TETRAMAX

SOLUBLE ANTIBIOTIC POWDER

Abbey Animal Health Pty Ltd
Material 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
Telephone Number: 02 8088 0720
Facsimile Number: 02 8088 0721
Emergency Number: Australian Poisons Information Centre: 13 11 26 (24 Hour Service).

PRODUCT NAME
TETRAMAX SOLUBLE ANTIBIOTIC POWDER

PRODUCT USE
For the control and treatment of diseases caused by micro-organisms sensitive to oxytetracycline in poultry, pigs, calves and cattle.

Section 2- Hazards Identification

Statement of Hazardous Nature: This product is NOT classified as hazardous according to the criteria of SWA.

ADG Classification: None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code criteria when transported by road or rail. Refer to Section 14.

GHS Signal word: NONE. Not hazardous
GHS Classification: None
Pictogram: None:

PREVENTION
P102: Keep out of reach of children.
P262: Do not get in eyes, on skin, or on clothing.
P281: Use personal protective equipment as required.

RESPONSE
P352: Wash with plenty of soap and water.

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P370+P378: In case of fire, use carbon dioxide, dry chemical, foam, water fog.

STORAGE
P410: Protect from sunlight.
P411: Store at temperatures not exceeding 25°C.
P402+P404: Store in a dry place. Store in a closed container.

Section 3- Composition / Information on Ingredients

INGREDIENTS:

Chemical Name	**CAS No.**	**Content (%w/w)**
Oxytetracycline hydrochloride	2058-46-0	93.1%
No-hazardous Ingredients	Secret	to 100

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other nonhazardous ingredients are also present.

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.

Swallowed: If swallowed do NOT induce vomiting. 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. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.

Eye: If this product comes in contact with the eyes: Wash out immediately with fresh 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. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

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.

Inhaled: If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.

Notes to Physician: Tetracycline are bond to plasma proteins and are widely distributed in the body tissues and fluids. The biological half-life is reported to be around 10-15 hours. They are excreted in urine and in faeces. Treat symptomatically.

Section 5- Fire Fighting Measures

Extinguishing media: Water spray or fog. Foam. Dry chemical powder. BCF (where regulations permit). Carbon dioxide.

Fire/Explosion Hazard:

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited-particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.
- In the same way a gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds as high temperatures (for dusts the LEL is often called the “Minimum Explosible Concentration”, MEC).

Hazardous combustion Products: carbon monoxide (CO), carbon dioxide (CO2), hydrogen chloride, phosgene, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.

Fire Incompatibility:
Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

Fire Fighting: Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water courses. Use water delivered as a fine spray to control fire and cool adjacent area. **DO NOT** approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.

Section 6 - Accidental Release Measures

Minor Spills: Clean up waste regularly and abnormal spills immediately. Avoid breathing dust and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust.

Major Spills:
Moderate hazard.

- CAUTION: Advise personnel in area.
- Alert Emergency Services and tell them location and nature of hazard.
- Control personnel contact by wearing protective clothing.
- Prevent, by any means available, spillage from entering drains or water courses.

Section 7 - Handling and Storage

Handling: Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. **DO NOT** enter confined spaces until atmosphere has been checked. **DO NOT** allow material to contact humans, exposed food or food utensils. Avoid contact with incompatible materials. When handling, **DO NOT** eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Always wash hands with soap and water after handling.

Organic powders when finely divided over the range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions). Minimise airborne dust and eliminate all ignition sources. Keep away from heavy, hot surfaces, sparks and flame. Establish good housekeeping practices. Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.

Storage: Store below 25°C (air conditioning) in a well closed container and dry place. Protect from light.

Section 8 - Exposure Controls / Personal Protection

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

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: AS/NZS 4501 set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**

Exposure limits have not been established by SWA for this product.

***Personal Protective Equipment*:**

Eye: When handling very small quantities of the material eye protection may not be required.
For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles.
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. Lens should be removed at the first signs of eye redness or irritation – lens should be removed in a clean environment only after workers have washed hands thoroughly. (CDC NIOSH Current Intelligence Bulletin 59), (AS/NZS 1336 or national equivalent).

Hands/Feet:
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.
The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.
Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- Rubber gloves (nitrile or low-protein, powder free latex, latex/nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Change gloves frequently and when contaminated, punctured or torn.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- Polychloroprene
- Nitrile rubber
- Butyl rubber
- Fluorocaoutchouc

Other:

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

- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.

Respirator: If there is a risk of inhalation of spray mists, wear a mask or respirator meeting the requirements of AS/NZS 1715.

Engineering Controls:
Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.
HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.
Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.
A fume hood or vented balance enclosure is recommended for weighing/transferring quantities exceeding 500 mg.
When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred.
Assess operations based upon available dust explosion information to determine the suitability preventive or protective systems as precautionary measures against dust explosions. If prevention is not possible, consider protection by use of containment, venting or suppression of dust handling equipment.

Section 9 - Physical and Chemical Properties

Physical state	Fine crystalline powder
Colour	Yellow to brown
pH	Not available
Boiling point	Not available
Flash point	Not available
Solubility	Miscible in water
Relative density	Not available
Evaporation rate	Not available
Melting point/ freezing point	Not available

Section 10 - Stability and Reactivity

Conditions contributing to Instability: Presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.

For incompatible materials-refer to section 7- Handling and storage.

Section 11 - Toxicological Information

POTENTIAL HEALTH EFFECTS

Acute Health Effects:

Swallowed: Accidental ingestion of the material may be damaging to the health of the individual. Animal testing showed that Oxytetracycline did not cause any adverse health effects, except for mild fatty change in the liver. Tetracyclines produce nausea, abdominal pain and burning, vomiting, transitory yellowish-brown discoloration of the tongue, loss of appetite, and diarrhea. Large oral doses may produce liver and kidney damage. Hypersensitivity reactions may also occur. Cross-sensitivity reactions between tetracyclines are common.

Eye: This material can cause eye irritation and damage in some persons.

Skin: This material can cause inflammation of the skin on contact in some persons. The material may accentuate any pre-existing dermatitis condition. Skin contact with the material may damage he health of the individual; systemic effects may result following absorption. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. Tetracyclines can cause yellow discoloration of the skin. Adverse effects can occur whether the drug is given orally or injected. A sunlight-induced dermatitis occurs, with swelling, redness, itch and warmth. Covered skin is less susceptible to such damage.

Inhaled: The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. If prior damage to the circulatory or nervous system has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result.

Chronic health Effects:

There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment. Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother. Substance accumulation and/or photosensitization (allergic response after UV exposure have been demonstrated with clinical use of oxytetracycline.

In a 12-month study in dogs, a degenerating epithelium in the testicular tubules was observed in males fed diets containing 10,000 ppm (equivalent to 250 mg/kg/day) Oxytetracycline hydrochloride. Effects on fertility (litter size) and embryo or Foetotoxicity were observed in rats at subcutaneous doses of Oxytetracycline at 1000 mg/kg.

In rabbits at intramuscular doses at 789 mg/kg, and in dogs at 643 mg/kg (no other details reported). Tetracyclines can disturb breathing and heart functions by chelating calcium ions and other positive ions. Repeated or prolonged exposures to tetracyclines can cause sore throat, hoarseness, a back hairy tongue, bulky loose stools, fat in the feces, and inflammation of the mouth cavity, difficulty swallowing, damage to the anogenital area and ulcers of the esophagus. Deposits in the eye may

cause abnormal pigmentation of the conjunctivitis. Tetracyclines can interfere with bone growth of the foetus. Hypersensitivity reactions include burning of the eyes, conjunctivitis, spotty and red rashes, dermatitis with sloughing, hives, itching, swollen cracked lips, an inflamed tongue, fever asthma, fatty liver, blockage of bile, loss of platelets, neutrophils, white blood cells or all blood cells, swelling due to blood vessels and nerves, inflammation of the membranous sac surrounding the heart, exacerbation of lupus, anaphylactic shockand skin rash due to capillary bleeds. Other signs and symptoms include lung infiltrates, diabetes, temporary muscle disorders, blood poisoning, psychotic reactions and fatal liver damage. Sensitivity to light aggravated by sunlight may occur. Loosening and pigmentation of the nails may occur at the same time. Increased pressure in the head can cause swelling of the optic nerve, headache, vision impairment, and bleeding from the retina, especially in children. Pregnant women seem to be most susceptible to liver damage caused by tetracyclines. Jaundice followed by uraemia, acidosis and irreversible shock is usual. Tetracyclines are secreted in the breast milk and readily cross the placenta to affect the foetus. The foetus will show retardation of skeletal development and underdevelopment of the enamel of the teeth. Long-term use of Oxytetracycline often results in kidney damage and failure, with increased urinary output, extreme thirst, and protein in the urine, acidosis, sugar and excess amino acids in the urine.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray. Prolonged or repeated use of antibiotics, at the therapeutic doses, may produce bacterial resistance for some types of bacteria. Prolonged use may result in the overgrowth of non-susceptible organisms (i.e. super-infection).

Oxytetracycline HCl:

Oral (mouse)	LD50	6696 mg/kg

Section 12 - Ecological Information

OXYTETRACYCLINE HYDROCHLORIDE

Endpoint	Test Duration (Hr)	Species	Value	Source
LC50	96	Fish	3.343mg/L	3
EC50	72	Algae or other aquatic plants	0.342mg/L	4
NOEC	72	Algae or other aquatic plants	0.183mg/L	4

Ecotoxicity

Ingredient	Persistance: Water/Soil	Persistance: Air	Bioaccumulation	Mobility

Oxytetracycline hydrochloride	HIGH	No data Available	LOW	LOW

Section 13 - Disposal Considerations

For 500g and 1kg pack sizes:
Dispose of container by wrapping with paper and putting in garbage.

For 5, 10, 20 and 25 kg pack sizes:
Single-rinse or shake container into the medicated feed or water. Do not dispose of undiluted chemicals on-site. Puncture bag and deliver to an approved waste management facility. If an approved waste management facility is not available, bury the container 500 mm below the surface in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and tree roots, in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.

Section 14 - Transport Information

No specific transport considerations apply since *TETRAMAX SOLUBLE POWDER* is NOT classified as a dangerous good according to Australian Dangerous Goods (ADG) Code.
NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: ADG7, IATA, IMDG

Section 15 - Regulatory Information

Poisons Schedule: *S4*

APVMA Approval Number: *81499*

Approved pack size: 500g, *1Kg, 5Kg, 10Kg, 20kg, 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.**