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## 1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

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### 1.1 Product identifier

**Product name** AMOXYCLAV FLAVOURED 250MG/500MG BROADSPECTRUM ANTIBIOTIC TABLETS  
**Synonyms** AMOXYCLAV FLAVOURED TABLETS

### 1.2 Uses and uses advised against

**Uses** ANTIBIOTIC • VETERINARY USE  
TREATMENT OF BACTERIAL INFECTIONS SENSITIVE TO AMOXICILLIN AND CLAVULANIC ACID IN DOGS AND CATS.

### 1.3 Details of the supplier of the product

**Supplier name** DECHRA VETERINARY PRODUCTS (AUSTRALIA) PTY LTD  
**Address** 2 Cal Close, Somersby, NSW, 2250, AUSTRALIA  
**Telephone** 1300 015 825; (02) 4372 1661  
**Fax** (02) 4372 1668  
**Email** [info.au@dechra.com](mailto:info.au@dechra.com)  
**Website** <http://www.dechra.com.au/>

### 1.4 Emergency telephone numbers

**Emergency** 13 11 26 (Poisons Information Centre)

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## 2. HAZARDS IDENTIFICATION

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### 2.1 Classification of the substance or mixture

CLASSIFIED AS HAZARDOUS ACCORDING TO SAFE WORK AUSTRALIA CRITERIA

#### Physical Hazards

Not classified as a Physical Hazard

#### Health Hazards

Skin Sensitisation: Category 1  
Respiratory Sensitisation: Category 1

#### Environmental Hazards

Not classified as an Environmental Hazard

### 2.2 GHS Label elements

**Signal word** DANGER

#### Pictograms



#### Hazard statements

H317 May cause an allergic skin reaction.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

# PRODUCT NAME AMOXYCLAV FLAVOURED 250/500 MG BROADSPECTRUM ANTIBIOTIC TABLETS

## Prevention statements

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P284	Wear respiratory protection.

## Response statements

P302 + P352	IF ON SKIN: Wash with plenty of water.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P321	Specific treatment is advised - see first aid instructions.
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.
P362 + P364	Take off contaminated clothing and wash it before reuse.

## Storage statements

None allocated.

## Disposal statements

P501	Dispose of contents/container in accordance with relevant regulations.
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## 2.3 Other hazards

No information provided.

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## 3. COMPOSITION/ INFORMATION ON INGREDIENTS

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### 3.1 Substances / Mixtures

Ingredient	CAS Number	EC Number	Content
AMOXICILLIN TRIHYDRATE	61336-70-7	612-127-4	30 to 60%
POTASSIUM CLAVULANATE	61177-45-5	262-640-9	<10%
NON HAZARDOUS INGREDIENTS	Not Available	Not Available	Remainder

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## 4. FIRST AID MEASURES

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### 4.1 Description of first aid measures

<b>Eye</b>	If in eyes, hold eyelids apart and flush continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre, a doctor, or for at least 15 minutes.
<b>Inhalation</b>	If inhaled, remove from contaminated area. Apply artificial respiration if not breathing.
<b>Skin</b>	If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.
<b>Ingestion</b>	For advice, contact a Poisons Information Centre on 13 11 26 (Australia Wide) or a doctor (at once). If swallowed, do not induce vomiting.
<b>First aid facilities</b>	None allocated.

### 4.2 Most important symptoms and effects, both acute and delayed

See Section 11 for more detailed information on health effects and symptoms.

### 4.3 Immediate medical attention and special treatment needed

Treat symptomatically.

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## 5. FIRE FIGHTING MEASURES

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### 5.1 Extinguishing media

Use an extinguishing agent suitable for the surrounding fire.

### 5.2 Special hazards arising from the substance or mixture

Non flammable. May evolve toxic gases if strongly heated. May evolve nitrogen oxides, carbon oxides, sulphur oxides and hydrogen cyanide when heated to decomposition.

### 5.3 Advice for firefighters

Treat as per requirements for surrounding fires. Evacuate area and contact emergency services. Remain upwind and notify those downwind of hazard. Wear full protective equipment including Self Contained Breathing Apparatus (SCBA) when combating fire. Use waterfog to cool intact containers and nearby storage areas.

**5.4 Hazchem code**

None allocated.

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**6. ACCIDENTAL RELEASE MEASURES**

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**6.1 Personal precautions, protective equipment and emergency procedures**

Wear Personal Protective Equipment (PPE) as detailed in section 8 of the SDS.

**6.2 Environmental precautions**

Prevent product from entering drains and waterways.

**6.3 Methods of cleaning up**

If spilt, collect and reuse where possible.

**6.4 Reference to other sections**

See Sections 8 and 13 for exposure controls and disposal.

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**7. HANDLING AND STORAGE**

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**7.1 Precautions for safe handling**

Before use carefully read the product label. Use of safe work practices are recommended to avoid eye or skin contact and inhalation. Observe good personal hygiene, including washing hands before eating. Prohibit eating, drinking and smoking in contaminated areas.

**7.2 Conditions for safe storage, including any incompatibilities**

Store in a cool, dry, well ventilated area, removed from incompatible substances, heat or ignition sources and foodstuffs. Ensure containers are labelled, protected from light, freezing or physical damage and tightly sealed when not in use. Keep out of reach of children. Store below 25°C.

**7.3 Specific end uses**

No information provided.

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**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

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**8.1 Control parameters****Exposure standards**

Ingredient	Reference	TWA		STEL	
		ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>
Nuisance dust	SWA [AUS]	--	10	--	--

**Biological limits**

No biological limit values have been entered for this product.

**8.2 Exposure controls**

**Engineering controls** Avoid inhalation. Use in well ventilated areas. Where an inhalation risk exists, use under a fume cupboard. Maintain dust levels below the recommended exposure standard.

**PPE**

<b>Eye / Face</b>	Not required under normal conditions of use.
<b>Hands</b>	Individuals with sensitive skin should consider wearing latex gloves.
<b>Body</b>	Not required under normal conditions of use.
<b>Respiratory</b>	At high dust levels, wear a Class P1 (Particulate) respirator.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

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**9.1 Information on basic physical and chemical properties**

<b>Appearance</b>	ROUND BEIGE TABLETS
<b>Odour</b>	CHARACTERISTIC PENICILLIN ODOUR
<b>Flammability</b>	NON FLAMMABLE
<b>Flash point</b>	NOT RELEVANT
<b>Boiling point</b>	NOT AVAILABLE

**9.1 Information on basic physical and chemical properties**

<b>Melting point</b>	NOT AVAILABLE
<b>Evaporation rate</b>	NOT AVAILABLE
<b>pH</b>	NOT AVAILABLE
<b>Vapour density</b>	NOT AVAILABLE
<b>Relative density</b>	NOT AVAILABLE
<b>Solubility (water)</b>	NOT AVAILABLE
<b>Vapour pressure</b>	NOT AVAILABLE
<b>Upper explosion limit</b>	NOT RELEVANT
<b>Lower explosion limit</b>	NOT RELEVANT
<b>Partition coefficient</b>	NOT AVAILABLE
<b>Autoignition temperature</b>	NOT AVAILABLE
<b>Decomposition temperature</b>	NOT AVAILABLE
<b>Viscosity</b>	NOT AVAILABLE
<b>Explosive properties</b>	NOT AVAILABLE
<b>Oxidising properties</b>	NOT AVAILABLE
<b>Odour threshold</b>	NOT AVAILABLE

**10. STABILITY AND REACTIVITY**

**10.1 Reactivity**

Carefully review all information provided in sections 10.2 to 10.6.

**10.2 Chemical stability**

Stable under recommended conditions of storage.

**10.3 Possibility of hazardous reactions**

Polymerization will not occur.

**10.4 Conditions to avoid**

Avoid heat, sparks, open flames and other ignition sources.

**10.5 Incompatible materials**

Incompatible with oxidising agents (e.g. hypochlorites), heat and ignition sources.

**10.6 Hazardous decomposition products**

May evolve nitrogen oxides, carbon oxides, sulphur oxides and hydrogen cyanide when heated to decomposition.

**11. TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects**

**Acute toxicity** This product is used in veterinary applications. Use safe work practices to avoid eye contact, prolonged skin contact and ingestion. Refer to medical doctor/specialist for advice regarding adverse side effects.

**Information available for the ingredients:**

<b>Ingredient</b>	<b>Oral LD50</b>	<b>Dermal LD50</b>	<b>Inhalation LC50</b>
AMOXICILLIN TRIHYDRATE	> 15000 mg/kg (rat)	--	--
POTASSIUM CLAVULANATE	4526 mg/kg (mouse)	--	--

<b>Skin</b>	Contact may result in irritation, redness, pain and rash.
<b>Eye</b>	Contact may result in irritation, lacrimation, pain and redness.
<b>Sensitisation</b>	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>Mutagenicity</b>	Not classified as a mutagen.
<b>Carcinogenicity</b>	Not classified as a carcinogen.
<b>Reproductive</b>	Not classified as a reproductive toxin.
<b>STOT - single exposure</b>	Not classified as causing organ damage from single exposure.
<b>STOT - repeated exposure</b>	Not classified as causing organ damage from repeated exposure.
<b>Aspiration</b>	Not classified as causing aspiration.

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not expected to be an environmental hazard.

### 12.2 Persistence and degradability

No information provided.

### 12.3 Bioaccumulative potential

No information provided.

### 12.4 Mobility in soil

No information provided.

### 12.5 Other adverse effects

No information provided.

## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

**Waste disposal** For small quantities, collect and place in sealable containers. Dispose of, as with other clinical waste, by high temperature incineration (recommended > 1100°C). Burial to landfill may be acceptable, but only at an approved and licensed waste disposal site.

**Legislation** Dispose of in accordance with relevant local legislation.

## 14. TRANSPORT INFORMATION

### NOT CLASSIFIED AS A DANGEROUS GOOD BY THE CRITERIA OF THE ADG CODE, IMDG OR IATA

	LAND TRANSPORT (ADG)	SEA TRANSPORT (IMDG / IMO)	AIR TRANSPORT (IATA / ICAO)
14.1 UN Number	None allocated.	None allocated.	None allocated.
14.2 Proper Shipping Name	None allocated.	None allocated.	None allocated.
14.3 Transport hazard class	None allocated.	None allocated.	None allocated.
14.4 Packing Group	None allocated.	None allocated.	None allocated.

### 14.5 Environmental hazards

Not a Marine Pollutant.

### 14.6 Special precautions for user

**Hazchem code** None allocated.

## 15. REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

**Poison schedule** Classified as a Schedule 4 (S4) Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

**APVMA Numbers** 89210 (500 mg) • 89054 (250 mg)

**Classifications** Safe Work Australia criteria is based on the Globally Harmonised System (GHS) of Classification and Labelling of Chemicals (GHS Revision 7).

**Inventory listings** **AUSTRALIA: AIIC (Australian Inventory of Industrial Chemicals)**  
All components are listed on AIIC, or are exempt.

## 16. OTHER INFORMATION

**Additional information**

## PRODUCT NAME **AMOXYCLAV FLAVOURED 250/500 MG BROADSPECTRUM ANTIBIOTIC TABLETS**

**RESPIRATORS:** In general the use of respirators should be limited and engineering controls employed to avoid exposure. If respiratory equipment must be worn ensure correct respirator selection and training is undertaken. Remember that some respirators may be extremely uncomfortable when used for long periods. The use of air powered or air supplied respirators should be considered where prolonged or repeated use is necessary.

**EXPOSURE STANDARDS - TIME WEIGHTED AVERAGE (TWA) or WES (WORKPLACE EXPOSURE STANDARD) (NZ):** Exposure standards are established on the premise of an 8 hour work period of normal intensity, under normal climatic conditions and where a 16 hour break between shifts exists to enable the body to eliminate absorbed contaminants. In the following circumstances, exposure standards must be reduced: Strenuous work conditions; hot, humid climates; high altitude conditions; extended shifts (which increase the exposure period and shorten the period of recuperation).

### **PERSONAL PROTECTIVE EQUIPMENT GUIDELINES:**

The recommendation for protective equipment contained within this report is provided as a guide only. Factors such as form of product, method of application, working environment, quantity used, product concentration and the availability of engineering controls should be considered before final selection of personal protective equipment is made.

### **HEALTH EFFECTS FROM EXPOSURE:**

It should be noted that the effects from exposure to this product will depend on several factors including: form of product; frequency and duration of use; quantity used; effectiveness of control measures; protective equipment used and method of application. Given that it is impractical to prepare a report which would encompass all possible scenarios, it is anticipated that users will assess the risks and apply control methods where appropriate.

### **Abbreviations**

ACGIH	American Conference of Governmental Industrial Hygienists
CAS #	Chemical Abstract Service number - used to uniquely identify chemical compounds
CNS	Central Nervous System
EC No.	EC No - European Community Number
EMS	Emergency Schedules (Emergency Procedures for Ships Carrying Dangerous Goods)
GHS	Globally Harmonized System
GTEPG	Group Text Emergency Procedure Guide
IARC	International Agency for Research on Cancer
LC50	Lethal Concentration, 50% / Median Lethal Concentration
LD50	Lethal Dose, 50% / Median Lethal Dose
mg/m <sup>3</sup>	Milligrams per Cubic Metre
OEL	Occupational Exposure Limit
pH	relates to hydrogen ion concentration using a scale of 0 (high acidic) to 14 (highly alkaline).
ppm	Parts Per Million
STEL	Short-Term Exposure Limit
STOT-RE	Specific target organ toxicity (repeated exposure)
STOT-SE	Specific target organ toxicity (single exposure)
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
SWA	Safe Work Australia
TLV	Threshold Limit Value
TWA	Time Weighted Average

### **Report status**

This SDS summarises our best knowledge of the health and safety hazard information of the product 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. Dechra Veterinary Products (Australia) Pty Ltd make no representation of merchantability, fitness for a particular purpose or application, or of any other nature with respect to the information or the product to which the information refers ("the product").

The information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability prior to use of the product. The physical data shown herein are typical values based on material tested. These values should not be construed as guaranteed analysis of any specific lot or as guaranteed specification for the product or specific lots hereof.

**[ End of SDS ]**