

SAFETY DATA SHEET



1. Identification

Product identifier Robenz®

Other means of identification
Synonyms ROBENZ® MEDICATED PREMIX * Robenidine Hydrochloride Medicated Premix * ROBENZ 66 (6.6%)

Recommended use Veterinary product used for coccidiosis (Feed additive)

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (USA) Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)

Rocky Mountain Poison and Drug Center 1-866-531-8896

Product Support/Technical Services 1-800-366-5288

Emergency telephone numbers CHEMTREC (24 hours): 1-800-424-9300
International CHEMTREC (24 hours): +1-703-527-3887

Company Name (CA) Zoetis Canada Inc.
16740 Trans-Canada Highway
Kirkland, Quebec, H9H 4M7

Emergency telephone number International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail productsupport@zoetis.com

Product Support 1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

Supplier Not available.

2. Hazard(s) identification

Physical hazards Combustible dusts Category 1

Health hazards Not classified.

Environmental hazards Hazardous to the aquatic environment, acute hazard Category 1
Hazardous to the aquatic environment, long-term hazard Category 1

Label elements



Signal word Warning

Hazard statement May form combustible dust concentrations in air. Very toxic to aquatic life with long lasting effects.

Precautionary statement
Prevention Prevent dust accumulation to minimize explosion hazard. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Avoid release to the environment. Observe good industrial hygiene practices.

Response	Take off contaminated clothing and wash it before reuse. In case of fire: Use appropriate media to extinguish. Collect spillage.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards	None known.
Supplemental information	Dusts may irritate the respiratory tract, skin and eyes.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Soybean meal		68308-36-1	80-90
Robenidine Hydrochloride		25875-50-7	6.6
Oil, Mineral		8042-47-5	<5
Silica		7631-86-9	<5

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. 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	Wash off with soap and water. Get medical attention if irritation develops and persists. Take off contaminated clothing and wash 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	IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell. Rinse mouth. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions. If ingestion of a large amount does occur, call a poison control centre immediately.
Most important symptoms/effects, acute and delayed	Dusts may irritate the respiratory tract, skin and eyes. Exposure may cause temporary irritation, redness, or discomfort. Coughing.
Indication of Immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed.
General information	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. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂). Apply extinguishing media carefully to avoid creating airborne dust.
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 firefighters	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. Use water spray to cool unopened containers. During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	May form combustible dust concentrations in air. Fine particles (such as mists) may fuel fires/explosions.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Ventilate the contaminated area. Wear appropriate protective equipment and clothing during clean-up. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Avoid the generation of dusts during clean-up. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Collect spill with an inert, non-combustible absorbent material and transfer to labeled container for disposal. Clean contaminated surface thoroughly. Prevent release to the environment.

Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions

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

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.

7. Handling and storage

Precautions for safe handling

Wear appropriate personal protective equipment. Provide 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. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Do not breathe dust. Provide appropriate exhaust ventilation at places where dust is formed. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. Keep away from heat and sources of ignition. Keep containers tightly closed in a dry, cool and well-ventilated place. < 25C / 77F. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Oil, Mineral (CAS 8042-47-5)	TWA	5 mg/m ³	Inhalable fraction.

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Oil, Mineral (CAS 8042-47-5)	STEL	10 mg/m ³	Mist.
	TWA	5 mg/m ³	Mist.

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Oil, Mineral (CAS 8042-47-5)	TWA	1 mg/m ³	Mist.
Silica (CAS 7631-86-9)	TWA	4 mg/m ³	Total
		1.5 mg/m ³	Respirable.

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value	Form
Oil, Mineral (CAS 8042-47-5)	TWA	5 mg/m ³	Inhalable fraction.

Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value	Form
Oil, Mineral (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.
Silica (CAS 7631-86-9)	TWA	6 mg/m3	Respirable dust.
Biological limit values	No biological exposure limits noted for the ingredient(s).		
Control banding approach	Robenidine hydrochloride: Zoetis OEB 1 (control exposure to the range of 1000ug/m3 to 3000ug/m3)		
Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. 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, such as personal protective equipment			
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.		
Skin protection			
Hand protection	Wear protective gloves.		
Other	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.		
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. 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. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.		
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.		
General hygiene considerations	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

Physical state	Solid.
Form	Powder.
Colour	White
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
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 Information	
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. Keep away from heat, sparks and open flame. Minimise dust generation and accumulation. Dust may form explosive mixture with air. Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. May include hydrogen chloride.

11. Toxicological information

Information on likely routes of exposure

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

Skin contact Dust or powder may irritate the skin.

Oil, Mineral
Species: Rabbit
Severity: Slight

Eye contact Dust may irritate the eyes.

Robenidine Hydrochloride
Species: Rabbit
Severity: Non-irritating

Oil, Mineral
Species: Rabbit
Severity: Slight

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Dusts may irritate the respiratory tract, skin and eyes. Exposure may cause temporary irritation, redness, or discomfort. Coughing.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel. Dusts may irritate the respiratory tract, skin and eyes.

Product	Species	Test results
Robenz®		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg (Calculated ATE)

Components	Species	Test results
Oil, Mineral (CAS 8042-47-5)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
Robenidine Hydrochloride (CAS 25875-50-7)		
Acute		
Dermal		
LD50	Rabbit	> 5000 mg/kg
Inhalation		
LC50	Rat	> 5.2 mg/l
Oral		
LD50	Rat	390 mg/kg
Chronic		
Oral		
NOAEL	Dog	13 mg/kg/day, 2 years (Liver)
	Rat	24 mg/kg/day, 84 weeks (None identified)
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Corrosivity		
Oil, Mineral	Species: Rabbit	Severity: Slight
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye contact		
Robenidine Hydrochloride	Species: Rabbit	Severity: Non-irritating
Oil, Mineral	Species: Rabbit	Severity: Slight
Respiratory or skin sensitisation		
Respiratory sensitisation	Not a respiratory sensitizer.	
Skin sensitisation	This product is not expected to cause skin sensitisation.	
Skin sensitisation		
Robenidine Hydrochloride	Species: Guinea Pig	Severity: negative
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Robenidine Hydrochloride	Bacterial Mutagenicity (Ames)	Result: negative
	Species: Salmonella , E. coli	
	Chromosome Aberration	Result: Positive at cytotoxic levels
	Species: Chinese Hamster Ovary (CHO) cells	
	Micronucleus	Result: negative
	Species: Bone marrow	
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
ACGIH Carcinogens		
Oil, Mineral (CAS 8042-47-5)	A4 Not classifiable as a human carcinogen.	
Canada - Manitoba OELs: carcinogenicity		
Oil, Mineral (CAS 8042-47-5)	Not classifiable as a human carcinogen.	

IARC Monographs. Overall Evaluation of Carcinogenicity

Oil, Mineral (CAS 8042-47-5)

3 Not classifiable as to carcinogenicity to humans.

Silica (CAS 7631-86-9)

3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity

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

Developmental effects

Robenidine Hydrochloride

20 mg/kg/day Embryo / Fetal Development, Fetotoxicity
Result: NOAEL
Species: Rabbit
Organ: Oral

Reproductivity

Robenidine Hydrochloride

500 mg/kg/day 2 Generation Reproductive Toxicity, No effects at maximum dose
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.

12. Ecological information

Ecotoxicity Very toxic to aquatic life with long lasting effects. Avoid release to the environment.

Components	Species	Test results
Robenidine Hydrochloride (CAS 25875-50-7)	EC50	Daphnia magna (Water Flea) 0.061 mg/l, 48 Hours
		Scenedesmus subspicatus (Green Alga) 0.03 mg/l, 72 Hours
	LC50	Brachydanio rerio (Zebra fish) 0.036 mg/l, 96 Hours

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

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

Robenidine Hydrochloride 3.3, (Log P, Measured)

Mobility in soil No data available.

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 instructions Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code None known.

Waste from residues / unused products 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

TDG

Not regulated as dangerous goods.

IATA

UN number UN3077
UN proper shipping name Environmentally Hazardous Substance, Solid, n.o.s (Robenidine hydrochloride)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards Yes
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IMDG

UN number UN3077
UN proper shipping name Environmentally Hazardous Substance, Solid, n.o.s (Robenidine hydrochloride), MARINE POLLUTANT (Robenidine hydrochloride)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards
Marine pollutant Yes
EmS F-A, S-F
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

IATA; IMDG



Marine pollutant



General information

IMDG Regulated Marine Pollutant. As of January 1, 2015, materials offered for transport that are classified for transportation only as Marine Pollutants and which are packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 Liters or less for liquids or having a net mass per single or inner packaging of 5 kilograms or less for solids are NOT subject to ICAO/IATA, IMDG, or ADR transport regulations provided the general packaging requirements of those regulations are met. Refer to ICAO/IATA A197, IMDG 2.10.2.7, ADR SP 375. Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

15. Regulatory information

Canadian regulations

This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

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)	Yes
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)	Yes
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
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 30-March-2017

Version No. 01

List of abbreviations 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 Product and Company Identification: Synonyms
 Composition / Information on Ingredients: Ingredients
 Physical & Chemical Properties: Multiple Properties
 Toxicological Information: Toxicological Data
 Transport Information: Material Transportation Information
 GHS: Classification

