(Monday - Friday: 7:30 a.m. - 4:00 p.m. CST)

Emergency Contact: INFOTRAC 800-535-5053 [U.S.A.]

Name: 4-Aminopyridine 1-002054-100 Code:

.....SAFETY DATA SHEET

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier 1.1

> Name 4-Aminopyridine 1-002054-100 Code

1.2 Use of Substance/Mixture

> Active Pharmaceutical Ingredient Use

Details of Manufacturer/Supplier 1.3

> Company Regis Technologies, Inc. 8210 N. Austin Avenue

Morton Grove, IL 60053

847-967-6000; 800-323-8144 (toll free) Email: cservice@registech.com

www.registech.com

Emergency Telephone 1.4

800-535-5053 [U.S.A.] **INFOTRAC**

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture

OSHA Hazards Toxic, Target Organ Effect

Target Organs Nerves, Seizures

Hazard Indication (67/548/EEC or 1999/45/EC) Symbol(s) Very toxic T+

Very toxic if swallowed. R-Phrase(s) R28

R36/37/38 Irritating to eyes, respiratory system and skin

GHS Classification

Acute toxicity (oral) Category 2 H300 Acute toxicity (dermal) Category 3 H311 Skin Corrosion/Irritation Category 2 H315 Serious Eye Damage/Eye Irritation Category 2 H319 STOT-SE (single exposure) Category 3 H335

GHS Label Elements

Pictograms or hazard symbols



GHS06

Signal Word Danger

Hazard Statement

H300 - Fatal if swallowed

H311 - Toxic in contact with skin H315 - Causes skin irritation

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

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......SAFETY DATA SHEET......

Precautionary Statements

[Prevention] P260-Do not breathe dust or vapor.

P262-Do not get in eyes, on skin, or on clothing.

[Response] P301+P310-IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses,

if present and easy to do. Continue rinsing.

P308+P313-IF exposed or concerned: Get medical advice/attention.

[Storage] P402+P404-Store in a dry place. Store in a closed container.

NFPA: Health 3 Flammability 0 Reactivity 0

HMIS: Health 3* Flammability 0 Physical Hazards 0

Note: Chronic Health Hazard is present if there is an * beside the HMIS Health rating number.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Name 4-Aminopyridine

Synonyms p-Aminopyridine (DOT); 4-AP; 4-Pyridinamine; Dalfampridine; Fampridine; 4-Pyridylamine

CAS No. 504-24-5 EINECS No. 207-987-9 Chem. Formula $C_5H_6N_2$ Mol. Weight 94.13

Ingredients Concentration (%/wt)

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

General: Oral overexposure may cause delayed effects from 12-72 hours.

Eye contact: Rinse eyes with plenty of water for at least 15 minutes; lift eyelids occasionally. If irritation persists, get

medical attention.

Skin contact: Immediately remove contaminated clothing and shoes, then wash skin with soap and plenty of water. If

irritation persists, get medical attention.

Inhalation: Remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and

keep person warm and at rest. Get medical attention.

Ingestion: Rinse mouth with water. Avoid vomiting. Get medical attention.

Physician note: Symptomatic and supportive care. See Indication of special medical attention below.

4.2 Most important symptoms and effects, both acute and delayed.

Common: Nausea, vomiting, headache, hyperexcitability.

Less common: Peripheral neuropathy (motor weakness), convulsions or seizures, and cyanosis, a blue discoloration of

fingernails, lips, or skin caused by low oxygen due to methemoglobinemia requiring prompt treatment.

4.3 Indication of immediate medical attention and special treatment needed.

Immediate: Exposure to 4-Aminopyridine may increase the risk of anemia, agranulocytosis, hemolysis or other

related blood disorders. Overexposure may result in methemoglobin depression, convulsions and

cyanosis requiring prompt treatment.

Seizures are a potential overdose-side-effect and may occur within 5 to 15 minutes of a large exposure,

thus creating a possible aspiration hazard.

Other: 4-Aminopyridine is excreted in breast milk and nursing mothers should avoid exposure to this material by

observing all precautions indicated. May cause hemolysis in breast-fed infants

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......SAFETY DATA SHEET......

SECTION 5 FIRE-FIGHTING MEASURES

5.1 Suitable Extinguishing Media

Water spray, carbon dioxide, dry chemical powder, or appropriate foam.

5.2 Specific hazards arising from the chemical.

Avoid inhalation of material or combustion by-products.

Emits toxic fumes under fire conditions: carbon oxides, nitrogen oxides

5.3 Advice for fire-fighters

Wear personal protective equipment for flammable conditions. Wear self-contained breathing apparatus (SCBA) if necessary.

SECTION 6 ACCIDENTAL RELEASE MEASURES......

6.1 Personal precautions, protective equipment, and emergency procedures

For non-emergency personnel - Do not breath dusts. Avoid material contact. Evacuate unnecessary personnel from area, observe emergency procedures, consult an expert.

For emergency responders - Protective equipment. See Section 8.3.

6.2 Environmental precautions

Prevent material from entering drains.

6.3 Methods of clean up

Ventilate area. Isolate spilled material. If in solution, absorb using chemically compatible spill pillows, or similar adsorbent material. Sweep up, if not absorbed in pillow, seal in appropriate hazardous waste container, and hold for proper waste disposal. Keep out of water supplies and sewers. Wash spill site after material pickup is complete.

SECTION 7 HANDLING AND STORAGE......

7.1 Safe Handling Precautions

Wear suitable protective equipment to avoid contact with skin, eyes, or inhalation of dust. Do not breathe dust. May be absorbed through skin. Wash thoroughly after handling. Immediately remove contaminated clothing. Handle only in area provided with appropriate exhaust ventilation.

7.2 Storage Conditions

Store under inert gas in a tightly sealed container. Keep in a dry, cool and well-ventilated place. Protect from ignition sources and store away from incompatible materials (See Section 10.).

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION.....

8.1 Control parameters

Exposure limits: 4-Aminopyridine (504-24-5) -

OSHA – PEL None ACGIH – TLV None

Environmental Do not empty into drains.

8.2 Appropriate engineering controls

Safety shower and eye wash

Local exhaust and mechanical ventilation required. Hood recommended. Fume scrubber.

8.3 Personal protection

Eye/Face Chemical safety eyewear or goggles

Hand Compatible chemical-resistant gloves: Rubber (e.g., natural rubber, neoprene, nitrile, or equivalent),

Silver Shield®, Viton®

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NIOSH/MSHA or European Standard EN 149 approved respirator for amine gas, dust, and mists if Respiratory

exposure limits are exceeded or irritation or other symptoms are experienced.

Protective Clothing (e.g., lab coat)--flame retardant anti-static material recommended. Dermal (not hand)

Hygiene

Avoid inhalation, ingestion; contact with eyes, skin, and clothing; prolonged or repeated exposure. Wash thoroughly after handling. Wash contaminated clothing before reuse. Discard contaminated footwear.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on physical and chemical data 9.1

> Chemical Formula $C_5H_6N_2$ Molecular Weight 94.13 Form Powder **Appearance** White Odor Odorless

Odor threshold No data available. рΗ No data available. Melting/freezing point 157-162°C (314-323°F)

Boiling point: 273°C (523°F)

Flammability (liquid, solid)

Flash Point None Method: Not Applicable UEL (upper explosive limit) Flammable limits (%,v/v) None

LEL (lower explosive limit) None

Autoignition temperature 640°C (1184°F) Decomposition temperature No data available. **OSHA Flammability Class** No data available. Evaporation Rate (BuAc = 1.0) No data available.

2.09 x 10⁻⁴ mm Hg (23°C) Vapor pressure (mmHq)

Vapor density (air=1): No data available.

Relative density (g/cm³) 1.203

Water Solubility No data available. Water reactive Not reactive.

very soluble in ethanol; soluble in water, ethyl ether, benzene, oxygenated solvents; Solubility (other)

> soluble in ligroin Log Kow (Pow) = -0.76

Partition coefficient: N-octanol/water

No data available. Viscosity % Volatiles No data available. Refractive Index $(n_D^{20} =)$: No data available. Dissociation constant (pKa) pKa = 9.17

2.5 x10⁻⁹ atm-m³/mol Henry's Constant

SECTION 10STABILITY AND REACTIVITY

10.1 Reactivity

Stable.

10.2 Chemical Stability

Stable when stored protected from heat and ignition sources.

10.3 Possibility of hazardous reactions

None.

10.4 Conditions to avoid

Avoid incompatibilities.

Protect from heat and ignition sources.

Keep out of water supplies, sewers, and environment

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10.5 Incompatible materials

Strong oxidizers, Strong acids Acid chlorides, Acid anhydrides

Excessive heat

10.6 Hazardous decomposition products

Combustion carbon oxides, nitrogen oxides

SECTION 11TOXICOLOGICAL INFORMATION.......

11.1 Toxicological Information

Acute toxicity orl man LDLo 590 ug/kg (RTECS; Hallucinations, distorted perceptions,

Dyspnea (shortness of breath), Nausea or vomiting.) orl wmn TDLo 120 ug/kg (RTECS; Convulsions or effect on seizure threshold.)

orl rat LD50 20 mg/kg (RTECS and NCI; No available data.)

scu rat LD50 19 mg/kg (RTECS; No available data.) scu mus LD50 20 mg/kg (RTECS; No available data.) 200 mg/kg < dermal LD50 < 2000 mg/kg (FIFRA: Tox. Category II)

Skin corrosion/irritation Irritating to skin (FIFRA: Tox. Category IV - Mild or slight irritation at

72 hours.)

Irritation reversible within 7 days.)

Respiratory irritation No data available.

Respiratory or skin sensitization
No sensitization data is available for 4-AP, however, severe allergic reactions and

anaphylaxis may occur with oral doses of certain formulations containing 4-AP. (AHPI)

Germ cell mutagenicity Not mutagenic in two studies found in literature. (NCI)

Carcinogenicity

IARC

NTP

OSHA

No data available

No data available.

No data available.

No data available.

Other U.S. EPA IRIS Classification D--not classifiable as a human carcinogen

Reproductive toxicity

No data available.

No data available.

STOT-single exposure May be irritating to mucous membranes. (ECHA C&L)

STOT-repeated exposure

No data available.

No data available.

Aspiration hazard

No data available.

RTECS Number US1750000 (4-Aminopyridine record updated last: May 2009.)

11.2 Further Information 4-Aminopyridine is the active ingredient in the U.S. EPA registered avicide, Avitrol.

SECTION 12 ECOLOGICAL INFORMATION.....

12.1 Ecotoxicity

Bird Toxicity orl quail LD50 7650 ug/kg; orl duck LD50 4200 mg/kg

Fish Toxicity 7560 ug/L 96 hour(s) LD50 (Mortality) Bluegill (Lepomis macrochirus)

Channel catfish TLm = 2.43 - 5.80 mg/l at 12 - 22 deg°C 96 hr (static bioassay) 3200 ug/L 48 hour(s) EC50 (Immobilization) Water flea (Daphnia magna)

Invertebrate Toxicity
Aq. Plant Toxicity
Bacteria Toxicity

No data available.
No data available.

Other Toxicity 2400 ug/L 96 day(s) LC50 (Mortality) Leopard frog (Rana sphenocephala)

12.2 Persistence and degradability 4-Aminopyridine released to the air as a vapor will remain as such at ambient

temperature and degrade photochemically within about 19 hours.

Biodegradability – aerobic – Material slowly hydrolyzes on contact with water.

See NLM-HSDB (ref. a)) (Hazardous Substance Database) No. 6037 Environmental Fate

& Exposure section for more details.

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12.3 Bioaccumulative potential BCF <0.2-0.6 and BCF <1.8-7.2 at a concentration of 50 and 5 mg/l; Log Kow = 0.79;

4-Aminopyridine released to water will have a low tendency to sorb to suspended sediments, biota, and sediments. It has a low tendency to bioconcentrate. Volatilization is expected to be low from water sources. Biodegradation in water is

expected to be slow.

12.4 Motility in soil 4-Aminopyridine released to soil is expected to have a high mobility. It is expected to

strongly absorb to organic carbon and clay. Aerobic and anaerobic biodegradation occurs at a slow rate. Volatilization from dry or moist soil surface is not expected...

12.5 Other adverse effects Highly toxic to aquatic life, birds, and mammals. U.S. EPA FIFRA use: avicide and bird

repellant. Small quantities may be lethal to birds due to convulsions and other nervous system effects. It is excreted in urine and rapidly detoxified in the liver so that the flesh of dead birds is not toxic to predatory animals. If 4-AP is directly consumed by animals,

it could be toxic. The terminal biological half-life (BHL) is about 4 hours.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Disposal methods

U. S. EPA Waste Codes Reportable Quantity Waste Characterization (per U. S. regulations)

Waste Disposal

P008

RQ must be included in the shipping name if over RQ trigger quantity (10 lbs).

RCRA Hazard Class (40CFR 261): Toxic.

Generator is responsible for proper waste characterization. NOTE: U.S. state hazardous waste regulations may differ considerably from U.S. Federal regulations. That which cannot be recovered or recycled, should be disposed of in accordance with all applicable international, national, regional, state, and local laws. Do NOT dump into

any sewer, on ground, or into any body of water. Empty containers or equipment rinsate may be considered hazardous under regulations. Refer to the European Waste

Catalogue (EWC) for appropriate code for disposal in the EC.

SECTION 14 TRANSPORT INFORMATION

DOT (US)

UN number UN 2671 Class 6.1 Packing Group II

Proper shipping name Aminopyridines (p-)

Marine pollutant no Poison Inhalation hazard no

IATA

UN number UN 2671 Class 6.1 Packing Group II

Proper shipping name Aminopyridines (p-)

IMDG/IMO

UN number UN 2671 Class 6.1 Packing Group II

Proper shipping name Aminopyridines (p-)

Marine pollutant no

ADR/RID

UN number UN 2671 Class 6.1 Packing Group II

Proper shipping name Aminopyridines (p-)

SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and Environmental regulations specific for the product in question.

No data available.

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Name: 4-Aminopyridine Code: 1-002054-100

5.2	,
	4-Aminopyridine
	CAS Number
	TSCA:
	This compound is sold strictly for pharmaceutical. EINECS:Y
	Number
	U.S. EPA FIFRA Status
	This chemical is being sold for strictly U.S. FDA defined pharmaceutical
	purposes and, as such, is exempt from FIFRA regulations.
	CERCLA [Section 103 (40 CFR 302.4)]:
	RQ (lbs)
	RCRA Waste Code
	OSHA Process Safety [29 CFR 1910.119]:
	TQ (lbs)NA
	Clean Air Act
	[Section 112r (40 CFR 68)]:NL
	TQ (lbs)NA
	Contains Ozone Depleters (Class I or Class II)N
	[Section 103 (40 CFR 302.4)]:NL
	SARA Title III Notification [40 CFR 302.4]:
	Section 302/304 (EHS) Ingredient [40 CFR 355.3]Y
	TPQ (lbs500/10,000
	RQ (lbs)
	Section 313 Ingredient [40 CFR 372.65]NL
	SARA Hazards AcuteY ChronicY FireN PressureN ReactivityN
	State Lists: Y
	States on CA, FL, MA, NJ, PA
	NL on MN
	On CA Prop. 65: Significant Risk LevelN

16.1 Literature References

- AHPI: AMPYRA® (dalfampridine) Highlights of Prescribing Information. Extended Release Tablets for Oral Human Use Initial U.S. Approval 2010 . Copyright 2013 Acorda Therapeutics, Inc. Last updated: 01/2013.
- ECHA C&L: ECHA REACH Pre-Registered Substance, Classification and Labelling (C&L) Inventory; EC No. 207-987-9; CAS No. 504-24-5; IUPAC Name 4-pyridylamine or 4-aminopyridine; last updated: 11/28/13.
- FIFRA: U.S. Environmental Protection Agency. Pesticide Registration Standard: 4 Aminopyridine: Avitrol. Office of Pesticides and Toxic Substances, Washington, DC, 1980.10-168. Also U.S. EPA FIFRA RED 4-Aminopyridine 070927 EPA 738-R-013.
- IRIS: U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS) on 4-Aminopyridine (504-24-5) Available from: http://www.epa.gov/ngispgm3/iris on the Substance File List as of March 15, 2000.
- NCI: National Cancer Institute); Aminopyridines; A Review Report Prepared for NCI Division of Cancer Biology by Technical Resources International, Inc. to support chemical nomination under contract no. N02-CB-07007 (06/03; rev. 11/05; 03/06).
- NLM-HSDB: U. S. National Library of Medicine; Hazardous Substance Database (Toxnet®) Number: 6037; 4-Aminopyridine; CAS 75-77-4; Last Revision Date: 20030214: Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 192.
- RTECS: RN US1750000; 4-Aminopyridine; Updated May 2009.

The above information is believed to be correct to the best of our present state knowledge, but does not purport to be all-inclusive and shall be used only as a guide. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product. *This is the last page of this SDS.*