

Section 1: Identification
Product Name Ketorolac Tromethamine USP

Commercial Name Toradol; Acular; Syntex

Product Use Not available.

Restrictions On Use Not available.

Product Code 50-3443

Company PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:

CHEMTREC (24hr) 1-800-424-9300
Section 2: Hazard(s) Identification
OSHA Haz Com: Acute toxicity, Oral (Category 3) Reproductive toxicity (Category 2) Specific target organ toxicity, repeated exposure (Category 1) (cardiovascular system, gastrointestinal tract)

CFR 1910.1200
Signal Word DANGER

Hazard Statement(s) Toxic if swallowed. Suspected of damaging fertility or the unborn child. Causes damage to organs (cardiovascular system, gastrointestinal tract) through prolonged or repeated exposure.

Pictogram(s) or Symbol(s)

Precautionary Statement(s):
Prevention

P201 Obtain special instructions before use P202 Do not handle until all safety precautions have been read and understood P261 Avoid breathing dust/fume/gas/mist/vapours/spray P280 Wear protective gloves/protective clothing/eye protection/face protection

Response

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician P302+P352 IF ON SKIN: Wash with plenty of soap and water. P305+ P351+ P338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing P308+P313 IF exposed or concerned: Get medical advice/attention P333+P313 If skin irritation or a rash occurs: Get medical advice/attention

Storage

P405 Store locked up.

Disposal

P501 Dispose of contents/container in a site approved for chemical and hazardous waste or burned in a specialised burning centre

Section 3: Composition/Information on Ingredients
Substance/Mixture Substance

Components Ketorolac Tromethamine USP

% By Weight 100

CAS# 74103-07-4

Molecular Weight 375.90

Chemical Formula C21 H23 Cl F N O2

Synonym(s) 1H-Pyrrolizine-1-carboxylic acid, 2,3-dihydro-5-benzoyl-, (+-)-, compd.with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1); (+/-)-5-benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid, 2-amino-2-(hydroxymethyl)-1,3-propanediol

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Ketorolac Tromethamine	74103-07-4	100		ORAL (LD50): Acute: 189 mg/kg [Rat]. 293 mg/kg [Mouse].

Section 4: First-Aid Measures

Inhalation	Allow the victim to rest in a well ventilated area. Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. In severe cases or if symptoms persists, seek medical attention.
Skin Contact	Allow the victim to rest in a well ventilated area. Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. In severe cases or if symptoms persists, seek medical attention.
Eye Contact	Allow the victim to rest in a well ventilated area. Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. In severe cases or if symptoms persists, seek medical attention.
Ingestion	Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.
Symptoms/Effects	
Acute	Not available
Delayed	Not available
Immediate Medical Attention	
Not available	

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

In case of fire use water, chemical type foam, carbon dioxide, dry chemical. Prevent run off of water from entering drains

Unsuitable Extinguishing Media

Not available.

Products of Combustion

The substance evolves toxic fumes due to the presence of CO, CO₂, NO_x, HCl, HF

Firefighters Special Equipment and Precautions

Wear: -Gas masks scuba -Complete protective equipment composed by: helmet whit face shield and neck protection, fireproof jacket and trousers with straps around arms, legs and waist. As not expected at this point, refer to the personal protective equipment recommended in Section 8 of this sheet

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Keep away any ignition source. Wear protective equipment. Keep unprotected persons away. Use respiratory protective device against the effects of fumes. Ensure adequate ventilation. Methods and materials for containment and cleaning up: Absorb spillage in earth or sand. Sweep or shovel-up spillage and remove to a safe place. Damp down to avoid dust generation. Environmental precautions: Do not allow to penetrate the ground/soil. Prevent seepage into sewage system, workpits and cellars. Inform respective authorities in case of seepage into water course or sewage system.

Section 7: Handling and Storage

Precautions for safe handling: This product should be handled only by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals, who should take into account the fire, health and chemical hazard data given on this sheet. It should always be handled in an efficient fume hood or equivalent system and, if necessary, wear protective equipment. Care should be taken to prevent the chemical from coming into contact with the skin or eyes and from contaminating personal clothing. Conditions for safe storage, including any incompatibilities: Avoid contact with oxidising substances For safety purposes, the substance does not require any special storage conditions. As an indication, the information provided by official monographs are: USP: Preserve in tight, light-resistant containers. EP: Protected from light. For storage of the substance for pharmaceutical use, or for registration purposes please refer to the stability data conducted in-house and reported in the document regulatory "Active Substance Master File" (ASMF or DMF).



Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Ketorolac Tromethamine USP

50-3443

Section 8: Exposure Controls/Personal Protection

Exposure Limits

Not available

Engineering Controls

Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with skin, eyes and clothing.

Personal Protection

Eye/face protection: Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Hand protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Skin and body protection: The type of protective equipment (es. Tyvek suit) must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Complete suit protecting against chemicals, flame retardant antistatic protective clothing. Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a fullface particle respirator type N99 (US) or type P2 (EN 143) with cartridges P1 (inert substances) P2 (harmful substances) P3 (toxic substances). Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Section 9: Physical and Chemical Properties

Appearance	crystalline powder, white or practically white		
Odor	odourless		
Odor Threshold	Not available		
Melting Point	152°C	pH	Not available
Freezing Point	Not available	Vapor Pressure	Not applicable
Boiling Point/Range	Not available	Vapor Density	Not available
Decomposition temperature	Not available	Viscosity	Not available
Partition Coefficient: n-octanol/water	log P 4.3	Evaporation Rate	Not available
Flash Point	Not available	Autoignition temperature	Not available
Flammability	Not available	Flammability or Explosive Limits:	
		Lower	Not available
		Upper	Not available
Solubility(ies)	insoluble in water.		
Other	Not available		

Section 10: Stability and Reactivity

Reactivity	Not available
Chemical Stability	The product is stable in usual working conditions
Hazardous Polymerization	Not available
Conditions to Avoid	Heat, flames and sparks
Incompatible Materials	Strong oxidising agents. Alkali metals, bases, strong acids, halogens
Hazardous Decomposition Products	The substance evolves toxic fumes due to the presence of CO, CO ₂ , NO _x , HCl, HF

Section 11: Toxicological Information

RTECS	Not available
Acute Toxicity	
Acute Oral LD 50 rat 128 mg/kg Acute Oral LD 50 mouse 71 mg/kg Acute Oral LD 50 dog 71 mg/kg	
Skin Corrosion/Irritation	
Not available	
Serious Eye Damage/Irritation	
Not available	
Respiratory or Skin Sensitization	
Not available	
Germ Cell Mutagenicity	
Not available	
Carcinogenicity	
Not available	
Reproductive Toxicity	
Not available	
Routes of Entry	
Not available.	
Symptoms Related to Exposure	
Not available	

Potential Health Effects

Rapidly absorbed and redistributed following ingestion. Crosses the blood-brain barrier and excreted into breast milk. Toxic if swallowed. Possible risk of harm to the unborn child. Risk of impaired fertility. Irritating to eyes, respiratory system and skin. May affect central nervous system leading into tremor, rigidity, altered movements. More rarely, may cause depression, insomnia or vertigo. May cause low blood pressure and slow heart rate. May induce dry mouth, blurred vision, excessive salivation. May cause sensitisation by skin contact. May cause photosensitivity and allergic reactions. May cause photosensitivity and allergic reactions.

Target Organ(s) Not available

Section 12: Ecological Information**Ecotoxicity**

Not available.

Persistence and Degradability

Not available

Bioaccumulative Potential

Not available

Mobility in Soil

Not available

Other Adverse Effects

Not available

Section 13: Disposal Considerations**Waste Disposal**

Do not empty into drains. Use appropriate containment to avoid environmental contamination. Disposal should be in accordance with local, state or national regulation.

Disposal of Container

The containers and packing materials contaminated with dangerous substances or preparations, have the same treatment products.

Other Considerations

Not available

Section 14: Transport Information**DOT Classification**

UN number ADR/RID: 2811 IMDG: 2811 IATA: 2811 UN proper shipping name ADR/RID SOLID ORGANIC TOXIC, N.A.S. (Haloperidol) IMDG TOXIC SOLID, ORGANIC, N.O.S. (Haloperidol) IATA Toxic solid, organic, n.o.s. (Haloperidol) Transport hazard class(es) ADR/RID: 6.1 IMDG: 6.1 IATA: 6.1 Packaging group ADR/RID: III IMDG: III IATA: III Environmental hazards ADR/RID: no IMDG: no IATA: no

Section 15: Regulatory Information**Regulations**

Safety, health and environmental regulations/legislation specific for the substance no data available REACH exempted as API (Active Pharmaceutical Ingredient) CLP notified with submission VP864940-03 02-2119453914-33-0000

Other

Not available.

Section 16: Other Information

Not available.