



# 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:** 16 Voyager Circuit, Glendenning NSW 2761, Australia

**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)

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

#### GHS Classification:

Category 2 - Toxic to Reproduction

Category 2- Specific Target Organ Toxicity - Repeated Exposure

Category 1- Short term (acute) aquatic hazard

Category 1- Long term (Chronic) aquatic hazard

**GHS signal word: WARNING**

## Pictograms:



## HAZARD STATEMENT(S):

H361: Suspected of damaging fertility or the unborn child.

H373: May cause damage to organs through prolonged or repeated exposure.

H410: Very toxic to aquatic life with long lasting effects.

## PREVENTION STATEMENTS(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.

P273: Avoid release to environment.

P280: Wear eye/face protection.

## RESPONSE STATEMENTS(S):

P308+P313: IF exposed or concerned: Get medical advice/ attention.

P391: Collect spillage.

## STORAGE STATEMENTS(S):

P405: Store locked up.

## DISPOSAL STATEMENTS(S):

P501: Dispose 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.***

**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 25°C (Air conditioning).

## Section 8 - Exposure Controls / Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment.



## Section 11 - Toxicological Information

### ACUTE TOXICITY

Florfenicol: When administered orally, was NOT acutely toxic to mice and rats and no LD<sub>50</sub> could be established (above 2000mg/kg bw). After IP administration, the LD<sub>50</sub> 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 embryoletality 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 dosetested (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

#### Ecotoxicity:

Product / Ingredient name	Result	Species	Exposure
<b>Florfenicol</b> <b>Toxicity to fish</b>	LC50: > 830 mg/l	Lepomis macrochirus (Bluegill sunfish)	96 h
	LC50: > 780 mg/l	Oncorhynchus mykiss (rainbow trout)	96 h
<b>Toxicity to daphnia and other aquatic invertebrates</b>	EC50: > 330 mg/l	Daphnia magna (Water flea)	48 h
<b>Toxicity to algae/aquatic plants</b>	EC50 :> 2.9 mg/l	Pseudokirchneriella subcapitata (green algae)	14 d
	NOEC :2.9 mg/l	Pseudokirchneriella subcapitata (green algae)	14 d
	IC50: 0.0336 mg/l	Skeletonema costatum (marine diatom)	72 h
	NOEC: 0.00423 mg/l	Skeletonema costatum (marine diatom)	72 h

## 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.

CLASSIFIED AS DANGEROUS GOODS when transported by sea or air.

### RTD

**UN NO.:** 3077

**UN proper shipping name:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Florfenicol)

**Class & Subsidiary Risk:** 9

**Packaging Group:** III

**Environmental hazards:** yes

### IATA

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### IMDG

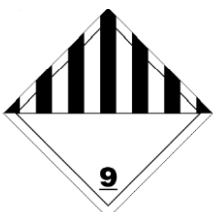
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(Florfenicol)

**Class & Subsidiary Risk:** 9

**Packaging Group:** III

**Marine Pollutant:** yes



**Marine Pollutant:**



**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.**