MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF PRODUCT AND COMPANY

Pfizer Inc  
Pfizer Animal Health  
235 East 42nd Street  
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

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

*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

<table>
<thead>
<tr>
<th>Compound</th>
<th>Issuer</th>
<th>Type</th>
<th>OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albendazole</td>
<td>Pfizer</td>
<td>TWA-8 HR</td>
<td>0.8 mg/m³</td>
</tr>
<tr>
<td>Glycerin</td>
<td>OSHA</td>
<td>TWA-8 Hr</td>
<td>5 mg/m³ (respirable fraction)</td>
</tr>
<tr>
<td></td>
<td>OSHA</td>
<td>TWA-8 Hr</td>
<td>15 mg/m³ (total dust)</td>
</tr>
<tr>
<td></td>
<td>ACGIH</td>
<td>TWA-8 Hr</td>
<td>10 mg/m³ (mist)</td>
</tr>
</tbody>
</table>

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 sideshields 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical form</td>
<td>Suspension</td>
</tr>
<tr>
<td>Color</td>
<td>White</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Molecular formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Soluble</td>
</tr>
<tr>
<td>Solvent solubility</td>
<td>No data available</td>
</tr>
</tbody>
</table>

SECTION 10 - STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Stable</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Avoid extreme temperatures</td>
</tr>
<tr>
<td>Incompatibilities</td>
<td>None known</td>
</tr>
<tr>
<td>Hazardous decomposition</td>
<td>No data available</td>
</tr>
<tr>
<td>Hazardous polymerization</td>
<td>Will not occur</td>
</tr>
</tbody>
</table>

SECTION 11 - TOXICOLOGY INFORMATION

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

## Acute toxicity

<table>
<thead>
<tr>
<th>Compound</th>
<th>Type</th>
<th>Route</th>
<th>Species</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albendazole</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Oral</td>
<td>Rat</td>
<td>&gt;1320 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Oral</td>
<td>Mouse</td>
<td>&gt;3000 mg/kg</td>
</tr>
<tr>
<td>Irritation</td>
<td>Dermal</td>
<td></td>
<td>Rabbit</td>
<td>500 mg: NEG</td>
</tr>
<tr>
<td>Irritation</td>
<td>Ocular</td>
<td></td>
<td>Rabbit</td>
<td>100 mg: NEG</td>
</tr>
<tr>
<td>Glycerin</td>
<td>Irritation</td>
<td>Dermal</td>
<td>Rabbit</td>
<td>500 mg: MLD</td>
</tr>
<tr>
<td></td>
<td>Irritation</td>
<td>Ocular</td>
<td>Rabbit</td>
<td>500 mg: MLD</td>
</tr>
</tbody>
</table>

### 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 (F<sub>1</sub>) generation receiving up to 20 mg/kg/day for 28 months. There were no effects noted in the first generation (F<sub>0</sub>), however, reduced hematologic counts and effects on testes and liver were observed in the high-dose F<sub>1</sub> 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
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

<table>
<thead>
<tr>
<th>Compound</th>
<th>Type</th>
<th>Species</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin</td>
<td>LC50/96h</td>
<td>Rainbow Trout</td>
<td>50-67 mg/L</td>
</tr>
</tbody>
</table>

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.

SECTION 14 - TRANSPORTATION INFORMATION

General shipping instructions

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15 - REGULATORY INFORMATION

EU Classification

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

<table>
<thead>
<tr>
<th>EU Labelling</th>
<th>T</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU Label Pictogram(s)</td>
<td><img src="image" alt="Pictogram" /></td>
</tr>
</tbody>
</table>

**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 WHMIS**
- Class 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.