



MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF PRODUCT AND COMPANY

Pfizer Inc
Pfizer Animal Health
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New York, NY 10017

Emergency telephone 1-866-531-8896
Hours of operation 24 Hours
Telephone 1-800-366-5288

Trade names VALBAZEN® SUSPENSION
Product Name Albendazole suspension
Therapeutic use Anthelmintic
Description Odorless, white, smooth, uniform liquid suspension

SECTION 2 - COMPOSITION

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Albendazole*	54965-21-8	<12.0%
Benzoic Acid*	65-85-0	Proprietary
Glycerin*	56-81-5	Proprietary
Magnesium aluminum silicate*	1327-43-1	Proprietary
Polysorbate 80 - NF	9005-65-6	Proprietary
Potassium sorbate*	590-00-1	Proprietary
Simethicone	8050-81-5	Proprietary
Sodium carboxymethyl cellulose USP	9004-32-4	Proprietary
Sorbitan monolaurate	1338-39-2	Proprietary

*Hazardous

Note: Ingredient(s) indicated as hazardous have been assessed under US OSHA Hazard Communication Standard for workplace safety (29 CFR 1910.1200).

SECTION 3 - HAZARDS IDENTIFICATION

Signal word WARNING!

Statements of hazard REPRODUCTIVE HAZARD

MAY CAUSE BLOOD, LIVER, OR TESTICULAR EFFECTS

Eye effects Active ingredient is not an irritant (based on animal data). May cause irritation based on components.

Skin effects Active ingredient is not a skin irritant (based on animal data). May cause irritation based on components. May cause allergic skin reaction based on components.

SECTION 3 - HAZARDS IDENTIFICATION ... continued

Inhalation effects	An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion effects	See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section.
Known clinical effects	Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache.
Other potential health effects	While incidental administration to mothers during the first trimester of pregnancy was without adverse effects on offspring, albendazole has caused teratogenic effects in animals and is considered to be a reproductive hazard.
NOTE:	This document has been prepared in accordance with the US OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace. If your workplace is regulated by OSHA, this document must be used as a part of a complete hazard-training program.

SECTION 4 - FIRST AID MEASURES

Skin	Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.
Eyes	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
Ingestion	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

SECTION 5 - FIRE FIGHTING MEASURES

General hazard	Toxic or corrosive emissions may be given off in a fire.
Fire fighting instructions	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.
Extinguishing media	Use water, carbon dioxide, foam or dry chemical extinguishers.
Flash point	Not applicable
Hazardous combustion products	Not known

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General	Review Sections 3, 8 and 12 before proceeding with clean up.
Small spill	Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly. Prevent discharge to drains.
Large spill	Use appropriate containment to avoid environmental contamination. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Close container and move it to a secure holding area.

SECTION 7 - HANDLING AND STORAGE

General handling	Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Use only in a well-ventilated area. Avoid breathing dust, vapor or mist.
Storage conditions	Avoid prolonged storage at elevated temperatures (greater than room temperature, approximately 20 degrees C). Keep in tightly closed containers or packages away from moisture. Protect from freezing.
Temperature range for storage	Store at room temperature 15-30°C (59-86°F)

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits			
<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Albendazole	Pfizer	TWA-8 HR	0.8 mg/m ³
Glycerin	OSHA	TWA-8 Hr	5 mg/m ³ (respirable fraction)
	OSHA	TWA-8 Hr	15 mg/m ³ (total dust)
	ACGIH	TWA-8 Hr	10 mg/m ³ (mist)
Exposure information	The exposure limit(s) listed for solid components are only relevant if dust may be generated.		
Measurement method	Albendazole: CAM-KAS-97-08 (contact Pfizer for additional details).		
Ventilation	Engineering controls should be used as the primary means to control exposures.		
Respiratory protection	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.		
Eye protection	Wear safety glasses with sasheshields if eye contact is possible.		

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ... continued

Skin protection	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. Wash hands and arms thoroughly after handling this material.
Hand protection	Wear protective gloves to avoid routine skin contact.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form	Suspension
Color	White
Odor	Odorless
Molecular weight	Mixture
Molecular formula	Mixture
pH	No data available
Boiling point	Not applicable
Melting point	No data available
Density	No data available
Vapor pressure	Not applicable
Water solubility	Soluble
Solvent solubility	No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Stable
Conditions to avoid	Avoid extreme temperatures
Incompatibilities	None known
Hazardous decomposition products	No data available
Hazardous polymerization	Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Toxicology summary	The information included in this section describes the potential hazards of the active ingredient, except where noted.
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SECTION 11 - TOXICOLOGY INFORMATION ... continued

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Albendazole	LD ₅₀	Oral	Rat	>1320 mg/kg
	LD ₅₀	Oral	Mouse	>3000 mg/kg
	Irritation	Dermal	Rabbit	500mg:NEG
	Irritation	Ocular	Rabbit	100mg:NEG
Glycerin	Irritation	Dermal	Rabbit	500mg:MLD
	Irritation	Ocular	Rabbit	500mg:MLD

Eye Some irritation may be expected based on components. See Acute toxicity table.

Skin Some irritation may be expected based on components. See Acute toxicity table.

Inhalation No data available

Ingestion See table above

Mutagenicity This material was not mutagenic in bacteria (Ames test) or animal cells (cell-mediated Chinese hamster ovary test).

Sensitization Albendazole is not a sensitizer. Sensitization (allergic skin reaction) may occur, based on effects of individual components.

Subchronic effects Oral administration of up to 1600 mg/kg/day to rats, mice, or dogs in studies of 4-weeks to six months in duration resulted in reduced hematological counts; liver, testes, adrenal and spleen effects; and significant mortality in rats and mice at 168 and 1600 mg/kg/day, respectively.

**Chronic effects/
carcinogenicity** In a two-year oral administration study in mice with doses up to 400 mg/kg/day, histopathologic changes in the testes of males and in the liver of males and females were noted at 400 and at both the 100 and 400 mg/kg/day dose levels, respectively.
A two-generation feeding study was conducted in rats, with the second (F₁) generation receiving up to 20 mg/kg/day for 28 months. There were no effects noted in the first generation (F₀), however, reduced hematologic counts and effects on testes and liver were observed in the high-dose F₁ animals.

Carcinogen status None of the components of this formulation is listed as a carcinogen by IARC, NTP or OSHA.

Reproductive effects Rat reproductive toxicity studies showed only minimal effects on male and female reproduction.

Teratogenicity Teratogenic effects (birth defects) and/or toxicity to developing offspring occurred in studies with rats, rabbits, sheep and swine at doses as low as 5 to 10 mg/kg.

Target organs Hematological system, testes, liver

SECTION 11 - TOXICOLOGY INFORMATION ... continued

At increased risk from exposure	This material produced developmental toxicity in studies with animals. Over exposure during pregnancy might have an adverse effect on developing offspring.
Additional information	FDA PREGNANCY CATEGORY C. Animal studies have shown adverse effects on the fetus. There are no adequate and well-controlled studies in pregnant women.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview	In the environment, the active ingredient in this formulation is expected to bind to soil or sediment and not persist. Harmful effects to aquatic organisms could occur.		
Mobility, persistence, and degradability:	The active ingredient in this formulation is expected to bind to soil, sediment, or with solids in a wastewater treatment facility and degrade rapidly when exposed to sunlight. [Half-life < 1/2 day in sunlight.]		
Bioaccumulation and toxicity:	Acute toxicity to aquatic organisms may occur. The active ingredient in this formulation has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. See aquatic toxicity data, below.		
Aquatic toxicity	<u>Compound</u> Glycerin	<u>Type</u> LC50/96h	<u>Species</u> Rainbow Trout
			<u>Dosage</u> 50-67 mg/L
Log P (octanol/water partition coefficient)	2.7 (albendazole)		
Adsorption Coefficient (Koc)	7800 - 27500 (albendazole)		

SECTION 13 - DISPOSAL INFORMATION

Disposal procedure	Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.
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SECTION 14 - TRANSPORTATION INFORMATION

General shipping instructions	Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
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SECTION 15 - REGULATORY INFORMATION

EU Classification	Substance toxic to reproduction, Category 2
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SECTION 15 - REGULATORY INFORMATION ... continued

EU Labelling**T****EU Label Pictogram(s)****Risk phrases**

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

R61 - May cause harm to the unborn child.

Safety phrases

S53 - Avoid exposure - obtain special instructions before use.

Canadian WHMISClass D, Division 2, Subdivision A

SECTION 16 - OTHER

Disclaimer

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.