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

USES:

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 (gastrointestinal tract, cardiovascular system) through prolonged or repeated exposure.

AUSTRALIA-ONLY HAZARDS:
Repeated exposure may cause skin dryness or cracking.
SAFETY DATA SHEET

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
Not applicable

SYNONYM
Propionic acid, 2-(3-benzoylphenyl)-

CHEMICAL FORMULA
C₁₆H₁₄O₃

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>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>KETOPROFEN</td>
<td>22071-15-4</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.

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.

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.

STORAGE CONDITIONS

Store in original container, tightly sealed container, protected from direct sunlight, in a dry, cool and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Preserve in tight containers.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
</tr>
<tr>
<td>AIHA WEEL</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>HSE</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>White or almost white, crystalline powder.</td>
</tr>
<tr>
<td>Solubility</td>
<td>Practically insoluble in water, freely soluble in acetone, in ethanol (96 per cent) and in methylene chloride.</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Flammability</td>
<td>May be combustible at high temperature</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Odor Threshold</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>Not available</td>
</tr>
<tr>
<td>MELTING POINT</td>
<td>(93 - 97)°C, (199.4 - 206.6)°F</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Boiling Point</th>
<th>431.3 °C, 808.34 °F (760 mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freezing Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Flash Point</td>
<td>147 °C, 296.6 °F</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specific Gravity</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaporation Rate</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosive Limit</td>
<td>Not available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Upper Flammable/ Explosive Limit(S)</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Flammable/ Explosive Limit(S)</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapor Density (AIR = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Relative Density (WATER = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Log P (OCTANOL-WATER)</td>
<td>3.12</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**SECTION 10: STABILITY AND REACTIVITY**

<table>
<thead>
<tr>
<th>Reactivity</th>
<th>Not established</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability</td>
<td>Stable under recommended storage conditions</td>
</tr>
<tr>
<td>Materials to Avoid</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>

Last Revision: 05/2016
## SECTION 11: TOXICOLOGICAL INFORMATION

### ACUTE TOXICITY

<table>
<thead>
<tr>
<th>Route</th>
<th>Animal</th>
<th>LD50 (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>62.4</td>
</tr>
<tr>
<td>Dermal</td>
<td>Rabbit</td>
<td>2000</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Rat</td>
<td>Not available</td>
</tr>
</tbody>
</table>

### SKIN CORROSION/IRRITATION

Causes skin irritation.

<table>
<thead>
<tr>
<th>Skin Irritancy Test</th>
<th>Animal</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pig</td>
<td>Skin: Mild to moderate irritant.</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>Skin: Mild irritant to non-irritant.</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Skin: Non-irritant</td>
</tr>
</tbody>
</table>

### SERIOUS EYE DAMAGE/EYE IRRITATION

Strong irritant with the danger of severe eye injury.

<table>
<thead>
<tr>
<th>Eye Irritancy Test</th>
<th>Animal</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rabbit</td>
<td>Eyes: Slight irritant.</td>
</tr>
</tbody>
</table>

### RESPIRATORY OR 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.

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ames test</td>
<td>Negative</td>
</tr>
<tr>
<td>In vivo sister chromatid exchange assay in human lymphocytes</td>
<td>Positive</td>
</tr>
</tbody>
</table>

### CARCINOGENICITY

<table>
<thead>
<tr>
<th>Agency</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA</td>
<td>KETOPROFEN is not listed.</td>
</tr>
<tr>
<td>NTP</td>
<td>KETOPROFEN is not listed.</td>
</tr>
<tr>
<td>IARC</td>
<td>KETOPROFEN is not evaluated.</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</td>
</tr>
</tbody>
</table>

### 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.

### 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.
SAFETY DATA SHEET

SIGN 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

<table>
<thead>
<tr>
<th>Route</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>May be harmful if inhaled. May cause respiratory tract irritation.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Toxic if swallowed.</td>
</tr>
<tr>
<td>Skin</td>
<td>May be harmful if absorbed through skin. Causes skin irritation. May cause allergic skin reaction.</td>
</tr>
<tr>
<td>Eyes</td>
<td>Causes eye irritation.</td>
</tr>
</tbody>
</table>

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY
EC50: 48 Hr: Daphnia magna: (mg/L): > 100
LC50: 96 Hr: Fish: (mg/L): Not available
IC50: 72 Hr: Algae: (mg/L): Not available

PERSISTENCE AND DEGRADABILITY
Not available

BIOACCUMULATIVE POTENTIAL
Log Pow: 3.12.

MOBILITY IN SOIL

OTHER ADVERSE EFFECTS
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

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

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA
SAFETY DATA SHEET

UN PROPER SHIPPING NAME: TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER: 2811
CLASS: 6.1
PACKING GROUP: III

AUSTRALIA
UN PROPER SHIPPING NAME: TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER: 2811
CLASS: 6.1
PACKING GROUP: III
HAZCHEM: 2X

ENVIRONMENTAL HAZARDS
Not available
SPECIAL SHIPPING INFORMATION
Not applicable

SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>KETOPROFEN 22071-15-4</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
</tr>
</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>
</tr>
</thead>
<tbody>
<tr>
<td>KETOPROFEN 22071-15-4</td>
<td>Not Listed</td>
<td>Listed as Schedule 4</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request

ABBREVIATIONS AND ACRONYMS
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: 05/2016
SUPERSEDES
Not applicable
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.