SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: KETOPROFEN, USP (Micronized)
PRODUCT CODE: 3039
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
- National Chemical Emergency Centre 44(0)1235239670

USES:
Analgesic, anti-inflammatory, NSAID

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 absorbed through 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.
Safety Data Sheet

Adverse Physiochemical, Human Health and Environmental Effects

Precautionary Statement(s)

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

Response
IF SWALLOWED: Immediately call a poison center or medical professional. Rinse mouth.
IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. 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 advice/attention.
IF EXPOSED OR CONCERNED: Get medical advice/attention.

Storage
Store locked up.

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, (±)

Botanical Name
Propionic acid, 2-(3-benzoylphenyl)-

Synonym
EC Number
10022071-15-4

CAS Number
22071-15-4

Alternate CAS Number
Not applicable

Molecular Weight
254.28

Composition

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Number</th>
<th>EC Number</th>
<th>% by Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketoprofen</td>
<td>22071-15-4</td>
<td>244-759-8</td>
<td>100</td>
</tr>
</tbody>
</table>

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.

Notes
Chemical family: Propionic acid derivative.

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
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. Preserve in tight containers.

SPECIFIC END USE(S)
See Section 1

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: KETOPROFEN  CAS #: 22071-15-4

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit value-8 hours</th>
<th>Limit value-Short Term</th>
<th>IDLH</th>
<th>REL</th>
<th>Advisory</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>ppm</td>
<td>mg/m³</td>
<td>ppm</td>
<td>mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

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/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. Fume hood, eye wash station, and safety shower.

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
ODOR THRESHOLD 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
VAPOUR DENSITY (AIR = 1) Not available
VAPOR PRESSURE 3.32 hPa
VISCOSITY Not available

Last Revision: 02/2020
The physical data presented above are typical values and should not be construed as a specification.

### SECTION 10: STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>REACTIVITY</th>
<th>Not established</th>
</tr>
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<tbody>
<tr>
<td>CHEMICAL STABILITY</td>
<td>Stable under recommended storage conditions</td>
</tr>
<tr>
<td>INCOMPATIBLE MATERIALS</td>
<td>Strong oxidants</td>
</tr>
<tr>
<td>HAZARDOUS DECOMPOSITION PRODUCTS</td>
<td>Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur</td>
</tr>
<tr>
<td>HAZARDOUS POLYMERIZATION</td>
<td>Will not occur</td>
</tr>
<tr>
<td>POSSIBILITY OF HAZARDOUS REACTION</td>
<td>Not established</td>
</tr>
<tr>
<td>CONDITIONS TO AVOID</td>
<td>Moisture, sunlight and extreme temperatures</td>
</tr>
</tbody>
</table>

### 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 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 | Carcinogenicity study: Mouse: 32 mg/kg/day: No evidence of carcinogenicity.  
Carcinogenicity study: Rat: 104 weeks: 6 mg/kg/day: No evidence of carcinogenicity.  
Based on available data, the classification criteria are not met. |

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KETOPROFEN, USP (Micronized)
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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.

Reproductive study: Mouse: 12 mg/kg/day: No evidence of birth defects or embryotoxicity.
Reproductive 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
Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms related to the physical, chemical, and toxicological characteristics:

Delayed and immediate effects of exposure:

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:

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

TOXICITY
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

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

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

<table>
<thead>
<tr>
<th>UN PROPER SHIPPING NAME</th>
<th>TOXIC SOLID, ORGANIC, N.O.S.</th>
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<tbody>
<tr>
<td>UN NUMBER</td>
<td>2811</td>
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<tr>
<td>CLASS</td>
<td>6.1</td>
</tr>
<tr>
<td>PACKING GROUP</td>
<td>III</td>
</tr>
</tbody>
</table>

**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**

<table>
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<tr>
<th></th>
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<tbody>
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<td>KEToprofen 22071-15-4</td>
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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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</tbody>
</table>

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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</thead>
<tbody>
<tr>
<td>KEToprofen 22071-15-4</td>
<td>N/L</td>
<td>Listed as Schedule 4</td>
<td>N/L</td>
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</table>

N/L = Not Listed

**EU REGULATIONS**
SAFETY DATA SHEET

--- | --- | --- | --- | --- | --- | --- | ---
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.

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 - Instituto 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
02/2020

SUPERSEDES
05/2016

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.