

**TOPMAX 9 PREMIX**

Version 1.2

Revision Date 10/17/2008

Print Date 01/27/2010

**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : TOPMAX 9 PREMIX  
**Substance Number** : 000004269755  
Common Name : Topmax 9 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 : AF0621

**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. May cause heart effects.**Emergency Overview**

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

**Potential Health Effects**

Eyes : Causes eye irritation.

Aggravated Medical Condition : Individuals with cardiovascular disease should exercise special caution to avoid



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exposure.

Primary Routes of Entry : Inhalation Skin contact

Additional Information : The active ingredient, ractopamine hydrochloride, is a beta-adrenergic agonist. May cause heart effects. Individuals with cardiovascular disease should exercise special caution to avoid exposure. The premix granular formulation poses a low dust potential under usual conditions of handling and mixing. May produce an allergic reaction.

### 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	2
Corn Cob Grits	NA	97
Soybean Oil	8001-22-7	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.

### Notes to physician

Treatment : Treat as for other beta adrenergic agonists.

## SECTION 5. FIRE-FIGHTING MEASURES

Flash point : no data available

Lower explosion limit : no data available



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Upper explosion limit : no data available

Suitable extinguishing media : Water Carbon dioxide (CO2). Dry chemical. Halons.

Unusual Fire and Explosion Hazard. : Dust may form explosive mixture in air. Hazardous decomposition products formed under fire conditions.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Methods for cleaning up : Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

**SECTION 7. HANDLING AND STORAGE**

**Handling**

Advice on safe handling : NOT FOR HUMAN USE! 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.

**Storage**

Requirements for storage areas and containers : Store at room temperature. Avoid moisture.



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**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.

**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/m<sup>3</sup> (4 h)  
(Monkey) > 13.9 mg/m<sup>3</sup> (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: guinea pig, Causes sensitization.

**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



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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.

### Toxicity to reproduction

- 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.

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity effects

#### 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



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### Elimination information (persistence and degradability)

#### Bioaccumulation

- Ractopamine Hydrochloride Bioconcentration factor (BCF): 0.13  
pH 7

#### 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, (pH 5, 7, 9)  
 Photolysis half-life (days): 16.3, 10.5, 0.64, (pH 5, 7, 9)  
 Photolysis rate constant (1/day): 0.0425, 0.0657, 1.086 (pH 5, 7, 9)  
 Hydrolysis half-life (days): none, none, 19 (pH 5, 7, 9)  
 Hydrolysis rate constant (1/day): none, none, 0.0364 (pH 5, 7, 9)  
 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)

### 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  
 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  
 Corn Cob Grits

#### California Prop. 65

This product does not contain any chemicals known to 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.



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### **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 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