

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

Product Name:	Utozyme Foaming Pessaries
Product Code:	503270 (20s)
Recommended Use:	Pessary for the post-natal treatment of infections, cleaning of the uterus, retained placenta and metritis of cattle, sheep, goats, pigs and horses.
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:	131126 (Australia-wide)
Emergency Telephone Number:	1800 023 312 (Monday – Friday, 9a.m. – 5p.m.)

Section 2: HAZARDS IDENTIFICATION

Hazard Classifications:	Considered a Hazardous Substance according to the criteria of GHS.
	Not considered a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.

GHS Hazard Classification:*

GHS Category	Hazard code	Hazard Statement
Carcinogenicity Category 2	H351	Suspected of causing cancer.
Reproductive Toxicity Category 1B*	H360	May damage fertility or the unborn child.*
Lactation Effects*	H362	May cause harm to breast-fed children.*

*LIMITED EVIDENCE

GHS Pictogram:

Health hazard

Signal Word:* DANGER**Precautionary Statements:*****Prevention**

- P201 Obtain special instructions before use.
- P260 Do not breathe dust.
- P263 Avoid contact during pregnancy/while nursing.
- P264 Wash hands thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P281 Use personal protective equipment as required.

Response

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

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
Oxytetracycline hydrochloride	2058-46-0	2.8%
Sodium bicarbonate	144-55-8	30-60%
Other non-hazardous ingredients	-	30-60%

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 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:** First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. Can cause an allergic reaction in certain individuals. If allergic reaction suspected seek medical advice.
- Skin:** 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:** Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

- Flash Point:** Not applicable.
- 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.
- Special Hazards:** **Fire Incompatibility:** None known.
- HAZCHEM:** Not applicable.

Section 6: ACCIDENTAL RELEASE MEASURES

- Spills and Disposal:** Avoid generating dust. Wear appropriate protective clothing. Exclude non-essential people from the area. Contain spill and sweep or vacuum up 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. DO NOT allow material to contact humans, exposed food or food utensils.
- Storage:** Utozyme Foaming Pessaries 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) in a dry place. 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 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. 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. Respirator – Particulate (only if product not sealed).
- 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, flat rectangular-shaped pessary with round ends. | Lower flammability limits: | Not applicable. |
| Odour: | No data. | Vapour Pressure: | Not applicable. |
| Odour threshold: | No data. | Vapour density: | Not applicable. |
| pH: | Not applicable. | Relative density: | No data. |
| Melting Point: | No data. | Specific Gravity: | Not applicable. |
| Boiling Point: | Not applicable. | Solubility in Water: | Partly soluble (disintegrates). |
| Flash Point: | Not flammable. | Partition coefficient: | Not applicable. |
| Evaporation Rate: | Not applicable. | Auto-ignition temperature: | No data. |
| Flammability: | Not applicable. | Decomposition temperature: | Not applicable. |
| Upper flammability limits: | Not applicable. | 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 labelling.
- Materials to Avoid:** None known.
- Hazardous Decomposition Products:** Decomposition may produce toxic fumes of hydrogen bromide. May emit poisonous fumes. May emit corrosive fumes.

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:	<p>Inhalation: The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum. Not normally a hazard due to the non-volatile nature of the product.</p> <p>Ingestion: The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". However, based on animal studies, Tetracyclines all produce GI irritation to varying degrees in some but not all individuals; such effects are more common after oral admin of the drugs. Can cause allergic reactions in certain individuals.</p> <p>Oxytetracycline hydrochloride: LD₅₀ (oral): 6696mg/kg (mouse). Sodium bicarbonate: LD₅₀ (oral): >4000mg/kg (rat).</p> <p>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.</p>
Skin Irritation/Corrosion:	<p>There is some evidence to suggest that the material may cause mild but significant inflammation of the skin either following direct contact or after a delay of some time. Sodium bicarbonate may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p> <p>Sodium bicarbonate: Skin (human): 30 mg/3d-I-mild.</p>
Serious Eye Damage/Irritation:	<p>Limited evidence suggests, that Oxytetracycline hydrochloride may cause eye irritation in a substantial number of individuals. Prolonged eye contact may cause inflammation characterised by a temporary redness of the conjunctiva (similar to windburn). Repeated or prolonged exposure to irritants may produce conjunctivitis.</p>
Respiratory or Skin Sensitisation:	<p>No data for the mixture is available. Based on available data for ingredients, repeated exposures to tetracyclines can cause asthma like symptoms.</p>
Mutagenicity:	<p>No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic.</p>
Carcinogenicity:	<p>Based on available data for the ingredients, the mixture is classified as Carcinogenicity Category 2- Suspected of causing cancer. There has been concern that Oxytetracycline hydrochloride can cause cancer based on limited evidence.</p>
Reproductive Toxicity:	<p>Based on available data for the ingredients, the mixture is classified as Reproductive Toxicity Category 1B & Lactation Effects - May damage fertility or the unborn child and may cause harm to breast-fed children. There is some evidence from animal testing that exposure to tetracyclines may result in toxic effects to the unborn baby. Tetracyclines cross the placenta and are excreted in breast milk. Effects on infants include permanent discoloration of teeth and inhibition of skeletal growth.</p>
STOT – Single Exposure:	<p>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.</p>
STOT - Repeat exposure:	<p>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 repeated exposure but exposure to the tetracyclines for prolonged periods may cause sore throat, hoarseness, a black hairy tongue, bulky loose stools, fat in the faeces, inflammation of the mouth cavity, difficulty swallowing, damage to the anogenital area and ulcers of the oesophagus. Deposits in the eye may cause abnormal pigmentation of the conjunctivae.</p>

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity:	<p>No data for the mixture is available. Based on available data for the ingredients, the mixture is not classified as not Ecotoxic to environment. However, DO NOT discharge the mixture into sewer or waterways.</p> <p>Oxytetracycline hydrochloride: Fish: LC50 (96 h): <200mg/L; Algae or other aquatic plants: EC50 (72 h): 0.342mg/L; Algae or other aquatic plants: NOEC (72 h): 0.183 mg/L.</p>
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Sodium bicarbonate: Fish: LC50 (96 h): 833.280mg/L;
 Algae or other aquatic plants: EC50 (96 h): 650mg/L;
 Crustacea: EC50 (48 h): 2350mg/L;
 Crustacea: NOEC (504 h): 576mg/L.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Oxytetracycline hydrochloride	HIGH	HIGH	LOW	LOW
Sodium bicarbonate	LOW	LOW	LOW	HIGH

Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to APVMA approved 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.

Section 15: REGULATORY INFORMATION

Poisons Schedule: S4

APVMA Registration No: 36317

ACIS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredient: Oxytetracycline hydrochloride is 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 Code for the Transport of Dangerous Goods by Road & Rail, 7th Edition.
- AICS** Australian Inventory of Chemical Substances.
- APVMA** Australian Pesticides and Veterinary Medicines Authority.
- CAS No.** Chemical Abstracts Service Registry Number.
- EPA** Environmental Protection Authority.
- 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.
- 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.
- NOEC** No Observed 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.

References

ChemID PlusLite, <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>, entry for Oxytetracycline hydrochloride (RN: 2058-46-0).

HSDB <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB> entry for OXYTETRACYCLINE (CASRN: 79-57-2).

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

This version issued: 02 August 2017 and is valid for 5 years from this date.

Supersedes: This SDS supercedes the version issued on 13 August 2012.

Revision History:

Date of Revision	Reason
02 August 2017	Updates to section 1, 2, 3, 4, 5, 7, 10, 11, 12, 13 & 15; Updates to Legend and addition of Revision History in Section 16.

END OF SDS