

1. Identification

Product identifier	Flurbiprofen	
Other means of identification		
Catalog number	1285750	
Chemical name	[1,1'-Biphenyl]-4-acetic acid, 2-fluoro-alpha-methyl-, (+/-)-	
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 3
	Acute toxicity, dermal	Category 3
	Sensitization, skin	Category 1
	Reproductive toxicity	Category 2
	Specific target organ toxicity, repeated exposure	Category 1 (cardiovascular system, gastrointestinal tract)
OSHA hazard(s)	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Toxic if swallowed. Toxic in contact with skin. May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child. Causes damage to organs (cardiovascular system, gastrointestinal tract) 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. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If on skin: Wash with plenty of water/. If exposed or concerned: Get medical advice/attention. Call a poison center/doctor/. Rinse mouth. If skin irritation or rash occurs: 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	%
Flurbiprofen		5104-49-4	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Take off immediately all contaminated clothing. Wash off with soap and plenty of water. For minor skin contact, avoid spreading material on unaffected skin. Call a POISON CENTER or doctor/physician if you feel unwell. If skin irritation or rash occurs: Get medical advice/attention.
Eye contact	Rinse cautiously with water for several minutes. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Most important symptoms/effects, acute and delayed	May cause allergic skin reaction. Cardiovascular effects.
Indication of immediate medical attention and special treatment needed	Treatment of nonsteroidal anti-inflammatory drug (NSAID) overdose should be symptomatic and supportive and may include the following: Induce vomiting (DO NOT use syrup of ipecac) or perform gastric lavage. Administer activated charcoal as a slurry. For gastrointestinal hemorrhage, monitor stool guaiac and administer antacids or sucralfate. For mild/moderate allergic reactions, administer antihistamines with or without inhaled beta agonists, corticosteroids, or epinephrine. For severe allergic reactions, administer oxygen, antihistamines, epinephrine, or corticosteroids. Nephritis or nephrotic syndrome, thrombocytopenia, or hemolytic anemia may respond to glucocorticoid administration. For severe acidosis, administer sodium bicarbonate. Administer as required: plasma volume expanders for severe hypotension; diazepam or other benzodiazepine for convulsions; vitamin K1 for hypoprothrombinemia; and/or dopamine plus dobutamine intravenously to prevent or reverse early indications of renal failure. Forced diuresis, alkalinization of urine, and hemoperfusion may not be useful. (Poisindex) (USP DI)

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.

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. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

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.

Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing 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 or slightly yellow crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Practically odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

230 - 242.6 °F (110 - 117 °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

0.0000005 kPa at 25 °C

Vapor density

Not available.

Relative density

Not available.

Solubility in water	Practically insoluble.
Partition coefficient (n-octanol/water)	4.16
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Propionic acid derivative.
Molecular formula	C15H13FO2
Molecular weight	244.26
Solubility (other)	Freely soluble in acetone, in dehydrated ethanol, in ether, and in methanol; soluble in acetonitrile.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable at 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. Strong acids. Strong bases.
Hazardous decomposition products	F-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Toxic if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Toxic in contact with skin. May cause an allergic skin reaction.
Eye contact	Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics For nonsteroidal anti-inflammatory drugs (NSAIDs): Nausea. Vomiting. Diarrhea. Constipation. Heartburn. Stomach pain. Black or tarry stools. Bleeding or bruising. Swelling. Sores, ulcers, or white spots on lips or mouth. Sweating. Bluish-colored skin. Insomnia. Mood, mental or behavioral changes. Confusion. Dizziness. Drowsiness. Headache. Itching. Rash. Weight gain. Vision, speech, or walking problems. Ringing in ears. Tremors. Trouble breathing. Fast heartbeat or palpitations.

Delayed and immediate effects of exposure For nonsteroidal anti-inflammatory drugs (NSAIDs): Gastrointestinal ulceration or bleeding. Hypertension. Kidney impairment. Blood disorders. Cardiovascular thrombotic events. Stroke. Central nervous system effects. Coma.

Cross sensitivity Persons sensitive to one nonsteroidal anti-inflammatory drug (NSAID), including aspirin, may be sensitive to this material also.

Medical conditions aggravated by exposure For nonsteroidal anti-inflammatory drugs (NSAIDs): Asthma. Aspirin allergy. Active alcoholism. Anemia. Impaired kidney or liver function. Cardiovascular disorders. Bleeding disorders. Peptic ulcer or gastrointestinal bleeding. Hypertension. Stomatitis.

Acute toxicity Toxic if swallowed. Toxic in contact with skin.

Product	Species	Test Results
Flurbiprofen (CAS 5104-49-4)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	500 mg/kg
<i>Oral</i>		
LD50	Mouse	640 mg/kg
	Rabbit	290 mg/kg
	Rat	117 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.	

Local effects

Irritancy test
Result: Irritant.
Species: Guinea pig
Organ: Skin
Severity: Minimal.

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization May cause an allergic skin reaction.

Sensitization

Guinea pig maximization test
Result: 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

In vivo micronucleus assay
Result: Negative.
In vivo sister-chromatid assay in human lymphocytes
Result: Positive.
Unscheduled DNA synthesis 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.

12 mg/kg/day Carcinogenicity study
Result: No evidence of carcinogenicity when administered orally.
Species: Mouse
Test Duration: 80 weeks
5 - 12 mg/kg/day Carcinogenicity study, 12 mg/kg/day for 32 weeks, then 5 mg/kg/day.
Result: No evidence of carcinogenicity when administered orally.
Species: Rat
Test Duration: 2 years

Reproductive toxicity Suspected of damaging fertility or the unborn child.
Therapeutic use of nonsteroidal anti-inflammatory agents (NSAIDs) during the second half of pregnancy is associated with adverse effects in the fetus such as premature closure of the ductus arteriosus, which may lead to persistent pulmonary hypertension in the newborn. Animal studies have shown that NSAIDs administered during late pregnancy can cause prolonged gestation, difficult labor, delayed birth, and decreased pup survival rates.

Reproductivity

0.4 - 25 mg/kg/day Reproductivity study
Result: Slower fetal growth, fetal distress, reduced birthweight, stillbirth, and decreased pup survival occurred at 0.4 mg/kg/day. No impairment of fertility occurred at 4 mg/kg/day. No increased incidence of birth defects occurred at 25 mg/kg/day.
Species: Rat
12 mg/kg/day Reproductivity study
Result: No increased incidence of birth defects occurred.
Species: Mouse
7.5 mg/kg/day Reproductivity study
Result: No increased incidence of birth defects occurred.
Species: Rabbit

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Causes damage to organs (cardiovascular system, gastrointestinal tract) 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

UN number	UN2811
UN proper shipping name	Toxic, solid, organic, n.o.s. (Flurbiprofen)
Transport hazard class(es)	6.1
Subsidiary class(es)	Not available.
Packing group	III

IATA

UN number	UN2811
UN proper shipping name	Toxic, solid, organic, n.o.s. (Flurbiprofen)
Transport hazard class(es)	6.1
Subsidiary class(es)	-
Packaging group	III

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

DOT; IATA



15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
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)	Yes
Canada	Domestic Substances List (DSL)	Yes
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)	Yes
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 01-30-2007

Revision date 05-01-2014

Version # 03

Further information Not available.

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Revision Information This document has undergone significant changes and should be reviewed in its entirety.