
SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name:	Oterna Ear Drops
Product Code:	500125 (15 mL)
Recommended Use:	For the removal of ear mites and treatment of otitis externa in dogs and cats.
Company Identification:	Jurox Pty Limited
Address:	85 Gardiner Street Rutherford NSW 2320 Australia
Customer Centre:	1800 023 312
National Poisons Information Centre:	131126 (Australia-wide)
Emergency Telephone Number:	1800 023 312 (9a.m. – 5p.m.)

Section 2: HAZARDS IDENTIFICATION

GHS Hazard Classifications: Reproductive Toxicity Category 1B
Respiratory Sensitizer Category 1
Skin Sensitizer Category 1

GHS Pictograms:



Exclamation mark



Health hazard

Signal Word:* **Danger**

Hazard Statements:*
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360 May damage fertility or the unborn child.

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 dust.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves e.g. PVC or vinyl.
P281 Use personal protective equipment as required.
P285 In case of inadequate ventilation wear respiratory protection.

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

Storage

P405 Store locked up.

Disposal

P501 Dispose of contents/container in accordance with local/national regulations.

* N.B.: These 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.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Monosulfiram	95-05-6	5%
Neomycin sulfate	1405-10-3	0.5%
Betamethasone	378-44-9	0.1%
Vegetable oils	68956-68-3	>60%

Section 4: FIRST AID MEASURES

- First Aid Measures:** Consult the National Poisons Centre on 131126 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 product container or label at hand.
- Inhalation:** If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually not necessary.
- Ingestion:** If swallowed, immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. Neomycin taken orally or by injection may sometimes cause severe allergic reactions that can be life-threatening in neomycin-sensitive individuals. If allergic reaction is suspected immediately seek medical advice/attention.
- Skin:** May cause skin rashes in sensitised persons. If skin contact occurs, immediately remove all contaminated clothing, including footwear. Wash affected area thoroughly with plenty of soap and water. If skin irritation or rash occurs, get medical advice/attention.
- Eye:** If eye contact occurs, rinse cautiously with water for at least 20 minutes. If eye irritation persists, get medical advice/attention.
- Advice to Doctor:** Neomycin is an aminoglycoside antibiotic. Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

- Flash Point:** > 200°C (vegetable oil).
- Hazardous Combustion Products:** If involved in a fire, may emit noxious fumes. Non-combustible – not considered to be a significant fire risk.
- 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.

Section 6: ACCIDENTAL RELEASE MEASURES

- Spills and Disposal:** Slippery when spilt. 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.
- Protective Clothing:** For appropriate personal protective equipment see section 8.
- Environmental Precautions:** If contamination of drains and waterways occurs, advise Emergency Services.

Section 7: HANDLING AND STORAGE

- Handling:** Avoid all personal contact, including inhalation. Use personal protective equipment as required.
- Storage:** Oterna Ear Drops are a Scheduled Poison (S4) and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Store in original container, away from foodstuffs. Store below 25°C (air conditioning). Protect from light. Keep out of reach of children.
- Other Information:** Always read the label before use. See label for further information on handling and storage.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This MSDS 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. Do not handle until all safety precautions have been read and understood.
- Protective Equipment:** Safety glasses with eye side shields or chemical goggles. Chemical protective gloves, e.g. PVC. Safety footwear or safety gumboots, e.g. rubber.
- Engineering Controls:** Handle in a well ventilated area.
- Hygiene Precautions:** Do not drink, eat or smoke when handling this product. Wash hands after use.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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|-----------------------------------|--|-----------------------------------|-----------------|
| Appearance: | Yellow oily liquid with a slight hazy precipitate. | Lower flammability limits: | No data. |
| Odour: | No data. | Vapour Pressure: | No data. |
| Odour threshold: | No data. | Vapour density: | No data. |
| pH: | No data. | Relative density: | Not applicable. |
| Melting Point: | Not applicable. | Specific Gravity: | No data. |
| Boiling Point: | No data. | Solubility in Water: | Immiscible. |
| Flash Point: | >200°C (vegetable oil) | Partition coefficient: | No data. |
| Evaporation Rate: | No data. | Auto-ignition temperature: | No data. |
| Flammability: | Combustible. | Decomposition temperature: | Not applicable. |
| Upper flammability limits: | No data. | Viscosity: | No data. |

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:** None known.

Section 11: TOXICOLOGICAL INFORMATION

- Inhalation:** May cause sensitisation in certain individuals.
- Ingestion:** High doses can lead to kidney damage. May cause severe allergic reactions that can be life-threatening in neomycin-sensitive individuals.
- Neomycin sulfate:
LD₅₀ (oral): > 8000 mg / kg (mouse).
- Betamethasone:
LD₅₀ (oral): > 4500mg/kg (mouse).
- Skin:** May cause sensitisation in certain individuals.
- Eye:** May cause sensitisation in certain individuals.
- Chronic Effects:** May cause allergic reactions, possibly serious in neomycin sensitive individuals. Ample evidence exists that exposure to this material can cause reduced fertility and developmental disorders. Long-term exposure to aminoglycoside antibiotics can damage the kidneys. Neomycin sulfate inhibits intestinal mucosal transport and can cause weight loss and malabsorption symptoms in patients regularly receiving this drug.
- Reproductive Toxicity:** Long term exposure to neomycin can cause reduced fertility and developmental disorders. Exposure to betamethasone for prolonged periods may cause physical defects in the developing embryo.
- Mutagenicity:** Not known to be mutagenic.
- Carcinogenicity:** Not known to be carcinogenic.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity:

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Monosulfiram	HIGH	No data available	LOW	HIGH
Neomycin sulfate	No data available	No data available	No data available	No data available
Betamethasone	HIGH	No data available	LOW	HIGH
Vegetable oils	No data available	No data available	No data available	No data available

Section 13: DISPOSAL INFORMATION

- Product Disposal:** Dispose of product only by using according to label or by approved waste collection.
- 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.
HAZCHEM Code:	None specified

Section 15: REGULATORY INFORMATION

Poisons Schedule:	S4
APVMA Registration No:	46972

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.

This SDS **supercedes the version created on 01 February 2008** and updates the format as per the Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals, December 2011, published by Safe Work Australia.

Legend

CAS No. means a unique number assigned to a chemical by the Chemical Abstracts Service.

GHS means the '*Globally Harmonized System of Classification and Labelling of Chemicals, 3rd Revised Edition*', published by the United Nations.

LD₅₀ means the median lethal dose, which represents the single dose of a substance that can be expected to cause death in 50% of animals.

PVC means Polyvinyl chloride.

References

ChemID PlusLite, <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>, entry for Neomycin sulphate (RN: 1405-10-3).

Environmental Protection Authority New Zealand, HSNO Chemical Classification and Information Database (CCID), entry for Neomycin sulphate (Cas Number: 1405-10-3) and Betamethasone (Cas No. 378-44-9).

HSDB <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB>, entry for Neomycin (CASRN: 1404-04-2).

THE VSDB (Veterinary Substances Database, <http://sitem.herts.ac.uk/aeru/vsdb/>), entry for neomycin and betamethasone.

END OF SDS