



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** Topmax 9 Premix

**Other means of identification**

**Item Code** AF0621

**Synonyms** Benzenemethanol, 4-hydroxy-alpha-[[[3-(4-hydroxyphenyl)-1-methylpropyl]amino]methyl]-, hydrochloride

**Recommended use** Veterinary Pharmaceutical

**Recommended restrictions** None known.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

**Company Name** Elanco Animal Health  
2500 Innovation Way  
Greenfield, IN 46140  
US

**Phone:** 1-877-Elanco1 (1-877-352-6261)

**Email:** lilly\_msds@lilly.com

**Emergency Telephone Numbers:**

Elanco Product Technical Support / Human or Animal Exposure Reporting:  
1-888-545-5973  
Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300  
(Outside U.S. 1-703-527-3887)

## 2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards** Sensitization, respiratory Category 1  
Sensitization, skin Category 1

**OSHA defined hazards** Combustible dust

### Label elements



**Signal word** Danger

### Hazard statement

H317 May form combustible dust concentrations in air.  
H334 May cause an allergic skin reaction.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### Precautionary statement

#### Prevention

P261 Avoid breathing dust.  
P280 Wear protective gloves.  
P285 In case of inadequate ventilation wear respiratory protection.

#### Response

P304 + P341 If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing  
P342 + P311 If experiencing respiratory symptoms: Call a poison center/doctor.

#### Storage

Not available.

#### Disposal

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazard(s) not otherwise classified (HNOC)** None known.

**Supplemental information** None.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Corn Cob Grits		NA	97
Ractopamine Hydrochloride	4-(3-{[2-hydroxy-2-(4-hydroxyphenyl)ethyl]amino}butyl)phenol hydrochloride	90274-24-1	2

**Composition comments** Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

### 4. First-aid measures

#### Inhalation

Oxygen or artificial respiration if needed. Call a physician immediately.

#### Skin contact

Wash off immediately with plenty of water for at least 15 minutes. Take off immediately all contaminated clothing. Get medical attention if irritation develops and persists. Wash clothing before reuse.

#### 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. Get medical attention.

#### Ingestion

If conscious, give the victim plenty of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control center immediately.

#### Most important symptoms/effects, acute and delayed

The active ingredient, ractopamine hydrochloride, is a beta-adrenergic agonist. May cause allergic skin reaction. Dusts may irritate the respiratory tract, skin and eyes. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Heart effects. Individuals with cardiovascular disease should exercise special caution to avoid exposure.

#### Indication of immediate medical attention and special treatment needed

Treat as for other beta adrenergic agonists.

#### General information

In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

### 5. Fire-fighting measures

**Suitable extinguishing media** Water. Carbon dioxide (CO<sub>2</sub>). Dry chemical.

**Unsuitable extinguishing media** None known.

**Specific hazards arising from the chemical** Fire or excessive heat may produce hazardous decomposition products.

**Special protective equipment and precautions for firefighters** Wear self-contained breathing apparatus and protective clothing.

**Fire fighting equipment/instructions** None known.

**Specific methods** Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards** Dust may form explosive mixture with air.

### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** Wear suitable protective clothing, gloves and eye/face protection. Avoid contact with skin, eyes and clothing.

**Methods and materials for containment and 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/wet material and remove by mopping or wet wiping. Wear appropriate protective equipment and clothing during clean-up. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

## 7. Handling and storage

### Precautions for safe handling

NOT FOR HUMAN USE! Minimize dust generation and accumulation. Wash thoroughly after handling.

### Conditions for safe storage, including any incompatibilities

Store in a cool, dry place with adequate ventilation. Keep away from incompatible materials, open flames, and high temperatures. Avoid contact with oxidizing agents. Do not store in open or unlabelled containers.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### Lilly (LEG)

#### Components

#### Type

#### Value

Ractopamine Hydrochloride  
(CAS 90274-24-1)

STEG (15min)

240 ug/m3

TWA (12hrs)

17 ug/m3

### Occupational exposure limits

#### ACGIH

#### Components

#### Type

#### Value

#### Form

Corn Cob Grits (CAS NA)

TWA

4 mg/m3

(grain dust)

#### U.S. - OSHA

#### Components

#### Type

#### Value

#### Form

Corn Cob Grits (CAS NA)

TWA

10 mg/m3

(grain dust)

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

#### Components

#### Type

#### Value

#### Form

Soybean Oil (CAS  
8001-22-7)

PEL

5 mg/m3

Respirable fraction.

15 mg/m3

Total dust.

#### US. NIOSH: Pocket Guide to Chemical Hazards

#### Components

#### Type

#### Value

#### Form

Soybean Oil (CAS  
8001-22-7)

TWA

5 mg/m3

Respirable.

10 mg/m3

Mist.

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear goggles/face shield.

#### Skin protection

##### Hand protection

Wear appropriate chemical resistant gloves. Chemical-resistant gloves and impermeable body covering to minimize skin contact.

##### Other

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.

#### Respiratory protection

Use an approved respirator. Select appropriate respirator for physical characteristics of material.

#### Thermal hazards

Not available.

### General hygiene considerations

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.

The API is an active pharmaceutical ingredient with a therapeutic dose in humans at or below 1 mg/day.

## 9. Physical and chemical properties

### Appearance

Granular.

#### Physical state

Solid.

#### Form

Solid.

<b>Color</b>	Tan
<b>Odor</b>	No data available.
<b>Odor threshold</b>	No data available.
<b>pH</b>	6 - 7 (50% aqueous solution)
<b>Melting point/freezing point</b>	No data available.
<b>Initial boiling point and boiling range</b>	No data available.
<b>Flash point</b>	No data available.
<b>Evaporation rate</b>	No data available.
<b>Flammability (solid, gas)</b>	No test data available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	No data available.
<b>Flammability limit - upper (%)</b>	No data available.
<b>Explosive limit - lower (%)</b>	No data available.
<b>Explosive limit - upper (%)</b>	No data available.
<b>Vapor pressure</b>	No data available.
<b>Vapor density</b>	No data available.
<b>Relative density</b>	No data available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	No data available.
<b>Partition coefficient (n-octanol/water)</b>	No data available.
<b>Auto-ignition temperature</b>	No data available.
<b>Decomposition temperature</b>	No data available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive
<b>Oxidizing properties</b>	The substance or mixture is not classified as oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Not available.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Fire or excessive heat may produce hazardous decomposition products.

## 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

<b>Components</b>	<b>Species</b>	<b>Test Results</b>
Ractopamine Hydrochloride (CAS 90274-24-1)		
<b>Acute</b>		
<i>Dermal</i>		
LD	Rabbit	> 2000 mg/kg

Components	Species	Test Results
<i>Inhalation</i>		
LC50	Monkey	> 13.9 mg/m <sup>3</sup> , 15 min (Increased heart rate)
	Rat	2801 mg/m <sup>3</sup> , 4 h
<i>Oral</i>		
LD	Dog	> 50 ug/ kg (Increased heart rate)
LD50	Rat	411 mg/kg
<b>Skin corrosion/irritation</b>	Rabbit: No irritation (Ractopamine Hydrochloride)	
<b>Serious eye damage/eye irritation</b>	Rabbit: Irritating. (Ractopamine Hydrochloride) Based on available data, the classification criteria are not met.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
<b>Skin sensitization</b>	May cause an allergic skin reaction. Guinea pig: Causes sensitization. (Ractopamine Hydrochloride)	
<b>Germ cell mutagenicity</b>	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. (Ractopamine Hydrochloride)	
<b>Carcinogenicity</b>	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. (Ractopamine Hydrochloride)	
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>		
Not listed.		
<b>Reproductive toxicity</b>	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. (Ractopamine Hydrochloride) Based on available data, the classification criteria are not met.	
<b>Specific target organ toxicity - single exposure</b>	No effects identified in animal studies. (Ractopamine Hydrochloride) Based on available data, the classification criteria are not met.	
<b>Specific target organ toxicity - repeated exposure</b>	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. Based on available data, the classification criteria are not met. (Ractopamine Hydrochloride)	
<b>Aspiration hazard</b>	No aspiration toxicity classification	
<b>Chronic effects</b>	Prolonged inhalation may be harmful. 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. (Ractopamine Hydrochloride)	

## 12. Ecological information

<b>Ecotoxicity</b>	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)
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Components	Species	Test Results
Ractopamine Hydrochloride (CAS 90274-24-1)		
<i>Acute</i>		
	EC50	1413 mg/l, 3 hr (Respiration inhibition of activated sludge)
	LC50	> 747 g/kg, 28 d (Eisenia fetida-earthworms)
Other		
	EC50	Selenastrum capricornutum (new name Pseudokirchnerella subca) > 101.2 mg/l, 72 hr
	LC50	Duck > 10 g/kg, 5 d (Mallard) (Dietary)
		Quail > 4990 mg/kg, 5 d (Bobwhite) (Dietary)
	LD50	Quail > 2000 mg/kg, 14 d (Bobwhite)
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Daphnia magna 34.5 mg/l, 48 hr
Fish	LC50	Bluegill (Lepomis macrochirus) 544 mg/l, 96 hr
		Rainbow Trout 693 mg/l, 96 hr

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

**Partition coefficient n-octanol / water (log Kow)**

Ractopamine Hydrochloride 0.009 (pH 7)  
0.24 (pH 5)  
1.24 (pH 9)

**Bioconcentration factor (BCF)**

Ractopamine Hydrochloride 0.13, (pH 7)

**Mobility in soil** No data available.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

**Ecotoxicological Properties**

**Drinking Water**

Components	Test Results
Ractopamine Hydrochloride	1.8 µg/l, (Lilly Aquatic Exposure Guideline)

**Chronic Exposure of Aquatic Organisms**

Components	Test Results
Ractopamine Hydrochloride	240 µg/l, (Lilly Aquatic Exposure Guideline)

**Acute Exposure of Aquatic Organisms**

Components	Test Results
Ractopamine Hydrochloride	2156 µg/l, (Lilly Aquatic Exposure Guideline)

**13. Disposal considerations**

**Disposal instructions** Dispose of contents/container in accordance with local/regional/national/international regulations. Do not allow this material to drain into sewers/water supplies.

**14. Transport information**

**DOT**

Not regulated as dangerous goods.

**IATA**

Not regulated as dangerous goods.

**IMDG**

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories**  
Immediate Hazard - Yes  
Delayed Hazard - No  
Fire Hazard - Yes  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations**

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations**

**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

**US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not listed.

**US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

**Issue date** 11-03-2014  
**Version #** 01

**Lilly Lab Code**

Health: 2  
Fire: 1  
Reactivity: 1  
Special 1: A

**List of abbreviations**

LEG = Lilly Exposure Guideline

**Disclaimer**

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 MERCHANT ABILITY 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  
00+1+877-352-6261  
00+1-800-428-4441