ISSUED: **26 May 2015**

MATERIAL SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name:	**TILMIX Injection**
Product Code:	503730 (100 mL); 503735 (250 mL)
Recommended Use:	For use in lot-fed cattle for the treatment of Bovine Respiratory Disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica, Pasteurella multocida*, and other organisms susceptible to tilmicosin.
Company Identification:	Jurox Pty Limited
Address:	85 Gardiner Road Rutherford NSW 2320 Australia
Customer Centre:	1800 023 312
National Poisons Information Centre:	131126 (Australia-wide)
Emergency Telephone Number:	1800 023 312

Section 2: HAZARDS IDENTIFICATION

Hazard Classifications:	**Considered a Hazardous Substance according to the criteria of NOHSC Australia.** **Not considered a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.**
Poisons Schedule:	S4
Caution statement:	**Injection of tilmicosin phosphate has been associated with human fatalities**
Risk phrases:	Harmful by inhalation, if swallowed or injected Irritating to eyes May cause SENSITISATION by inhalation ad skin contact Cumulative effects may result following exposure Very toxic to aquatic organisms May cause long-term adverse effects in the aquatic environment
Safety phrases:	Keep out of reach of children Read label before use Exercise extreme caution to avoid accidental self-injection Avoid contact with skin Avoid contact with eyes Do not breathe vapours Wear suitable protective clothing (including eye/face protection) Use only in well-ventilated areas Keep container in a well-ventilated place Use water to clean the floor and all objects contaminated by this material Keep container tightly closed Keep away from food, drink and animal feeding stuffs If exposed, IMMEDIATELY contact a Doctor or Poisons Information Centre (show this container or label)

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Tilmicosin phosphate	137330-13-3	30 %
Non-hazardous ingredients		70%

Section 4: FIRST AID MEASURES

First Aid Measures: **Seek medical advice, or contact the National Poisons Centre on 131126. Urgent medical and/or hospital treatment is likely to be needed following exposure by any route.** Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have product container or label at hand.

Inhalation: Sensitive individuals may exhibit allergic reactions, possibly life-threatening. If suspected, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is difficult, give oxygen. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. Perform CPR if necessary. Seek medical assistance immediately.

Ingestion: Severe symptoms related to the cardiovascular, gastrointestinal and other systems are possible. Sensitive individuals may exhibit allergic reactions, possibly life-threatening. If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. Seek medical advice, or contact the National Poisons Centre on 131126. Urgent medical and/or hospital treatment is likely to be needed.

Skin: Severe symptoms related to the cardiovascular, gastrointestinal and other systems are possible. Possible skin sensitiser. Seek medical advice, or contact the National Poisons Centre on 131126. Urgent medical and/or hospital treatment is likely to be needed. Wash affected area thoroughly with plenty of soap and water for at least 15 minutes. Remove and wash / dispose of contaminated clothing promptly.

Eye: Seek medical advice, or contact the National Poisons Centre on 131126. Urgent hospital treatment is likely to be needed. Rinse eye cautiously with water for at least 15 minutes. Continue rinsing. If eye irritation persists, get medical advice/attention.

Injected: **Injection of this drug in humans has been associated with fatalities.** In case of human injection, consult a doctor or Poison Information Centre (131 126) immediately and apply ice to injection site and perform supportive treatment. Do not massage injection site.

Chronic: Severe symptoms related to the cardiovascular, gastrointestinal and other systems are possible. May cause allergic reactions, possibly serious in sensitised individuals. Seek medical advice, or contact the National Poisons Centre on 131126.

Advice to Doctor: The cardiovascular system is the target of toxicity and should be monitored closely. Cardiovascular toxicity may be due to calcium channel blockade. This antibiotic persists in tissues for several days.

The following findings from animal studies may be useful:- i) In dogs, administration of intravenous calcium offset tilmicosin-induced tachycardia and negative inotropy (decreased contractility). ii) Dobutamine partially offset the negative inotropic effects induced by tilmicosin in dog studies. iii) Epinephrine potentiated the lethality of tilmicosin in pig studies. iv) β-adrenergic antagonists, such as propanolol, exacerbated the negative inotropic effects induced by tilmicosin in dog studies.

Section 5: FIRE FIGHTING MEASURES

Flash Point: Not combustible.

Hazardous Combustion Products: In severe fire may give off toxic fumes.

Extinguishing Media: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

Protective Equipment: Gas-tight chemical resistant suit, protective gloves and breathing apparatus

HAZCHEM Code: None specified

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Clean up spills immediately. Avoid breathing vapours and contact with skin and eyes. Wear personal protective equipment. Wipe up spill with absorbent material and place in sealed labelled containers. Due to the nature of the packaging, large spills are unlikely to occur. In the event of a large spill, wear appropriate protective clothing. Exclude non-essential people from the area. Contain spill and sweep up / absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely in an approved landfill or refer to the relevant Land Waste Management Authority.

Protective Clothing: For appropriate personal protective equipment see section 8.

Environmental Precautions: Prevent, by any means available, spillage from entering drains, waterways or sewers. If spill does enter waterways contact local authority.

Section 7: HANDLING AND STORAGE

Handling: Keep out of reach of children. This is a Schedule 4 (Prescription Animal Remedy) product, available only to or through a veterinarian. Tilmix Injection must be administered by appropriately trained personnel who are using techniques to reduce the risk of accidental self injection. **Exercise extreme caution to avoid accidental self-injection due to the risk of severe injury or death on injection in humans.** Keep a protective cover on needles until ready to use**.** Never carry a loaded syringe in pocket or clothing. **Do not use in automatically powered syringes.** Avoid swallowing, inhaling, and contact with skin and eyes. Use personal protective equipment as required, e.g. goggles to protect eyes, face protection and impermeable gloves. Wash thoroughly with soap and water after handling. Properly restrain animals prior to administration. Do not administer Tilmix Injection if the animal cannot be restrained.

Storage: Keep out of reach of children. Store below 30ºC, under secure conditions appropriate to local requirements for this class of drug. Protect from light. Use the contents of the vial within 90 days of initial broaching and appropriately discard any unused portion.

Other Information: Always read the label / carton and enclosed leaflet before use.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limits: No exposure limits have been assigned for this product. However, the Lilly Exposure Guideline (LEG) for the active ingredient tilmicosin is < 100 µg/m^3 time weighted average (TWA) for 12 hours. Do not handle until all safety precautions have been read and understood.

Protective Equipment: Protective gloves, eyewear and/or face protection. For handling bulk product, wear protective gloves/clothing and eye/face protection. In addition, use a respirator if ventilation is inadequate.

Engineering Controls: Handle bulk product in a well-ventilated area.

Hygiene Precautions: As for good veterinary and farm practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear yellow to orange liquid.

Specific Gravity: Approx. 1.10

Solubility in Water: Soluble

Flash Point: Not combustible.

pH: 5.5 – 5.6

Section 10: STABILITY AND REACTIVITY

Stability: When stored appropriately this product should show no significant degradation for at least 24 months from the date of manufacture.

Hazardous Polymerisation: Not known to occur.

Materials to Avoid: Avoid oxidising agents.

Section 11: TOXICOLOGICAL INFORMATION

Inhalation: Inhalation of vapours may produce respiratory discomfort and distress. Sensitive individuals may exhibit allergic reactions, possibly life-threatening.

Data for tilmicosin: 2750 mg/m^3 for 4 hours (rat) resulted in reduced activity, laboured breathing, blood in urine, but no deaths.

Ingestion: Tilmicosin is a macrolide antibiotic. Accidental ingestion may be harmful or even fatal. Symptoms in humans include taste abnormality, headache, paresthesia of the mouth or lips, vomiting, nausea, chest pain, dizziness, tachycardia, anxiety, numbness, malaise, fever, light-headedness and muscle pain. Macrolide antibiotics commonly cause gastrointestinal discomfort and less commonly allergic sensitisation. Tilmicosin may cause alterations in heart rate and rhythm and heart muscle degeneration.

Reduced activity, incoordination, drooping eyelids, soft faeces, distended abdomen and thin body seen in fasted rats on single exposure.

Data for tilmicosin: LD50 (oral): = 855 mg/kg (fasted rat).

Injection: **Accidental self-injection may cause severe injury or death in humans.** Pharmacovigilance reports on exposure to one tilmicosin product list the following results of accidental injection in humans: injection site pain, bleeding, swelling or inflammation are the most common signs, followed by nausea, tachycardia, dizziness, anxiety, an abnormal taste, headache, lightheadedness, limb pain, paresthesia, chest pain, and soreness. More serious adverse events include tachycardia, bradycardia, hyperetension, hypotension, heart disorder, chest pain, tachypnea or death. (Ref: JAVMA, Vol. 229, No. 11, December 1, 2006, pages 1737 – 1742).

In animal studies, tilmicosin has been shown to particularly affect the heart (increased heart weight and size, heart muscle degeneration, severe and persistent increase in heart rate, ECG changes) and liver (increase liver weight and enzyme activity). Other effects include increased weights of the adrenal glands and kidneys, increase cell size in the adrenal cortex, oedema of the mucosa of the gall bladder, accumulation of subretinal fluid, decreased food consumption and weight gain, slightly decreased uriine pH, occult blood in urine, increased serum alanine transaminase.

Data for tilmicosin: LD50 (subcutaneous injection): = 185 mg/kg (rat). Symptoms included coma, lethargy, incoordination, reduced activity. Studies have shown that tilmicosin products may cause deaths in pigs and monkeys.

Skin: Mild irritant. Possible skin sensitiser. Entry into the bloodstream may produce systemic effects, of which the most common clinical signs in humans include taste abnormality, nausea, headache, chest pain, paraesthesia, anxiety, dizziness, fever, tachycardia, vomiting, weakness, application site erythema, application site pain, numbness, diarrhoea, dyspnoea, lightheadedness, sweating, malaise, abdominal pain and nervousness.

Eye: Mild irritant.

Chronic Effects: Allergic reactions, particularly by inhalation. Possibly serious in sensitized individuals.

Reproductive Toxicity: No effects identified in animal studies, except slight increase in offspring mortality at maternally toxic doses.

Mutagenicity: Not known to be mutagenic.

Carcinogenicity: Not known to be carcinogenic.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: Data is only available for the active ingredient:-

Tilmicosin

Fish LC50 (96 h): 851 mg/L (rainbow trout), 716 mg/L (bluegill sunfish)
Daphnia EC50 (48 h) 57.3 mg/L
Other LC50 (5 day dietary) > 4820 ppm (bobwhite), > 4710 ppm (mallard)
Other LC50 (28 day) > 918 mg/kg (earthworm)

Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to label or by approved waste collection. Discarded needles should immediately be placed in a designated and appropriately labelled “sharps” container.

Container Disposal: Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not classed as a Dangerous Good for transport purposes by road, sea or air.

Section 15: REGULATORY INFORMATION

APVMA Registration No: 63564

Section 16: OTHER INFORMATION

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein does so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.