



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Aminoglutethimide</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1025205	
<b>CAS number</b>	125-84-8	
<b>Synonyms</b>	p-Aminoglutethimide	
<b>Chemical name</b>	2,6-Piperidinedione, 3-(4-aminophenyl)-3-ethyl-	
<b>Recommended use</b>	Specified quality tests and assay use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
<b>Telephone</b>	RS Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Reproductive toxicity	Category 1
	Specific target organ toxicity, repeated exposure	Category 1 (endocrine system)
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger
<b>Hazard statement</b>	Harmful if swallowed. May damage fertility or the unborn child. Causes damage to organs (endocrine system) through prolonged or repeated exposure.
<b>Precautionary statement</b>	
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed or concerned: Get medical advice/attention.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.

<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	Pharmacologically active material.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Aminoglutethimide	p-Aminoglutethimide	125-84-8	100

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.
<b>Most important symptoms/effects, acute and delayed</b>	Adrenal suppression. Reproductive system effects. Pharmacologically active material. Occupational exposure may cause physiological effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Overdose treatment may include the following: Perform gastric lavage to decrease absorption. Dialysis may be used to enhance elimination if toxicity is severe. Support respiratory function. If hypovolemia or hypotension occur, intravenous norepinephrine plus rehydration may be used. Intravenous hydrocortisone may be used if glucocorticoid insufficiency develops. Fludrocortisone therapy may be instituted if mineralcorticoid insufficiency develops.
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Methods and materials for containment and cleaning up</b>	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. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

### 7. Handling and storage

<b>Precautions for safe handling</b>	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.
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<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
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## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	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

<b>Eye/face protection</b>	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.
<b>Skin protection</b>	
<b>Hand protection</b>	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.
<b>Other</b>	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.
<b>Respiratory protection</b>	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.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.

<b>General hygiene considerations</b>	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.
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## 9. Physical and chemical properties

<b>Appearance</b>	Appearance descriptions are general information and not specific to any USP lot.
<b>Physical state</b>	Solid.
<b>Form</b>	Crystalline powder.
<b>Color</b>	White. Cream.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	300.2 - 302 °F (149 - 150 °C)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	< 0.0000001 kPa at 25 °C
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Practically insoluble.
<b>Solubility (other)</b>	Acetone: Freely soluble.

	Dichloromethane: Soluble. Methanol: Soluble.
<b>Partition coefficient (n-octanol/water)</b>	1 = log Pow at 25 °C
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Piperidine derivative.
<b>Molecular formula</b>	C13H16N2O2
<b>Molecular weight</b>	232.31

## 10. Stability and reactivity

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

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Harmful if swallowed.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	Dizziness. Drowsiness. Headache. Confusion. Unsteadiness. Tiredness. Weakness. Depression. Slurred speech. Uncontrolled eye movements. Loss of appetite. Fever. Chills. Cold sweats. Muscle pain. Skin rash. Gastrointestinal disturbances.

### Information on toxicological effects

<b>Acute toxicity</b>	Harmful if swallowed.
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Product	Species	Test Results
Aminoglutethimide (CAS 125-84-8)		
<u>Acute</u>		
<b>Dermal</b>		
LD50	Rabbit	> 3038 mg/kg
<b>Inhalation</b>		
LC50	Rat	> 1280 mg/m3, 4 hours
<b>Oral</b>		
LD50	Rat	1800 mg/kg
		770 mg/kg
<b>Skin corrosion/irritation</b>	Knowledge about health hazard is incomplete.	
<b>Serious eye damage/eye irritation</b>	Knowledge about health hazard is incomplete.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Skin sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Germ cell mutagenicity</b>	Knowledge about mutagenicity is incomplete.	

**Carcinogenicity** Knowledge about carcinogenicity is incomplete.

10 - 60 mg/kg/day Carcinogenicity

Result: Benign and malignant tumors of the adrenal cortex, ovaries, thyroid, and urinary bladder.

Species: Rat

#### **IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

#### **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

#### **US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

#### **Reproductive toxicity**

May damage fertility or the unborn child.

Aminoglutethimide has caused abnormalities in female infants whose mothers were treated with it and other medications. Studies in rats have shown that aminoglutethimide causes fetal death and birth defects.

#### **Reproductivity**

Reproductivity / developmental, doses five to fifteen times the human dose.

Result: Virilization of female external genitalia, feminization of male external genitalia, and increased fetal deaths.

Species: Rat

#### **Specific target organ toxicity - single exposure**

Knowledge about health hazard is incomplete.

#### **Specific target organ toxicity - repeated exposure**

Causes damage to organs (endocrine system) through prolonged or repeated exposure.

#### **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**

Aminoglutethimide (CAS 125-84-8)

##### **Aquatic**

##### *Acute*

Fish

LC50

Zebra danio (Danio rerio)

430 mg/l, 96 hours

#### **Persistence and degradability**

Not readily biodegradable.

#### **Bioaccumulative potential**

##### **Octanol/water partition coefficient log Kow**

1, = log Pow at 25 °C

#### **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 1910.1001-1052)

Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**Classified hazard categories** Acute toxicity (any route of exposure)  
Reproductive toxicity  
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



**WARNING:** This product can expose you to Aminoglutethimide, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

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

Aminoglutethimide (CAS 125-84-8)

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)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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

<b>Issue date</b>	01-29-2004
<b>Revision date</b>	09-27-2019
<b>Version #</b>	03
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