

Scientific Documentation

Ketoprofen, Micronized, USP

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



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Specification for Ketoprofen, Micronized, USP (K1392)

| | |
|-------------------|--|
| Item Number | K1392 |
| Item | Ketoprofen, Micronized, USP |
| CAS Number | 22071-15-4 |
| Molecular Formula | C ₁₆ H ₁₄ O ₃ |
| Molecular Weight | 254.28 |
| MDL Number | |
| Synonyms | (+/-)-m-Benzoylhydratropic acid |

| Test | Specification | |
|---|---------------|---------|
| | Min | Max |
| ASSAY (DRIED BASIS) | 98.5 | 101.0 % |
| MELTING RANGE | 92.0° | 97.0°C |
| SPECIFIC ROTATION, [α] _D ²⁵ | +1° to -1° | |
| LOSS ON DRYING | | 0.5 % |
| ORGANIC IMPURITIES | TO PASS TEST | |
| RESIDUE OF IGNITION | | 0.2 % |
| ELEMENTAL IMPURITIES | AS REPORTED | |
| IDENTIFICATION | TO PASS TEST | |
| EXPIRATION DATE | | |
| DATE OF MANUFACTURE | | |
| APPEARANCE | | |
| RESIDUAL SOLVENTS | TO PASS TEST | |

Spectrum Chemical Mfg Corp

| | |
|--------------------------------|-----------------------------|
| Corporate Headquarters: | West Coast Facility: |
| 769 Jersey Ave. | 14422 S. San Pedro St. |
| New Brunswick, NJ 08901 | Gardena, CA 90248 |
| 732.214.1300 | 310.516.8000 |

Certificate Of Analysis

| | | | |
|-------------------|--|-------------------|--------------|
| Item Number | K1392 | Lot Number | 4MF0025 |
| Item | Ketoprofen, Micronized, USP | Manufacturer Lot | KTF-2204037M |
| CAS Number | 22071-15-4 | Manufacturer Code | 13524 |
| Molecular Formula | C ₁₆ H ₁₄ O ₃ | Molecular Weight | 254.28 |

| TEST | SPECIFICATION | | RESULT |
|---|---------------|---------|---------------------------------|
| | MIN | MAX | |
| ASSAY (DRIED BASIS) | 98.5 | 101.0 % | 100.9% |
| MELTING RANGE | 92.0° | 97.0°C | 92.3 - 94.0°C |
| SPECIFIC ROTATION, [α] _D ²⁵ | +1° to -1° | | 0.0° |
| LOSS ON DRYING | | 0.5 % | 0.0% |
| ORGANIC IMPURITIES | TO PASS TEST | | PASSES TEST |
| RESIDUE OF IGNITION | | 0.2 % | 0.0% |
| ELEMENTAL IMPURITIES | AS REPORTED | | NO ELEMENTAL IMPURITIES PRESENT |
| IDENTIFICATION | TO PASS TEST | | PASSES TEST |
| EXPIRATION DATE | | | 31-MAR-2027 |
| DATE OF MANUFACTURE | | | 01-APR-2022 |
| APPEARANCE | | | WHITE POWDER |
| RESIDUAL SOLVENTS | TO PASS TEST | | PASSES TEST |
| CLASS 2 (solvent) / TOLUENE | | | 141 ppm |
| CLASS 1 (solvent) / BENZENE | | | NOT DETECTED |

Certificate of Analysis Results Entered By:

GHERRERA
Genaro Herrera
27-JUN-23 12:20:45

Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
27-JUN-23 12:21:04

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by B E C Chemicals Private Limited at Plot No. 24, MIDC, Dhatav, Roha, Raigad, Maharashtra 402116, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

Preparation Date: 1/11/2018

Revision date 1/11/2019

Revision Number: G1

1. Identification

Product identifier

Product code: K1392
Product Name: KETOPROFEN, MICRONIZED, USP

Other means of identification

Synonyms: m-Benzoylhydratropic acid
 3-Benzoylhydratropic acid
 (+-)-3-Benzoyl-alpha-methylbenzeneacetic acid
 2-(m-Benzoylphenyl)propionic acid
 2-(3-Benzoylphenyl)propionic acid
 Hydratropic acid, m-benzoyl-, (+-)-
 Ketoprofen (+-)
 Ketopropene/Ketoprophene
 Acide (benzoyl-3-phenyl)-2-propionique
 Ketoprofeno
 Ketoprofenum
 Propinoic acid, 2-(3-benzoylphenyl)-
CAS #: 22071-15-4
RTECS # UE7570000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Drug. Medication.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>
Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Tom Tyner (USA - West Coast)
Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

| | |
|--|-------------|
| Acute toxicity - Oral | Category 3 |
| Skin corrosion/irritation | Category 2 |
| Serious eye damage/eye irritation | Category 2A |
| Specific target organ toxicity (single exposure) | Category 3 |

Label elements

Danger

Hazard statements

Toxic if swallowed
Causes skin irritation
Causes serious eye irritation
May cause respiratory irritation



Hazards not otherwise classified (HNOC)

May be harmful if inhaled
May be harmful if in contact with skin

Other hazards

Not available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wear protective gloves
Wear eye/face protection

Precautionary Statements - Response

Immediately call a POISON CENTER or doctor/physician

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 ON SKIN: Wash with plenty of water

If skin irritation occurs: Get medical advice/attention

Take off contaminated clothing and wash it before reuse

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

IF SWALLOWED:

Rinse mouth

IF SWALLOWED: Rinse mouth.

Precautionary Statements - Storage

Store locked up

Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

| Component | CAS No | Weight-% |
|------------|------------|----------|
| Ketoprofen | 22071-15-4 | 100 |

4. FIRST AID MEASURES

First aid measures

- General Advice:** National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. First aider needs to protect himself.
- Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.
- Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention.
- Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. WARNING! It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.
- Ingestion:** Toxic if swallowed. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Immediate medical attention is required. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

- Symptoms**
- Toxic if swallowed
 - Causes serious eye irritation
 - Causes skin irritation
 - May cause gastritis
 - Dryness of mouth
 - Eructation (Belching)
 - Thirst
 - May cause abdominal pain, nausea, vomiting, diarrhea
 - Flatulence
 - May cause constipation
 - May cause loss of appetite
 - Skin rash
 - May cause an allergic skin reaction
 - Fever
 - Ingestion of larger amounts may cause effects to the central nervous system (e.g. dizziness, headache)
 - Somnolence
 - Insomnia
 - Confusion
 - Hallucinations
 - May cause personality and mood changes
 - Irregular heartbeat
 - Cardiac arrhythmias
 - Weak, rapid pulse or rapid heart rate (Tachycardia)
 - It may affect the kidneys
 - Visual disturbances
 - May cause metabolic acidosis
 - May affect respiration

Dyspnea (Shortness of breath and difficulty breathing)
May cause bleeding or ulceration from the stomach
Prolonged or repeated ingestion may affect behavior/central nervous system (symptoms similar to acute ingestion), metabolism (weight loss), and may cause kidney and liver damage. Metabolic acidosis/electrolyte abnormality in conjunction with acute renal failure may also occur.

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO₂). Water spray, mist, or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous combustion products Carbon dioxide (CO₂). Carbon monoxide.

Specific hazards May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods: No information available

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid dust formation. Ensure adequate ventilation. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not breathe dust. Do not ingest. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Store in a segregated and approved area.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

| Component | CAS No | OSHA | NIOSH | ACGIH | AIHA WEEL |
|------------|------------|------|-------|-------|-----------|
| Ketoprofen | 22071-15-4 | None | None | None | None |

Canada

| Component | CAS No | Canada - Alberta | Canada - British Columbia | Canada - Ontario | Canada - Quebec |
|------------|------------|------------------|---------------------------|------------------|-----------------|
| Ketoprofen | 22071-15-4 | None | None | None | None |

Australia and Mexico

| Component | CAS No | Australia | Mexico |
|------------|------------|-----------|--------|
| Ketoprofen | 22071-15-4 | None | None |

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation, especially in confined areas. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

| | |
|----------------------------------|--|
| Eye protection: | Goggles or Safety glasses with side-shields. |
| Skin and body protection: | Chemical resistant apron Gloves Long sleeved clothing |
| Respiratory protection: | Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent. |
| Hygiene measures: | Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|--|
| Physical state: Solid | Appearance: Crystalline powder. | Color: White. Off-white. |
| Odor: Odorless. | Taste No information available. | Formula C16H14O3 |
| Molecular/Formula weight (g/mole): 254.28 g/mol | Flammability (solid, gas) no data available | Flashpoint (°C/°F): 147°C/297°F |
| Flash Point Tested according to: Not available | Autoignition Temperature (°C/°F): No information available | Lower Explosion Limit (%): No information available |
| Upper Explosion Limit (%): No information available | Melting point/range(°C/°F): 92-97°C/197.6-206.6°F | Decomposition temperature(°C/°F): No information available |
| Boiling point/range(°C/°F): 431°C/808°F | Bulk density: No information available | Density (g/cm3): 1.198 |
| Specific gravity: No information available | pH No information available | Vapor pressure @ 20°C (kPa): No information available |
| Evaporation rate: No information available | Vapor density: No information available | VOC content (g/L): No information available |
| Odor threshold (ppm): No information available | Partition coefficient (n-octanol/water): No information available | Viscosity: No information available |
| Miscibility: No information available | Solubility: Very slightly soluble in water Easily soluble in diethyl ether Easily soluble in acetone Freely soluble in Ethanol Freely soluble in Chloroform Very soluble in Methanol Soluble in Dichloromethane Soluble in Benzene Soluble in Alkalis Sparingly soluble in Dimethylformamide Soluble in ethyl acetate | |

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Ignition sources. Incompatible materials.

Incompatible Materials: Oxidizing agents

Hazardous decomposition products: carbon oxides.

Other Information

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure****Principal Routes of Exposure:**

Skin. Eyes. Ingestion. Inhalation.

Acute Toxicity**Component Information**

| | |
|------------|------------|
| Ketoprofen | |
| CAS No | 22071-15-4 |

LD50/oral/rat = 62400 µg/kg Oral LD50 Rat = 62.4 mg/kg Oral LD50 Rat

LD50/oral/mouse = 360 mg/kg oral LD50 mouse

LD50/dermal/rabbit = 2000 mg/kg dermal LD50 rabbit

LD50/dermal/rat = No information available

LC50/inhalation/rat = 1000 mg/L inhalation LC50 rat 8h

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = 1300 mg/kg oral LD50 guinea pig

Product Information

LD50/oral/rat =

Value - Acute Tox = 62.4 mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = 360 mg/kg

LD50/dermal/rabbit

Value - Acute Tox = 2000 mg/kg

LD50/dermal/rat

Product code: K1392

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MICRONIZED, USP

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VALUE - Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

Symptoms

| | |
|--------------------------|---|
| Skin Contact: | Causes skin irritation. Skin contact may result in redness, pain, inflammation, itching, scaling, and/or blistering. |
| Eye Contact: | Causes severe eye irritation and possible burns. Symptoms may include stinging, tearing, redness. |
| Inhalation | May cause irritation of the respiratory tract and mucous membranes irritation. |
| Ingestion | Toxic if swallowed. May cause gastrointestinal tract irritation and symptoms such as gastritis, dry mouth, eructation, stomatitis, salivation, thirst, abdominal pain, nausea, vomiting, dyspepsia, diarrhea, flatulence, constipation. Other symptoms may include increased or decreased appetite, purpuric rash, exfoliative dermatitis, photosensitivity, skin discoloration, alopecia, eczema, sweating, bullous rash, urticaria, pruritis, anaphylactoid reaction, allergic reaction, tinnitus, fever, chills, central nervous system effects (headache, dizziness, somnolence, depression, malaise, insomnia, nervousness, dreams, amnesia, confusion, vertigo, paresthesia, migraine, dysphoria, hallucination, nightmares, personality disorder, etc.), myalgia, heart palpitations, tachycardia, hypertension, congestive heart failure, peripheral vascular disease, vasodilation, arrhythmias, myocardial infarction, libido disturbances, metabolic acidosis, visual disturbances. It may also affect the kidneys (hematuria, renal failure, interstitial nephritis, nephrotic syndrome), and respiratory system (dyspnea, bronchospasm, hemoptysis, epistaxis, pharyngitis, rhinitis, laryngeal edema. Health effects for nonsteroidal anti-inflammatory drugs (NSAIDs): nausea, vomiting, diarrhea, constipation, heartburn, stomach/abdominal pain, black or tarry stools, inhibition of platelet aggregation, prolonged bleeding time/bruising, swelling, sores/ulcers/white spots on lips and mouth, sweating, bluish colored skin, insomnia, mood/mental/personality changes, confusion, dizziness/drowsiness, headache, analgesia, itching, rash, weight gain/loss, vision and speech problems, ringing in the ears, tremors, difficulty breathing, increased heart rate or palpitations. Delayed effects may include gastrointestinal ulceration or bleeding, hypertension, kidney impairment, decreased urine output, interstitial nephritis, blood disorders, cardiovascular thrombotic events, stroke, congestive heart failure, fluid retention and edema, other central nervous system effects (coma, convulsions, seizures, somnolence, analgesia, depression, anxiety, fatigue). NSAIDs may also cause serious adverse skin reactions such as exfoliative dermatitis, Stevens-Johnson Syndrome, and toxic epidermal necrosis, and may affect the liver (borderline elevations of one or more liver tests). |
| Aspiration hazard | No information available. |

Delayed and immediate effects as well as chronic effects from short and long-term exposure

| | |
|-------------------------|---|
| Chronic Toxicity | Prolonged or repeated ingestion may cause gastrointestinal bleeding, buccal |
|-------------------------|---|

necrosis, ulcerative colitis, melena, fecal occult blood, peptic ulcer, intestinal ulceration, dysphagia, gastric ulcer, gastroenteritis, weight loss or weight gain, abnormal liver function tests, colitis, cholestatic jaundice, kidney damage (renal papillary necrosis and other abnormal renal pathology), renal failure, hematologic effects (agranulocytosis, anemia, hemolysis, purpura, thrombocytopenia, hypocoagulability). Prolonged or repeated ingestion may also cause allergic reactions in sensitive individuals as well as other symptoms similar that of acute ingestion.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

| Component | CAS No | IARC | ACGIH - Carcinogens | NTP | OSHA HCS - Carcinogens | Australia - Notifiable Carcinogenic Substances | Australia - Prohibited Carcinogenic Substances |
|------------|------------|------------|---------------------|------------|------------------------|--|--|
| Ketoprofen | 22071-15-4 | Not listed | Not listed | Not listed | Not listed | Not listed | Not listed |

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity No data is available

Reproductive Effects: No information available

Developmental Effects: No information available

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure respiratory system.

STOT - repeated exposure No information available.

Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility in soil No information available

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal Do not re-use empty containers
Dispose of as unused product.

| Component | CAS No | RCRA - F Series Wastes | RCRA - K Series Wastes | RCRA - P Series Wastes | RCRA - U Series Wastes |
|------------|------------|---------------------------|---------------------------|---------------------------|---------------------------|
| Ketoprofen | 22071-15-4 | None | None | None | None |

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (ketoprofen)
Hazard Class 6.1
Subsidiary Class No information available
Packing group: III
Emergency Response Guide Number 154
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions IB8, IP3, T1, TP33
Symbol(s): [DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.
Description: UN2811, Toxic solids, organic, n.o.s. (Ketoprofen), 6.1, III

TDG (Canada)

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant No Information available
Description: UN2811, Toxic solid, organic, n.o.s. (Ketoprofen), 6.1, III

ADR

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Packing group III
Subsidiary Risk: No information available
Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s. (Ketoprofen), 6.1, III

IMDG

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (ketoprofen)
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant No information available

EMS: F-A
Special Provisions 223, 274
Description UN2811, Toxic solid, organic, n.o.s. (Ketoprofen), 6.1, III

RID

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Subsidiary Risk: No information available
Packing group III
Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s. (Ketoprofen), 6.1, III

ICAO (air)

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class 6.1
Subsidiary Risk: No information available
Packing Group: III
Description: UN2811, Toxic solid, organic, n.o.s. (Ketoprofen), 6.1, III
Special Provisions A3, A5

IATA

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Subsidiary Risk: No information available
Packing group III
Precautionary Statements - Response 6L
Special Provisions No information available
Description: UN2811, Toxic solid, organic, n.o.s. (Ketoprofen), 6.1, III

15. REGULATORY INFORMATION

International Inventories

| Component | CAS No | U.S. TSCA | KOREA KECL | Philippines (PICCS) | Japan ENCS | China IECSC | Australia AICS | EINECS-No. |
|-------------------|------------|-----------|---------------------|---------------------|-------------|-------------|----------------|----------------------|
| <i>Ketoprofen</i> | 22071-15-4 | Present | Present KE-02767 | Present | Not present | Not listed | Present | Present 244-759-8 |

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

| Component | CAS No | Carcinogen | Developmental Toxicity | Male Reproductive Toxicity | Female Reproductive Toxicity: |
|-------------------|------------|------------|------------------------|----------------------------|-------------------------------|
| <i>Ketoprofen</i> | 22071-15-4 | Not Listed | Not Listed | Not Listed | Not Listed |

CERCLA/SARA

Product code: K1392

Product name: KETOPROFEN,
MICRONIZED, USP

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| Component | CAS No | CERCLA - Hazardous Substances and their Reportable Quantities | Section 302 Extremely Hazardous Substances and TPQs | Section 302 Extremely Hazardous Substances and RQs | Section 313 - Chemical Category | Section 313 - Reporting de minimis |
|------------|------------|---|---|--|---------------------------------|------------------------------------|
| Ketoprofen | 22071-15-4 | None | None | None | None | None |

U.S. TSCA

| Component | CAS No | TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS) | TSCA 8(d) -Health and Safety Reporting |
|------------|------------|---|--|
| Ketoprofen | 22071-15-4 | Not Applicable | Not Applicable |

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

| Component | CAS No | Canada (DSL) | Canada (NDSL) |
|------------|------------|--------------|---------------|
| Ketoprofen | 22071-15-4 | Not Listed | Present |

| Component | CAS No | CEPA Schedule I - Toxic Substances |
|------------|------------|---|
| Ketoprofen | 22071-15-4 | Not listed |
| Component | CAS No | CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting |
| Ketoprofen | 22071-15-4 | Not listed |

EU Classification

EU GHS - SV - CLP 1272/2008

| Component | CAS No | EU GHS - SV - CLP (1272/2008) |
|------------|------------|-------------------------------|
| Ketoprofen | 22071-15-4 | No information |

EU - CLP (1272/2008)

R-phrases

R25 - Toxic if swallowed

R36/37/38 - Irritating to eyes, respiratory system and skin

S-phrases

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S28 - After contact with skin, wash immediately with plenty of water

S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

S62 - If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label

S 1/2 - Keep locked up and out of the reach of children.

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection

Product code: K1392

Product name: KETOPROFEN,
MICRONIZED, USP

Page

| Component | CAS No | Classification | Concentration Limits: | Safety Phrases |
|------------|------------|----------------|-----------------------|----------------|
| Ketoprofen | 22071-15-4 | | No information | |

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

T - Toxic

Xi - Irritant

T



Xi



16. OTHER INFORMATION

Preparation Date: 1/11/2018
Revision date 1/11/2019
Prepared by: Roumann Pangilinan

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

| Catalog Number | Product Name |
|----------------|-----------------------------|
| K1392 | Ketoprofen, Micronized, USP |

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

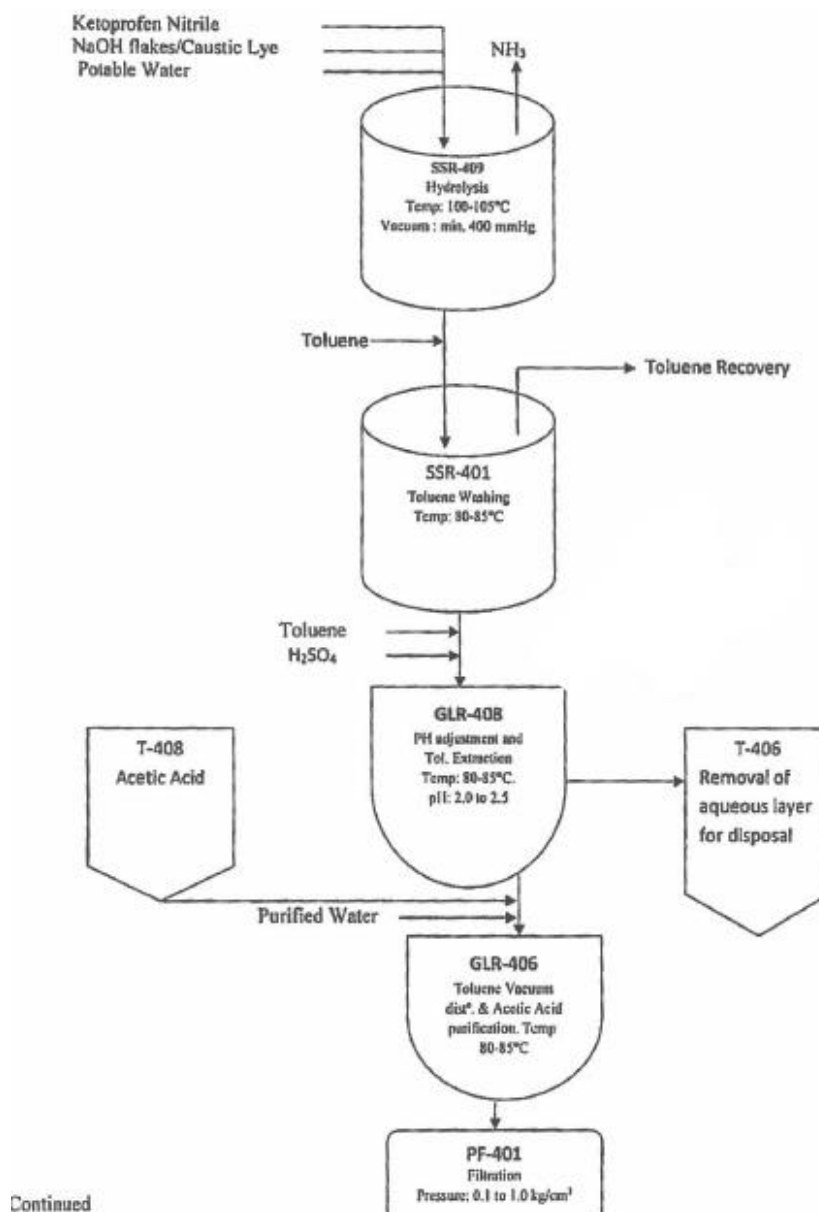
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Ketoprofen, Micronized, USP (Cat# K1392)



CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

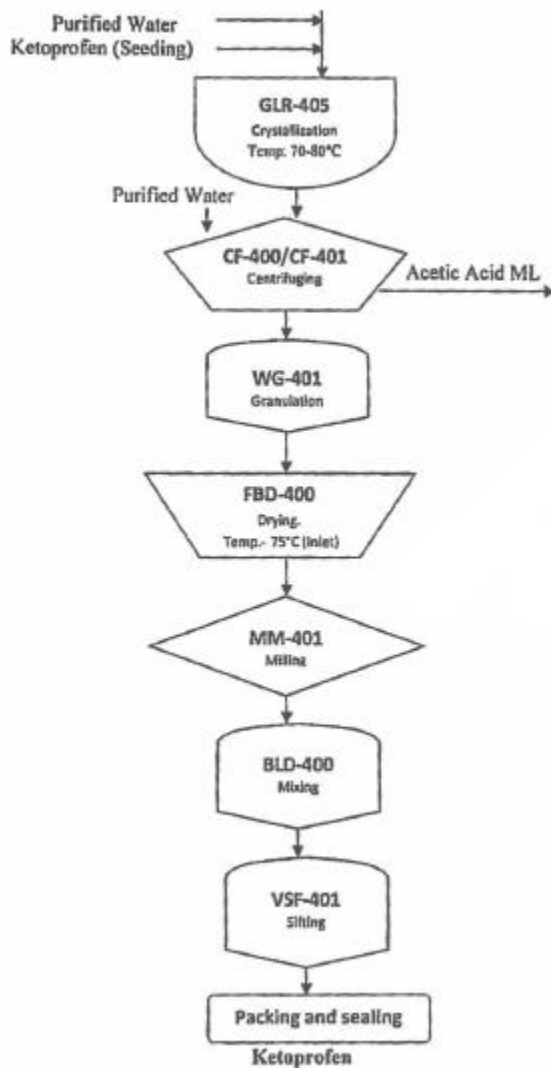
WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



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Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

K1392, Ketoprofen, Micronized, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the above mentioned catalog item and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Ketoprofen, Micronized, USP (Cat# K1392)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

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RE: Residual Solvents - Ketoprofen, Micronized, USP (Cat# K1392)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

| Residual Solvent | Class | Expected Concentration |
|------------------|-------|------------------------|
| Benzene | 1 | < 2 ppm |
| Toluene | 2 | < 890 ppm |
| Acetic Acid | 3 | < 5000 ppm |
| 2-Propanol | 3 | < 5000 ppm |

No other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.



Exp. Date: 00-00-0000



DANGER
 • Toxic if swallowed • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation.
 • Do not eat, drink or smoke when using this product • Wear protective gloves, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.
FIRST AID: Immediately call a POISON CENTER or physician. 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 attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.
KEEP FROM CHILDREN

K1392

SIZ SY

Ketoprofen
 [(±)-*m*-Benzoylhydratropic Acid]
 Micronized, USP
 CAS 22071-15-4

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

DOT: UN2811, Toxic solid, organic, n.o.s. (ketoprofen), 6.1, PG III

Chemical Emergency: (800)424-9300
 www.SpectrumChemical.com

$C_{16}H_{14}O_3$ F.W. 254.28

Manufacturer/Supplier Code?
 Manufacturer Lot Number?

Assay (Dried Basis) 98.5-101.0%
 Melting Range 92.0°-97.0°C
 Specific Rotation, $[\alpha]_D^{25}$ +1° to -1°

MAXIMUM LIMITS

Loss on Drying 0.5%
 Organic Impurities:
 Any Individual Impurity 0.2%
 Total Impurities 1.0%
 Residue on Ignition 0.2%
 Elemental Impurities As reported
 Residual Solvents To pass test

WARNING: Cancer and Reproductive Harm-
 www.P65Warnings.ca.gov

Repackaged by Spectrum as:
 Lot No. XQ####

Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
 New Brunswick, NJ 08901
 732.214.1300

West Coast Facility:

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