


SECTION 1: PRODUCT IDENTIFICATION

| | |
|----------------------------|--|
| PRODUCT NAME | KETOPROFEN, USP |
| PRODUCT CODE | 0078 |
| 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 5) Skin Irritation (Category 2) Eye Irritation (Category 2A) Sensitization - Skin (Category 1) Toxic to Reproduction (Category 2) Specific Target Organ Toxicity - Repeated Exposure (Category 1) - Gastrointestinal tract, cardiovascular system |
| PICTOGRAM |  |
| SIGNAL WORD | Danger |
| HAZARD STATEMENT(S) | Toxic if swallowed. May be harmful if in contact with skin. Causes skin irritation. Causes serious eye irritation. May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child Causes damage to organs through prolonged or repeated exposure. |

**ADVERSE PHYSIOCHEMICAL,
HUMAN HEALTH AND
ENVIRONMENTAL EFFECTS
PRECAUTIONARY STATEMENT(S)**

Not Applicable.

Prevention

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

Response

IF SWALLOWED: Immediately call a poison center. Get emergency medical help immediately. Rinse mouth.
IF ON SKIN: Get Medical Help. Wash with plenty of water. If skin irritation occurs, get medical help. Take off contaminated clothing and wash it before reuse.
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 help..
IF EXPOSED OR CONCERNED: Get medical advice.
Get medical help, if you feel unwell.

Storage

Store locked up.

Store locked up.

Store locked up.

Not applicable

Disposal

Dispose of contents/container in accordance with local regulation).

HMIS CLASSIFICATION
Health Hazard

2

Flammability

1

Reactivity

0

Personal Protection

G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
CHEMICAL NAME

Benzeneacetic acid, 3-benzoyl- α -methy, (\pm)

BOTANICAL NAME

Not applicable

SYNONYM

Propionic acid, 2-(3-benzoylphenyl)-

CHEMICAL FORMULA

C₁₆H₁₄O₃

CHEMICAL FAMILY

Propionic acid derivative

CAS NUMBER

22071-15-4

ALTERNATE CAS NUMBER

Not applicable

MOLECULAR WEIGHT

254.28

COMPOSITION

| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT |
|---------------|------------|-----------|-------------|
| KETOPROFEN | 22071-15-4 | 244-759-8 | 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 such as during shipping, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION
Chemical Name: KETOPROFEN CAS #: 22071-15-4

| | 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 | N/A | 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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

| | | | | | |
|-------------------------------------|--|---|--------------------------------|---|--------------------------------|
| PHYSICAL STATE | Solid | | | | |
| DESCRIPTION | White or almost white, crystalline powder. | | | | |
| SOLUBILITY | Practically insoluble in water, freely soluble in acetone, in ethanol (96 per cent) and in methylene chloride. | | | | |
| ODOR | Odorless | | | | |
| FLAMMABILITY | May be combustible at high temperature | | | | |
| AUTO-IGNITION TEMPERATURE | Not available | BOILING POINT | 431.3 °C, 808.34 °F (760 mmHg) | DECOMPOSITION TEMPERATURE | Not available |
| EVAPORATION RATE | Not available | EXPLOSIVE LIMIT | Not available | FLASH POINT | 147 °C, 296,6 °F |
| log P (OCTANOL-WATER) | 3.12 | LOWER FLAMMABLE/EXPLOSIVE LIMIT(S) | Not available | MELTING/FREEZING POINT | (93 - 97)°C, (199.4 - 206.6)°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) | Not available | VAPOR PRESSURE | 3.32 hPa | 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 oxidants |
| 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): 62.4 Dermal: Rabbit: LD50: (mg/kg): 2000 Inhalation: Rat: LC50: (mg/L/4hr): Not available |
| SKIN CORROSION/IRRITATION | Causes skin irritation. Irritancy test: Pig: Skin: Mild to moderate irritant. Irritancy test: Rabbit: Skin: Mild irritant to non-irritant. Irritancy test: Rat: Skin: : Non-irritant |
| SERIOUS EYE DAMAGE/EYE IRRITATION | Strong irritant with the danger of severe eye injury. Irritancy test: Rabbit: Eye: Slight irritant. |
| RESPIRATORY SENSITIZATION | Due to lack of data the classification is not possible. |
| SKIN SENSITIZATION | May cause an allergic skin reaction. Allergic skin reactions have been reported in literature. Cross sensitivity: Persons sensitive to one nonsteroidal anti-inflammatory drug (NSAID), including aspirin, may be sensitive to this material also. |
| GERM CELL MUTAGENICITY | Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found. Mutagenicity: Ames test: Negative. In vivo sister chromatid exchange assay in human lymphocytes: Positive. |
| CARCINOGENICITY | OSHA KETOPROFEN is not listed. NTP KETOPROFEN is not listed. IARC KETOPROFEN is not evaluated. California Proposition 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 | Based on available data, the classification criteria are not met. Carcinogenicity study: Mouse: 32 mg/kg/day: No evidence of carcinogenicity. Carcinogenicity study: Rat: 104 weeks: 6 mg/kg/day: No evidence of carcinogenicity. |
| 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 study: Mouse: 12 mg/kg/day: No evidence of birth defects or embryotoxicity. Reproductivity study: Rat: 9 mg/kg/day: No evidence of birth defects or embryotoxicity. No impairment of fertility in male rats. Decrease in implantation sites seen in female rats. |
| 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 (gastrointestinal tract, cardiovascular system) through prolonged or repeated exposure. |
| ASPIRATION HAZARDS | Based on available data, the classification criteria are not met. |

SIGNS AND SYMPTOMS OF EXPOSURE
ROUTES OF EXPOSURE:

Oral

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

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.

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.

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 cause respiratory tract irritation.

Ingestion

Toxic if swallowed.

Skin

May be harmful if absorbed through skin. Causes skin irritation. May cause allergic skin reaction.

Eyes

Causes eye irritation.

SECTION 12: ECOLOGICAL INFORMATION
ECOTOXICITY

EC50: 48 Hr: Daphnia magna: (mg/L): > 100

LC50: 96 Hr: Fish: (mg/L): Not available

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

PERSISTENCE AND DEGRADABILITY

Not available

BIOACCUMULATIVE POTENTIAL

Log Pow: 3.12.

MOBILITY IN SOIL

Practically insoluble in water. Water Solubility: 51 mg/L (22°C).

Henry's Law Constant: 2.12E-11 atm-m³/mole (25°C).

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment

NOTES

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: DISPOSAL CONSIDERATIONS
DISPOSAL METHODS

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

SECTION 14: TRANSPORT INFORMATION
UN PROPER SHIPPING NAME

TOXIC SOLID, ORGANIC, N.O.S.

UN NUMBER

2811

CLASS

6.1

PACKING GROUP

III

AUSTRALIA
HAZCHEM

2X

EU
**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 | EPA 40 CFR Part 355 | | Pennsylvania | Right-to-know | | California Prop 65 |
|------------------------|--------------------------------|-------------------------------|---------------------|------------|--------------|---------------|---------------|-----------------------|
| | | | Appendix A | Appendix B | | New Jersey | Massachusetts | |
| KETOPROFEN 22071-15-4 | 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 | Therapeutic Goods Act | Code of Practices - Illicit Drug | Poisons Standard | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|------------------------|-------------------------------------|--------------------------|--|---------------------|--|---|
| KETOPROFEN 22071-15-4 | 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 |
|-----------------------|------------------|-----------------|--------------|-------------|--------------|---|------------|
| KETOPROFEN 22071-15-4 | 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

ABBREVIATIONS AND ACRONYMS

Available upon request

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

01/2023

SUPERSEDES

05/2021

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.