



# Material Safety Data Sheet

<b>NFPA</b>  	<b>HMIS</b>  <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="background-color: #00FFFF;">Health Hazard</td> <td style="text-align: center; border: 1px solid black;">2</td> </tr> <tr> <td style="background-color: #FFC0CB;">Fire Hazard</td> <td style="text-align: center; border: 1px solid black;">1</td> </tr> <tr> <td style="background-color: #FFFF00;">Reactivity</td> <td style="text-align: center; border: 1px solid black;">0</td> </tr> </table>	Health Hazard	2	Fire Hazard	1	Reactivity	0	<b>Personal Protective Equipment</b>    See Section 15.
Health Hazard	2							
Fire Hazard	1							
Reactivity	0							

Section 1. Chemical Product and Company Identification		Page Number: 1
<b>Common Name/ Trade Name</b>	Ketotifen Fumarate Salt	<b>Catalog Number(s).</b> K3012; K3113
		<b>CAS#</b> 34580-14-8
<b>Manufacturer</b>	SPECTRUM LABORATORY PRODUCTS INC. 14422 S. SAN PEDRO STREET GARDENA, CA 90248	<b>RTECS</b> DE8260000
		<b>TSCA</b> TSCA 8(b) inventory: No products were found.
<b>Commercial Name(s)</b>	Ketotifen Hydrogen Fumarate; Zaditen: Zaditor	<b>CI#</b> Not available.
<b>Synonym</b>	4,9-Dihydro-4-(methylpiperidin-4-ylidene)-10H-benzo[4,5]cyclohepta[1,2-b]thiophen-10-one, fumarate; 4-(1-Methylpiperidin-4-ylidene)-4H-benzo[4,5]cyclohepta[1,2-b]thiophen-10-one, fumarate	<b>IN CASE OF EMERGENCY</b> <a href="tel:800-424-9300">CHEMTREC (24hr) 800-424-9300</a>  CALL (310) 516-8000
<b>Chemical Name</b>	10H-Benzo(4,5)cyclohepta(1,2-b)thiophen-10-one, 4,9-dihydro-4-(1-methyl-4-piperdinylidene)-, (E)-2-butenedioate (1:1)	
<b>Chemical Family</b>	Not available.	
<b>Chemical Formula</b>	C19-H19-N-O-S.C4-H4-O4	
<b>Supplier</b>	SPECTRUM LABORATORY PRODUCTS INC. 14422 S. SAN PEDRO STREET GARDENA, CA 90248	

Section 2. Composition and Information on Ingredients					
		<i>Exposure Limits</i>			
Name	CAS #	TWA (mg/m <sup>3</sup> )	STEL (mg/m <sup>3</sup> )	CEIL (mg/m <sup>3</sup> )	% by Weight
1) Ketotifen Fumarate Salt	34580-14-8				100
<b>Toxicological Data on Ingredients</b>		<b>Ketotifen Fumarate Salt:</b> ORAL (LD50): Acute: 360 mg/kg [Rat]. 585 mg/kg [Mouse].			

Section 3. Hazards Identification	
<b>Potential Acute Health Effects</b>	Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of inhalation.
<b>Potential Chronic Health Effects</b>	<b>CARCINOGENIC EFFECTS:</b> Not available. <b>MUTAGENIC EFFECTS:</b> Not available. <b>TERATOGENIC EFFECTS:</b> Not available. <b>DEVELOPMENTAL TOXICITY:</b> Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

**Section 4. First Aid Measures**

<b>Eye Contact</b>	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.
<b>Skin Contact</b>	Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.
<b>Serious Skin Contact</b>	Not available.
<b>Inhalation</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
<b>Serious Inhalation</b>	Not available.
<b>Ingestion</b>	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.
<b>Serious Ingestion</b>	Not available.

**Section 5. Fire and Explosion Data**

<b>Flammability of the Product</b>	May be combustible at high temperature.
<b>Auto-Ignition Temperature</b>	Not available.
<b>Flash Points</b>	Not available.
<b>Flammable Limits</b>	Not available.
<b>Products of Combustion</b>	These products are carbon oxides (CO, CO <sub>2</sub> ), nitrogen oxides (NO, NO <sub>2</sub> ...), sulfur oxides (SO <sub>2</sub> , SO <sub>3</sub> ...).
<b>Fire Hazards in Presence of Various Substances</b>	Slightly flammable to flammable in presence of heat.
<b>Explosion Hazards in Presence of Various Substances</b>	Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.
<b>Fire Fighting Media and Instructions</b>	SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.
<b>Special Remarks on Fire Hazards</b>	As with most organic solids, fire is possible at elevated temperatures
<b>Special Remarks on Explosion Hazards</b>	Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

**Section 6. Accidental Release Measures**

<b>Small Spill</b>	Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.
<b>Large Spill</b>	Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

**Section 7. Handling and Storage**

<b>Precautions</b>	Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents.
<b>Storage</b>	Keep container tightly closed. Keep container in a cool, well-ventilated area.

**Section 8. Exposure Controls/Personal Protection**

<b>Engineering Controls</b>	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.
<b>Personal Protection</b>	Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.
<b>Personal Protection in Case of a Large Spill</b>	Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.
<b>Exposure Limits</b>	Not available.

**Section 9. Physical and Chemical Properties**

<b>Physical state and appearance</b>	Solid. (Powdered solid. Crystalline powder.)	<b>Odor</b>	Not available.
<b>Molecular Weight</b>	425.5 g/mole	<b>Taste</b>	Not available.
<b>pH (1% soln/water)</b>	Not available.	<b>Color</b>	White to brownish-yellow
<b>Boiling Point</b>	Not available.		
<b>Melting Point</b>	Not available.		
<b>Critical Temperature</b>	Not available.		
<b>Specific Gravity</b>	Not available.		
<b>Vapor Pressure</b>	Not applicable.		
<b>Vapor Density</b>	Not available.		
<b>Volatility</b>	Not available.		
<b>Odor Threshold</b>	Not available.		
<b>Water/Oil Dist. Coeff.</b>	Not available.		
<b>Ionicity (in Water)</b>	Not available.		
<b>Dispersion Properties</b>	Not available.		
<b>Solubility</b>	Sparingly soluble in cold water. Slightly soluble in methanol. Very slightly soluble in acetonitrile.		

**Section 10. Stability and Reactivity Data**

<b>Stability</b>	The product is stable.
<b>Instability Temperature</b>	Not available.
<b>Conditions of Instability</b>	Excess heat, incompatible materials
<b>Incompatibility with various substances</b>	Reactive with oxidizing agents.
<b>Corrosivity</b>	Not available.
<b>Special Remarks on Reactivity</b>	Not available.
<b>Special Remarks on Corrosivity</b>	Not available.
<b>Polymerization</b>	Will not occur.

**Section 11. Toxicological Information**

<b>Routes of Entry</b>	Inhalation. Ingestion.
<b>Toxicity to Animals</b>	Acute oral toxicity (LD50): 360 mg/kg [Rat].
<b>Chronic Effects on Humans</b>	Not available.
<b>Other Toxic Effects on Humans</b>	Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of inhalation.
<b>Special Remarks on Toxicity to Animals</b>	Not available.
<b>Special Remarks on Chronic Effects on Humans</b>	Not available.
<b>Special Remarks on other Toxic Effects on Humans</b>	Acute Potential Health Effects: Skin: May cause skin irritation. Eyes: May cause eye irritation. May cause conjunctivitis Inhalation: Dust may cause respiratory tract irritation. Ingestion: Harmful if swallowed. May cause dry mouth, abdominal pain, nausea, diarrhea, vomiting. May affect behavior/central nervous system (dizziness, headache, CNS stimulation - irritability, excitation, nervousness, insomnia-, drowsiness, confusion, lightheadness, disorientation, convulsions, hallucinations/distorted perceptions, ataxia, somnolence, unusual tiredness, unconsciousness), respiration (dyspnea, respiration depression), spleen, urinary system (cystitis), (cardiovascular system (bradycardia, tachycardia, hypotension, syncope). May also cause joint pain, muscle pain, sore throat, sweating, skin rash with skin redness, itching, peeling, rhinitis, pharyngitis. Chronic Potential Health Effects: Skin: Prolonged or repeated skin contact may cause dermatitis. Ingestion: Prolonged or repeated ingestion may increase appetite and cause weight gain. It may also affect the liver (jaundice, hepatitis), and cause other symptoms similar to that of acute ingestion.


**Section 12. Ecological Information**

<b>Ecotoxicity</b>	Not available.
<b>BOD5 and COD</b>	Not available.
<b>Products of Biodegradation</b>	Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
<b>Toxicity of the Products of Biodegradation</b>	The products of degradation are less toxic than the product itself.
<b>Special Remarks on the Products of Biodegradation</b>	Not available.

**Section 13. Disposal Considerations**

<b>Waste Disposal</b>	Waste must be disposed of in accordance with federal, state and local environmental control regulations.
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**Section 14. Transport Information**

<b>DOT Classification</b>	Not a DOT controlled material (United States).
<b>Identification</b>	Not applicable.
<b>Special Provisions for Transport</b>	Not applicable.
<b>DOT (Pictograms)</b>	

**Section 15. Other Regulatory Information and Pictograms**

**Federal and State Regulations** No products were found.

**California Proposition 65 Warnings** California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer which would require a warning under the statute: No products were found.  
California prop. 65: This product contains the following ingredients for which the State of California has found to cause birth defects which would require a warning under the statute: No products were found.

**Other Regulations** OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200).  
EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances (EINECS No. 252-100-0).  
Canada: Not listed on Canadian Domestic Substance List (DSL) or Canadian Non-Domestic Substances List (NDSL)  
China: Not listed on National Inventory.  
Japan: Not listed on National Inventory (ENCS).  
Korea: Listed on National Inventory (KECI).  
Philippines: Not listed on National Inventory (PICCS).  
Australia: Listed on AICS.

**Other Classifications**  
**WHMIS (Canada)** CLASS D-1B: Material causing immediate and serious toxic effects (TOXIC).  
**DSCL (EEC)** R22- Harmful if swallowed. S46- If swallowed, seek medical advice immediately and show this container or label.

<b>HMIS (U.S.A.)</b>	<b>Health Hazard</b> 2	<b>National Fire Protection Association (U.S.A.)</b>	<b>Flammability</b>	
	<b>Fire Hazard</b> 1			
	<b>Reactivity</b> 0			<b>Reactivity</b>
	<b>Personal Protection</b> E			

Health 


**WHMIS (Canada) (Pictograms)** 


**DSCL (Europe) (Pictograms)** 


**TDG (Canada) (Pictograms)** 

**ADR (Europe) (Pictograms)** 

**Protective Equipment**

 Gloves.

 Lab coat.

 Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.



Safety glasses.

**Section 16. Other Information****MSDS Code** K0025**References** Not available.**Other Special Considerations** Major Use: Drug - Antihistimine; Ophthalmologic agent

Validated by Sonia Owen on 7/10/2009.

Verified by Sonia Owen.

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CALL (310) 516-8000

**Notice to Reader**

*All chemicals may pose unknown hazards and should be used with caution. This Material Safety Data Sheet (MSDS) 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 MSDS. 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 MSDS is based on technical data judged to be reliable, Spectrum Quality Products, Inc. assumes no responsibility for the completeness or accuracy of the information contained herein.*