

The logo for Elanco, featuring the word "ELANCO" in white, bold, uppercase letters on a blue rectangular background.

Elanco Animal Health
Material Safety Data Sheet

PAYLEAN 20 Premix

Revision 1.2, 18 October 2006

Reason for revision: Pagination changed to page number only. Section 1: Added CHEMWATCH contact details.. Section 15: Deleted contact point details. (moved to section 1)

STATEMENT OF HAZARDOUS NATURE:

“Hazardous according to criteria of Worksafe Australia”

R48/20/22 Harmful. Danger of serious damage to health by prolonged exposure through inhalation and in contact with skin.

Irritant; R36 Irritating to eyes.

Irritant; R43 May cause sensitisation by skin contact.

Section 1 - Chemical Product and Company

Company Name and Address:

Elanco Animal Health
A Division of Eli Lilly, Australia Pty Ltd
A.C.N 000 233 992
112 Wharf Rd
West Ryde, N.S.W, 2114, Australia

Contact Numbers:

Tel: (02) 9878 7777

Fax: (02) 9878 7720

Emergency Telephone Numbers:

Elanco Animal Health: 1800 226 324 *OR*
Poisons Information Centre: 131126

CHEMWATCH 1800 039 008 24 hour
emergency contact number (spills and
accidents)

Common Name: PAYLEAN 20 Premix

Other Names: Ractopamine 2% Premix, Ractopamine Hydrochloride

Manufacturer's Product Code: AF0602 (Paylean 20 Premix)

UN Number: None allocated

Dangerous Goods Class/Subsidiary Risk: None allocated

Hazchem Code: None allocated

Poisons Schedule Number: S5

Pack Size and Container Type: 10 kg bag

Use: For increased rate of weight gain, improved feed efficiency, increased carcass leanness and increased dressing percentage in finisher pigs.

Section 2 - Composition / Information on Ingredients

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration</u> <u>%</u>
Ractopamine Hydrochloride	90274-24-1	2
Corn Cob Grits	NA	98
Anti-dusting Oil	NA	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.

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

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

Caution Statement: PAYLEAN Premixes 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.

Potential Signs and Symptoms of Occupational Exposure: 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 formulations pose 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 Poisons Information Centre. 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.

Advice to Doctor: Treat as for other beta-adrenergic agonists.

SPECIFIC FIRST AID DIRECTIONS AS PER AUSTRALIAN REQUIREMENTS¹: If poisoning occurs, contact a doctor or Poisons Information Centre. Phone 13 1126.

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.

¹ Proposed inclusion in Handbook of First Aid Instructions and Safety Directions for Agricultural and Veterinary Chemicals (including Pesticides). Therapeutic Goods Administration

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

Section 6 - Accidental Release Measures

Spills: Contain dry material by sweeping up or vacuuming. Vacuuming may disperse dust if appropriate dust collection filter is not part of the vacuum. Be aware of potential for dust explosion when using electrical equipment. 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 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 below 30°C (Room temperature) in a dry place.

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.

Other Handling 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.

SPECIFIC SAFETY INSTRUCTIONS AS PER AUSTRALIAN REQUIREMENTS²: Will irritate the eyes and skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. If product in eyes, wash it out immediately with water. Wash hands after use. When opening the container and preparing stock feed wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and a washable hat, elbow length

² Handbook of First Aid Instructions and Safety Directions for Agricultural and Veterinary Chemicals (including Pesticides). Therapeutic Goods Administration

PVC gloves and face shield or goggles. After each day's use, wash gloves and contaminated clothing.

Section 9 - Physical and Chemical Properties

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

Animal Toxicity Data Single Exposure

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

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

Skin: PAYLEAN Premixes - 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 Premixes - Rabbit, slight irritant.

Eye Contact: PAYLEAN Premixes - Rabbit, irritant.

Animal Toxicity Data Repeat Exposure

No data are available for PAYLEAN Premixes. 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 Premixes. 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

Disposal of bags: Shake and empty contents into medicated feed. Do not dispose of undiluted chemicals on site. Puncture or shred and bury empty bags in a local authority landfill. If not available bury the bag below 500mm in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and roots. Empty bags and product should not be burnt.

Section 14 - Transport Information

No special transport requirements necessary.

Section 15 - Other 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.

GLOSSARY

(Abbreviations Used in Material Safety Data Sheets)

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)
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
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
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)