SECTION-1: Identification of the substance / mixture and the company / undertaking

Catalogue Number	CS-O-04571
Product Name	Ketotifen
CAS No.	34580-13-7
Category	API
Synonyms	4-(1-methylpiperidin-4-ylidene)-4,9-dihydro-10H-benzo[4,5]cyclohepta[1,2-b]thiophen-10-one
Brand	Clearsynth Labs Ltd.
Identified uses	Laboratory Chemicals
Uses advised against	Not available
Company	Clearsynth Labs Ltd. Mumbai, India
Emergency Phone #	+91-22-245045900
REACH No.	Not available

SECTION 2: Hazards identification

Disclaimer: This is sample MSDS. Please email **sales@clearsynth.com** for more details.

2.1 Classification of the substance or mixture-Regulation (EC) No 1272/2008:

Acute toxicity (Category 4)

2.2 Label Elements

Signal Word: Warning

Hazard Statement(s)

Code	Statement
H302	Harmful if swallowed.

Precautionary Statement(s)

Code	Statement

P264	Wash hands thoroughly after handling.
P270	Not available
P301+P317	Not available
P330	Not available
P501	Dispose of contents/container in accordance with local/regional/national/international regulatio

SECTION 3: Composition / information on ingredients

3.1 Substance

Component : Ketotifen
CAS Number : 34580-13-7
Molecular Formula : C19H19NOS
Molecular Weight : 309.43
Parent Chemical : Ketotifen
Synonyms : 4-(1-methylpiperidin-4-ylidene)-4,9-dihydro-10H-benzo[4,5]cyclohepta[1,2-b]thiophen-10-one
Concentration : Not available

SECTION 4: First aid measures

Not available

SECTION 5: Firefighting measures

Not available

SECTION 6: Accidental release measures

Not available

SECTION-7: Handling and storage

Not available

SECTION 8: Exposure controls / personal protection

Not available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Test	Result
Appearance	No data available
IR spectrum	No data available
pH	No data available
Solubility	No data available

Property	Value
a) Physical State	No data available
b) Color	No data available
c) Odor	No data available
d) pH	No data available
e) Vapour Pressure	No data available
f) Viscosity	No data available
g) Initial Boiling Point and boiling range	No data available
h) Melting Point / Freezing Point	No data available
i) Auto Ignition Temperature	No data available
j) Flash Point	No data available
k) Explosion Limit, Lower	No data available
l) Explosion Limit, Upper	No data available
m) Decomposition Temperature	No data available
n) Loss on Drying	No data available
o) Relative Density	No data available
p) Solubility (in DMSO)	No data available
q) Oxidizing Properties	No data available

SECTION 10: Stability and reactivity

Not available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- Acute toxicity: /LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ In female rats treated orally with 2, 10, and 50 mg/kg of ketotifen from day 15 postcoitum to day 21 postpartum, no adverse effects on the pre- and postnatal development of the offspring were found in the two lower dose groups. However, the 50 mg/kg dose produced mortality in 10% of the mothers as well as an increase loss of pups, resulting in slightly decreased litter size and reduced weight gain during the first four days. /Ketotifen fumarate/ /LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ In the offspring of the rats that received ketotifen orally from day 15 of pregnancy to day 21 postpartum at a dose of 15 mg/kg per day, the incidence of postnatal mortality was slightly increased, and body weight gain during the first 4 days postpartum was slightly decreased. /Ketotifen fumarate/
- Skin corrosion/irritation: No data available.
- Serious eye damage/eye irritation: No data available.
- Respiratory or skin sensitization: No data available.
- Germ cell mutagenicity: /GENOTOXICITY/ Ketotifen fumarate was determined to be non-mutagenic in a battery of in vitro and in vivo mutagenicity assays including: Ames test, in vitro chromosomal aberration test with V79 Chinese hamster cells, in vivo micronucleus assay in mouse, and mouse dominant lethal test.
- Carcinogenicity: No data available.
- Reproductive toxicity: /LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ In female rats treated orally with 2, 10, and 50 mg/kg of ketotifen from day 15 postcoitum to day 21 postpartum, no adverse effects on the pre- and postnatal development of the offspring were found in the two lower dose groups. However, the 50 mg/kg dose produced mortality in 10% of the mothers as well as an increase loss of pups, resulting in slightly decreased litter size and reduced weight gain during the first four days. /Ketotifen fumarate/ /LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ In the offspring of the rats that received ketotifen orally from day 15 of pregnancy to day 21 postpartum at a dose of 15 mg/kg per day, the incidence of postnatal mortality was slightly increased, and body weight gain during the first 4 days postpartum was slightly decreased. /Ketotifen fumarate/
- STOT-single exposure: No data available.
- STOT-repeated exposure: No data available.
- Aspiration hazard: No data available.

Likely routes of exposure
- No data available.

Symptoms related to the physical, chemical and toxicological characteristics
- /HUMAN EXPOSURE STUDIES/ Eight patients aged 6 to 34 years took overdoses of ketotifen in doses stated to range from 10 to 120 mg. Plasma concentrations of ketotifen base in 4 patients were 5 to 122 ng per mL (therapeutic range 1to 4 ng per mL) Symptoms included drowsiness, dyspnea, bradycardia or tachycardia, disorientation and convulsions. Gastric lavage was performed in 6 and all recovered within 12 hours after supportive treatment.

SECTION 12: Ecological information

Not available

SECTION 13: Disposal considerations

Not available

SECTION 14: Transport information

Not available

SECTION 15: Regulatory information

Not available

SECTION 16: Other information

Not available

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