/kg/day Developmental test; administered during organogenesis

Result: No evidence of developmental toxicity.

Species: Rat

0 - 11 mg/kg/day Reproductivity test

Result: No malformations but some reduced fetal weights were observed.

Species: Rabbit

0 - 9 mg/kg/day Reproductivity test

Result: No adverse reproductive effects.

Species: Rat

Specific target organ toxicity - single exposure

Causes damage to organs (nervous system).

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**

Product	Species		Test Results
Dalfampridine (CAS 504-24-5)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	2.3 - 4.5 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	2.7 - 3.8 mg/l, 96 hours

Persistence and degradability

No data is available on the degradability of this substance.

Bioaccumulative potential**Octanol/water partition coefficient log Kow**

0.32

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.

US RCRA Hazardous Waste P List: Reference

Dalfampridine (CAS 504-24-5)

P008

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

UN number	UN2671
UN proper shipping name	Aminopyridines (Dalfampridine)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II
Packaging exceptions	153
Packaging non bulk	212
Packaging bulk	242

IATA

UN number	UN2671
UN proper shipping name	Aminopyridines (Dalfampridine)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II
Other information	

Passenger and cargo aircraft	Allowed with restrictions.
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Cargo aircraft only	Allowed with restrictions.
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Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
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DOT; IATA



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.

Toxic Substances Control Act (TSCA)

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Dalfampridine (CAS 504-24-5)	Listed.
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SARA 304 Emergency release notification

Pyridine, 4-amino- (CAS 504-24-5)	1000 LBS
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OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
Dalfampridine	504-24-5	1000		500	10000

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Acute toxicity (any route of exposure)
Specific target organ toxicity (single or repeated exposure)

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**California Proposition 65**

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. For more information go to www.P65Warnings.ca.gov.

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)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*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 08-09-2013
Revision date 10-06-2021
Version # 04

Disclaimer

USP materials are sold for analytical laboratory use only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.