

SAFETY DATA SHEET



1. Identification

Product identifier	Gromax®
Other means of identification	
Synonyms	GROMAX * Maduramicin (CYGRO) * Nicarbazin (CYCARB)
Recommended use of the chemical and restrictions on use	
Recommended use	Veterinary product used for coccidiosis (Feed additive)
Restrictions on use	Not for human use
Details of manufacturer or importer	
Company Name (AU)	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
Tel	1800 814 883
Fax	(02) 8876 0444
Email	australia.animalhealth@zoetis.com
Emergency Phone	1800 814 883 (all hours)
Police and Fire Brigade	Dial 000
If ineffective	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2A
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3

Label elements, including precautionary statements

Hazard symbol(s)



Exclamation mark

Signal word	Warning
Hazard statement(s)	Causes serious eye irritation. Harmful to aquatic life.
Precautionary statement(s)	

Prevention	Wash thoroughly after handling. Avoid release to the environment. Wear eye protection/face protection. Prevent dust accumulation to minimize explosion hazard. Ground/bond container and receiving equipment. Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Response	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards which do not result in classification May form combustible dust concentrations in air.

Supplemental information May be absorbed through the skin and cause systemic effects. May cause slight skin irritation.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Corncob meal	68525-86-0	88.25
Nicarbazin	330-95-0	8
Benzyl alcohol	100-51-6	3
Maduramicin Ammonium	84878-61-5	0.75

4. First-aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
Skin contact	Remove contaminated clothing. Wash off with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Eye contact	Do not rub eyes. Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Personal protection for first-aid responders	IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
Symptoms caused by exposure	Dusts may irritate the respiratory tract, skin and eyes. Coughing. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Mild skin irritation.
Medical attention and special treatment	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂). Apply extinguishing media carefully to avoid creating airborne dust. Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed. Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Special protective equipment and precautions for fire fighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.
Hazchem Code	None.
General fire hazards	May form combustible dust concentrations in air.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.
For emergency responders	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Ensure adequate ventilation. Remove all possible sources of ignition in the surrounding area. Wear appropriate protective equipment and clothing during clean-up. Avoid the generation of dusts during clean-up. Avoid inhalation of dust from the spilled material. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protection recommended in Section 8 of the SDS.
Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Avoid the generation of dusts during clean-up. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Put material in suitable, covered, labeled containers. Clean surface thoroughly to remove residual contamination.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling

Use only with adequate ventilation. Minimise dust generation and accumulation. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Provide appropriate exhaust ventilation at places where dust is formed. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Avoid prolonged exposure. Wear personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks and open flame. Do not store in direct sunlight. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
Benzyl alcohol (CAS 100-51-6)	TWA	22 mg/m3	Vapor and aerosol.
		5 ppm	Vapor and aerosol.

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

No exposure standards allocated.

Control banding approach

Nicarbazin: Zoetis OEB 1 (control exposure to the range of 1000 ug/m3 to 3000 ug/m3)

Maduramicin Ammonium: Zoetis OEB 3 - Skin, Severe Eye Irritant (control exposure to the range of 10ug/m3 to < 100ug/m3, provide additional precautions to protect from skin contact)

Appropriate engineering controls

Provide adequate general and local exhaust ventilation. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection

Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection

Wear appropriate chemical resistant gloves.

Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. If engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL (occupational exposure limit), suitable respiratory protection must be worn. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	Powder.
Physical state	Solid.
Form	Powder.
Colour	Yellow. - Brown.
Odour	None.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	265 - 267 °C (509 - 512.6 °F)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other physical and chemical parameters	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.

Conditions to avoid	Contact with incompatible materials. Sunlight. Avoid dispersion as a dust cloud. Minimise dust generation and accumulation. Keep away from heat, spark, open flames and other sources of ignition.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on possible routes of exposure

Inhalation Dust may irritate respiratory system. Prolonged inhalation may be harmful.

Skin contact Dust or powder may irritate the skin. May be absorbed through the skin and cause systemic effects.

Benzyl alcohol Species: Guinea Pig
Severity: Moderate

Maduramicin Ammonium Species: Rabbit
Severity: Irritant

Benzyl alcohol Species: Rabbit
Severity: Minimal

Eye contact Causes serious eye irritation.

Nicarbazin Result: Irritant
Species: Rabbit

Maduramicin Ammonium Species: Rabbit
Severity: Severe irritant

Benzyl alcohol Species: Rabbit
Severity: Severe

Ingestion May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to exposure Dusts may irritate the respiratory tract, skin and eyes. Coughing. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Mild skin irritation.

Acute toxicity May be harmful if swallowed.

Product	Species	Test results
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Gromax®

Acute

Dermal

ATE 8333 mg/kg

Oral

ATE 4167 mg/kg

Components	Species	Test results
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Benzyl alcohol (CAS 100-51-6)

Acute

Dermal

LD50 Rabbit 2000 mg/kg

Inhalation

LC50 Rat > 4.178 mg/l
1000 mg/l, 8 Hours

Oral

LD50 Mouse 1580 mg/kg
Rat 1230 mg/kg

Components	Species	Test results
Maduramicin Ammonium (CAS 84878-61-5)		
Acute		
Dermal		
LD50	Rat	71 mg/kg
Oral		
LD50	Rat	35 mg/kg
Chronic		
Oral		
NOAEL	Dog	12 mg/kg/day, 28 days (Target organs: None identified) 0.2 mg/kg/day, 1 years (Target organs: Eyes)
	Mouse	> 5 mg/kg/day, 2 years (Not carcinogenic)
	Rat	> 8 mg/kg/day, 28 days (No effects at maximum dose) 3 mg/kg/day, 90 days (Target organs: None identified) 0.1 mg/kg/day, 2 years (Not carcinogenic; Target organs: Thyroid)
Nicarbazin (CAS 330-95-0)		
Chronic		
Oral		
NOAEL	Dog	240 mg/kg/day, 2 years (Target organs: liver)
	Rat	400 mg/kg/day, 2 years (Highest dose tested)
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Corrosivity		
Maduramicin Ammonium	Species: Rabbit Severity: Irritant	
Serious eye damage/irritation	Causes serious eye irritation.	
Eye contact		
Nicarbazin	Result: Irritant Species: Rabbit	
Maduramicin Ammonium	Species: Rabbit Severity: Severe irritant	
Benzyl alcohol	Species: Rabbit Severity: Severe	
Respiratory or skin sensitisation		
Respiratory sensitisation	Not a respiratory sensitizer.	
Skin sensitisation	This product is not expected to cause skin sensitisation.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Maduramicin Ammonium	In Vitro Chromosome Aberration Result: negative Species: Chinese Hamster Ovary (CHO) cells	
	In Vitro Chromosome Aberration Result: negative Species: Human lymphocytes	

Mutagenicity

Maduramicin Ammonium

In Vitro HGPRT Forward Gene Mutation Assay

Result: negative

Species: Rat Hepatocyte

In Vitro Unscheduled DNA Synthesis

Result: negative

Species: Rat Hepatocyte

In Vivo Direct DNA Damage

Result: negative

Species: Rat

Carcinogenicity

Due to partial or complete lack of data the classification is not possible.

Reproductive toxicity

This product is not expected to cause reproductive or developmental effects.

Developmental effects

Maduramicin Ammonium

0.2 mg/kg/day Embryo / Fetal Development, (No effects at maximum dose)

Result: NOAEL

Species: Rabbit

Organ: Oral

1 mg/kg/day Embryo / Fetal Development, (Maternal Toxicity)

Result: NOAEL

Species: Rat

Organ: Oral

Nicarbazin

200 mg/kg/day Embryo/Fetal Development, (Maternal toxicity, Fetal toxicity)

Result: NOAEL

Species: Rat

Organ: Oral

Reproductivity

Maduramicin Ammonium

1 mg/kg/day 2 Generation Reproductive Toxicity, (Neonatal toxicity)

Result: NOAEL

Species: Rat

Organ: Oral

Nicarbazin

400 mg/kg/day 2-generation, (No significant effects at highest dose tested)

Result: NOAEL

Species: Rat

Organ: Oral

Specific target organ toxicity - single exposure

Not classified.

Specific target organ toxicity - repeated exposure

Not classified.

Aspiration hazard

Not an aspiration hazard.

Chronic effects

Prolonged inhalation may be harmful.

12. Ecological information**Ecotoxicity**

Harmful to aquatic life. Avoid release to the environment.

Components**Species****Test results**

Benzyl alcohol (CAS 100-51-6)

EC50

Daphnia magna (Water Flea)

230 mg/l, 48 Hours

66 mg/l, 21 day(s) Toxicity for reproduction

Pseudokirchneriella subcapitata (Green Alga)

500 mg/l, 72 Hours

Components		Species	Test results
	LC50	Pimephales promelas (Fathead Minnow)	460 mg/l, 96 Hours
Aquatic			
Fish	LC50	Bluegill (Lepomis macrochirus)	10 mg/l, 96 hours
Maduramicin Ammonium (CAS 84878-61-5)			
	EC50	Daphnia magna (Water Flea)	8.1 mg/l, 48 hours
		Pseudokirchneriella subcapitata (Green Alga)	5.8 mg/l, 72 hours
	LC50	Oncorhynchus mykiss (Rainbow Trout)	2 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Biodegradability

Percent degradation (Aerobic biodegradation)

Benzyl alcohol 92 - 96 %
Test Duration: 28 days

Bioaccumulative potential No data available for this product.

**Partition coefficient
n-octanol / water (log Kow)**

Benzyl alcohol 1.1

Mobility in soil No data available for this product.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal methods Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

ADG

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

Safety, health and environmental regulations

National regulations

This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

Poison Schedule (Product) – Schedule 5

APVMA Registration No.: 55130

This SDS replaces version: Issued October 2016

Australia Medicines & Poisons Appendix B

NICABAZIN (CAS 330-95-0)

Australia Medicines & Poisons Appendix J

MADURAMICIN (CAS 84878-61-5)

Australia Medicines & Poisons Schedule 5

MADURAMICIN (CAS 84878-61-5)

Australia Medicines & Poisons Schedule 7

MADURAMICIN (CAS 84878-61-5)

High Volume Industrial Chemicals (HVIC)

Benzyl alcohol (CAS 100-51-6)

10000 - 99999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date	11-September-2017
Key abbreviations or acronyms used	ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).
Disclaimer	Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties Toxicological Information: Toxicological Data Transport Information: Proper Shipping Name/Packing Group GHS: Classification