

Section 1 - Identification of Chemical Product and Company

Norbrook NZ Ltd
KPMG Centre, 18 Viaduct Harbour Ave
Auckland, New Zealand

Freecall: 0800 224 022

Trade Name: Noroclav Tablets 500 mg

Product Use: For the treatment of bacterial infections sensitive to clavulanic acid and amoxicillin, in pre-ruminant calves and large dogs.

This version issued: March, 2025 and is valid for 5 years from this date.

National Poisons Centre: Phone 0800 764 766 from anywhere in New Zealand

Section 2 - Hazards Identification

Hazard Class	Hazard Category	Hazard statement code	Hazard Statement
Skin sensitisation	Category 1	H317	May cause an allergic skin reaction
Specific target organ toxicity (repeated exposure)	Category 2	H373	May cause damage to organs through prolonged or repeated exposure
Hazardous to the aquatic environment acute	Category 1	H400	Very toxic to aquatic life
Hazardous to the aquatic environment chronic	Category 1	H410	Very toxic to aquatic life with long lasting effects

Signal word Warning

GHS Pictogram



Precautionary statements:

Prevention

- P260: Do not breathe dust.
P272: Contaminated work clothing should not be allowed out of the workplace.
P273: Avoid release to the environment.
P280: Wear protective gloves.

Response

- P321: See first aid instruction on the label.
P302 + P352: IF ON SKIN: Wash with plenty of water.
P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364: Take off contaminated clothing and wash it before reuse.
P314: Get medical advice/attention if you feel unwell.

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P391: Collect spillage.

Disposal

P501: Dispose of product, packaging and waste at an approved landfill or other equivalent facility.

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Concentration
Amoxicillin trihydrate	61336-70-7	262.4 g/kg
Potassium clavulanate	61177-45-5	71.5 g/kg
Other ingredients	secret	balance

Section 4 - First Aid Measures

General Information: For advice contact the National Poisons Centre 0800 POISON (0800 764 766) in New Zealand and is available at all times. Have this SDS and product label with you when you call. Get medical attention if you feel unwell.

Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell.

Skin Contact: Wash with plenty of water or until chemical is removed. If skin irritation or rash occurs: Get medical attention.

Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.

Ingestion: If product is swallowed or gets in mouth, do NOT induce vomiting; rinse mouth with water. If symptoms develop, or if in doubt Call a POISON CENTER or doctor.

Section 5 - Fire Fighting Measures

Flash point: No data

Fire and Explosion Hazards: The major hazard in fires is usually inhalation of heated and toxic or oxygen deficient (or both), fire gases. Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

Fire Fighting Equipment: Use self-contained breathing apparatus and full protective clothing.

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.

Section 6 - Accidental Release Measures

Personal Precautions: Use appropriate protective clothing. Wear protective gloves.

Environmental Precautions: Prevent spilled material from entering water ways. Avoid release to the environment.

Methods and Materials for Containment and Cleaning up:

Minor spills: Clean up and absorb spills with inert material and place in waste containers, labelled for disposal. Contain in a secure location until disposal method is established. Dispose of waste safely.

Major spills: Prevent spillage from entering drains or water ways 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. Do not breathe dust. Wear protective gloves. Contaminated work clothing should not be allowed out of the workplace. Take off contaminated clothing and wash it before reuse.

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.

Certified handler: Not required

Tracking: Not required

Storage: Store below 25°C (Room temperature), in a dry place. Check packaging, there may be further storage instructions on the label.

Section 8 - Exposure Controls and Personal Protection

Occupational exposure limits:

SWA Exposure Limits

TWA (mg/m³)

STEL (mg/m³)

Exposure limits have not been established for any of the significant ingredients in this product.

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.

Engineering Controls: Handle in accordance with good industrial hygiene and safety practice. Wash hands and exposed skin thoroughly after handling.

Ventilation: Make sure that the work environment remains clean and that dusts are minimised.

Eye Protection: Wear safety goggles. Maintain eye wash facilities in work areas.

Skin Protection: Wear protective gloves when handling this product.

Protective Material Types: Protective clothing be made from rubber or PVC.

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**.

Section 9 - Physical and Chemical Properties

Physical Description & Colour:	A pink circular tablet with a score line and "500" on opposing faces.
Odour:	No data
Odour Threshold:	No data
pH:	No data
Melting point/Freezing point:	No data. Solid at normal temperatures.
Initial boiling point and boiling range:	No data
Flash point:	No data
Flammability (solid, gas):	No data
Upper/Lower flammability or explosive limits:	No data
Vapour pressure:	No data
Vapour density:	No data

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Relative density:	1.17
Solubility (ies):	No data
Partition coefficient: n-octanol/water:	No data
Auto-ignition temperature:	No data
Decomposition temperature:	No data
Kinematic viscosity:	No data
Particle characteristics:	No data

Section 10 - Stability and Reactivity

Reactivity: No data related to reactivity available for this product or its ingredients. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Conditions to Avoid: Store below 25°C (Room temperature), in a dry place.

Incompatibilities: No information.

Hazardous Decomposition Products: Under normal conditions of storage and use, hazardous decomposition products should not be produced. In the event of fire: see section 5.

Section 11 - Toxicological Information

Data for ingredients

Acute toxicity:	No data
Skin corrosion/irritation:	No data
Serious eye damage/eye irritation:	No data
Respiratory or skin sensitisation:	Amoxicillin trihydrate: Res. Sens. 1 Classification description: H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Classification key study: Contact Sensitisation R-PHRASES: R43. [sigma aldrich]Respiratory Sensitisation R-PHRASES: R42. [sigma aldrich] Amoxicillin trihydrate: Skin Sens. 1 Classification description: H317: May cause an allergic skin reaction. Classification key study: Contact Sensitisation R-PHRASES: R43. [sigma aldrich]Respiratory Sensitisation R-PHRASES: R42. [sigma aldrich]
Germ cell mutagenicity:	No data
Carcinogenicity:	No data
Reproductive toxicity:	No data
Specific target organ toxicity-single exposure:	No data

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**Specific target organ toxicity-
repeated exposure:****Potassium clavulanate:**

STOT Rep. Exp. 2

Classification description:

H373: May cause damage to organs through prolonged or repeated exposure.

Classification key study:

Repeated dose toxicity

Oral Route

A 28 and 90 day oral toxicity study with potassium clavulanate performed both in the rat and in the dog. Clinical, biochemical, and haematological effects, reduced weight gain, gastrointestinal irritation and liver toxicity were observed.

In the rat the most sensitive indicators of potassium clavulanate effects were decreased urine output and increased osmolarity and increased white blood cell count. In the dog, clinical signs (emesis, salivation) and hepatocyte hydropic changes were observed. In both species the LOEL and NOEL in 90 day studies were 50 and 20 mg/kg bw. Caecal enlargement was observed in the rat at a lower dose level (LOEL and NOEL 20 and 10mg/kg bw in the 90 day study).

[EMEA]

Aspiration hazard:

No data

Section 12 - Ecological Information**Data for ingredients****Aquatic:****Amoxicillin trihydrate:**

Aquatic Acute 1

Classification description:

H400: Very toxic to aquatic life.

Classification key study:

Freshwater Algae And Cyanobacteria

EC50 for freshwater algae: 0.0037 mg/L

REMARK: Refer to data for amoxicillin CAS # 26787-78-0

Aquatic Chronic 1

Classification description:

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

Classification key study:

Freshwater Algae And Cyanobacteria

REMARK: Refer to data for amoxicillin CAS # 26787-78-0

Terrestrial:

No data

Persistence and degradability:

No data

Bioaccumulative:

No data

Mobility in soil:

No data

Section 13 - Disposal Considerations**Disposal:** Dispose of product, packaging and waste at an approved landfill or other equivalent facility.**Section 14 - Transport Information****UN Number:**

3077

UN Proper Shipping Name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Amoxicillin trihydrate).**SAFETY DATA SHEET**

UN Dangerous Goods Class: 9
UN Packaging Group: III
Environmental Hazards: Marine Pollutant
Special Precautions When Transporting The Substance: No information
Transport of Dangerous Goods Pictogram: 

Section 15 - Regulatory Information

HSNO Approval number: Veterinary Medicines (Limited Pack Size, Finished Dose) Group Standard 2020, HSR100757
ACVM registration number: A009737

Section 16 - Other Information

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

Acronyms:

CAS number: Chemical Abstracts Service Registry Number
GHS: Globally Harmonized System
HSNO: Hazardous Substances and New Organisms Act
UN Number: United Nations Number
SWA: Safe Work Australia
TWA: Time Weighted Average
STEL: Short Term Exposure Limit
NOEL: No Observed Effect Level
LOEL: Lowest Observed Effect Level

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.

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