



SAFETY DATA SHEET

1. Identification

Product identifier	Flurbiprofen	
Other means of identification		
Catalog number	1285750	
CAS number	5104-49-4	
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		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTRAC within US & Canada	1-800-424-9300
	CHEMTRAC 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)
Environmental hazards	Not classified.	
OSHA defined hazards	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. Do not breathe dust/fume/gas/mist/vapors/spray. 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 swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. Call a poison center/doctor if you feel unwell. If skin irritation or rash occurs: Get medical advice/attention. Take off immediately all contaminated clothing and wash it before reuse. 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)	None known.

Supplemental information Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Flurbiprofen		5104-49-4	100

4. First-aid measures

Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact

Remove contaminated clothing immediately and wash skin with soap and water. Get medical advice/attention if you feel unwell. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.

Eye contact

Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion

Call a physician or poison control center immediately. Rinse mouth. 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 substance is ingested. 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

Cardiovascular effects. Pharmacologically active material. Occupational exposure may cause physiological effects.

Indication of immediate medical attention and special treatment needed

Treat symptomatically. Treatment of nonsteroidal anti-inflammatory drug (NSAID) overdose 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 or urine, and hemoperfusion may not be useful.

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

Water. Foam. Dry chemical or CO₂. Use fire-extinguishing media appropriate for surrounding materials.

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.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures**Personal precautions, protective equipment and emergency procedures**

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.

Methods and materials for containment and cleaning up

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.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

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**Occupational exposure limits**

No exposure limits noted for ingredient(s).

Biological limit values

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

Appropriate engineering controls

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**Eye/face protection**

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.

Skin protection**Hand protection**

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.

Other

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.

Respiratory protection

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.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

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.

9. Physical and chemical properties**Appearance**

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Crystalline powder.

Color

White. Light yellow.

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 available.
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(ies)	
Solubility (water)	Practically insoluble.
Solubility (other)	Acetone: Freely soluble. Acetonitrile: Freely soluble. Dehydrated alcohol: Freely soluble. Ether: Freely soluble. Methanol: Freely soluble.
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

10. Stability and reactivity

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

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Toxic in contact with skin. May cause an allergic skin reaction.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Toxic if swallowed.
Symptoms related to the physical, chemical, and toxicological characteristics	For nonsteroidal anti-inflammatory drugs (NSAIDs): Gastrointestinal disturbances. Bleeding or bruising. Swelling. Ringing in ears. Confusion. Dizziness. Headache. Sweating. Bluish-colored skin. Trouble breathing. Fast heartbeat or palpitations.

Information on toxicological effects

Acute toxicity	Toxic in contact with skin. Toxic if swallowed.
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Product	Species	Test Results
Flurbiprofen (CAS 5104-49-4)		
Acute		
Dermal		
LD50	Rabbit	500 mg/kg
Oral		
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	Knowledge about health hazard is incomplete.	
Local effects		
Irritation test		
Result: Irritant.		
Species: Guinea pig		
Organ: Skin		
Severity: Minimal.		
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about sensitization hazard is incomplete.	
Skin sensitization	May cause an allergic skin reaction.	
Guinea pig maximization test		
Result: Sensitizing.		
Species: Guinea pig		
Organ: Skin		
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
Mutagenicity		
In vitro unscheduled DNA synthesis		
Result: Negative.		
In vivo micronucleus test		
Result: Negative.		
Mutagenicity: In vivo sister-chromatid assay in human lymphocytes.		
Result: Positive.		
Carcinogenicity	Based on available data, the classification criteria are not met..	
12 mg/kg/day Carcinogenicity		
Result: No evidence of carcinogenicity when administered orally.		
Species: Mouse		
Test Duration: 80 weeks		
5 - 12 mg/kg/day Carcinogenicity, 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		
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	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 Reproduction Test

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 Reproduction Test

Result: No increased incidence of birth defects occurred.

Species: Mouse

7.5 mg/kg/day Reproduction Test

Result: No increased incidence of birth defects occurred.

Species: Rabbit

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

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.

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this substance.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

4.16

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

UN number UN2811

UN proper shipping name Toxic, solid, organic, n.o.s. (Flurbiprofen)

Transport hazard class(es)

Class 6.1

Subsidiary risk -

Packing group III

IATA

UN number UN2811

UN proper shipping name Toxic, solid, organic, n.o.s. (Flurbiprofen)

Transport hazard class(es)

Class 6.1

Subsidiary risk -

Packing group III

Other information

Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
DOT; IATA	



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.
CERCLA/SARA Hazardous Substances - Not applicable.

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)
Respiratory or skin sensitization
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 Flurbiprofen, 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.

California Proposition 65 - CRT: Listed date/Developmental toxin

Flurbiprofen (CAS 5104-49-4)

Listed: August 20, 1999

California Proposition 65 - CRT: Listed date/Female reproductive toxin

Flurbiprofen (CAS 5104-49-4)

Listed: August 20, 1999

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
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**Issue date** 01-30-2007**Revision date** 08-01-2019**Version #** 04

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