

1. Identification

Product identifier	Flutamide	
Other means of identification		
Catalog number	1285851	
Chemical name	Propanamide, 2-methyl-N-[4-nitro-3-(trifluoromethyl)-phenyl]-	
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
	Serious eye damage/eye irritation	Category 2B
	Carcinogenicity	Category 2
	Reproductive toxicity	Category 1
	Specific target organ toxicity, repeated exposure	Category 1 (endocrine system, liver)
OSHA hazard(s)	Not classified.	
Label elements		



Signal word	Danger	
Hazard statement	Harmful if swallowed. Causes eye irritation. Suspected of causing cancer. May damage fertility or the unborn child. Causes damage to organs (endocrine system, liver) through prolonged or repeated exposure.	
Precautionary statement		
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.	
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If in eyes: 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. If exposed or concerned: Get medical advice/attention.	
Storage	Store locked up.	
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	%
Flutamide		13311-84-7	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 cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
Most important symptoms/effects, acute and delayed	Irritation of eyes and mucous membranes. Gastrointestinal disturbances.
Indication of immediate medical attention and special treatment needed	Treatment for overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. Consider gastric lavage if it can be performed soon after ingestion, unless contraindicated. Control seizures prior to initiation and protect airway. In agitated patients with hypertension and tachycardia, sedate with benzodiazepines. For severe hypertension, administer nitroprusside, labetalol, nitroglycerin, or phentolamine. For methemoglobinemia, slowly administer methylene blue intravenously. Monitor liver and kidney function tests and ECG. Hemodialysis is not likely to be effective. [Meditext]
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 CO ₂ .
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

Exposure limit values

Industrial Use

Material	Type	Value
Flutamide (CAS 13311-84-7)	TWA	0.75 mg/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

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

Buff to yellow powder.

Physical state

Solid.

Form

Powder.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

230 - 237.2 °F (110 - 114 °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

0.0000001 kPa at 25 °C

Vapor density

Not available.

Relative density	Not available.
Solubility in water	Practically insoluble.
Partition coefficient (n-octanol/water)	3.35
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Acetanilid.
Molecular formula	C11H11F3N2O3
Molecular weight	276.21
Solubility (other)	Freely soluble in alcohol, in acetone, in ethyl acetate, and in methanol; soluble in chloroform and in ether; practically insoluble in petroleum ether and in liquid paraffin.

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. Avoid exposure to light and ignition sources.
Incompatible materials	Not available.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. F-.

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	Causes eye irritation.
Symptoms related to the physical, chemical, and toxicological characteristics	Nausea. Vomiting. Diarrhea. Fatigue. Weakness. Flushing. Sweating. Swelling or tenderness of breasts. Swelling of face. Swelling of extremities. Cough. Hoarseness. Skin rash. Fever. Chills. Lower back or side pain. Numbness, pain, tingling, or weakness in hands or feet. Skin sensitivity to sunlight. Bluish skin.

Delayed and immediate effects of exposure	Respiratory depression. Liver damage.
Medical conditions aggravated by exposure	Impaired liver function. G6PD deficiency. Blood disorders.

Acute toxicity	Harmful if swallowed.
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Product	Species	Test Results
Flutamide (CAS 13311-84-7)		
<i>Oral</i>		
LD50	Rat	787 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Causes eye irritation.	
Local effects		
Eye irritation		
Result: Slight.		
Species: Rabbit		
Skin irritation		
Result: Slight.		
Species: Rabbit		
Respiratory sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	Due to lack of data the classification is not possible.	
Germ cell mutagenicity	Based on available data, the classification criteria are not met.	
Mutagenicity		
Ames test		
Result: Negative.		

Mutagenicity

Dominant lethal study (rats)
Result: Negative.

Carcinogenicity

Suspected of causing cancer. Therapeutic use of this material has caused rare malignant breast tumors in men.
This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

10 - 50 mg/kg/day Carcinogenicity study
Result: Testicular interstitial cell adenomas and mammary adenomas, adenocarcinomas, and fibroadenomas in male rats.
Species: Rat
40 mg/kg/day Carcinogenicity study
Result: Negative.
Species: Dog
90 mg/kg/day Carcinogenicity study
Result: Negative.
Species: Monkey

Reproductive toxicity

May damage fertility or the unborn child. Decreased sperm counts occurred in men taking flutamide in a six-week study. The antiandrogenic effects of flutamide may cause feminization of a male fetus in humans.

Reproductivity

10 mg/kg/day Reproductive study
Result: Feminization of male fetus.
Species: Rat
100 - 200 mg/kg/day Reproductive study
Result: Feminization of male offspring, slight increase in minor skeletal development.
Species: Rat
3 - 30 mg/kg Gestational study (subcutaneous dose day 16-21)
Result: Reproductive anomalies include absence of testes, prostate gland, and seminal vesicles.
Species: Rat
32 - 180 mg/kg/day Fertility study (52 weeks)
Result: Suppression of spermatogenesis.
Species: Rat

Specific target organ toxicity - single exposure

Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure

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

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 - Yes
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 WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

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)	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)	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 10-19-2007

Revision date 06-26-2014

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.