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

Catalogue Number	CS-SS-24015
Product Name	Amlodipine besylate (besilate)
CAS No.	88150-42-9
Category	Secondary Standards
Synonyms	Not available
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:

Skin irritation (Category 2)
Acute toxicity (Category 4)

2.2 Label Elements

Signal Word: Warning

Hazard Statement(s)

Code	Statement
H301	Not available
H318	Causes serious eye damage.
H373	Not available

H400	Not available
H410	Not available
H315	Causes skin irritation.
H314	Not available
H341	Not available
H411	Toxic to aquatic life with long lasting effects.
H302	Harmful if swallowed.

Precautionary Statement(s)

Code	Statement
P260	Not available
P264	Wash hands thoroughly after handling.
P264+P265	Not available
P270	Not available
P273	Not available
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P316	Not available
P305+P354+P338	Not available
P317	Not available
P319	Get medical help if you feel unwell.
P321	Specific treatment (see … on this label).
P330	Not available
P391	Not available
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulatio
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P332+P317	If skin irritation occurs: Get medical help.
P362+P364	Take off contaminated clothing and wash it before reuse.
P203	Not available
P301+P330+P331	Not available

P302+P361+P354	Not available
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P316	Not available
P318	Not available
P363	Not available
P301+P317	Not available

SECTION 3: Composition / information on ingredients

3.1 Substance

Component : Amlodipine besylate (besilate)
CAS Number : 88150-42-9
Molecular Formula : C20H25ClN2O5
Molecular Weight : 567.05
Parent Chemical : Amlodipine
Synonyms : Not available
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: HUMAN EXPOSURE AND TOXICITY: One patient ingested 250 mg amlodipine and was asymptomatic. Another patient ingested 120 mg, underwent gastric lavage, and remained normotensive. A third patient took 105 mg and had hypotension (90/50 mmHG), which normalized following plasma expansion. A 19-month old ingested 30 mg (2 mg/kg) and had no evidence of hypotension but had a heart rate of 180 bpm. Children who ingested > 10 mg were 4.4 times more likely to develop clinically important responses than those ingesting < or = 5 mg. Hypotension may occur in children with amlodipine doses as low as 2.5 mg. Signs and Symptoms of Overdose: Amlodipine overdose and toxicity can lead to massive vasodilation, hypotension, and reflex tachycardia as compensatory mechanisms. Prolonged systemic hypotension can progress to shock and even death.
- Skin corrosion/irritation: No data available.
- Serious eye damage/eye irritation: No data available.
- Respiratory or skin sensitization: No data available.
- Germ cell mutagenicity: Mutagenicity studies conducted with amlodipine maleate revealed no drug related effects at either the gene or chromosome level.
- Carcinogenicity: Rats and mice treated with amlodipine maleate in the diet for up to two years, at concentrations calculated to provide daily dosage levels of 0.5, 1.25, and 2.5 amlodipine mg/kg/day, showed no evidence of a carcinogenic effect of the drug.
- Reproductive toxicity: Amlodipine has been shown to prolong the duration of labor in rats. No evidence of teratogenicity or other embryo/fetal toxicity was observed in rats or rabbits given up to 10 mg/kg during periods of major organogenesis. However, the number of intrauterine deaths increased about five-fold, and rat litter size was decreased by 50%.
- STOT-single exposure: No data available.
- STOT-repeated exposure: Chronic therapy with amlodipine is associated with a low rate of serum enzyme elevations at rates that are similar to matched control populations. The enzyme elevations are usually mild, transient and asymptomatic and may resolve even during continued therapy. Clinically apparent liver injury from amlodipine is rare and described only in isolated case reports. In the few idiosyncratic cases reported, the latency period to onset of liver injury was usually 4 to 12 weeks, but examples with prolonged latency have also been published (10 months and several years). The latency period is shorter with recurrence on reexposure, including several instances of recurrence after liver injury due to other calcium channel blockers. The pattern of serum enzyme elevations is usually mixed or cholestatic. Rash, fever and eosinophilia have not been described and autoantibodies are not typical.
- Aspiration hazard: No data available.

Likely routes of exposure
- No data available.

Symptoms related to the physical, chemical and toxicological characteristics
- One patient ingested 250 mg amlodipine and was asymptomatic. Another patient ingested 120 mg, underwent gastric lavage, and remained normotensive. A third patient took 105 mg and had hypotension (90/50 mmHG), which normalized following plasma expansion. A 19-month old ingested 30 mg (2 mg/kg) and had no evidence of hypotension but had a heart rate of 180 bpm. Children who ingested > 10 mg were 4.4 times more likely to develop clinically important responses than those ingesting < or = 5 mg. Hypotension may occur in children with amlodipine doses as low as 2.5 mg. Signs and Symptoms of Overdose: Amlodipine overdose and toxicity can lead to massive vasodilation, hypotension, and reflex tachycardia as compensatory mechanisms. Prolonged systemic hypotension can progress to shock and even death.

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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