

**Optaflexx Premix**

Version 1.2

Revision Date 02/17/2010

Print Date 02/19/2010

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Optaflexx Premix
Substance Number : 000004269926
Common Name : Optaflexx Premix

Chemical Name : Benzenemethanol, 4-hydroxy-alpha-[[[3-(4-hydroxyphenyl)-1-methylpropyl]amino]methyl]-, hydrochloride

Company : Elanco Animal Health
Division of Eli Lilly and Company
2001 West Main St
Greenfield, IN 46140

Telephone : 1-800-428-4441
Emergency telephone : CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

Item Code : AF0630, MS8280, MS8285

SECTION 2. HAZARDS IDENTIFICATION**Emergency Overview****Lilly Lab Labeling Code****Health:** 2**Fire:** 1**Reactivity:** 1**Primary Hazards:** Irritant (eyes), Suspect Allergen, Heart**Hazard Summary (Caution):** May cause eye irritation. May produce an allergic reaction. Effects of exposure may include: Increased heart rate.**Emergency Overview**

Form : granular
Colour : tan
Odour : No information available.

Potential Health Effects

Eyes : May irritate eyes.



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- Skin : May cause allergic skin reaction.
- Inhalation : May cause allergic respiratory reaction.
- Aggravated Medical Condition : Heart disease
- Primary Routes of Entry : Inhalation Skin contact
- Additional Information : May produce an allergic reaction. On the basis of animal studies and the known pharmacology of ractopamine hydrochloride (a partial beta adrenergic agonist), anticipated effects from accidental exposure to ractopamine would principally include cardiovascular effects characterized by increased heart rate and cardiac output. Manufacturing personnel wearing appropriate protective clothing have not reported ill effects. Based on animal data, may be irritating to the eyes. The Optaflexx Premix formulation poses a low dust potential.

Carcinogenicity

- NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
- IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
- OSHA No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Concentration [%]
Ractopamine Hydrochloride	90274-24-1	10
Corn Cob Grits	NA	89
Anti-dusting Oil	NA	1

NA = Not applicable, Not assigned, or Not available.

SECTION 4. FIRST AID MEASURES

- Inhalation : Remove to fresh air. If breathing is irregular or stopped, administer artificial respiration. Call a physician immediately.
- Skin contact : Wash off immediately with plenty of water for at least 15 minutes. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists. Wash contaminated clothing before re-use.
- Eye contact : In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.
- Ingestion : If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a physician immediately.



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Engineering measures

Laboratory fume hood or local exhaust ventilation.

Personal protective equipment

Respiratory protection : Use an approved respirator.

Eye protection : Goggles Face-shield

Skin and body protection : When mixing and handling, use protective clothing, impervious gloves, and dust respirator. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse with plenty of water. In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required. Under normal use and handling conditions, wear goggles to protect eyes and wear impermeable gloves and protective equipment to avoid direct contact with skin. Wash thoroughly with soap and water after handling.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form : granular

Physical state : solid

Colour : tan

Odour : No information available.

Safety data

pH : 6 - 7
(50% aqueous solution)

Flash point : no data available

Lower explosion limit : no data available

Upper explosion limit : no data available

Water solubility : slightly soluble, (Active ingredient)

SECTION 10. STABILITY AND REACTIVITY

Materials to avoid : Strong oxidizing agents

Hazardous decomposition products : Hazardous decomposition products formed under fire conditions.

Thermal decomposition : Stable under normal conditions.

Hazardous reactions : Hazardous polymerisation does not occur.

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SECTION 11. TOXICOLOGICAL INFORMATION**Acute oral toxicity**

- Ractopamine Hydrochloride: LD50 (rat) 411 mg/kg
(dog) 50 µg/kg
Increased heart rate.

Acute inhalation toxicity

- Ractopamine Hydrochloride: LC50 (rat) 2,801 mg/m³ (4 h)
(Monkey) 13.9 mg/m³ (15 min)
Increased heart rate.

Acute dermal toxicity

- Ractopamine Hydrochloride: LD50 (rabbit) > 2,000 mg/kg

Skin irritation

- Ractopamine Hydrochloride: rabbit, No irritation

Eye irritation

- Ractopamine Hydrochloride: rabbit, Irritant

Sensitisation

- Ractopamine Hydrochloride: Causes sensitization on guinea-pigs.

Repeated dose toxicity

- Ractopamine Hydrochloride: Ingestion and inhalation of ractopamine hydrochloride produces effects consistent with its pharmacology as a partial beta adrenergic agonist. Principal effects in animals included cardiovascular effects characterized by increased heart rate, increased blood and pulse pressure, peripheral dilation of blood vessels, and increased cardiac output.

Carcinogenicity

- Ractopamine Hydrochloride: Treatment of rats and mice in carcinogenicity studies by Lilly Research Laboratories did not result in increased incidence of any cancer (malignant tumors). The only tumors with increased incidence were benign smooth muscle tumors (leiomyomas). This finding is a rodent-specific, exaggerated pharmacologic effect of beta-adrenergic agonists.

Reproductive toxicity

- Ractopamine Hydrochloride: In studies with rats, there were no effects on mating performance or fertility, but increased mortality, reduced growth, and structural abnormalities were reported in offspring at doses of 150 mg/kg/day which were maternally toxic.

Mutagenicity

- Ractopamine Hydrochloride: Not mutagenic in a battery of tests using both bacterial and mammalian cell assays, with the exception of weak positive responses in the mouse lymphoma and human lymphocyte assays. Since two in vivo cytogenetic tests demonstrated no mutagenicity, and rodent carcinogenicity tests demonstrated no relevant carcinogenic effects, it can be concluded that ractopamine hydrochloride does not present a genotoxic hazard in man.



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SECTION 12. ECOLOGICAL INFORMATION

Toxicity to fish

- Ractopamine Hydrochloride LC50 / 96 h / *Oncorhynchus mykiss* (rainbow trout): 693 mg/l
LC50 / 96 h / *Lepomis macrochirus* (Bluegill sunfish): 544 mg/l

Toxicity to algae

- Ractopamine Hydrochloride EC50 / 72 h / *Selenastrum capricornutum*: > 101.2 mg/l

Effects on micro-organisms

- Ractopamine Hydrochloride EC50 / 3 h / Respiration inhibition of activated sludge: 1,413 mg/l

Toxicity to daphnia

- Ractopamine Hydrochloride EC50 / 48 h / *Daphnia magna* (Water flea) : 34.5 mg/l

Toxicity to birds

- Ractopamine Hydrochloride LD50 / 14 d / *Colinus virginianus* (Bobwhite quail): > 2,000 mg/kg
LC50 / 5 d / *Colinus virginianus* (Bobwhite quail): > 4,990 mg/kg
Dietary
LC50 / 5 d / *Anas platyrhynchos* (Mallard duck): > 10 g/kg
Dietary

Toxicity to other organisms

- Ractopamine Hydrochloride LC50 / 28 d / *Eisenia fetida* (earthworms): > 747 mg/kg

Lilly Aquatic Exposure Guideline

- Ractopamine Hydrochloride Drinking Water: 1.8 µg/l
Chronic Exposure of Aquatic Organisms: 240 µg/l
Acute Exposure of Aquatic Organisms: 2,156 µg/l

Additional Ecological Information

Ractopamine Hydrochloride

Plant growth in soil no observed effect concentration: 1 mg/kg

Soil adsorption coefficient (Kd): 14.5, 29.6, 36 (sandy loam, loam, clay loam)

Organic carbon coefficient (Koc): 2090, 2698, 2007 (sandy loam, loam, clay loam)

Water solubility (g/L): 51.9, 31.0, 41.2, (pH5, pH7, pH9)

Photolysis half-life (days): 16.3, 10.5, 0.64, (pH5, pH7, pH9)

Photolysis rate constant (1/day): 0.0425, 0.0657, 1.086 (pH5, pH7, pH9)

Hydrolysis half-life (days): none, none, 19 (pH5, pH7, pH9)

Hydrolysis rate constant (1/day): none, none, 0.0364 (pH5, pH7, pH9)

UV light absorption in methyl alcohol (nm): 225.8 and 277.6

Soil degradation half-life (1/day): 1.1, 51 (1st phase, 2nd phase)

Aerobic biodegradation (64 days): 7 - 8.9%, 70% (carbon dioxide, metabolites)

Bioaccumulation

- Ractopamine Hydrochloride Bioconcentration factor (BCF): 0.13

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pH 7

SECTION 13. DISPOSAL CONSIDERATIONS

Waste disposal methods : In accordance with local and national regulations.

SECTION 14. TRANSPORT INFORMATION

Other information : Not dangerous goods in the meaning of DOT, IMO/IMDG, ICAO/IATA

SECTION 15. REGULATORY INFORMATION

TSCA Status: Not On TSCA Inventory
90274-24-1 Ractopamine Hydrochloride
Anti-dusting Oil
Corn Cob Grits

DSL Status: This product contains the following components that are not on the Canadian DSL nor NDSL lists.
90274-24-1 Ractopamine Hydrochloride
Anti-dusting Oil
Corn Cob Grits

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SECTION 16. OTHER INFORMATION**Further information**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated



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with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health

317-276-2000

1-800-428-4441