SAFETY DATA SHEET

1. Identification

Product identifier **Paylean 9 Premix**

Other means of identification

Item Code AF0602, AF0601, AF0605, AF0632, QD389A, QD357S, QA425U, QI0336, AF0610

Synonyms Paylean 2.25 * Paylean 45

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

May form combustible dust concentrations in air.

H317 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/protective clothing.

P285 In case of inadequate ventilation wear respiratory protection.

Response

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

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	Not applicable.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Ractopamine Hydrochloride	4-(3-{[2-hydroxy-2-(4-hydroxyphenyl)ethyl]amino}butyl)phenol hydrochloride	90274-24-1	1 - 10
Excipient: Grain Dust		NA	89 - 99
Anti-dusting Oil	MINERAL OIL	8012-95-1	0 - 1

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

4. First-aid measures

Inhalation Move to fresh air. Oxygen or artificial respiration if needed. Call a physician or poison control center immediately.

Skin contact Wash off immediately with soap and plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if irritation develops and persists.

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 May cause allergic respiratory and skin reactions. Increased heart rate.

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 (CO2). Dry chemical.

Unsuitable extinguishing media Not available.

Specific hazards arising from the chemical Fire or excessive heat may produce hazardous decomposition products. Dust may form explosive mixture with air.

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

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Avoid contact with skin, eyes and clothing. Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.

Methods and materials for containment and cleaning up

Small Spillages:
Do not sweep. Collect spill using a vacuum cleaner with a HEPA filter. 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.

Large Spillages:
Prevent further migration into the environment. Remove sources of ignition. Collect in a non-combustible container for prompt disposal. Local authorities should be advised if significant spillages cannot be contained. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance.

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

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. Minimize dust generation and accumulation. Keep away from heat and sources of ignition. Avoid release to the environment.
Conditions for safe storage, including any incompatibilities	Keep container tightly closed. Store in a cool, dry place with adequate ventilation. Keep away from incompatible materials, open flames, and high temperatures. Avoid contact with oxidizing agents. Avoid moisture. 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
Excipient: Grain Dust (CAS NA)	TWA	4 mg/m3	(grain dust)

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Anti-dusting oil (CAS 8012-95-1)	TWA	5 mg/m3	Inhalable fraction.

U.S. - OSHA

Components	Type	Value	Form
Excipient: Grain Dust (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
Anti-dusting oil (CAS 8012-95-1)	PEL	5 mg/m3	Mist.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Anti-dusting oil (CAS 8012-95-1)	STEL	10 mg/m3	Mist.
	TWA	5 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	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Other	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Respiratory protection	Use an approved respirator. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor.
Thermal hazards	Not available.

General hygiene considerations	Use good industrial hygiene practices in handling this material. 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. When mixing and handling, use protective clothing, impervious gloves, and dust respirator (recommended). Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse with plenty of water. 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.

9. Physical and chemical properties

Appearance	Dry flowable granules.
Physical state	Solid.
Form	Solid.
Color	Tan
Odor	No data available.
Odor threshold	No data available.
pH	6 - 7 (50% aqueous solution)
Melting point/freezing point	No data available.
Initial boiling point and boiling range	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability (solid, gas)	No test data available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	No data available.
Flammability limit - upper (%)	No data available.
Explosive limit - lower (%)	No ignition up to 2.0 oz/cu ft
Explosive limit - upper (%)	No data available.
Vapor pressure	No data available.
Vapor density	No data available.
Relative density	No data available.
Solubility(ies)	
Solubility (water)	No data available.
Solubility (other)	No data available.
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Viscosity	No data available.
Other information	
Density	No data available.
Dust explosion properties	
Minimum ignition temperature (MIT) - dust layer	419 °F (215 °C)
Explosive properties	Not explosive.

Oxidizing properties	The substance or mixture is not classified as oxidizing.
Percent volatile	No data available.
VOC (Weight %)	No data available.

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Product	**Species**	**Test Results**
Paylean 9 Premix (CAS Mixture)		
Acute		
Dermal		
LD	Rabbit	> 5000 mg/kg No mortality.
Oral		
LD	Rat	> 2000 mg/kg No mortality. No toxicity.
Components	**Species**	**Test Results**
Ractopamine Hydrochloride (CAS 90274-24-1)		
Acute		
Dermal		
LD	Rabbit	> 2000 mg/kg
Inhalation		
LC50	Monkey	> 13.9 mg/m3, 15 min (Increased heart rate)
	Rat	2801 mg/m3, 4 h
Oral		
LD	Dog	> 50 ug/ kg (Increased heart rate)
LD50	Rat	411 mg/kg

Skin corrosion/irritation	Rabbit: No irritation (Ractopamine Hydrochloride) Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Rabbit: Irritating. (Ractopamine Hydrochloride) Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	
Respiratory sensitization	May cause allergy or asthma symptoms or breathing difficulties if inhaled. (Grain dust)
Skin sensitization	Guinea pig: Causes sensitization. (Ractopamine Hydrochloride)
Germ cell mutagenicity	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. Based on available data, the classification criteria are not met.
Carcinogenicity	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) Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Anti-dusting Oil (CAS 8012-95-1) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity

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.

Specific target organ toxicity - single exposure

No effects identified in animal studies. (Ractopamine Hydrochloride)
Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure

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.

Aspiration hazard

No aspiration toxicity classification.

Chronic effects

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.

Further information

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.

12. Ecological information

Ecotoxicity

Additional Ecolological 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)

Components		Species	Test Results
Ractopamine Hydrochloride (CAS 90274-24-1)			
Acute			
	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)
Aquatic			
Acute			
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 on bioaccumulation.

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 Not available.

Other adverse effects Not available.

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

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

Anti-dusting Oil (CAS 8012-95-1)

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

Anti-dusting Oil (CAS 8012-95-1)

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

Anti-dusting Oil (CAS 8012-95-1)

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 10-29-2014

Version # 01

Lilly Lab Code

Health: 2
Fire: 1
Reactivity: 0
Special 1: A

List of abbreviations

LEG: Lilly Exposure Guideline
STEG: Short Term Exposure Guideline
TWA: Time Weighted Average

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.

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Revision Information	Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties Toxicological Information: Toxicological Data Regulatory Information: Risk Phrases - Class. GHS: Classification