
SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name:	Prednil Tablets
Product Identifier:	Corticosteroid/antihistamine containing 4.34% prednisolone and 1.74% chlorpheniramine maleate.
Product Code:	60930 (1000 tablets)
Recommended Use:	For the treatment of allergic reactions and dermatitis, and as an aid in the treatment of arthritic and rheumatic joint diseases in dogs and cats.
Restrictions on Use:	For animal treatment only.
Company Identification:	Jurox Pty Limited
Address:	85 Gardiner Street, Rutherford, NSW 2320, Australia
Email:	customerservice@jurox.com.au
Customer Centre:	1800 023 312
National Poisons Information Centre:	13 1126 (24 hours)
Emergency Telephone Number:	1800 023 312 (9am – 5pm, Monday to Friday)

Section 2: HAZARDS IDENTIFICATION

Hazard Classifications: This product has been assessed according to GHS and is classified as follows:

GHS Category	Hazard code	Hazard Statement
Skin Sensitization: Category 1	H317	May cause an allergic skin reaction
Specific Target Organ Toxicity (Repeat Exposure): Category 2	H373	May cause damage to organs through prolonged or repeated exposure
Chronic Aquatic Hazard: Category 3	H412	Harmful to aquatic life with long lasting effects

Signal word: WARNING

GHS Pictograms:



Exclamation
mark



Health
hazard

Precautionary statements:

Prevention

- P101 If medical advice is needed, have product container or label at hand.
- P102 Keep out of reach of children.
- P103 Read label before use
- P260 Do not breathe dust.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P273 Avoid release to the environment.
- P280 Wear protective gloves.

Response

- P302 + P352 IF ON SKIN: Wash with plenty of water.
- P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
- P362 + P364 Take off contaminated clothing and wash it before reuse.
- P314 Get medical advice/attention if you feel unwell.

Disposal

- P501 Dispose of contents/container in accordance with label directions.

N.B.: The above statements are determined by Work Health and Safety regulations and may not reflect Signal Headings and First Aid and Safety statements on product labelling, which are determined by a competent authority during assessment for registration.

Other hazards: None known.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Prednisolone	50-24-8	4.34%
Chlorpheniramine maleate	113-92-8	1.74%
Ingredients not contributing to the hazards	-	> 90%

Section 4: FIRST AID MEASURES

General Information: Consult the National Poisons Centre on 13 1126 or a doctor immediately in every case of suspected chemical poisoning. 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 this SDS, product container or label at hand.

Symptoms and Effects of Exposure: Overdose can cause neuromuscular blockade leading to muscular weakness and possible paralysis. Exposure can aggravate some medical conditions. Exposure to selective serotonin reuptake inhibitors such as chlorpheniramine can cause cognitive, autonomic and somatic effects. Psychiatric conditions can occur following exposure to corticosteroids.

Inhalation: If fumes or combustion products are inhaled remove from contaminated area. If respiratory symptoms occur, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen and seek medical assistance immediately.

Ingestion: IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. For advice contact a Poisons Information Centre or a doctor. Urgent hospital treatment is likely to be needed. In the meantime, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. If medical attention is not available on the worksite or surroundings send the patient to hospital together with a copy of the SDS. **Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:** INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-

down position, if possible) to maintain open airway and prevent aspiration. Wear a protective glove when inducing vomiting by mechanical means.

Skin: If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.

Eye: If eye contact occurs: Immediately flush the eye continuously with running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Continue flushing for at least 15 minutes. If eye irritation persists, get medical advice/attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

Recommended First Aid Facilities: Ready access to running water and soap is required. Accessible eyewash is required.

Advice to Doctor: Contains prednisolone which is a corticosteroid and chlorpheniramine maleate which is an antihistamine. Treat symptomatically. Empty the stomach by aspiration and lavage. The use of charcoal to prevent absorption, followed by lavage has been suggested. Excitement may be controlled by diazepam or other short acting barbiturates. Supportive therapy may require oxygen and assisted respiration, ice-bags or alcohol sponges for hyperpyrexia, especially in children, bladder catheterisation and the administration of fluids.

Section 5: FIRE FIGHTING MEASURES

Flash Point: Not flammable.

Hazardous Combustion Products: If involved in a fire, may emit poisonous and corrosive 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: Protective gloves and boots and breathing apparatus.

HAZCHEM Code: Not specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Wear gloves and appropriate protective clothing. Avoid breathing dust and contact with skin and eyes. For small spills, use dry clean up procedures and avoid generating dust. Vacuum up or sweep up. For large spills, advise personnel in the area. Alert Emergency Services and tell them of location and nature of hazard. Wear full body protective clothing with breathing apparatus. Recover product wherever possible.

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: Handle this product with care to avoid exposure, taking all recommended precautions. Avoid all personal contact, including inhalation of dust. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Do not allow material to contact humans, exposed food or food utensils.

Storage: Prednil Tablets are a Scheduled Poison (S4) and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Store below 30°C (room temperature), in securely sealed, original containers, in a dry area, protected from environmental extremes.

Other Information: Avoid contact with incompatible substances as listed in Section 10. Always read the label before use.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

Exposure Limits: No exposure limits have been assigned for this product or its ingredients.

Engineering Controls: Handle in a well-ventilated area. Ensure that the work environment remains clean.

Personal Protective Equipment (PPE):

Eye protection: When handling very small quantities of the material, eye protection may not be required. Chemical goggles or a face shield are recommended when handling bulk quantities of this product. An eye wash unit should be at hand.

Skin protection: Prevent skin contact by wearing chemical protective gloves e.g. PVC. Change gloves frequently when contaminated, punctured or torn. Wash hands immediately after removing gloves.

Respiratory protection: Not required for the normal use of this product. Respirators may be necessary when engineering and administrative controls do not adequately prevent exposure.

Other: For quantities up to 500 g a laboratory coat may be suitable. For quantities up to 1 kg a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kg and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Round, flat lime green tablet, one side half scored.	Lower flammability limits	Not available
Odour:	Not available	Vapour Pressure:	Not available
Odour threshold:	Not available	Vapour density:	Not available
pH:	Not available	Relative density:	Not applicable
Melting Point:	Not available	Specific Gravity:	Not available
Boiling Point:	Not available	Solubility in Water:	Partly soluble (disintegrates)
Flash Point:	Not flammable	Partition coefficient:	Not available
Evaporation Rate:	Not available	Auto-ignition temperature:	Not applicable
Flammability:	Not applicable	Decomposition temperature:	Not available
Upper flammability limits:	Not available	Viscosity:	Not applicable

Section 10: STABILITY AND REACTIVITY

Reactivity: This product is unlikely to react or polymerise under normal storage conditions.

Stability: When stored appropriately this product should show no significant degradation within the expiry period shown on the label.

Conditions to Avoid: Extreme temperatures.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: Combustion products include carbon monoxide and carbon dioxide.

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:

Ingestion: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an acute oral toxicant. Accidental ingestion of the material may be damaging to the health of the individual.

Prednisolone : Oral LD₅₀ : 3857 mg/kg (rat) ;
 Chlorpheniramine maleate : Oral LD₅₀ : 118 mg/kg (rat).

Inhalation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the inhalation route. Inhalation of dust generated by the material during the course of normal handling may be damaging to the health of the individual.

Prednisolone: No data;
 Chlorpheniramine maleate : No data.

Dermal: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route.

Prednisolone: No data;
 Chlorpheniramine maleate : No data.

Skin Corrosion / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not thought to cause skin corrosion or irritation.

Serious Eye Damage / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not thought to cause serious eye damage or irritation.

Respiratory or Skin Sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Skin Sensitiser: Category 1**. There is some evidence that skin contact with this material is more likely to cause a sensitisation reaction in some persons compared to the general population.

Germ Cell Mutagenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic.

Carcinogenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic.

Reproductive Toxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not thought to be a reproductive toxicant. There is some evidence that prednisolone causes malformations in animals when administered parenterally. The teratogenic effect greatly reduces when administered orally.

STOT: Single exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not thought to be a Specific Target Organ Toxicant after single exposure.

STOT: Repeat exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as a **Specific Target Organ Toxicant (Repeat Exposure): Category 2**. Due to the presence of prednisolone, prolonged or repeated exposure may result in changes in hormone production, increased susceptibility to infection, osteoporosis, cataracts, glaucoma, accentuation or precipitation of the diabetic state, mental and neurological disturbances, muscular weakness and fatigue, menstrual disturbances and peptic ulcers. Due to the presence of chlorpheniramine maleate, prolonged or repeated exposure can lead to allergic sensitisation reactions, sugar in the urine, obstructive jaundice, skin discolouration, early menstruation, loss of milk production, breast development in males, decreased sex drive and disturbances in the blood.

Aspiration Hazard: No data available.

Narcotic Effects: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to have any narcotic effects.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is considered to be a **Chronic Aquatic Hazard: Category 3**. Chlorpheniramine maleate is very toxic to aquatic organisms and may cause long term adverse effects in the aquatic environment. DO NOT discharge into sewer or waterways.

Fish

Prednisolone: LC₅₀ (96h): 167.822 mg/L;

Chlorpheniramine maleate: No data.

Crustacea

Prednisolone: No data;

Chlorpheniramine maleate: No data.

Algae and other aquatic plants

Prednisolone: EC₅₀ (96h): 216.995 mg/L;

Chlorpheniramine maleate: No data.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Prednisolone	HIGH	HIGH	LOW (logKOW = 1.62)	LOW (KOC = 36.36)
Chlorpheniramine maleate	No data	No data	No data	No data

Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to label or at an approved landfill.

Container Disposal: Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not classified as a Dangerous good according to the criteria of the Australian Dangerous Goods (ADG) code.

Section 15: REGULATORY INFORMATION

Poison Schedule (SUSMP): S4

APVMA No.: 47744

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. Chlorpheniramine and Prednisolone are mentioned in SUSMP.

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.

Legend:

ADG	Australian Dangerous Goods.
AICS	Australian Inventory of Chemical Substances.
APVMA	Australian Pesticides and Veterinary Medicines Authority.
CAS No.	Chemical Abstracts Service Registry Number.
EC₅₀	The median effect concentration, being a statistically derived concentration of a substance that can be expected to cause an adverse reaction in 50% of organisms or a 50% reduction in growth or in the growth rate of organisms.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
KOC	Soil-Water Partition Coefficient. The ratio of a chemical's concentration that is adsorbed in the soil to the concentration of chemical in solution.
KOW	Octanol Water Partition Coefficient. The ratio of a compound's concentration in a known volume of n-octanol to its concentration in a known volume of water after the octanol and water have reached equilibrium.
LC₅₀	The median lethal concentration, being a statistically derived concentration of a substance that can be expected to cause death in 50% of animals.
LD₅₀	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme.
PPE	Personal Protective Equipment.
PVC	Polyvinyl chloride.
SDS	Safety Data Sheet.
STOT	Specific Target Organ Toxicity.
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons.
SWA	Safe Work Australia.

References:

ChemID Plus

Chemwatch

EPA New Zealand Chemical Classification and Information Database (CCID)

HSDB (Hazardous Substances Data Bank)

This version issued: 06 December 2018 and is valid for 5 years from this date.**Supersedes:** This SDS supersedes the version issued on 16 October 2017.**Revision History:**

Date of Revision	Reason
16 October 2017	Update to Hazard Statement in section 2.
06 December 2018	Added product identifier in section 1. Updated sections 2, 3, 4, 5, 6, 7, 8, 10 11 and 12. Additions made to the legend.

END OF SDS