

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

Catalogue Number	CS-O-32806
Product Name	Ractopamine
CAS No.	97825-25-7
Category	API
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:

Not available

2.2 Label Elements

Signal Word: Not available

Not available

Hazard Statement(s)

Code	Statement
Not available	Not available

Precautionary Statement(s)

Code	Statement
Not available	Not available

SECTION 3: Composition / information on ingredients

3.1 Substance

Component : Ractopamine
CAS Number : 97825-25-7
Molecular Formula : C₁₉H₂₃NO₃
Molecular Weight : 301.38 g/mol
Parent Chemical : Ractopamine
Synonyms : Not available
Concentration : Not available

SECTION 4: First aid measures

SECTION 4: First-aid measures

4.1 Description of first aid measures

General advice: Seek medical attention if symptoms occur or persist. Show this SDS to the physician.

Inhalation: Move person to fresh air. If breathing is difficult, seek medical attention.

Skin contact: Wash with plenty of soap and water. Remove contaminated clothing and wash before reuse. Seek medical attention if irritation develops.

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do.

Continue rinsing. Seek medical attention if irritation persists.

Ingestion: Rinse mouth. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically. No data available.

SECTION 5: Firefighting measures

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media: Use extinguishing measures appropriate to local circumstances and the surrounding environment (e.g., water spray, alcohol-resistant foam, dry chemical, carbon dioxide).

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Not available.

Specific hazards: Not available.

5.3 Advice for firefighters

Wear self-contained breathing apparatus (SCBA) and full protective gear. Avoid inhalation of combustion products.

Use water spray to cool unopened containers exposed to fire.

SECTION 6: Accidental release measures

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing dust. Use appropriate personal protective equipment (see Section 8). Ensure adequate ventilation.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Avoid release to the environment. Prevent entry into drains, surface waters, or soil.

6.3 Methods and material for containment and cleaning up

Contain spill. Sweep up or vacuum (use equipment suitable for dusts) and place in a suitable, closed container for disposal. Avoid generating airborne dust. Clean contaminated area.

6.4 Reference to other sections

See Section 8 for personal protective equipment and Section 13 for disposal considerations.

SECTION-7: Handling and storage

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid breathing dust. Minimize dust generation. Use with adequate ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Store in a tightly closed container in a cool, dry, well-ventilated place. Protect from moisture. Keep away from incompatible materials.

Incompatible materials: Not available.

7.3 Specific end use(s)

API. No further information available.

SECTION 8: Exposure controls / personal protection

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits: Not available.

Biological limit values: Not available.

8.2 Exposure controls

Engineering controls: Provide adequate general and/or local exhaust ventilation to control airborne levels. Use dust control measures where applicable.

Personal protective equipment (PPE):

- Eye/face protection: Safety glasses with side shields or chemical splash goggles as appropriate.
- Skin protection: Protective gloves. Wear protective clothing as needed to prevent skin contact.
- Respiratory protection: If ventilation is inadequate or dust is generated, use a properly fitted particulate respirator in accordance with applicable regulations.
- Hygiene measures: Wash hands after handling. Do not eat, drink, or smoke when using this product. Remove contaminated clothing and wash before reuse.

Environmental exposure controls: Avoid release to the environment; use appropriate containment.

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

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10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Avoid dust formation and exposure to moisture. Avoid excessive heat.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- Acute toxicity: /OTHER TOXICITY INFORMATION/ The Committee concluded that the response in monkeys is more predictive of the acute cardiovascular response in humans exposed to dietary ractopamine than is that in dogs. Monitoring in the studies in animals and humans was appropriately timed to reveal the onset, time-to-peak, and duration of ractopamine-induced cardiac effects. The time course of the cardiostimulatory effects of ractopamine was comparable in humans, monkeys, and dogs. /OTHER TOXICITY INFORMATION/ The Committee reviewed publicly available literature on nontherapeutic effects in humans after long-term use of beta-adrenoceptor agonists. The reported side-effects of prolonged therapeutic use of beta-adrenoceptor agonists include tachycardia, vasodilation, skeletal muscle tremor, nervousness, metabolic disturbances (hyperglycaemia and hypokalaemia), and beta-adrenoceptor desensitization. These effects are pharmacologically predictable, dose-related and potency-related, with cardiovascular effects being the most commonly reported side-effects. Non-pharmacological effects include airway hyper-responsiveness and increased airway inflammation. The incidence and severity of side-effects varies for any given compound. Tolerance to pharmacologically-predictable, non-therapeutic effects occurs readily. There is no evidence for any increased incidence of smooth muscle tumors such as leiomyomas, or of any other tumors, among human users of these drugs. Little or no relaxant response to beta2-adrenoceptor agonists has been reported for the non-pregnant human uterus.

- Skin corrosion/irritation: No data available.

- Serious eye damage/eye irritation: No data available.

- Respiratory or skin sensitization: /SIGNS AND SYMPTOMS/ Adverse effects of prolonged therapeutic use of beta-agonists including tachycardia, vasodilation, skeletal muscle tremor, nervousness, metabolic disturbances, and beta-adrenoceptor desensitization are pharmacologically predictable, dose-related and potency-related. Non-pharmacological effects include airway hyper-responsiveness and increased airway inflammation. The incidence and severity of adverse reactions may vary for any given compound. The impact of the R- and S-enantiomers of beta-agonists on adverse effects remains unclear. /beta-Agonists/ /OTHER TOXICITY INFORMATION/ The Committee reviewed publicly available literature on nontherapeutic effects in humans after long-term use of beta-adrenoceptor agonists. The reported side-effects of prolonged therapeutic use of beta-adrenoceptor agonists include tachycardia, vasodilation, skeletal muscle tremor, nervousness, metabolic disturbances (hyperglycaemia and hypokalaemia), and beta-adrenoceptor desensitization. These effects are pharmacologically predictable, dose-related and potency-related, with cardiovascular effects being the most

commonly reported side-effects. Non-pharmacological effects include airway hyper-responsiveness and increased airway inflammation. The incidence and severity of side-effects varies for any given compound. Tolerance to pharmacologically-predictable, non-therapeutic effects occurs readily. There is no evidence for any increased incidence of smooth muscle tumors such as leiomyomas, or of any other tumors, among human users of these drugs. Little or no relaxant response to beta2-adrenoceptor agonists has been reported for the non-pregnant human uterus.

- Germ cell mutagenicity: No data available.

- Carcinogenicity: /OTHER TOXICITY INFORMATION/ The Committee reviewed publicly available literature on nontherapeutic effects in humans after long-term use of beta-adrenoceptor agonists. The reported side-effects of prolonged therapeutic use of beta-adrenoceptor agonists include tachycardia, vasodilation, skeletal muscle tremor, nervousness, metabolic disturbances (hyperglycaemia and hypokalaemia), and beta-adrenoceptor desensitization. These effects are pharmacologically predictable, dose-related and potencyrelated, with cardiovascular effects being the most commonly reported side-effects. Non-pharmacological effects include airway hyper-responsiveness and increased airway inflammation. The incidence and severity of side-effects varies for any given compound. Tolerance to pharmacologically-predictable, non-therapeutic effects occurs readily. There is no evidence for any increased incidence of smooth muscle tumors such as leiomyomas, or of any other tumors, among human users of these drugs. Little or no relaxant response to beta2-adrenoceptor agonists has been reported for the non-pregnant human uterus.

- Reproductive toxicity: No data available.

- STOT-single exposure: No data available.

- STOT-repeated exposure: /OTHER TOXICITY INFORMATION/ The Committee reviewed publicly available literature on nontherapeutic effects in humans after long-term use of beta-adrenoceptor agonists. The reported side-effects of prolonged therapeutic use of beta-adrenoceptor agonists include tachycardia, vasodilation, skeletal muscle tremor, nervousness, metabolic disturbances (hyperglycaemia and hypokalaemia), and beta-adrenoceptor desensitization. These effects are pharmacologically predictable, dose-related and potencyrelated, with cardiovascular effects being the most commonly reported side-effects. Non-pharmacological effects include airway hyper-responsiveness and increased airway inflammation. The incidence and severity of side-effects varies for any given compound. Tolerance to pharmacologically-predictable, non-therapeutic effects occurs readily. There is no evidence for any increased incidence of smooth muscle tumors such as leiomyomas, or of any other tumors, among human users of these drugs. Little or no relaxant response to beta2-adrenoceptor agonists has been reported for the non-pregnant human uterus. /LABORATORY ANIMALS: Acute Exposure/ Groups of four male and four female beagle dogs (aged 10-19 months) were given ractopamine orally at a dose of 0, 2, 50, or 125 ug/kg bw. The lowest dose of 2 ug/kg bw was selected to be higher than the human exposure anticipated from eating 125 g of pig kidney from an animal that had not been removed from treatment with ractopamine before slaughter (zero time withdrawal). The intermediate dose of 50 ug/kg was selected because this dose had produced skin erythema without any statistically significant increase in heart rate in a previous study in dogs. The highest dose was selected because it was known to increase heart rate in this study and corresponded to the NOEL previously identified in a long-term study in monkeys. The study was designed as a double Latin square that allowed testing for residual effects and was certified for compliance with GLP and quality assurance. Left ventricular pressure, aortic blood pressure, heart rate and electrocardiograms were recorded to provide data on the effects of an oral dose of ractopamine on left ventricular function and systemic blood pressure. The peak value of the first derivative of left ventricular pressure (dP/dtmax) was used as an index of left ventricular inotropic state. Systolic, diastolic, mean aortic, and aortic pulse pressures were derived by the data acquisition system from the aortic pressure signal. Heart rate and left ventricular end-diastolic pressure were obtained from the ventricular pressure signals. All dogs survived the treatment. There was no residual carry-over effect from one treatment to the next in the Latin square design. Ractopamine caused statistically significant dose-dependent increases in heart rate and left ventricular inotropic state at 50 and 125 ug/kg

bw. Maximum effects occurred approximately 2 hr after dosing with an increased heart rate of 40 and 80 beats per min at the intermediate and highest doses, respectively. Increases in left ventricular inotropy were recorded during the 6-h period after dosing. No significant change in heart rate or left ventricular inotropic state was observed at 2 ug/kg. A drop in blood pressure was evident in both the systolic and diastolic (and therefore the mean) pressures in response to treatment at 50 and 125 ug/kg during the 6-hr period immediately after dosing. Treatment at 125 ug/kg caused a decrease in aortic pulse pressure. Analysis of electrocardiograms did not indicate any treatment-related effects. Two dogs at 50 ug/kg and seven dogs at 125 ug/kg had a slight pinking of the abdominal skin (erythema). No other clinical signs were observed in the study. At 2 ug/kg, there was no significant effect on any of the parameters measured. In conclusion, treatment with ractopamine at 50 and 125 ug/kg bw caused tachycardia, an increased left ventricular inotropic state, and a fall in systemic blood pressure in dogs. The increase in heart rate was consistent with a reflex tachycardia since the increased heart rate was always accompanied by a fall in systemic in blood pressure. The results of this study are consistent with expected pharmacological effects associated with vascular beta2-adrenoceptor stimulation and subsequent vasodilation. It is possible that the increased left tachycardia and ventricular inotropy were the result of some direct effect on cardiac beta1- and beta2-adrenoceptors in the dogs. The NOEL was 2 ug/kg bw in this study [Joint FAO/WHO Expert Committee on Food Additives; WHO Food Additive Series 53: Toxicological Evaluation of Certain Veterinary Drug Residues in Food: Ractopamine - Addendum (2004). Available from, as of July 25, 2006:

<http://www.inchem.org/documents/jecfa/jecmono/v53je01.htm>]

- Aspiration hazard: No data available.

Likely routes of exposure

- No data available.

Symptoms related to the physical, chemical and toxicological characteristics

- /HUMAN EXPOSURE STUDIES/ The dose-dependent effects of ractopamine on the human cardiovascular system were studied in a limited number of human volunteers (six persons) given ascending single oral doses equal to 67, 133, 200, 333, and 597 ug/kg bw, with an interval of 48 h between doses. Occasional mild to moderate sensations of increase in heart rate and heart pounding were reported at doses of 200, 333, and 597 ug/kg bw. Dose dependent increases in heart rate and cardiac output, and shortened electromechanical systole, as measured by echocardiography, were observed. The changes appeared within the first hour after the administration of ractopamine and values gradually returned to those before treatment. The systolic blood pressure increased in a dose dependent manner. Unlike in monkeys and dogs, ractopamine had little effect on diastolic blood pressure in humans. Only minor cardiovascular effects were observed at 133 ug/kg bw. The NOELs for the relevant cardiac variables were 67 ug/kg bw for electromechanical systole, ventricular ejection time, and maximum velocity of circumferential fibre shortening, 133 ug/kg bw for heart rate and 200 ug/kg bw for cardiac output.

SECTION 12: Ecological information

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12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Endocrine disrupting properties

Not available.

12.7 Other adverse effects

No data available.

SECTION 13: Disposal considerations

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13.1 Waste treatment methods

Dispose of contents/container in accordance with local/regional/national/international regulations. Do not discharge to drains or the environment.

Waste treatment: Not available.

Contaminated packaging: Dispose of as unused product or according to local regulations.

SECTION 14: Transport information

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14.1 UN number

Not available.

14.2 UN proper shipping name

Not available.

14.3 Transport hazard class(es)

Not available.

14.4 Packing group

Not available.

14.5 Environmental hazards

Not available.

14.6 Special precautions for user

Not available.

14.7 Maritime transport in bulk according to IMO instruments

Not available.

SECTION 15: Regulatory information

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15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Not available.

15.2 Chemical safety assessment

Not available.

SECTION 16: Other information

SECTION 16: Other information

Product name: Ractopamine

Catalog No.: CS-O-32806

CAS No.: 97825-25-7

Molecular weight: 301.38 g/mol

Supplier: Clearsynth Labs Ltd., Mumbai, India

Emergency phone: +91-22-245045900

Revision date: Not available.

SDS version: Not available.

Disclaimer: The information provided is believed to be accurate based on available data, but does not purport to be complete. It is intended for guidance for safe handling, use, processing, storage, transportation, disposal, and release, and is not considered a warranty or quality specification.

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