

Section 1: Identification

Product Name Ketotifen Fumarate EP
Commercial Name Not available.
Product Use Being a pharmacological active ingredient, it is used only by manufactures of pharmaceutical product
Restrictions On Use Not available
Product Code 30-4345
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: EYE IRRIT. 2
CFR 1910.1200
Signal Word WARNING
Hazard Statement(s) H319 Causes serious eye irritation.
Pictogram(s) or Symbol(s)


Precautionary Statement(s):

Prevention P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P264 Wash thoroughly after handling P271 Use only outdoors or in a well-ventilated area P280 Wear protective gloves/protective clothing/eye protection/face protection.
Response P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 Call a POISON CENTER or doctor/physician if you feel unwell.
Storage P404 Store in a closed container.
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 10H- Benzo(4 ,5)cyclohepta(1,2 - b)thiophen -1 0 -one 4,9- dihydro -4 -(1- methyl-4- piperidinylidene) -, (E)- 2- butenedi
% By Weight 100
CAS# 34580-14-8
Molecular Weight 425.5 g/mole
Chemical Formula C19-H19-N-O-S.C4-H4-O4
Synonym(s) 4,9-Dihydro-4-(methylpiperidin-4-ylidene)-10H-benzo[4,5]cyclohepta[1 fumarate;4-(1-Methylpiperidin-4-ylidene) -4H-benzo[4,5]cyclohepta[1,2-b]thiophehydrogen fumarate

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
10H- Benzo(4 ,5)cyclohepta(1,2 - b)thiophen -1 0 -one 4,9- dihydro -4 -(1- methyl-4- piperidinylidene) -, (E)- 2- butenedioate (1:1	34580-14-8	100	N/A	N/A

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	After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.
Eye Contact	Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation 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 drain

Unsuitable Extinguishing Media

Not available.

Products of Combustion

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

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.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Keep away any ignition source. Wear protective equipment. Keep nprotected 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 the original packaging tightly closed EP: Preserve in the original packaging tightly closed 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).

Section 8: Exposure Controls/Personal Protection

Exposure Limits	Not available.
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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 full-face 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	Fine crystalline powder of white to yellowish-brown		
Odor	Odorless		
Odor Threshold	Not available.		
Melting Point	192-195C with decomposition	pH	Not available.
Freezing Point	Not available.	Vapor Pressure	Not available.
Boiling Point/Range	Not available.	Vapor Density	Not available.
Decomposition temperature	192-195°C	Viscosity	Not available.
Partition Coefficient: n-octanol/water	Not available.	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)	Sparingly soluble 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 ,Nox,SO _x

Section 11: Toxicological Information

RTECS	DE8260000
Acute Toxicity	
Acute Oral LD 50 rat mg/kg 360 Acute Oral LD 50 mouse mg/kg 585 Acute sub. cut. LD 50 rat mg/kg 370 Acute sub. cut. LD 50 mouse mg/kg 820 Acute I.V. LD 50 rat mg/kg 51 Acute I.V. LD 50 mouse mg/kg 18,8	
Skin Corrosion/Irritation	Not available.
Serious Eye Damage/Irritation	Causes serious eye irritation
Respiratory or Skin Sensitization	Not available.
Germ Cell Mutagenicity	No evidence
Carcinogenicity	Not listed
Reproductive Toxicity	No evidence
Routes of Entry	Inhalation May be harmful if inhaled. Ingestion May be harmful if swallowed. Skin May cause skin irritation
Symptoms Related to Exposure	No evidence

Potential Health Effects

Not available.

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**

Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA).

Section 15: Regulatory Information**Regulations**

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006 Safety, health and environmental regulations/legislation specific for the substance no data available REACH exempted as API (Active Pharmaceutical Ingredient) CLP notified with submission AD861005-63 02-2119451866-28-0000

Other

WHMIS (Canada): CLASS D-1B: Material causing immediate and serious toxic effects (TOXIC).

Section 16: Other Information

Manufacturer disclaimer: Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for particular uses are beyond our control; all risks of use of the product are therefore assumed by the user. Nothing is intended as a recommendation for uses which infringe valid patents or as extending licences under valid patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.