

SECTION 1 Identification

1.1. Product identifier

Product form : Mixture
Trade name : FIRDAPSE
Product code : 69616-0211

1.2. Other means of identification

No additional information available

1.3. Recommended use of the chemical and restrictions on use

Recommended use : Used to treat Lambert-Eaton myasthenic syndrome (LEMS)
Restrictions on use : Only for commercial and clinical use. By prescription only. Inteded only ages 6 and up.

1.4. Supplier's details

Catalyst Pharmaceuticals Inc
355, Alhambra Circle
Ste. 801
Coral Gables, Florida 33134
T 305-420-3200
sds@catalystpharma.com

1.5. Emergency phone number

Emergency number : For Hazardous Materials or Dangerous Goods Incident Spill, Leak, Fire, Exposure, or Accident
Call CHEMTREC Day or Night: 1-800-424-9300 (Toll Free, USA) / 703-527-3887 (Virginia, USA)
CCN 1017517
Back-up Emergency Number: +1 703-741-5970 (Washington, DC)

SECTION 2 Hazard Identification

2.1. Classification of the substance or mixture

GHS US classification

Acute toxicity (oral), Category 4	H302	Harmful if swallowed.
Acute toxicity (dermal), Category 4	H312	Harmful in contact with skin.
Acute toxicity (inhalation:dust,mist), Category 3	H331	Toxic if inhaled.
Combustible dust		May form combustible dust concentrations in air [if small particles are generated during further processing, handling or by other means.].

Full text of H statements : see section 16

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US)



Signal word (GHS US) : Danger
Hazard statements (GHS US) : CODU - May form combustible dust concentrations in air [if small particles are generated during further processing, handling or by other means.]

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Precautionary statements (GHS US)

H302+H312 - Harmful if swallowed or in contact with skin

H331 - Toxic if inhaled

: Avoid breathing dust.

Wash hands, forearms and face thoroughly after handling.

Do not eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Wear protective clothing, eye and face protection, protective gloves, respiratory protection.

If swallowed: Call a poison center or doctor if you feel unwell.

Rinse mouth.

If on skin: Wash with plenty of water.

Take off contaminated clothing and wash it before reuse.

If inhaled: Remove person to fresh air and keep comfortable for breathing.

Call a poison center or doctor.

Store in a well-ventilated place. Keep container tightly closed.

Store locked up.

Dispose of contents and/or container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulations.

2.3. Hazards associated with known or reasonably anticipated uses

No additional information available

2.4. Hazards not otherwise classified

Other hazards which do not result in classification : May form combustible dust concentrations in air.

2.5. Unknown acute toxicity

No additional information available

SECTION 3 Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Cellulose	CAS-No.: 9004-34-6	89.9	Comb. Dust 1
3,4-Diaminopyridine phosphate	CAS-No.: 446254-47-3	7.6	Acute Tox. 2 (Oral), H300 Acute Tox. 3 (Dermal), H311 Acute Tox. 2 (Inhalation), H330 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335 Comb. Dust 1
Calcium Stearate	CAS-No.: 1592-23-0	2	Not classified

Full text of hazard classes and H-statements : see section 16

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

SECTION 4 First aid measures

4.1. Description of necessary first-aid measures

First-aid measures general	: First aider: Pay attention to self-protection. Never give anything by mouth to an unconscious person. Give artificial respiration if necessary. Induce artificial respiration with mask fitted with one-way valve or other suitable device but, not mouth-to-mouth. Call a poison center/doctor/physician if you feel unwell.
First-aid measures after inhalation	: Move the affected person away from the contaminated area and into the fresh air. If unconscious, place in the recovery position and seek medical advice. Call a physician immediately.
First-aid measures after skin contact	: After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water. Call a poison center/doctor.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth out with water. Do not induce vomiting. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Call a physician immediately.

4.2. Most important symptoms/effects, acute and delayed

Symptoms/effects	: Tingling around the mouth, tongue, face, fingers, toes, and other body parts. Irritation to lungs and upper respiratory tract shown as rhinitis, pharyngitis and pneumonia. Gastrointestinal disturbances. Headache.
Symptoms/effects after inhalation	: Toxic if inhaled.
Symptoms/effects after skin contact	: Harmful in contact with skin.
Symptoms/effects after eye contact	: Eye irritation signs and symptoms may include a burning sensation, redness, swelling, and/or blurred vision.
Symptoms/effects after ingestion	: Harmful if swallowed.
Most Important Symptoms/Effects	: Active Pharmaceutical Ingredient (API). Occupational exposure may cause adverse physiological effects.

4.3. Indication of immediate medical attention and special treatment needed, if necessary

Other medical advice or treatment	: Treat symptomatically.
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SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Alcohol-resistant foam.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Specific hazards arising from the chemical

Fire hazard	: May form combustible dust concentrations in air.
Explosion hazard	: No direct explosion hazard.
Hazardous decomposition products in case of fire	: Toxic fumes may be released. Thermal decomposition may produce: Carbon dioxide. Carbon monoxide. Phosphorus pentoxide. Nitrogen oxides. Silicon oxides. Calcium oxides.

5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions	: Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection. Move containers from fire area if it can be done without personal risk. Cool down the containers exposed to heat with a water spray. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

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Safety Data Sheet

According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

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| Protective equipment | : | Wear recommended personal protective equipment. |
| Emergency procedures | : | Evacuate the danger area. If outdoors, move to an area upwind of the danger area. Avoid contact with skin, eyes and clothing. If possible without taking personal risks, remove ignition sources, ventilate area. Use only non-sparking tools. Prevent other non-emergency personnel from entering the danger area. |

For emergency responders

- | | | |
|----------------------|---|---|
| Protective equipment | : | Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection". |
| Emergency procedures | : | Evacuate unnecessary personnel. Avoid dust formation. Do not touch or walk on the spilled product. Remove all sources of ignition. Ventilate the area thoroughly. Prevent from entering sewers, basements and workpits, or any place where its accumulation can be dangerous. |

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|---------------------------|---|-----------------------------------|
| Environmental precautions | : | Avoid release to the environment. |
|---------------------------|---|-----------------------------------|

6.2. Methods and materials for containment and cleaning up

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|-------------------------|---|--|
| For containment | : | Avoid dust formation. Using a clean shovel, put the material in a dry container and cover without compressing it. Contain with non-combustible inert absorbent. |
| Methods for cleaning up | : | Take up in non-combustible inert absorbent and place into container for disposal. Contaminated absorbent material may pose the same hazard as the spilt product. Decontaminate surfaces and equipment with water and detergent. Until a sufficient level of dilution is achieved, the decontamination water may pose the same hazards as the product. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations. |

For further information refer to section 8: "Exposure controls/personal protection", For further information refer to section 13: "Disposal considerations".

SECTION 7 Handling and storage

7.1. Precautions for safe handling

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| Precautions for safe handling | : | Ensure good ventilation of the work station. Do not handle until all safety precautions have been read and understood. Handle in accordance with good industrial hygiene and safety procedures. Wear personal protective equipment. Avoid all personal contact including breathing in the dust. Avoid contact with skin, eyes and clothing. Avoid dust formation. |
| Technical measures | : | Empty containers retain product residue and can be hazardous. |
| Hygiene measures | : | Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. |

7.2. Conditions for safe storage, including incompatibilities

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|-----------------------|---|--|
| Technical measures | : | Keep in a cool, well-ventilated place away from heat. |
| Storage conditions | : | Protect from moisture. Store in a cool, dry and well-ventilated area away from incompatible substances. Protect from sunlight. |
| Incompatible products | : | Strong oxidizers. |
| Storage temperature | : | 20 – 25 °C / 68 - 77 °F |
| Packaging materials | : | Always store product in container of same material as original container. |

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

SECTION 8 Exposure controls/personal protection

8.1. Control parameters

Cellulose (9004-34-6)

USA - ACGIH® - Threshold Limit Values

Local name	Cellulose
ACGIH® TLV® TWA	10 mg/m ³
Remark (ACGIH®)	TLV® Basis: URT irr
Regulatory reference	ACGIH 2026

USA - OSHA - Occupational Exposure Limits

Local name	Cellulose
OSHA PEL TWA	15 mg/m ³ (Total dust) 5 mg/m ³ (Respirable fraction)
Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1

USA - NIOSH - Occupational Exposure Limits

Local name	Cellulose
NIOSH REL 10h TWA	10 mg/m ³ (Total dust) 5 mg/m ³ (Respirable fraction)
Regulatory reference (US-NIOSH)	OSHA Annotated Table Z-1 (NIOSH Pocket Guide to Chemical Hazards (NPG))

8.2. Appropriate engineering controls

Appropriate engineering controls	: Ensure good ventilation of the work station. Use general ventilation, local exhaust ventilation, or process enclosure to keep the airborne concentrations below the permissible exposure limits. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.
Environmental exposure controls	: Avoid release to the environment.

8.3. Individual protection measures, such as personal protective equipment

Personal protective equipment:

Wear recommended personal protective equipment. Body protection should be chosen depending on activity and possible exposure.

Materials for protective clothing:

Wear suitable protective clothing

Hand protection:

Protective gloves. Any specific glove information provided is based on published literature and glove manufacturer data. Glove suitability and breakthrough time will differ depending on the specific use conditions. Contact the glove manufacturer for specific advice on glove selection and breakthrough times for your use conditions. Inspect and replace worn or damaged gloves. The types of gloves to be considered for this material include: Neoprene or nitrile rubber gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Respiratory protection:

Use NIOSH approved respirator if ventilation is inadequate. SCBA for emergency responders. Must be used in accordance with an OSHA compliant respiratory protection program. Dust protection- Particle filter P3, color code white

Personal protective equipment symbol(s):



SECTION 9 Physical and chemical properties

9.1. Basic physical and chemical properties

Physical state	: Solid
Appearance	: Tablets.
Color	: White to off-white
Odor	: No data available
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Flammability (solid, gas)	: Non flammable.
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
Viscosity, kinematic	: Not applicable
Explosion limits	: Not applicable
Explosive properties	: May form combustible dust concentrations in air [if small particles are generated during further processing, handling or by other means.].
Particle characteristics	: No data available

9.2. Data relevant with regard to physical hazard classes (supplemental)

No additional information available

SECTION 10 Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

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Safety Data Sheet

According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

10.4. Conditions to avoid

Avoid dust generation. Keep away from open flames, hot surfaces and sources of ignition. Avoid exposure to incompatible products. Protect from moisture. Exposure to air or moisture over prolonged periods. Incompatible materials.

10.5. Incompatible materials

Oxidizing agents.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Toxic fumes may be released. Carbon dioxide. Carbon monoxide. Nitrogen oxides. Phosphorus pentoxide. Calcium oxides. Silicon oxides.

SECTION 11 Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Harmful if swallowed.
Acute toxicity (dermal) : Harmful in contact with skin.
Acute toxicity (inhalation) : Inhalation:dust,mist: Toxic if inhaled.

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ATE US (oral)	556.538 mg/kg body weight
ATE US (dermal)	1402.852 mg/kg body weight
ATE US (dust, mist)	0.658 mg/l/4h

3,4-Diaminopyridine phosphate	
LD50 oral rat	47 mg/kg body weight
LD50 dermal rabbit	> 200 mg/kg body weight

Cellulose	
LD50 oral rat	> 5000 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 Inhalation - Rat	> 5.05 mg/l/4h

Calcium Stearate	
LD50 oral rat	> 10000 mg/kg body weight
LD50 dermal rat	> 2000 mg/kg body weight

Skin corrosion/irritation : Not classified

Cellulose	
pH	5 – 7.5

Calcium Stearate	
pH	6.86 Temp.: 29 °C Concentration: 1 vol%

Serious eye damage/irritation : Not classified

Cellulose	
pH	5 – 7.5

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Calcium Stearate	
pH	6.86 Temp.: 29 °C Concentration: 1 vol%
Reconstructed Human Cornea-like Epithelium (RhCE) Test	Not irritating

Respiratory or skin sensitization : Not classified

Calcium Stearate	
Local lymph node assay, mouse	Non-sensitizing.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

3,4-Diaminopyridine phosphate	
NOAEL (chronic,oral,animal/female,2 years)	15 mg/kg body weight

Reproductive toxicity : Not classified
Reproductive toxicity, rat: 0 - 75 mg/kg/day ((male and female) Dosed prior to and during mating, and continuing in females throughout organogenesis. Produced no adverse effects on fertility. Plasma amifampridine exposure (AUC) at the highest dose tested is approximately 7 times that in humans at the maximum recommended human dose (MRHD) of 80 mg amifampridine/day)

STOT-single exposure : Not classified

3,4-Diaminopyridine phosphate	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified

Calcium Stearate	
NOAEL (oral,rat,90 days)	1000 mg/kg body weight
Aspiration hazard	: Not classified

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Viscosity, kinematic	Not applicable
Symptoms/effects	: Tingling around the mouth, tongue, face, fingers, toes, and other body parts. Irritation to lungs and upper respiratory tract shown as rhinitis, pharyngitis and pneumonia. Gastrointestinal disturbances. Headache.
Symptoms/effects after inhalation	: Toxic if inhaled.
Symptoms/effects after skin contact	: Harmful in contact with skin.
Symptoms/effects after eye contact	: Eye irritation signs and symptoms may include a burning sensation, redness, swelling, and/or blurred vision.
Symptoms/effects after ingestion	: Harmful if swallowed.
Most Important Symptoms/Effects	: Active Pharmaceutical Ingredient (API). Occupational exposure may cause adverse physiological effects.

SECTION 12 Ecological information

12.1. Ecotoxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

Hazardous to the aquatic environment, short-term (acute) : Not classified

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Hazardous to the aquatic environment, long-term (chronic) : Not classified

12.2. Persistence and degradability

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Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

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Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Ozone	: Not classified
Fluorinated greenhouse gases	: No

SECTION 13 Disposal considerations

Regional waste regulation	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Comply with applicable regulations for solid waste disposal. Disposal must be done according to official regulations.
Additional information	: Do not re-use empty containers.

SECTION 14 Transport information

In accordance with DOT / IMDG / IATA

DOT	IMDG	IATA
14.1. UN number		
Not regulated for transport		
14.2. Proper Shipping Name		
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
	Not regulated	
No supplementary information available		

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

14.6. Transport in bulk

Not applicable

14.7. Special precautions for user

DOT

Not regulated

IMDG

Not regulated

IATA

Not regulated

SECTION 15 Regulatory information

15.1. Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:

3,4-Diaminopyridine phosphate	CAS-No. 446254-47-3	7.6%
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This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

CANADA

3,4-Diaminopyridine phosphate (446254-47-3)

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

Cellulose (9004-34-6)

Listed on the Canadian DSL (Domestic Substances List)

Calcium Stearate (1592-23-0)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

Cellulose (9004-34-6)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Calcium Stearate (1592-23-0)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

15.3. State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

Component	State or local regulations
Cellulose(9004-34-6)	U.S. - Massachusetts - Right To Know List; U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16 Other information

According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Revision date : 6/17/2026

Issue date : 6/17/2025

Full text of hazard classes and H-statements	
H300	Fatal if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H312	Harmful in contact with skin
H315	Causes skin irritation
H319	Causes serious eye irritation
H330	Fatal if inhaled
H331	Toxic if inhaled
H335	May cause respiratory irritation

Abbreviations and acronyms	
ACGIH	American Conference of Governmental Industrial Hygienists
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical oxygen demand (BOD)
CAS-No.	Chemical Abstracts Service number
ED	Endocrine disruptor
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
Log Kow	Partition coefficient n-octanol/water (Log Kow)
Log Pow	Partition coefficient n-octanol/water (Log Pow)

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Abbreviations and acronyms	
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
N.O.S.	Not Otherwise Specified
OEL	Occupational Exposure Limit
OSHA	Occupational Safety Health Administration
PNEC	Predicted No-Effect Concentration
PPE	Personal protection equipment
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
TWA	Time Weighted Average

Indication of changes:		
Section	Changed item	Comments
8.1	Occupational exposure limits	Modified
14	UN-No. (IMDG)	Removed
14	UN-No. (IATA)	Removed
14	UN-No. (DOT)	Removed

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.