


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	IBUPROFEN, USP
PRODUCT CODE	0299
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 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
USES	Analgesic, anti-inflammatory, NSAID

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 4) Eye Irritation (Category 2A) Toxic to Reproduction (Category 2) Acute Aquatic Toxicity (Category 3) Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (cardiovascular system, gastrointestinal tract)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Harmful if swallowed. Causes serious eye irritation. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure. May cause allergic reaction. Harmful to aquatic life.
AUSTRALIA-ONLY HAZARDS	Repeated exposure may cause skin dryness or cracking.
PRECAUTIONARY STATEMENT(S)	Prevention Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/ vapors/spray. Obtain special instructions before use. Wear protective gloves, protective clothing, eye protection, face protection. Avoid release to the environment.

HMIS CLASSIFICATION	Response	IF SWALLOWED: Immediately call a poison center or medical professional; 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 and/or container in accordance with local regulations.		
	Health Hazard	2	Flammability	0
	Reactivity	0	Personal Protection	G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Benzeneacetic acid, α -methyl-4-(2-methylpropyl)-, (\pm)						
BOTANICAL NAME	Not applicable						
SYNONYM	p-Isobutylhydratropic acid						
CHEMICAL FORMULA	C ₁₃ H ₁₈ O ₂						
CAS NUMBER	15687-27-1						
ALTERNATE CAS NUMBER	Not applicable						
MOLECULAR WEIGHT	206.28						
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>IBUPROFEN</td> <td>15687-27-1</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	% BY WEIGHT	IBUPROFEN	15687-27-1	100
CHEMICAL NAME	CAS NUMBER	% BY WEIGHT					
IBUPROFEN	15687-27-1	100					
NOTES	<p>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.</p> <p>Chemical family: Propionic acid derivative.</p>						

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

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Dust explosion hazard.
FLAMMABLE PROPERTIES	May be combustible at high temperature.
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , 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.

NOTES

Dust explosion properties:

Kst: 200 - 300 bar.m/s

St class: 2

Minimum ignition energy (MIE) – dust cloud : 3 - 5 mJ


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.

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 unlabelled 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. Recommended storage temperature between 20 - 40°C. Preserve in tight containers.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: IBUPROFEN CAS #: 15687-27-1

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

N/L = Not Listed

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.

SPECIFIC ENGINEERING CONTROLS

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

NOTES

USP: ELV: Industrial: TWA: 2 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	Solid				
DESCRIPTION	White to off-white, crystalline powder, having a slight, characteristic odor.				
SOLUBILITY	Practically insoluble in water; very soluble in alcohol, in methanol, in acetone, and in chloroform; slightly soluble in ethyl acetate.				
ODOR	Slight characteristic odor.				
FLAMMABILITY	May be combustible at high temperature				
ODOR THRESHOLD	Not available	pH	Not available	MELTING POINT	(75 - 78)°C, (167-172.4)°F
BOILING POINT	Not available	FREEZING POINT	(75 - 78)°C, (167-172.4)°F	FLASH POINT	Not available
SPECIFIC GRAVITY	Not available	EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available
UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	VAPOR PRESSURE	0.000012 hPa (25°C)
VAPOR DENSITY (AIR = 1)	7.1	RELATIVE DENSITY (WATER = 1)	Not available	log P (OCTANOL-WATER)	3.5 (20°C)
AUTO-IGNITION TEMPERATURE	Not available	DECOMPOSITION TEMPERATURE	Not available	VISCOSITY	Not available

NOTES

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

SECTION 10: STABILITY AND REACTIVITY
REACTIVITY

Not established.

STABILITY

Stable under recommended storage conditions.

MATERIALS TO AVOID

Oxidizing agents. Strong alkalis.

**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): 636
Dermal: Rabbit LD50: (mg/kg): Not available
Inhalation: Rat: LC50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION

Due to lack of data the classification is not possible.

SERIOUS EYE DAMAGE/EYE IRRITATION

Causes serious eye irritation.

RESPIRATORY OR SKIN SENSITIZATION

NSAIDs have produced a wide range of hypersensitivity reactions in susceptible individuals; the most common include skin rashes, urticaria, rhinitis, angioedema, bronchoconstriction, and anaphylactic shock. Hypersensitivity to NSAIDs appears to occur more frequently in patients with asthma or allergic disorders but other risk factors have been identified. Based on available data, the classification criteria are not met.

GERM CELL MUTAGENICITY

Due to lack of data the classification is not possible.

CARCINOGENICITY**OSHA** IBUPROFEN is not listed.**NTP** IBUPROFEN is not listed.**IARC** IBUPROFEN is not evaluated.**California Proposition 65** This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.**ADDITIONAL CARCINOGENICITY INFORMATION**

180 mg/kg/day Carcinogenicity study
Result: No evidence of carcinogenicity.
Species: Rat
300 mg/kg/day Carcinogenicity study
Result: No evidence of carcinogenicity.
Species: Mouse

REPRODUCTIVE TOXICITY

Investigated as a mutagen, reproductive effector. 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.

100 mg/kg Reproductivity study:
Result: No evidence of adverse effects on fetal development.
Species: Mouse

120 mg/kg Reproductivity study:
Result: No evidence of adverse effects on fetal development.
Species: Rat

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 HAZARDS

Based on available data, the classification criteria are not met.

SIGNS AND SYMPTOMS OF EXPOSURE

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.

POTENTIAL HEALTH EFFECTS

Inhalation	May be harmful if inhaled. May irritate the respiratory tract. Symptoms may include coughing, sore throat, and shortness of breath.
Ingestion	Harmful if swallowed. Symptoms may include gastrointestinal irritation or ulceration, constipation, nausea, heartburn, skin rashes, dizziness, fluid
Skin	May be harmful if absorbed through skin. May cause skin irritation. May cause photosensitization and allergic skin reactions.
Eyes	Causes serious eye irritation.

SECTION 12: ECOLOGICAL INFORMATION**TOXICITY**

EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 9.06 - 11.5

LC50: 96 Hr: Fish: (mg/L): > 100

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

Biodegradation: 87

Half Life: 1.8 - 2hr

BIOACCUMULATIVE POTENTIAL

LogPow: 3.5 (20°C)

MOBILITY IN SOIL

Water solubility: 21 mg/L (25°C)

Henry's Law Constant: 1.50E-07 atm-m³/mole (25°C)

OTHER ADVERSE EFFECTS

Not available.

This product is not intended to be released into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS**WASTE DISPOSAL**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION**UNITED STATES & CANADA****UN PROPER SHIPPING NAME**

Not dangerous good

UN NUMBER Not applicable

CLASS Not applicable

PACKING GROUP Not applicable

AUSTRALIA

UN PROPER SHIPPING NAME Not dangerous good

UN NUMBER Not applicable

CLASS Not applicable

PACKING GROUP Not applicable

HAZCHEM Not applicable

ENVIRONMENTAL HAZARDS Not available

SPECIAL SHIPPING INFORMATION Not applicable

SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
IBUPROFEN 15687-27-1	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
IBUPROFEN 15687-27-1	N/L	Listed as Schedule 4	N/L

SECTION 16: OTHER INFORMATION
REFERENCES
ABBREVIATIONS AND ACRONYMS

Available upon request

CAS – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** – Mine Safety and Health Administration; **ACGIH** – American Conference of Governmental Industrial Hygienists; **IDHL** – Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** – Recommended Exposure Limit

LAST REVISION

11/2018

SUPERSEDES

12/2015

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.