


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	FLURBIPROFEN, USP/EP
PRODUCT CODE	2739
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 3) Acute Toxicity - Dermal (Category 3) Toxic to Reproduction (Category 2) Sensitization - Skin (Category 1) Chronic Aquatic Toxicity (Category 1) Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (cardiovascular system, gastrointestinal tract)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Toxic if swallowed. Toxic in contact with skin. Suspected of damaging fertility or the unborn child. May cause an allergic skin reaction. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable.

PRECAUTIONARY STATEMENT(S)

Prevention Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Do not breathe dust, fume, gas, mist, vapors, spray.
 Do not get in eyes, on skin, or on clothing.
 Do not handle until all safety precautions have been read and understood.
 Contaminated work clothing should not be allowed out of the workplace.
 Obtain, read and follow all special instructions before use.
 Wear protective gloves, protective clothing, eye protection, face protection.
 Avoid release to the environment.

Response IF SWALLOWED: Immediately call a poison center. Get emergency medical help immediately. Rinse mouth.
 IF ON SKIN (HAIR): Wash with plenty of water; Get emergency help immediately. Immediately call a poison center or medical professional; Take off immediately all contaminated clothing and wash it before reuse.
 IF EXPOSED OR CONCERNED: Get medical advice.
COLLECT SPILLAGE.
 Get medical help if you feel unwell.

Storage Store locked up.

Disposal Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION

Health Hazard	2	Flammability	0
Reactivity	0	Personal Protection	J

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME 2-(3-fluoro-4-phenylphenyl)propanoic acid
BOTANICAL NAME Not applicable
SYNONYM Not applicable
CHEMICAL FORMULA C₁₅H₁₃FO₂
CHEMICAL FAMILY Propionic acid derivative
CAS NUMBER 5104-49-4
ALTERNATE CAS NUMBER Not applicable
MOLECULAR WEIGHT 244.2637

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
FLURBIPROFEN	5104-49-4	225-827-6	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

MEDICAL ATTENTION AND SPECIAL TREATMENT

Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES**SPECIFIC HAZARDS ARISING FROM THE CHEMICAL**

Not applicable.

FLAMMABLE PROPERTIES

May be combustible at high temperature.

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES**PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE**PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION
Chemical Name: FLURBIPROFEN CAS #: 5104-49-4

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

 Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³
PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

 Work exposure level: LTEL: 1 mg/m³ (8hr-TWA)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

White or almost white, crystalline powder.

SOLUBILITY

Freely soluble in acetone, in dehydrated alcohol, in ether, methylene chloride and in methanol; soluble in acetonitrile; practically insoluble in water. It dissolves in aqueous solutions of alkali hydroxides and carbonates.

ODOR

Characteristic odor

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)	4.16	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(110-117)°C, (230-242.6)°F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	Not available
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	0.6 x 10E-3 mg/100L	VAPOR PRESSURE	0.0000005 kPa (25°C)	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established.
CHEMICAL STABILITY	Stable under recommended storage conditions.
INCOMPATIBLE MATERIALS	Strong oxidizing agents. Strong acids. Strong bases.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.
HAZARDOUS POLYMERIZATION	Will not occur.
POSSIBILITY OF HAZARDOUS REACTION	Not established.
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 117 Dermal: Rabbit LD50: (mg/kg): 500 Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met. Local effects; Irritancy test; Result: Irritant.; Species: Guinea pig; Organ: Skin; Severity: Minimal.
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	May cause an allergic skin reaction. Guinea pig maximization test; Result: Sensitizing.; Species: Guinea pig; Organ: Skin
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible. Mutagenicity: In vivo sister-chromatid assay in human: lymphocytes: Result: Positive. In vitro unscheduled DNA synthesis: Result: Negative. In vivo micronucleus test: Result: Negative.
CARCINOGENICITY	OSHA FLURBIPROFEN is not listed. NTP FLURBIPROFEN is not listed. IARC FLURBIPROFEN is not evaluated.

ADDITIONAL CARCINOGENICITY INFORMATION	<p>California Proposition 65 This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: FLURBIPROFEN</p> <p>Based on available data, the classification criteria are not met.</p> <p>12 mg/kg/day Carcinogenicity study; Species: Mouse: Result: No evidence of carcinogenicity when administered orally: Test Duration: 80 weeks 5 - 12 mg/kg/day Carcinogenicity study, 12 mg/kg/day for 32 weeks, then 5 mg/kg/day: Species: Rat: Result: No evidence of carcinogenicity when administered orally.: Test Duration: 2 years</p>
REPRODUCTIVE TOXICITY	<p>Suspected of damaging the unborn child.</p> <p>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.</p> <p>Suspected toxic for reproduction: CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (good reliability)</p> <p>Species: Rat; 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: Mouse; 12 mg/kg/day Reproduction Test Result: No increased incidence of birth defects occurred. Species: Rabbit; 7.5 mg/kg/day Reproduction Test Result: No increased incidence of birth defects occurred.</p> <p>Based on available data, the classification criteria are not met.</p>
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	<p>Causes damage to organs (cardiovascular system, gastrointestinal tract) through prolonged or repeated exposure.</p>
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	<p>Based on available data, the classification criteria are not met.</p>
ASPIRATION HAZARDS	<p>Based on available data, the classification criteria are not met.</p>
SIGNS AND SYMPTOMS OF EXPOSURE	<p>ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact</p> <p>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available</p> <p>DELAYED HEALTH EFFECT FROM 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.</p> <p>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.</p> <p>Cross sensitivity: Persons sensitive to one nonsteroidal anti-inflammatory drug (NSAID), including aspirin, may be sensitive to this material also.</p> <p>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.</p>
POTENTIAL HEALTH EFFECTS	<p>Inhalation Harmful if inhaled. May cause respiratory tract irritation.</p> <p>Ingestion Toxic if swallowed.</p> <p>Skin Toxic in contact with skin. May cause skin irritation</p> <p>Eyes Causes eye irritation.</p>

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: Fathead Minnow: (mg/L): 1.9* LC50: 96 Hr: Fish: (mg/L): 1 - 10* EC50: 72 or 96Hr: Algae (or other aqua plants): (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.
BIOACCUMULATIVE POTENTIAL	High: LogPow: 4.16
MOBILITY IN SOIL	Practically insoluble in water. Water Solubility: 8 mg/L (22°C) Vapor Pressure: 1.96E-06 mm Hg (25°C) Henry's Law Constant: 5.26E-09 atm-m ³ /mole (25°C)
OTHER ADVERSE EFFECTS	Not available.
NOTES	This product is not intended to be released into the environment. *VEGA (Q)SAR platform prediction (moderate reliability).

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER	2811
CLASS	6.1
PACKING GROUP	III
<u>AUSTRALIA</u>	
HAZCHEM	2X
<u>EU</u>	
TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not Listed
ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
FLURBIPROFEN, 5104-49-4	N/L	N/L	N/L	N/L	N/L	N/L	N/L	X

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
FLURBIPROFEN, 5104-49-4	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
FLURBIPROFEN, 5104-49-4	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT

Not applicable

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** - American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** - Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** - Chemical Abstract Service; **CERCLA** - Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** - Effective Concentration, 50%; **EPA** - Environmental Protection Agency; **GHS** - Global Harmonized System; **HMIS** - Hazardous Materials Information System; **HSE** - Health and Safety Executive; **HSIS** - Hazardous Substances Information System; **IARC** - International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** - Ready Biodegradability Model; **ISS** - Istituto Superiore Sanità; **LC50** - Lethal Concentration, 50%; **LD50** - Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** - National Institute for Occupational Safety and Health; **NTP** - National Toxicology Program; **OSHA PEL** - Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** - Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** - Superfund Amendments and Reauthorization Act; **STEL** - Short Term Exposure Limit; **TLV** - Threshold Limit Value; **TWA** - Time Weighted Average; **WHMIS** - Workplace Hazardous Materials Information System

LAST REVISION

04/2025

SUPERSEDES

03/2023

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA[®] shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.