



**MATERIAL SAFETY DATA SHEET  
APRALAN SOLUBLE POWDER**

**AH0635**

Revision 3.5, 18 October 2006

**STATEMENT OF HAZARDOUS NATURE:**

"Hazardous according to criteria of Worksafe Australia"  
Irritant; R38 Irritating to skin.

**Company Name and Address:**

Elanco Animal Health  
A Division of Eli Lilly Australia Pty Ltd  
A.B.N. 39 000 233 992  
112 Wharf Road, 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 (Toll free)  
OR

Poisons Information Centre:  
131126 (Australia-wide)

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

**Section 1 - Identification**

Product Name: ElancoAH0635 Apralan Soluble Powder

Other Names: Apramycin sulphate

Manufacturer's Product Code: AH0635

UN Number: None allocated

Dangerous Goods Class/Subsidiary Risk: None allocated

Hazchem Code: None allocated

Poisons Schedule Number: S4

Pack Size and Container Type: 400 mL polythene bottle

**Use:**

Major Recommended Uses: Apralan Soluble Powder is for treatment as follows:

PIGS: For the treatment of bacterial enteritis caused by susceptible strains of *Escherichia coli* and other organisms susceptible to apramycin.

CALVES: For the prophylaxis or treatment of bacterial enteritis in calves caused by *Escherichia coli* and *Salmonella* organisms susceptible to apramycin.

BROILERS: For use in the control and treatment of colisepticaemia (colibacillosis) in broilers caused by susceptible strains of *E. coli*.

Major Recommended Method(s) of Application: Powder for oral use

## **Section 2 - Composition / Information on Ingredients**

Ingredient	CAS
Apramycin Sulfate	65710-07-8

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

Exposure Guidelines: Apramycin - LEG 4 mg/m<sup>3</sup> TWA for 8 or 12 hours.

## **Section 3 - Hazards Identification**

Appearance: Tan to brown free-flowing powder

Physical State: Solid

Odor: Musty

Emergency Overview

Primary Physical and Health Hazards: Irritant (skin).

Caution Statement: Apralan Soluble Powder contains apramycin sulfate and may be irritating to the skin.

Routes of Entry: Inhalation and skin contact.

Potential Signs and Symptoms of Occupational Exposure: Skin irritation has been reported with occupational exposure to apramycin.

Medical Conditions Aggravated by Exposure: None known.

Carcinogenicity: Apramycin - Not listed by IARC, NTP, ACGIH, or OSHA. Not considered carcinogenic in animal studies conducted by Lilly Research Laboratories.

## **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. Phone 13 1126 (Australia-wide). 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.

## **Section 5 - Fire Fighting Measures**

**Flash Point:** No applicable information found.

**UEL:** No applicable information found.

**LEL:** No applicable information found.

**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:** 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. 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. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

## **Section 7 - Handling and Storage**

**Storage:** 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: Safety glasses.

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.

## **Section 9 - Physical and Chemical Properties**

Boiling Point: Not applicable.

Melting Point: Not applicable.

Specific Gravity: No applicable information found.

pH: No applicable information found.

Evaporation Rate: No applicable information found.

Water Solubility: Soluble.

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

Toxicity data for the active ingredient, apramycin sulfate, are reported.

Oral: Apramycin sulfate - Rat, 4160 mg/kg, no deaths.

Skin: Apramycin sulfate - Rabbit, 1040 mg/kg, no deaths or toxicity.

Inhalation: Apramycin sulfate - Rat, 211 mg/m<sup>3</sup> for 1 hour, no deaths or toxicity.

Skin Contact: Apramycin sulfate - Rabbit, slight irritant.

Eye Contact: Apramycin sulfate - Rabbit, slight irritant.

**Animal Toxicity Data Repeat Exposure**

No data are available for Apralan Soluble Powder. Toxicity data for the active ingredient, apramycin sulfate, are reported.

Target Organ Effects: Apramycin sulfate - No effects identified in animal studies.

Other Effects: Apramycin sulfate - Decreased body weight, vomiting, dark coloured faeces.

Reproduction: Apramycin sulfate - Decreased offspring survival and decreased foetal weight at doses toxic to the mother.

Sensitization: Apramycin sulfate - Guinea pig, not a contact sensitizer.

Mutagenicity: Apramycin sulfate - Not mutagenic in bacterial or mammalian cells.

**Section 12 - Ecological Information**

No data are available for this product. Environmental data for apramycin, the active ingredient, are presented.

Ecotoxicity Data: Apramycin

Rainbow trout 96-hour median lethal concentration: > 300 ppm

Bluegill 96-hour median lethal concentration: > 300 ppm

Daphnia magna 48-hour median effective concentration: 101.6 ppm

Bobwhite 14-day oral median lethal dose: 1669 mg/kg

Bobwhite 5-day dietary median lethal concentration: > 5000 ppm

Mallard 5-day dietary median lethal concentration: > 5000 ppm

Earthworm 14-day median lethal concentration: > 100 ppm

Microorganisms:

N-fixing bacteria (*Azotobacter chroococcum*) inhibition at 0.1 ppm

N-fixing algae (*Anabaena flos aquae*) inhibition at 0.1 ppm

N-fixing bacteria (*R. leguminosarum*) inhibition at 0.1 ppm

N-fixing bacteria (*R. japonicum*) inhibition between 1 and 10 ppm

Green algae (*S. capricornutum*) 72-hour median effective concentration average specific growth rate: 818 micrograms/L

Soil microflora respiration and nitrification inhibition: >20 ppm

Environmental Fate: Apramycin

Dissociation constant (pKa): 5.4 to 8.5

Solubility (g/L): > 300

Log octanol-water partition coefficient (Kow): -3.3

Field soil decline: <= 25% after 2 years

Bioconcentration factor: 0.022

Greenhouse soil decline in manure: < 25% after 1 year

Greenhouse soil decline: approximately 33% after 1 year

Soil adsorption coefficient (Koc) range in 3 soils: 341,900 - 659,609

Soil desorption (Koc) range in 3 soils: 763,633 - 1,887,467

Environmental summary: Apramycin - Practically non-toxic to fish, earthworms, daphnids, and birds. Not toxic to soil microflora at highest concentration tested. Moderately to highly toxic to nitrogen-fixing microorganisms. Highly toxic to green algae. Low potential to bioconcentrate in aquatic organisms. Persistent in the soil environment. Extensive soil adsorption with minimal soil desorption.

Lilly Aquatic Exposure Guideline (LAEG): Apramycin

LAEG for Drinking Water: 240 micrograms/L

LAEG for Chronic Exposure of Aquatic Organisms: 130 micrograms/L

LAEG for Acute Exposure of Aquatic Organisms: 820 micrograms/L

### **Section 13 - Disposal Considerations**

Disposal: Dispose of empty container by wrapping with paper and putting in garbage.

### **Section 14 - Transport Information**

No special transport requirements necessary.

### **Section 15 - Other Information**

Sections revised: Section 1 Chemwatch details

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)