

SAFETY DATA SHEET**Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY**

Product Name:	Chlorasone Eye Ointment
Product Code:	503870 (4g)
Recommended Use:	An antibiotic steroid combination for the topical treatment of ocular infections 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:	jenq@jurox.com.au
Customer Centre:	1800 023 312
National Poisons Information Centre:	13 1126 (Australia-wide)
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
Respiratory Sensitizer Category 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
Skin Sensitizer Category 1	H317	May cause an allergic skin reaction
Germ Cell Mutagenicity Category 1B	H340	May cause genetic defects
Carcinogenicity Category 1B	H350	May cause cancer
Acute Aquatic Hazard Category 3	H402	Harmful to aquatic life
Chronic Aquatic Hazard Category 3	H412	Harmful to aquatic life with long lasting effects

Signal word: Danger

GHS Pictograms:



Health hazard Exclamation mark

Precautionary statements:Prevention

- P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing vapours.
P280 Wear protective gloves.
P281 Use personal protective equipment as required.
P285 In case of inadequate ventilation wear respiratory protection.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.

Response

- P308 + P313 IF exposed or concerned: Get medical advice/attention.
P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.

Storage

- P405 Store locked up.

Disposal

- Dispose of unused product and container by wrapping with paper and putting in garbage.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Chloramphenicol	56-75-7	1%
Hydrocortisone	50-23-7	0.5%
Ingredients not contributing to the hazards		> 90%

Section 4: FIRST AID MEASURES

General Information: 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: None known.

Inhalation: If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually not necessary. 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 do NOT induce vomiting. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully.

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 rash or 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 20 minutes. If eye irritation persists, get medical advice/attention.

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

Advice to Doctor: Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

Flash Point: No data.

Hazardous Combustion Products: If involved in a fire, may emit noxious and irritant 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 breathing apparatus.

HAZCHEM Code: None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Wear gloves and appropriate protective clothing. For small spills, clean up spilled product then wipe area and put empty container in garbage. For large spills, exclude non-essential people from the area. Prevent spillage from entering drains or water courses and call emergency services.

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

Environmental Precautions: Prevent from entering drains, waterways or sewers. If spill does enter waterways contact local authority.

Section 7: HANDLING AND STORAGE

Handling: This is a Schedule 4 (Prescription Animal Remedy) product and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Handle this product with care to avoid exposure, taking all recommended precautions. Avoid contact with skin, eyes and inhalation of vapours. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

Storage: Keep out of reach of children. Store below 30°C (room temperature).

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: Make sure that the work environment remains clean.

Personal Protective Equipment (PPE):

Eye protection: Protective glasses or goggles are recommended when handling bulk quantities of this product.

Skin protection: Prevent skin contact by wearing chemical protective gloves e.g. PVC.

Respiratory protection: Not required for the normal use of this product.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White to pale yellow ointment	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 applicable	Specific Gravity:	Not available
Boiling Point:	Not available	Solubility in Water:	Immiscible
Flash Point:	Not available	Partition coefficient:	Not available
Evaporation Rate:	Not available	Auto-ignition temperature:	Not available
Flammability:	Not flammable	Decomposition temperature:	Not available
Upper flammability limits:	Not available	Viscosity:	25,000 – 50,000 cps

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: No data available.

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 acutely toxic by the oral route.

Chloramphenicol: Oral LD₅₀: 500 mg/kg (guinea pig), Oral LDLo: 400 mg/kg (woman);
Hydrocortisone: Oral TDLo: 400 mg/kg (man).

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.

Chloramphenicol: No data.
Hydrocortisone: 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.

Chloramphenicol: No data.
Hydrocortisone: No data.

Skin Corrosion / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a skin irritant.

Serious Eye Damage / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an eye irritant.

Respiratory or Skin Sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Respiratory Sensitizer Category 1** and **Skin Sensitizer Category 1**. Chloramphenicol is a known respiratory sensitizer and known skin sensitiser.

Germ Cell Mutagenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture has a classification of **Germ Cell Mutagenicity Category 1B**.

Carcinogenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture has a classification of **Carcinogenicity Category 1B**. Chloramphenicol has been classified by the IARC as Group 2A: Probably carcinogenic to humans. Leukaemia risk may be increased following chloramphenicol use, according to one study which depended on parental recall during interviews.

Reproductive Toxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a reproductive toxicant. Chloramphenicol readily crosses the placental barrier. Chloramphenicol is excreted in the breast milk.

STOT: Single exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered 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 not considered to be a specific target organ toxicant after repeat exposure. One of the most serious adverse effects of chloramphenicol is bone marrow depression. Although rare, blood dyscrasias such as aplastic anaemia, hypoplastic anaemia, thrombocytopenia, and granulocytopenia have occurred during or following both short-term and prolonged therapy. Other adverse effects include hypersensitivity reactions, gastrointestinal complaints and neurological complications after long-term treatment.

Aspiration hazard: No data available.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Chronic Aquatic Hazard Category 3**.

Fish

Chloramphenicol: LC₅₀ (96h): 0.97 mg/L;

Hydrocortisone: LC₅₀ (96h): 116.6 mg/L.

Crustacea

Chloramphenicol: EC₅₀ (48h): > 50 mg/L, NOEC (24h) 2 mg/L;

Hydrocortisone: NOEC (144h): 0.1 mg/L.

Algae and other aquatic plants

Chloramphenicol: EC₅₀ (96h): 0.97 mg/L;

Hydrocortisone: EC₅₀ (96h): 147.3 mg/L.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Chloramphenicol	HIGH	HIGH	LOW (LogKOW = 1.14)	LOW (KOC = 10)
Hydrocortisone	HIGH	HIGH	LOW (LogKOW = 1.61)	LOW (KOC = 36.36)

Section 13: DISPOSAL INFORMATION

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

Container Disposal: Crush or puncture and bury in an approved landfill if an approved recycling system is not available.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not considered a Dangerous Good for land, sea and air transport.

Section 15: REGULATORY INFORMATION

Poison Schedule (SUSMP): S4

APVMA No.: 36329

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

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:

AICS	Australian Inventory of Chemical Substances.
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.
IARC	International Agency for Research on Cancer
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.
LDLo	The lowest lethal dose, that is, the minimum amount of a substance that is lethal to a specified type of animal.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme.
NOEC	No-observable-effect-concentration.
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.
TDLo	The lowest toxic dose, that is, the minimum amount of a substance that is toxic to a specified type of animal.

References:

ChemID Plus

EPA New Zealand Chemical Classification and Information Database (CCID)

HSDB (Hazardous Substances Data Bank)

This version issued: 18 May 2016 and is valid for 5 years from this date.**Supersedes:** This SDS supersedes the version issued on 8 October 2013.**Revision History:**

Date of Revision	Reason
18 May 2016	Reclassification of substance to GHS classification and update of SDS to comply with SWA Code of Practice.

END OF SDS