



PAYLEAN Premix

Effective Date: 18-Nov-2003

Elanco Animal Health
Material Safety Data Sheet

Section 1 - Chemical Product and Company

Manufacturer:

Elanco Animal Health
 Division of Eli Lilly and Company
 2001 West Main St
 PO Box 708
 Greenfield, IN 46140

Manufacturer's Emergency Phone:

1-800-428-4441

CHEMTREC:

1-800-424-9300 (North America)

1-703-527-3887 (International)

Common Name: PAYLEAN Premix

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

Synonym(s): 031537 Formulation; 031537 Premix; Ractopamine Hydrochloride; Ractopamine

Trademarks(s): Paylean

Lilly Item Code(s): AF0601; AF0602; AF0605; AF0610; AF0632; QA425U; QD357S; QD389A; QI0336

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

Ingredient	CAS	Concentration %
Ractopamine Hydrochloride	90274-24-1	1 - 10
Corn Cob Grits	NAIF	89 - 99
Anti-dusting Oil	NAIF	0 - 1

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

Exposure Guidelines: Ractopamine hydrochloride - LEG 17 micrograms/m³ TWA for 12 hours, 240 micrograms/m³ TWA for 15 minutes STEG.

Grain dust - PEL 10 mg/m³ TWA. TLV 4 mg/m³ TWA for 8 or 12 hours (total). Lilly preferred exposure limit is TLV.

UK - Maximum Exposure Limit 10 mg/m³ TWA (total) (Sens).

Ireland - Occupational Exposure Limit 10 mg/m³ TWA (Sens).

The anti-dusting oil reduces potential exposure under normal conditions of use.

Section 3 - Hazards Identification

Appearance: Yellowish-tan to reddish-tan free-flowing granular material

Physical State: Solid

Odor: No applicable information found

Emergency Overview



Emergency Overview Effective Date: 15-Apr-1995

Lilly Laboratory Labeling Codes:

Health 2

Fire 1

Reactivity 0

Primary Physical and Health Hazards: Irritant (eyes). Suspect Allergen. Heart Effects.

Caution Statement: PAYLEAN Premix may be irritating to the eyes and may cause allergic reactions. Effects of exposure may include increased heart rate.

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: 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 PAYLEAN Premix formulation poses a low dust potential.

Medical Conditions Aggravated by Exposure: 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.

Carcinogenicity: Ractopamine hydrochloride - Not listed by IARC, NTP, ACGIH, or OSHA. 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.

Remaining ingredients - Not listed by IARC, NTP, ACGIH, or OSHA.

Section 4 - First Aid Measures

Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an

ophthalmologist (eye doctor) or other physician immediately.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Notes to Physician: Treat as for other beta adrenergic agonists.

Section 5 - Fire Fighting Measures

Flash Point: No applicable information found

UEL: No applicable information found

LEL: No applicable information found

Minimum Ignition Temperature of Dust Layer: 215 C (419 F)

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

Spills: 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

Storage Conditions: Store at room temperature. Product should not be used after the date printed on the bag.

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

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.

Eye Protection: Chemical goggles and/or face shield.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: 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.

Additional Exposure Precautions: 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: Yellowish-tan to reddish-tan free-flowing granular material

Odor: No applicable information found

Boiling Point: Not applicable

Melting Point: Not applicable

Specific Gravity: Not applicable

pH: 6-7 (aqueous 50/50)

Evaporation Rate: No applicable information found

Water Solubility: Ractopamine hydrochloride - Slightly soluble

Ground corn cobs (inert ingredients) - Insoluble

Vapor Density: No applicable information found

Vapor Pressure: No applicable information found

Section 10 - Stability and Reactivity

Stability: Stable at normal temperatures and pressures.

Incompatibility: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

Hazardous Decomposition: May emit toxic fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Acute Exposure

Data for PAYLEAN Premix and ractopamine hydrochloride are presented where indicated.

Oral: PAYLEAN Premix - Rat, 2000 mg/kg, no deaths, leg weakness, reduced activity.

Skin: PAYLEAN Premix - Rabbit, 5000 mg/kg, no deaths or toxicity.

Inhalation: Ractopamine hydrochloride - Rat, median lethal concentration 2801 mg/m³ for 4 hours, reduced activity, labored breathing.
Monkey, 13.9 mg/m³ for 15 minutes, increased heart rate.

Skin Contact: PAYLEAN Premix - Rabbit, slight irritant

Eye Contact: PAYLEAN Premix - Rabbit, irritant

Chronic Exposure

No data are available for PAYLEAN Premix. Toxicity data for ractopamine hydrochloride are presented.

Target Organ Effects: 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.

Other Effects: Ractopamine hydrochloride - Reduced body weight gain, change in blood cell counts, blood chemistry, and organ weights, apparent metabolic activation of brown fat.

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.

Sensitization: Ractopamine hydrochloride - Guinea pig, positive contact sensitizer.

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

No data are available for PAYLEAN Premix. Environmental data for the active ingredient, ractopamine hydrochloride, are presented.

Ecotoxicity Data: Ractopamine hydrochloride

Rainbow trout 96-hour median lethal concentration: 693 mg/L

Bluegill 96-hour median lethal concentration: 544 mg/L

Daphnia magna 48-hour median effective concentration: 34.5 mg/L

Bobwhite 14-day oral median lethal dose: >2000 mg/kg
Bobwhite 5-day dietary median lethal concentration: >4990 mg/kg
Mallard 5-day dietary median lethal concentration: >10 g/kg
Earthworm 28-day median lethal concentration: >747 mg/kg
Green algae (*S. capricornutum*) 72-hour median lethal concentration: >101.2 mg/L
Plant growth in soil no observed effect concentration: 1 mg/kg
Activated sludge respiration inhibition 3-hour median effective concentration: 1413 mg/L

Environmental Fate: Ractopamine hydrochloride

Log Kow: 0.24, 0.009, 1.24 (pH 5, 7, 9)

Bioconcentration factor: 0.13 (pH 7)

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)

Environmental Summary: Ractopamine hydrochloride - Practically non-toxic to fish, birds, earthworms, green algae, and activated sludge microorganisms. Slightly toxic to aquatic invertebrates and moderately toxic to plants. Non-volatile, very soluble solid which adsorbs extensively to soil and does not readily desorb. Not expected to significantly bioconcentrate in aquatic organisms and likely to dissipate from the aquatic environment by photolysis and biodegradation.

Lilly Aquatic Exposure Guideline (LAEG): Ractopamine hydrochloride

LAEG for Drinking Water: 1.8 micrograms/L

LAEG for Chronic Exposure of Aquatic Organisms: 240 micrograms/L

LAEG for Acute Exposure of Aquatic Organisms: 2156 micrograms/L

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Container Disposal: No special package disposal required.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Elanco Animal Health usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

Ractopamine hydrochloride, corn cob grits, and anti-dusting oil

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

NADA Number: 140-863

EU Regulations

EC Classification

Contains corn cob grits (C= 89-99%).

Xn (Harmful)

Xi (Irritant)

Risk Phrases

R 36 - Irritating to eyes.

R 43 - May cause sensitization by skin contact.

Safety Phrases

S 24/25 - Avoid contact with skin and eyes.

S 26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 37 - Wear suitable gloves.

Section 16 - Other Information

MSDS Sections Revised: Sections 1 and 16.

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

1-800-428-4441

1-317-276-2000

GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists

AIHA = American Industrial Hygiene Association

BEI = Biological Exposure Index

CAS Number = Chemical Abstract Service Registry Number

CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)

CHAN = Chemical Hazard Alert Notice

CHEMTREC = Chemical Transportation Emergency Center

DOT = Department of Transportation

EC = European Community

EINECS = European Inventory of Existing Chemical Substances

ELINCS = European List of New Chemical Substances

EPA = Environmental Protection Agency

HEPA = High Efficiency Particulate Air (Filter)

IARC = International Agency for Research on Cancer

ICAO/IATA = International Civil Aviation Organization/International Air Transport Association

IEG = Lilly Interim Exposure Guideline

IMO = International Maritime Organization

Kow = Octanol/Water Partition Coefficient

LEG = Lilly Exposure Guideline

LEL = Lower Explosive Limit

MSDS = Material Safety Data Sheet

MSHA = Mine Safety and Health Administration

NA = Not Applicable, except in Section 14 where NA = North America

NADA = New Animal Drug Application

NAIF = No Applicable Information Found

NCI = National Cancer Institute

NIOSH = National Institute for Occupational Safety and Health

NOS = Not Otherwise Specified

NTP = National Toxicology Program

OSHA = Occupational Safety and Health Administration

PEL = Permissible Exposure Limit (OSHA)

RCRA = Resource Conservation and Recovery Act

RQ = Reportable Quantity

RTECS = Registry of Toxic Effects of Chemical Substances

SARA = Superfund Amendments and Reauthorization Act

STEG = Lilly Short Term Exposure Guideline

STEL = Short Term Exposure Limit

TLV = Threshold Limit Value (ACGIH)

TPQ = Threshold Planning Quantity

TSCA = Toxic Substances Control Act

TWA = Time Weighted Average/8 Hours Unless Otherwise Noted

UEL = Upper Explosive Limit

UN = United Nations

WEEL = Workplace Environmental Exposure Level (AIHA)