


Section 1: Identification

Common Name/Trade Name	KETOTIFEN HYDROGEN FUMARATE	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours) NSW Poisons Information Centre: 131 126 (24 hours)
Distributor Name	Bella Corp Trading Pty Ltd 6/34 Dominions Road, Ashmore QLD 4214, Australia Telephone: 07 5597 4169 Email: bellacorp@bellacorp.com.au	
Product Synonym(s)	4,9-Dihydro-4-(1-methyl-4-piperidinylidene)-10H-benzo[4,5]cyclohepta[1,2- α] thiophen-10-one Fumarate	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, Oral (Category 4)	
Signal Word	Warning	
Hazard Statement(s)	H302	Harmful if swallowed
Pictogram(s)		
Precautionary Statement(s)	P264 P270 P301+P312 P330 P501	Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	4,9-Dihydro-4-(1-methyl-4-piperidinylidene)-10H-benzo[4,5]cyclohepta[1,2- α] thiophen-10-one Fumarate
Common Name	Ketotifen Hydrogen Fumarate
CAS Number	34580-14-8
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
If Inhaled	Remove to fresh air. If breathing becomes difficult, call a physician.
In Case of Skin Contact	Rinse immediately with plenty of water and seek medical advice.
In Case of Eye Contact	In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.
If Swallowed	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician.
Most Important Symptoms and Effects	No information available.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Use dry chemical, CO ₂ , water spray or alcohol.
Special Hazards Arising From the Substance/Mixture	Burning produces irritant fumes.
Special PPE and/or Precautions for Firefighters	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Use personal protective equipment.
Methods and Materials Used for Containment	Prevent product from entering drains.
Cleanup Procedures	Sweep up and shovel into suitable containers for disposal.

Section 7: Handling and Storage

Precautions for Safe Handling	Use only in area provided with appropriate exhaust ventilation. Wear personal protective equipment.
Conditions for Safe Storage	Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Incompatible Products: Oxidizing and spontaneously flammable products. Storage: Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	No data available
Appropriate Engineering Controls	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
PPE - Eye/Face Protection	Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
PPE - Skin 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.
PPE - Body Protection	Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
PPE - Respiratory Protection	For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. 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	White to brownish-yellow, fine, crystalline powder.
Upper/Lower Flammability or Explosive Limits	No data available
Odor	No data available
Vapor Pressure	No data available
Odor Threshold	No data available
Vapor Density	No data available
pH	No data available
Relative Density	No data available
Melting Point/Freezing Point	No data available
Solubility	Practically insoluble in water. Soluble in acetone and in methylene chloride, sparingly soluble in methanol.
Initial Boiling Point and Boiling Range	No data available
Flash Point	No data available
Evaporation Rate	No data available
Flammability (Solid, Gas)	No data available
Partition Coefficient	No data available
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	Stable under recommended storage conditions.
Chemical Stability	Stable under recommended storage conditions.
Possibility of Hazardous Reactions	Polymerization: None under normal processing. Hazardous Decomposition Products: Nitrogen oxides (NOx) / ammonia / CN-, Sulphur oxides.
Conditions to Avoid	Exposure to air or moisture over prolonged periods.
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	Hazardous Decomposition Products: Nitrogen oxides (NOx) / ammonia / CN-, Sulphur oxides.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	Oral Rat: LD 50: 360 mg/kg RTECS Chronic Toxicity: Chronic exposure may cause nausea and vomiting, higher exposure causes unconsciousness. Local Effects: Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. Specific Effects: May include moderate to severe erythema (redness) and moderate edema (raised skin), nausea, vomiting, headache.
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	No data available
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	No data available
Serious Eye Damage/Irritation	No data available
Respiratory or Skin Sensitization	No data available
Germ Cell Mutagenicity	No data available
Carcinogenicity IARC	No data available
Carcinogenicity ACGIH	No data available
Carcinogenicity NTP	No data available
Carcinogenicity OSHA	No data available
Reproductive Toxicity	No data available
Specific Target Organ Toxicity - Single Exposure	No data available
Specific Target Organ Toxicity - Repeated Exposure	No data available
Aspiration Hazard	No data available

Section 12: Ecological Information

Toxicity	May cause long-term adverse effects in the aquatic environment.
Persistence and Degradability	No data available
Bio-accumulative Potential	No data available
Mobility in Soil	No data available
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Waste from Residues / Unused Products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous. Contaminated Packaging: Do not re-use empty containers.
Waste Treatment Methods Packaging	Contaminated Packaging: Do not re-use empty containers.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods.
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	N/A

Section 15: Regulatory Information

Indication of Danger: Xn - Harmful.

Section 16: Other Information

Additional Information	N/A
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