

Section 1 - Identification of The Material and Supplier

Norbrook Laboratories Australia Pty Ltd
Unit 7/1 Trade Park Drive
Tullamarine, Vic 3043 AUSTRALIA

Freecall: 1800 665 866

Chemical nature: Clavulanic acid is biosynthetically generated from the amino acid arginine and the sugar glyceraldehyde 3-phosphate. Amoxicillin is a moderate-spectrum, bacteriolytic, β -lactam antibiotic.

Trade Name: **NOROCLAV 500mg Tablets for Dogs and Calves**

APVMA Code: 55507

Product Use: Oral treatment of bacterial infections caused by susceptible organisms in dogs and calves.

Creation Date: **August, 2008**

This version issued: **August, 2024** and is valid for 5 years from this date.

Poisons Information Centre: Phone 13 1126 from anywhere in Australia

Section 2 - Hazards Identification**Statement of Hazardous Nature****SUSMP Classification:** S4**ADG Classification:** Class 9: Miscellaneous Dangerous Goods.**UN Number:** 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (AMOXYCILLIN, CLAVULANIC ACID)**GHS Signal word: WARNING**

Skin Sensitisation Category 1

Specific Target Organ toxicity - single exposure Category 2

Hazardous to aquatic environment Short term/Chronic Category 1

HAZARD STATEMENT:

H317: May cause an allergic skin reaction.

H371: May cause damage to organs.

H410: Very toxic to aquatic life with long lasting effects.

PREVENTION

P102: Keep out of reach of children.

P261: Avoid breathing mists.

P262: Do not get in eyes, on skin, or on clothing.

P264: Wash contacted areas thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.

P272: Contaminated work clothing should not be allowed out of the workplace.

P273: Avoid release to the environment.

P280: Wear protective gloves, protective clothing and eye or face protection.

RESPONSE

P314: Get medical advice or attention if you feel unwell.

P363: Wash contaminated clothing before reuse.

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P302+P352: IF ON SKIN: Wash with plenty of soap and water.

P309+P311 If exposed or if you feel unwell: Call a POISON CENTRE or doctor/physician.

P333+P313: If skin irritation or rash occurs: Get medical advice.

P391: Collect spillage.

P370+P378: Not combustible. Use extinguishing media suited to burning materials. Water fog or fine spray is the preferred medium for large fires.

STORAGE

P403: Store in a well-ventilated place.

P410: Protect from sunlight.

P411: Store at temperatures not exceeding 25°C.

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P402+P404: Store in a dry place. Store in a closed container.

DISPOSAL

P501: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Emergency Overview

Physical Description & Colour: Circular, pink tablets.

Odour: No data.

Major Health Hazards: This is an antibiotic preparation. Any person with a history of allergies to this class of substances should avoid all contact with this product as it may cause sensitisation. This is also a physiologically active product and so contact should be minimised, especially if the user is taking a form of medication, as interactions can sometimes give unexpected and undesired results.

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc,%	TWA (mg/m ³)	STEL (mg/m ³)
Clavulanic acid (as the potassium salt)	58001-44-8	100mg/tab	not set	not set
Amoxicillin (as the trihydrate)	26787-78-0	400mg/tab	not set	not set
Other non hazardous ingredients	secret	to 100%	not set	not set

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

The SWA TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak" is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

Section 4 - First Aid Measures**General Information:**

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

Inhalation: First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Skin Contact: Gently brush away any particles. Wash gently and thoroughly with water (use non-abrasive soap if necessary) for 5 minutes or until chemical is removed.

Eye Contact: Quickly and gently blot material from eyes. No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the product is removed. Obtain medical advice if irritation becomes painful or lasts more than a few minutes. Take special care if exposed person is wearing contact lenses.

Ingestion: If product is swallowed or gets in mouth, do NOT induce vomiting; wash mouth with water and give some water to drink. If symptoms develop, or if in doubt contact a Poisons Information Centre or a doctor.

Section 5 - Fire Fighting Measures

Fire and Explosion Hazards: There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

Extinguishing Media: Use extinguishing media suited to burning materials.

Fire Fighting: If a significant quantity of this product is involved in a fire, call the fire brigade.

Flammability Class: No data.

Section 6 - Accidental Release Measures

Accidental release: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, clean up, rinsing to sewer and put empty container in garbage. Although no special protective clothing is normally necessary because of occasional minor contact with this product, it is good practice to wear impermeable gloves when handling chemical products. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

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Section 7 - Handling and Storage

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: This product is a Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this schedule of poison. Store packages of this product in a cool place. Make sure that containers of this product are kept tightly closed. Keep containers dry and away from water. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Check packaging - there may be further storage instructions on the label.

Section 8 - Exposure Controls and 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**.

SWA Exposure Limits **TWA (mg/m³)** **STEL (mg/m³)**
Exposure limits have not been established by SWA for any of the significant ingredients in this product.

The ADI for Clavulanic acid is set at 0.01mg/kg/day. The corresponding NOEL is set at 10mg/kg/day.

The ADI for Amoxicillin is set at 0.2mg/kg/day. The corresponding NOEL is set at 200mg/kg/day. ADI means Acceptable Daily Intake and NOEL means No-observable-effect-level. Values taken from Australian ADI List, June 2013.

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

Ventilation: No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that dusts are minimised.

Eye Protection: Eye protection is not normally necessary when this product is being used. However, if in doubt, wear suitable protective glasses or goggles.

Skin Protection: You should avoid contact even with mild skin irritants. Therefore you should wear suitable impervious elbow-length gloves and facial protection when handling this product. See below for suitable types.

Protective Material Types: We suggest that protective clothing be made from the following materials: latex.

Respirator: Usually, no respirator is necessary when using this product. However, if you have any doubts consult the Australian Standard mentioned above.

Safety deluge showers should, if practical, be provided near to where this product is being used.

Section 9 - Physical and Chemical Properties:

Physical Description & colour:	Circular, pink tablets.
Odour:	No data.
Boiling Point:	Not applicable.
Flash point:	No data
Upper Flammability Limit:	No data.
Lower Flammability Limit:	No data.
Autoignition temperature:	No data.
Freezing/Melting Point:	Decomposes before melting.
Volatiles:	No data.
Vapour Pressure:	No data.
Vapour Density:	No data.
Specific Gravity:	No data.
Water Solubility:	No data.
pH:	No data.
Volatility:	No data.
Odour Threshold:	No data.
Evaporation Rate:	No data.
Coeff Oil/water Distribution:	No data
Particle Characteristics:	Tablets. Respirable particles typically not present.

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Section 10 – Stability and Reactivity

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Conditions to Avoid: This product should be kept in a cool place, preferably below 30°C. Keep containers tightly closed. Containers should be kept dry.

Incompatibilities: water, acids, bases.

Fire Decomposition: Carbon dioxide, and if combustion is incomplete, carbon monoxide. Nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. Oxides of sulfur (sulfur dioxide is a respiratory hazard) and other sulfur compounds. Most will have a foul odour. Water. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

Polymerisation: This product will not undergo polymerisation reactions.

Section 11 - Toxicological Information

Local Effects:

Target Organs: There is no data to hand indicating any particular target organs.

Classification of Hazardous Ingredients

Ingredient

Health Hazard Statement Codes

No ingredient mentioned in the HCIS Database is present in this product at hazardous concentrations.

Potential Health Effects

Persons with a history of allergies to antibiotics should avoid contact with this product as it may cause sensitisation.

Inhalation:

Short Term Exposure: Long term inhalation of high amounts of any nuisance dust may overload lung clearance mechanism. Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.

Long Term Exposure: No data for health effects associated with long term inhalation.

Skin Contact:

Short Term Exposure: Available data indicates that this product is not harmful. It should present no hazards in normal use. In addition product is unlikely to cause any discomfort in normal use.

Long Term Exposure: No data for health effects associated with long term skin exposure.

Eye Contact:

Short Term Exposure: This product may be mildly irritating to eyes, but is unlikely to cause anything more than mild discomfort which should disappear once product is removed.

Long Term Exposure: No data for health effects associated with long term eye exposure.

Ingestion:

Short Term Exposure: Significant oral exposure is considered to be unlikely. However, this product may be mildly irritating to mucous membranes but is unlikely to cause anything more than mild transient discomfort.

Long Term Exposure: No data for health effects associated with long term ingestion.

Carcinogen Status:

SWA: No significant ingredient is classified as carcinogenic by SWA.

NTP: No significant ingredient is classified as carcinogenic by NTP.

IARC: No significant ingredient is classified as carcinogenic by IARC.

Section 12 - Ecological Information

This product is biodegradable. It will not accumulate in the soil or water or cause long term problems.

Section 13 - Disposal Considerations

Disposal: You should not attempt to reclaim or recycle this product. We suggest that, subject to the regulations in your area, this product should be disposed in landfill.

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Section 14 - Transport Information

Not subject to the ADG Code when transported by Road or Rail in Australia, in packages 500kg(L) or less; or IBCs, but classed as Dangerous by IATA and IMDG/IMSBC when carried by Air or Sea transport (see details below).

UN Number: 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (AMOXYCILLIN, CLAVULANIC ACID)

Hazchem Code: 2Z

Special Provisions: 274, 331, 335, 375, AU01

Limited quantities: ADG 7 specifies a Limited Quantity value of 5 kg for this class of product.

Dangerous Goods Class: Class 9: Miscellaneous Dangerous Goods.

Packing Group: III

Packing Instruction: P002, IBC08, LP02

Class 9 Miscellaneous Dangerous Goods shall not be loaded in the same vehicle or packed in the same freight container with Dangerous Goods of Class 1 (Explosives).

Section 15 - Regulatory Information

AIC: All of the significant ingredients in this formulation are compliant with AICIS regulations.

Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

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.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS. OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (July 2020) and GHS Revision 7

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<http://www.kilford.com.au/> Phone (02)8321 8866

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