

SAFETY DATA SHEET

Preparation Date: 9/17/2019

Revision date Not applicable

Revision Number: Not applicable

1. IDENTIFICATION

Product identifier

Product code: KE902
Product Name: KETOROLAC TROMETHAMINE, USP

Other means of identification

Synonyms: No information available
CAS #: 74103-07-4
RTECS # UY7759900
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Analgesic. Anti-inflammatory.
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 serious eye irritation
 Causes skin irritation
 May cause respiratory irritation



Hazards not otherwise classified (HNOC)

Not Applicable

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
Use only outdoors or in a well-ventilated area
Wear protective gloves
Wear eye/face protection

Precautionary Statements - Response

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
If skin irritation occurs: Get medical attention
Take off contaminated clothing and wash it before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.
IF SWALLOWED: Immediately call a POISON CENTER or physician
Rinse mouth

Precautionary Statements - Storage

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

Precautionary Statements - Disposal

Dispose of contents and container to an approved waste disposal plant in accordance with local, regional, national and international regulations as applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Ketorolac Tromethamine	74103-07-4	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.

- 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** Causes skin irritation
Causes serious eye irritation
Irritating to respiratory system
For Non-steroidal anti-inflammatory drugs (NSAIDs): Nausea, vomiting, diarrhea, headache, diarrhea, constipation, heartburn, abdominal pain, black/tarry stools, swelling, ringing in ears, tremors, somnolence, insomnia, anxiety, confusion, dizziness, drowsiness and other central nervous system effects, itching, gastrointestinal ulceration/bleeding, hypertension, kidney failure, decreased urinary output, difficult or troubled breathing, blood disorders, cardiovascular thrombotic events, cardiovascular effects, myocardial infarction, stroke, prolonged bleeding/bruising

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. Foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous combustion products Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NO_x).

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: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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 Use appropriate tools to put the spilled solid in a suitable 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. 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. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

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
Ketorolac Tromethamine	74103-07-4	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
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Ketorolac Tromethamine	74103-07-4	None	None	None	None
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Australia and Mexico

Component	CAS No	Australia	Mexico
Ketorolac Tromethamine	74103-07-4	None	None

Appropriate engineering controls

Engineering measures to reduce exposure: 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:** Safety glasses with side-shields.
- Skin and body protection:** Long sleeved clothing
Chemical resistant apron
Gloves
- Respiratory protection:** Wear respirator with dust filter. 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 C15H13NO3-C4H11NO3
Molecular/Formula weight (g/mole): 376.40	Flammability (solid, gas) no data available	Flashpoint (°C/°F): No information available
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): 162-165°C/ 323.6-329°F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
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:
Soluble in Water

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Sensitive to light. Exposure to light accelerates decomposition. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Incompatible materials. Exposure to light.

Incompatible Materials: Oxidizing agents

Hazardous decomposition products: Carbon oxides. Nitrogen oxides (NOx).

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Inhalation. Ingestion.

Acute Toxicity

Component Information

Ketorolac Tromethamine

CAS No 74103-07-4

LD50/oral/rat = 189 mg/kg Oral LD50 Rat

LD50/oral/mouse = 293 mg/kg

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = No information available

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LD50/oral/rat =
Value - Acute Toxicity = 189 mg/kg

LD50/oral/mouse =
Value - Acute Tox = 293 mg/kg

LD50/dermal/rabbit
Value - Acute Toxicity = No information available

LD50/dermal/rat
VALUE - Acute Tox = 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.

Eye Contact: Causes serious eye irritation.

Inhalation Causes respiratory tract and mucous membrane irritation.

Ingestion Toxic if swallowed. May cause gastrointestinal tract irritation with gastritis, flatulence, gastrointestinal fullness, stomatitis, abnormal taste, swelling of tongue, nausea constipation or diarrhea, dyspepsia, gastrointestinal ulcerations and pain, bleeding and perforation. May affect behavior/Central Nervous System (ataxia, somnolence, depression, insomnia, paresthesia, hallucinations, headache, drowsiness, dizziness, inability to concentrate, dry mouth, excessive thirst, nervousness, tremor, insomnia, abnormal dreams, euphoria, stupor, hyperkinesia, distorted perceptions, vertigo, convulsions), blood (inhibits platelet aggregation and may prolong bleeding time; leukopenia; eosinophilia), metabolism (anorexia or increase in appetite), cardiovascular system (flushing, hypertension, palpitation, hypotension, pallor, syncope), respiratory system (rhinitis, cough, dyspnea, bronchiolar constriction, pulmonary edema), vision (blurred vision, abnormal vision), hearing (tinnitus, hearing loss), immune system (allergic/anaphylaxis, skin rash, Pruritis - in individuals with previously demonstrated hypersensitivity or in individuals with the complete or partial syndrome of nasal polyps, angioedema, asthma, or other allergic reactions to aspirin or other nonsteroidal anti-inflammatory drugs), kidneys (hematuria, proteinuria, polyuria, glomerular nephritis, interstitial nephritis, renal papillary necrosis, acute renal failure, nephrotic syndrome), and liver (elevation of liver enzymes). 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 Possible allergic reaction if the material is ingested, inhaled or in contact with skin. Ingestion: Prolonged or repeated ingestion may cause weight loss or weight gain and may have symptoms similar to that of acute ingestion. Medical Conditions Aggravated by Exposure: Impaired renal function, impaired liver function or liver disease, previously demonstrated hypersensitivity to Ketorolac Tromethamine, the complete or partial syndrome of nasal polyps, angioedema, asthma, or other allergic reactions to aspirin or other nonsteroidal anti-inflammatory drugs. Prolonged or repeated ingestion may cause stomach ulcers and increase the risk of stomach bleeding particularly if taken with other drugs that may cause bleeding (blood thinners. anti-platelet drugs, or other Non-steroidal Anti-inflammatory Drugs such as Aspirin, Ibuprofen, naproxen, or Ketorolac.

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
Ketorolac Tromethamine	74103-07-4	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: Blood. Kidneys. Liver. Central nervous system.

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

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Ketorolac Tromethamine	74103-07-4	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated

Proper Shipping Name: Toxic solids, organic, n.o.s. (clonidine hydrochloride)

Hazard Class 6.1

Subsidiary Class No information available

Packing group: No information available

Emergency Response Guide Number No information available

Marine Pollutant No data available

DOT RQ (lbs): No information available

Special Provisions No Information available

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. ,6.1,PG 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.,6.1,PG III

ADR

Product code: KE902

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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
Description: UN2811 Toxic solid, organic, n.o.s.,6.1,III

IMDG

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
EMS: F-A

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
Description: UN2811 Toxic solid, organic, n.o.s.,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.,6.1,PG III

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.,6.1,PG 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>Ketorolac Tromethamine</i>	74103-07-4	Not Listed	Not present	Not present	Not present	Not listed	Not listed	Not present

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:
Ketorolac Tromethamine	74103-07-4	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

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
<i>Ketorolac Tromethamine</i>	74103-07-4	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
Ketorolac Tromethamine	74103-07-4	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 not 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)
Ketorolac Tromethamine	74103-07-4	Not Listed	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Ketorolac Tromethamine	74103-07-4	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Ketorolac Tromethamine	74103-07-4	Not listed

EU Classification**EU GHS - SV - CLP 1272/2008**

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Ketorolac Tromethamine	74103-07-4	

EU - CLP (1272/2008)

R-phrase(s)

R25 - Toxic if swallowed

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

S -phrase(s)

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

S36 - Wear suitable protective clothing

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

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Ketorolac Tromethamine	74103-07-4		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC**Indication of danger:**

T - Toxic

T

**16. OTHER INFORMATION**

Preparation Date: 9/17/2019
Revision date Not applicable
Prepared by: Sonia Owen

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