AbbeyFlor PREMIX

Abbey Animal Health Pty Ltd

SAFETY DATA SHEET

Section 1- Identification of Product and Supplier

Supplier Company Details: Abbey Animal Health Pty Ltd
Address: 39 Buckenderra Road, Middlingbank NSW 2630
Telephone Number: 02 8088 0720
Facsimile Number: 02 8088 0721
Emergency Number: Australian Poisons Information Centre: 13 11 26 (24 Hour Service).

PRODUCT NAME
AbbeyFlor PREMIX

PRODUCT USE
For the treatment of pig respiratory disease associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Mycoplasma* spp. and *Streptococcus suis* Type 2.

Section 2- Hazards Identification

Statement of Hazardous Nature: Classified as hazardous according to the criteria of Safe Work Australia (SWA) for Classifying Hazardous Substances [NOHSC:1008(2004)], available on Hazardous Substances Information System (HSIS) and the Globally Harmonized System (GHS) classification.

ADG Classification: None allocated. Not classified as a Dangerous Good according to the Australian Dangerous Goods (ADG) Code.

Poisons Schedule: S4

GHS Classification:
Serious eye damage/irritation- Category 2A, Toxic to Reproduction- Category 2; Specific Target organ Toxicity - Repeated Exposure- Category 2.

GHS signal word: WARNING

Pictograms:

HAZARD STATEMENT(S):

H319: Causes serious eye irritation.
H361: Suspected of damaging fertility or the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.

PREVENTION STATEMETS(S):

P201: Obtain special Instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P260: Do not breathe dust/fume/ gas/mist/ vapours/spray.
P264: Wash hands thoroughly after handling.
P280: Wear eye/face protection.
P281: Use personal protective equipment as required.

RESPONSE STATEMETS(S):

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313: IF exposed or concerned: Get medical advice/ attention.
P314: Get medical advice/ attention if you feel unwell.
P337 + P313 If eye irritation persists: Get medical advice/attention.

STORAGE STATEMETS(S):

P405: Store locked up.

DISPOSAL STATEMETS(S):

P501: Dispose e of contents/container in accordance with relevant regulations.

Section 3- Composition / Information on Ingredients

INGREDIENTS:

Chemical Name	**CAS Number**	**Conc, %**
Florfenicol	73231-34-2	4
Other non-hazardous ingredients	secret	to 100

Section 4- First Aid Measures

Call Poisons Information Centre Phone Australia 131 126, if you feel that you may have been poisoned or irritated by this product.

SAFETY DIRECTIONS: Will irritate the eyes. Avoid contact with eyes. When opening the container and preparing the product for use, wear goggles. If product in eyes, wash it out immediately with water. Wash hands after use. After each day's use wash goggles.

Inhalation: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a doctor.

Skin contact: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a doctor.

Eye contact: In case of eye contact, IMMEDIATELY rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. Get IMMEDIATE medical attention.

Ingestion: If product is swallowed or gets into mouth, do NOT induce vomiting; wash mouth with water and give some water to drink. If symptoms develop, or if in doubt contact Poisons Information Centre or a doctor.

Section 5- Fire Fighting Measures

Fire/Explosion Hazard: Non-flammable.
Flash point: Non-flammable.
Extinguishing Media & Methods: Not combustible. Use extinguishing media suited to burning materials such as Carbon dioxide, extinguishing powder or water spray.

Section 6 - Accidental Release Measures

Spills and Disposal: For minor spill, clean up, rinsing to sewer and dispose empty container in garbage. Wear protective equipment to prevent skin and eye contact. Do not burn container.
In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.
Methods for cleaning up: Before attempting clean up, refer to hazard data (section 2) given above. Keep personnel away from the clean-up area. Wear appropriate personal protective equipment as specified in Section 8. Avoid generation of dust during clean-up. Prevent large spills from entering sewers or waterways. Contact emergency services for advice if required.

Section 7 - Handling and Storage

Handling: Before use read carefully the product label instructions. Do not inhale DUST when opening the container or mixing. Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed.

Storage: Store below 25ºC (Air conditioning).

Section 8 - Exposure Controls / Personal Protection

Workplace Exposure Standards: No exposure limits have been established for this product.

Engineering Controls: Natural ventilation should be adequate under normal operating conditions. Keep containers closed when not in use. No special ventilation requirements are normally necessary for this product. However, make sure that the work environment remains clean and that vapours and mists are minimised.

Personal Protective Equipment (PPE): Use of goggles or full-face protection is required if there is potential for contact with this material. Use good industrial hygiene. Avoid eye and skin contact. Prevent dispersion of dust. Respirators are not normally required; however, if inhalation risk occurs, wear vapour respirator. Wear protective clothing when opening container and handling such as goggles, cotton overalls buttoned to neck, elbow-length PVC gloves, washable hat, and disposable dust mask. Always wash hands and face after use, especially before eating, drinking or smoking. After each day's use wash goggles.

Personal Hygiene: Do not eat, drink or smoke when handling this product.

Section 9 - Physical and Chemical Properties

Physical State:	White to off white free flowing powder
Boiling Point:	Not applicable
Vapour Pressure:	Not applicable
Odor:	Unknown
Specific Gravity:	Not applicable

Section 10 - Stability and Reactivity

Stability: Product is stable under normal conditions of storage.
Reactivity: This product is unlikely to react or decompose under normal storage conditions.
Conditions to avoid: Not available.
Hazardous reactions: Hazardous polymerisation does not occur.

Section 11 - Toxicological Information

No adverse health effects expected if the product is handled in accordance with this Safety Data Sheet and product label.

Please refer to **Section 2- Hazards Identification** when using this product.

Symptoms that may arise if the product is mishandled and over exposure occurs are:

This product is likely to cause decreased fertility in humans and may cause allergic reactions in susceptible individuals**.**

Eye: Florfenicol cause eye irritation, avoid contact with eyes.

Swallowed: May cause stomach distress, nausea or vomiting.

Skin: Contact with skin will result in mild irritation. Repeated or prolonged skin contact may lead to irritant contact dermatitis.

Inhaled: Dusts of this product may cause irritation of the nose, throat, and respiratory tract.

ACUTE TOXICITY

Florfenicol: When administered orally, was NOT acutely toxic to mice and rats and no LD_{50} could be established (above 2000mg/kg bw). After IP administration, the LD_{50} was close to 2000 mg/kg bw in rats.

REPEATED DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY

Florfenicol was administered orally to dogs, rats, and mice at dosages as high as 100 to 400 mg/kg/day for up to 13 weeks. Effects including decreased body weight, changes in liver weight or liver enzyme levels, changes in testicular weight, testicular atrophy, decreased white blood cell counts, and decreased hemoglobin levels were observed at high dosages. Cellular changes in the liver or lymph nodes of rats and mice, and histopathologic changes in the brain and spinal cord of dogs were also noted at these high dosages. Although some effects were reversible after a 4-week withdrawal from treatment, testicular effects in rats persisted. Intramuscular injections of 45 mg/kg of florfenicol in swine produced diarrhea, injection site lesions, decreased body weight, decreased food and water consumption, changes in serum electrolytes and proteins, decreased red blood cell and white blood cell counts, decreased spleen weight, and decreased kidney weight.

In 52-week oral toxicity studies in dogs and rats, high dosages of florfenicol (12 and 48 mg/kg/day, respectively) increased liver weight and produced cellular changes in the gall bladder of dogs. In rats, florfenicol at the high dosage reduced body weight gain, reduced testicular weight, induced changes in haematologic and clinical chemistry parameters, and increased the incidence of testicular tubular atrophy.

In two-year chronic studies in mice and rats, florfenicol caused similar effects as those observed in other long-term studies including reduced body weight gain, reduced red blood cell count, reduced haemoglobin levels, and testicular effects such as small testes, tubular atrophy and as per matogenesis in both the high dosage rats (48 mg/kg/day) and mice (200 mg/kg/day).

REPRODUCTIVE / DEVELOPMENTAL TOXICITY

In a two-generation reproductive study, oral administration as high as 12 mg/kg/day of florfenicol reduced epididymal weights, decreased pup survival, and reduced lactation index in rats [NOAEL: 3 mg/kg/day]. There was no evidence of teratogenicity in rats administered florfenicol at dosages of 4, 12 or 40 mg/kg/day. Slight maternal toxicity, evidenced by decreased food and water consumption, was observed above 4 mg/kg/day. At 40 mg/kg/day, an increased incidence of

delayed ossification and decreased foetal weight occurred. The NOAEL for maternal and foetal toxicity in rats was determined to be 4 mg florfenicol/kg/day.
Two teratogenicity studies were performed in mice. In the first study, the mice were administered florfenicol at dosages of 40, 120, or 400 mg/kg by gavage on days 6-15 of gestation. Florfenicol produced embryolethality at the 400 mg/kg/day dose level, which was evidenced by the high incidence of intrauterine deaths. Significant decreases in mean foetal body weight, soft tissue defects, and retarded skeletal ossification were also observed at 400 mg/kg/day. Skeletal ossification was less pronounced, in a dose-related fashion, at the lower dosestested (40 and 120 mg/kg/day). A developmental NOAEL could not be determined for these data [NOAEL for maternal: 120 mg/kg]. In the second teratogenicity study, florfenicol was retested at lower administered dosages of 1, 3, or 60 mg/kg/day. Maternal effects were limited to a slight increase in water consumption at the 60 mg/kg/day dose. There was no evidence of any adverse effects on the embryo/ foetus at doses as high as 60 mg/kg/day in this study. However, based upon the retarded skeletal ossification effects observed in the first study at 40 mg/kg/day the NOAEL for the two studies combined was determined to be between 3 and 40 mg/kg/day.

MUTAGENICITY / GENOTOXICITY

Florfenicol was negative in a bacterial mutagenicity study (Ames), a mammalian mutagenicity study (mouse lymphoma), a bone marrow micronucleus assay, an in vitro chromosomal aberration assay in CHO cells, a cytogenetics assay in bone marrow, and an unscheduled DNA synthesis assay in rat hepatocytes.

CARCINOGENICITY

Florfenicol was not carcinogenic in a 2-year study in rats administered dosages up to 48 mg/kg/day for 5 days a week or in mice at dosages up to 200 mg/kg/day for 5 days per week.

Section 12 - Ecological Information

Potential Environmental Considerations: No environmental data exists for this product. However, avoid contamination of waterways.

Section 13 - Disposal Considerations

Disposal

Shake and empty contents into medicated feed. Do not dispose of undiluted chemicals on site. Puncture or shred and bury empty bag in a local authority landfill. If no landfill is 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 bag and left-over product should not be burnt.

Section 14 - Transport Information

No specific transport considerations apply since AbbeyFlor PREMIX is NOT classified as a dangerous good according to Australian Dangerous Goods (ADG) Code.

Section 15 - Regulatory Information

Poisons Schedule: *S4*

APVMA Approval Number: *86149*

Approved pack size: *5kg, 25kg*

For more information please refer to the APVMA approved product label

Section 16 – Other Information

Abbey Animal Health Pty Ltd

Telephone Number: 02 8088 0720
Facsimile Number: 02 8088 0721

Emergency Number: Australian Poisons Information Centre: 13 11 26 (24 Hour service).

This Safety Data Sheet (SDS) summarizes our best knowledge of the health and safety hazard information of the product according to the GHS requirements and how to safely handle and use the product in the workplace.

Each user must review this SDS in the context of how the product will be handled and used in the workplace.

If clarification or further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.

***Note: This SDS is valid for 5 years from the effective date.**