SAFETY DATA SHEET

1. Identification

Product identifier **Cabergoline**

Other means of identification

Catalog number 1084306

Chemical name Ergoline-8beta-carboxamide, N-[3-(dimethylamino)propyl]-N-[(ethylamino)carbonyl]-6-(2-propenyl)-

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 4
Reproductive toxicity Effects on or via lactation

OSHA hazard(s) Not classified.

Label elements

Signal word Warning

Hazard statement Harmful if swallowed. May cause harm to breast-fed children.

Precautionary statement

Prevention Wash thoroughly after handling. Obtain special instructions before use. Avoid contact during pregnancy/while nursing.

Response If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed or concerned: Get medical advice/attention.

Storage Not available.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

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

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Cabergoline		81409-90-7	100

4. First-aid measures

Inhalation Move 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. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Not available.
Indication of immediate medical attention and special treatment needed	Treatment of overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. For dyskinesia, administer diazepam orally. Monitor vital signs, liver function, CBC, and CNS function. If patient is vomiting, monitor fluid and electrolyte status. [Poisindex 2008]
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	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.
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.

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. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. 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. Clean surface thoroughly to remove residual contamination.

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

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.
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. 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 disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties 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	Not available.
Melting point/freezing point	212 - 221 °F (100 - 105 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
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	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Insoluble.
Partition coefficient (n-octanol/water)	-2.3
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Ergot derivative.
Molecular formula	C26H37N5O2
Molecular weight	451.6
Solubility (other)	Freely soluble in ethanol; soluble in chloroform and in dimethyl formamide; very slightly soluble in hexane; slightly soluble in 0.1 M hydrochloric acid; miscible in acetone, in ethyl acetate, and in ether.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.

Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents.
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

Ingestion	Harmful 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	Nausea. Vomiting. Abdominal pain. Loss of appetite. Diarrhea. Nasal congestion. Constipation. Headache. Fainting. Dizziness. Tiredness. Drowsiness. Depression. Nervousness. Hallucinations. Visual disturbances. Breast pain.
Delayed and immediate effects of exposure	Low blood pressure. Congestive heart failure. Heart valve disorders. Lung disorders.
Cross sensitivity	Persons sensitive to other ergot derivatives may be sensitive to this material as well.
Medical conditions aggravated by exposure	Liver impairment. Hypertension. Heart or lung disorders linked to fibrotic tissue.
Acute toxicity	Harmful if swallowed.

Product	Species	Test Results
Cabergoline (CAS 81409-90-7)		
Oral		
LD50	Mouse	202 mg/kg
	Rat	383 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	Based on available data, the classification criteria are not met.

Sensitization

Sensitization test
Result: Non-sensitizing.
Species: Guinea pig
Organ: Skin.

Germ cell mutagenicity Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity

Chromosomal aberrations in human lymphocytes
Result: Negative.
Direct DNA damage in bacteria
Result: Negative.
Hamster cell mutagenicity study
Result: Negative.
Micronucleus test in mouse bone marrow cells
Result: Negative.
S. typhimurium Ames assay
Result: Negative.

Carcinogenicity Based on available data, the classification criteria are not met. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

0.32 mg/kg/day Carcinogenicity study
Result: Slight increase in malignant tumors of the cervix and uterus and interstitial cell adenomas.
Species: Rat
Test Duration: 24 months
0.98 mg/kg/day Carcinogenicity study
Result: Slight increase in the incidence of cervical and uterine leiomyomas and uterine leiomyosarcomas.
Species: Mouse
Test Duration: 21 months

Reproductive toxicity May cause harm to breastfed babies. This material suppresses lactation.

Reproductivity

0.003 mg/kg Reproductivity study
Result: This dose administered prior to and during mating inhibited conception in females.
Species: Rat
0.012 mg/kg/day Reproductivity study
Result: This dose administered during organogenesis increased post-implantation fetal loss.
Species: Rat
0.032 mg/kg/day Reproductivity study
Result: Did not impair fertility in male rats.
Species: Rat
4 mg/kg/day Reproductivity study
Result: Showed increase incidence of malformations.
Species: Rabbit
8 mg/kg/day Reproductivity study
Result: No increase in birth defects.
Species: Mouse
8 mg/kg/day Reproductivity study
Result: No treatment-related malformations or embryotoxicity.
Species: Rabbit

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

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 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 Not available.

Hazardous waste code Not available.

Waste from residues / unused products Dispose of in accordance with local regulations. 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

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

US federal regulations 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.
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)	No
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)	No
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	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)

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

Issue date	04-16-2008
Revision date	02-28-2014
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.