

Section 1 - Identification of the Substance/Mixture and Supplier

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Product Identifier:	Cycostat 100 Coccidiostat
APVMA Approval No:	66233
Other names:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Robenidine Hydrochloride). Cycostat Robenidine Hydrochloride 10%
Recommended Use:	Feed additive; veterinary product used for coccidiosis.
Restrictions on use	NOT FOR HUMAN USE. For veterinary use only.
Emergency Phone:	1800 814 883 (all hours)

Section 2 - Hazards Identification

Statement of Hazardous Nature

This product is classified as: Xn, Harmful. N, Dangerous to the environment. Hazardous according to the criteria of SWA.

Not subject to the ADG Code when transported in Australia by Road or Rail in packages 500kg or less; or IBCs (refer to Special Provision AU01). However if transported by Air or Sea, this Special Provision does not apply. Then the product is classed as Dangerous Goods (Class 9 Environmentally Hazardous) by IATA and IMDG respectively. See details below and in Section 14 of this SDS.

Risk Phrases: R22, R50/53. Harmful if swallowed. Very toxic to aquatic organisms, may cause long-term adverse effects to the aquatic environment.

Safety Phrases: S20, S22, S36, S61. When using, do not eat or drink. Do not breathe dust. Wear suitable protective clothing. Avoid release to the environment. Refer to special instructions/Safety Data Sheets.

ADG Classification: Class 9: Miscellaneous Dangerous Goods.

GHS Label Elements:



PRECAUTIONARY STATEMENTS

GHS Signal word: WARNING

HAZARD STATEMENT:

H302: Harmful if swallowed.

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

PREVENTION

P102: Keep out of reach of children.

P261: Avoid breathing dusts.

P273: Avoid release to environment

P264: Wash contacted areas thoroughly after handling.

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

P210: Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

RESPONSE

P353: Rinse skin or shower with water.

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

P332+P313: If skin irritation occurs: Get medical advice.

P337+P313: If eye irritation persists: Get medical advice.

P391: Collect spillage.

SAFETY DATA SHEET

P370+P378: In case of fire, use carbon dioxide, dry chemical, foam, water fog. Water fog or fine spray is the preferred medium for large fires.

STORAGE

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

P403+P235: Store in a well-ventilated place. Keep cool.

DISPOSAL

P501: If they can not be recycled, dispose of contents to an approved waste disposal plant and containers to landfill (see Section 13 of this SDS).

Emergency Overview

Physical Description & colour: Grey granular solid

Odour: No data.

Major Health Hazards: harmful if swallowed. 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.

No specific medical attention is advised. Treat symptomatically.

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc,%	TWA (mg/m ³)	STEL (mg/m ³)
Robenidine hydrochloride	25875-50-7	10	not set	not set
Calcium carbonate	1317-65-3	secret	10	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 and is available at all times. Have this SDS with you when you call.

Inhalation: First aid is not generally required. However, if inhalation has occurred, and irritation has developed, remove to fresh air and observe until recovered. If irritation becomes painful or persists more than about 30 minutes, contact a Poisons Information Centre or a doctor.

Skin Contact: Gently brush away excess particles. Irritation is unlikely. However, if irritation does occur, flush with lukewarm, gently flowing water for 5 minutes or until chemical is removed.

Eye Contact: Quickly and gently brush particles 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.

Most Important Symptoms and Effects, both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, see Section 2- Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known.

Indication of the Immediate Medical Attention and Special Treatment Needed:

Notes to Physician: None.

Section 5 - Fire Fighting Measures

Hazards arising from the product: The major hazard in fires is usually inhalation of heated and toxic or oxygen deficient (or both), fire gases. There is little risk of an explosion from this product if commercial quantities are involved in a fire. Only small quantities of decomposition products are expected from this product at temperatures normally achieved in a fire. Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

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Suitable Extinguishing Media: In case of fire, use carbon dioxide, dry chemical, foam, water fog. Water fog or fine spray is the preferred medium for large fires. Try to contain spills, minimise spillage entering drains or water courses.

Special Protective Equipment and Precautions for Firefighters: If a significant quantity of this product is involved in a fire, call the fire brigade. There is little danger of a violent reaction or explosion if significant quantities of this product are involved in a fire. Recommended personal protective equipment is full fire kit and breathing apparatus.

Hazchem Code: 2Z

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures:

Avoid dust formation. Eliminate all sources of ignition and ventilate area using explosion-proof equipment. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions:

Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:

Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labelled container for disposal. Avoid generating airborne dust. Remove or shut off all sources of ignition. Instruct all personnel not involved in cleanup operations to keep at a designated, safe distance. Wear protective clothing and equipment consistent with the degree of hazard. Water can be used for cleanup and decontamination operations. No specific detoxification procedures have been identified for this substance. Prevent discharge to drains.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately, and report nature of spill due to the environmentally hazardous nature of this product. Clean up operations should only be undertaken by trained personnel.

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: Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labelled containers. Keep away from heat, sparks and flames.

Specific end use(s): No data available

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)

Calcium carbonate

10

not set

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.

Engineering Controls: Explosion-proof Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Ventilation: This product should only be used in a well ventilated area. If natural ventilation is inadequate, use of a fan is suggested.

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: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

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Protective Material Types: We suggest that protective clothing be made from the following materials: cotton, rubber, PVC.

Respirator: If there is a significant chance that dusts are likely to build up in the area where this product is being used, we recommend that you use a suitable Dust Mask.

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

Section 9 - Physical and Chemical Properties:

Appearance:	Grey granular solid
Odour:	No data.
Odour Threshold:	No data.
pH:	No data.
Freezing/Melting Point:	Decomposes before melting.
Boiling Point:	Not applicable.
Flash point:	Does not burn.
Upper Flammability Limit:	Does not burn.
Lower Flammability Limit:	Does not burn.
Autoignition temperature:	Not applicable - does not burn.
Flammability (solid, gas):	Not applicable.
Flammability Class:	Does not burn.
Decomposition Temperature:	No data.
Volatiles:	No specific data. Expected to be low at 100°C.
Vapour Pressure:	Negligible at normal ambient temperatures.
Vapour Density:	Not applicable.
Relative Density:	No data.
Water Solubility:	Slightly soluble.
Solvent Solubility:	No data.
Volatility:	Negligible at normal ambient temperatures.
Evaporation Rate:	Not applicable.
Partition Coefficient (n-octanol/water):	3.3 (log P octanol/water)
Viscosity:	Not applicable.
Autoignition temp:	Not applicable - does not burn.

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.

Stability: Stable under normal conditions of use.

Conditions to Avoid: Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

Incompatibilities: acids, bases, oxidising agents.

Hazardous decomposition products: Only small quantities of decomposition products are expected from this product at temperatures normally achieved in a fire. Combustion forms carbon dioxide, and if incomplete, carbon monoxide and possibly smoke. Water is also formed. Aromatic hydrocarbons tend to form dense clouds of black smoke. May form nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. May form hydrogen chloride gas, other compounds of chlorine. 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

Symptoms caused by Exposure

General Information: May cause irritation, but there is no known significant health risk to humans under normal use situations.

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Routes of exposure: Inhalation, dermal, eye contact.

Symptoms of exposure: No data.

Inhalation:

Short term exposure: Available data indicates that this product is not harmful. However product may be mildly irritating, although unlikely to cause anything more than mild transient discomfort.

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. However product may be mildly irritating, but is unlikely to cause anything more than mild discomfort which should disappear once contact ceases.

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

Eye Contact:

Short term exposure: This product may be irritating to eyes, but is unlikely to cause anything more than mild transient discomfort.

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. Available data shows that this product is harmful, but symptoms are not available. 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.

Classification of Hazardous Ingredients

Ingredient

Risk Phrases

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

Robenidine Hydrochloride: LD₅₀ Oral, Rat 390mg/kg LD₅₀ Dermal, Rabbit = >5000mg/kg
LC₅₀ Inhalation, Rat = >5.2mg/L/4hr

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

Irritation / Sensitization: (Study Type, Species, Severity)

Robenidine hydrochloride

Eye Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

Skin Sensitization - M & K Guinea Pig Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Robenidine hydrochloride

2 Year(s) Dog Oral 13 mg/kg/day NOAEL Liver

84 Week(s) Rat Oral 24 mg/kg/day NOAEL None identified

Respiratory or Skin Sensitisation: Not a sensitiser.

Germ Cell Mutagenicity: Not mutagenic.

Carcinogenicity: Not carcinogenic.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

2 Generation Reproductive Toxicity Rat Oral 500 mg/kg/day NOAEL: No effects at maximum dose

Embryo / Foetal Development Rabbit Oral 20 mg/kg/day NOAEL Foetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Robenidine hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive at cytotoxic levels

Micronucleus Bone Marrow Negative

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.

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Section 12 - Ecological Information

This product is very toxic to aquatic organisms. This product may cause long term adverse effects to the aquatic environment. Very toxic to aquatic organisms, may cause long-term adverse effects to the aquatic environment. This product is not readily biodegradable. However, likely to degrade slowly in the soil or water and not cause long term problems.

Robenidine hydrochloride

Fish: LC₅₀ *Brachydanio rerio* (zebra fish): 0.036mg/L

Algae: EC₅₀ 0.03mg/L

Daphnia: EC₅₀ 0.061mg/L

Toxicity information: No data.

Persistence and degradability: No data.

Bioaccumulative potential: No data.

Mobility in soil: No data.

Other adverse effects: No data.

Section 13 - Disposal Considerations

Disposal: This product may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to separate the contamination in some way. Only if neither of these options is suitable, consider landfill. 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 minimisation be practiced. The best available technology should be utilised to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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 Goods by IATA and IMDG when carried by Air or Sea transport (see details below).

Additional Information:

IMDG and IATA classification:

UN Number: 3077

Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Robenidine Hydrochloride 10%)

Class: 9 – Miscellaneous Dangerous Goods

Marine pollutant: Marine Pollutant

Environmental Hazard: This product is classed as environmentally hazardous. Take appropriate precautions when transporting, handling or cleaning up spills.

Special precaution for user: 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

Poison Schedule: None allocated.

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

Section 16 - Other Information

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

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Acronyms:

ADG Code Australian Code for the Transport of Dangerous Goods by Road and Rail (7th edition)

AICS Australian Inventory of Chemical Substances

SWA Safe Work Australia, formerly ASCC and NOHSC

CAS number Chemical Abstracts Service Registry Number

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Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
IARC	International Agency for Research on Cancer
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
R-Phrase	Risk Phrase
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

This version issued: 19 November 2015 and is valid until December 2018.

Supersedes: None (first issue)

Revision History:

Date of Revision	Reason
19/11/2015	Zoetis Address Update

Contact Points:

Zoetis	1800 814 883
Police and Fire Brigade:	Dial 000

If ineffective:

**Dial Poisons Information Centre
(13 1126 from anywhere in Australia)**

THIS SDS SUMMARISES OUR CURRENT AND BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION ABOUT THE PRODUCT DETAILED IN THIS SDS, AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE FOR THE RECOMMENDED USE. EACH USER OF THE PRODUCT MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THEIR OWN WORKPLACE. IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT ZOETIS.

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" (December 2011)

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Prepared by Kilford & Kilford Pty Ltd

End of Safety Data Sheet

SAFETY DATA SHEET