SAFETY DATA SHEETS

This SDS packet was issued with item:

078056544

N/A

Merck Animal Health
One Merck Dr.
Whitehouse Station, NJ 08889

MATERIAL SAFETY DATA SHEET

Merck Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: **20% Fenbendazole Suspension**

SYNONYM(S): PANACUR AQUASOL
SAFE-GUARD
Suspension de Fenbendazole a 20%

MSDS NUMBER: SP002033

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)
Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

MERCK MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Suspension
White to off-white
Odor unknown
May be irritating to eyes, skin or respiratory tract.
May cause developmental effects.
May cause effects to:
liver
gastrointestinal tract
immune system
blood
central nervous system
fetus
Very toxic to aquatic organisms.
May cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS:

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

The active ingredient fenbendazole is a benzimidazole carbamate anthelmintic that is structurally related to mebendazole. Therapeutic use of mebendazole, a substance of the same chemical class as fenbendazole, has been reported to cause gastrointestinal disturbances (transient abdominal pain), diarrhea, headache, and dizziness. Frequent effects reported after treatment with high-doses of mebendazole have included allergic reactions (fever and skin reactions), raised liver enzyme values, alopecia, bone marrow depression, reduced leucocyte count and raised serum-transaminase values.

A number of oral subchronic and chronic animal studies have been conducted with fenbendazole and have demonstrated that the liver is the main target tissue. In addition, stomach, kidneys, blood, immune system, and central nervous system are also affected by treatment with fenbendazole. Devlopmental effects have been reported in rabbits following treatment with fenbendazole.

Benzyl alcohol is corrosive and irritating at high concentrations. It causes eye irritation and can be absorbed through the skin with anesthetic or irritant effect. Acute exposure to benzyl alcohol may cause nausea, vomiting, diarrhea, central nervous system depression, and dizziness. Inhalation of benzyl alcohol or its vapor may cause irritation of upper respiratory tract. When ingested, benzyl alcohol may produce severe irritation of the gastrointestinal tract, followed by nausea, vomiting, cramps and diarrhea; tissue lesions may result. Chronic exposure to benzyl alcohol has been reported to cause allergic contact inflammation. Its effects are presumed to be similar to those effects observed following acute exposure. Prolonged or excessive inhalation may result in headache, nausea, vomiting, and diarrhea. Respiratory stimulation, respiratory and muscular paralysis, convulsions, narcosis, and death may occur following excessive exposure.

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Veterinary product

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT
Fenbendazole	43210-67-9	20
Benzyl Alcohol	100-51-6	< 10

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

EXPLOSION HAZARDS:
Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed. The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO_2), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

ENVIRONMENTAL PRECAUTIONS:
This product is toxic to aquatic organisms. Do not allow product to reach ground water, water course, sewage or drainage systems.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

MSD is a tradename of Merck & Co., Inc., with headquarters in Whitehouse Station, N.J., U.S.A.

SAFETY DATA SHEET

This SDS was created in accordance with Regulation EC 1907/2006 and all amendments. MSD Animal Health urges each user or recipient of this SDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

PRODUCT IDENTIFIER

SDS NAME: **20% Fenbendazole Suspension**

SYNONYM(S): PANACUR AQUASOL
SAFE-GUARD
Suspension de Fenbendazole a 20%

SDS Number: SP002033

REACH REGISTRATION NUMBER Not available

RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

IDENTIFIED USE(S): Veterinary Product

USE(S) ADVISED AGAINST: None known.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

EU SUPPLIER/MANUFACTURER: MSD Animal Health
Rue de Lyons
27460 IGOVILLE France

INFORMATION: +33 (0)2 32 98 92 70 (MSD Animal Health - Igoville, France)

MERCK SDS HELPLINE: +1 (908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SDS EMAIL: mercksds@merck.com

EMERGENCY TELEPHONE NUMBER

EMERGENCY NUMBER(S): +1 (908) 423-6000 (24/7/365) English Only

EU Transportation Emergencies - Carechem24:
+44 (0)208 762 8322 (24 hours/7 days/week)

SECTION 2. HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to EC Directive 1272/2008:
Repr. 2 (H361d), Aquatic Acute 1 (H400), Aquatic Chronic 2 (H411)

Classification according to EC Directives 67/548/EEC (substances) or 1999/45/EC (mixtures):
Repr.Cat.3;R63 N;R50/53

COLOR: White to off-white
FORM: Suspension
ODOR: Odor unknown

LABEL ELEMENTS

SIGNAL WORD: WARNING

HAZARD STATEMENT(S):
Suspected of damaging the unborn child
Very toxic to aquatic life
Toxic to aquatic life with long lasting effects
PRECAUTIONARY STATEMENT(S):
Use personal protective equipment as required. IF exposed or concerned: Get medical attention/advice. Avoid release to the environment. Collect spillage.

OTHER HAZARDS

Health-Related Hazards:

May cause developmental effects.
May cause effects to:
liver
gastrointestinal tract
immune system
blood
central nervous system
fetus

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by IARC or EU Directive 90/394 (Annex I) in this mixture.

Environmental-Related Hazards:

This substance has not been fully tested to meet the criteria for listing as a PBT or a vPvB.

Other Hazards:

Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed. The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

SUBSTANCE

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EC NUMBER	REACH REGISTRATION NUMBER	EU CLASSIFICATION	GHS CLASSIFICATION	PERCENT	REASON FOR LISTING
Fenbendazole	43210-67-9	256-145-7	Not available	Repr. Cat.3;R63 N;R50-53	Repr. 2 (H361d) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	20	Active Pharmaceutical Ingredient Classified
Benzyl Alcohol	100-51-6	202-859-9	x	Xn; R20/22 R52/53	Acute Tox. 4 (H332) Acute Tox. 4 (H302); Aquatic Chronic 2 (H411)	< 10	Classified Community workplace exposure limit

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

See section 16 for definitions of risk phrases and GHS classifications.

SECTION 4. FIRST AID MEASURES

FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

FIRST AID RESPONDER PROTECTION: Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves with appropriate personal protective equipment. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. DO NOT use mouth-to-mouth method if victim ingested or inhaled the substance.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

The active ingredient fenbendazole is a benzimidazole carbamate anthelmintic that is structurally related to mebendazole. Therapeutic use of mebendazole, a substance of the same chemical class as fenbendazole, has been reported to cause gastrointestinal disturbances (transient abdominal pain), diarrhea, headache, and dizziness. Frequent effects reported after treatment with high-doses of mebendazole have included allergic reactions (fever and skin reactions), raised liver enzyme values, alopecia, bone marrow depression, reduced leucocyte count and raised serum-transaminase values.

A number of oral subchronic and chronic animal studies have been conducted with fenbendazole and have demonstrated that the liver is the main target tissue. In addition, stomach, kidneys, blood, immune system, and central nervous system are also affected by treatment with fenbendazole. Devlopmental effects have been reported in rabbits following treatment with fenbendazole.

Benzyl alcohol is corrosive and irritating at high concentrations. It causes eye irritation and can be absorbed through the skin with anesthetic or irritant effect. Acute exposure to benzyl alcohol may cause nausea, vomiting, diarrhea, central nervous system depression, and dizziness. Inhalation of benzyl alcohol or its vapor may cause irritation of upper respiratory tract. When ingested, benzyl alcohol may produce severe irritation of the gastrointestinal tract, followed by nausea, vomiting, cramps and diarrhea; tissue lesions may result. Chronic exposure to benzyl alcohol has been reported to cause allergic contact inflammation. Its effects are presumed to be similar to those effects observed following acute exposure. Prolonged or excessive inhalation may result in headache, nausea, vomiting, and diarrhea. Respiratory stimulation, respiratory and muscular paralysis, convulsions, narcosis, and death may occur following excessive exposure.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

NOTE TO PHYSICIAN: In cases of overexposure treat supportively and symtomatically.

SECTION 5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO2), extinguishing powder or water spray.

UNSUITABLE EXTINGUISHING MEDIA:
None known.

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

EXPLOSION HAZARDS:
Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed. The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

SPECIAL FIRE HAZARDS:
None known.

ADVICE FOR FIREFIGHTERS

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

PERSONAL PRECAUTIONS:
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

ENVIRONMENTAL PRECAUTIONS:

This product is toxic to aquatic organisms. Do not allow product to reach ground water, water course, sewage or drainage systems.

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY IMCOMPATIBILITIES

STORAGE:
Store in a cool, dry, well ventilated area.

SPECIFIC END USE(S)
Refer to Section 1 for identified use(s).

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation. The end-user should perform an appropriate risk assessment when handling other forms or formulations of this active ingredient.

CONTROL PARAMETERS

OCCUPATIONAL EXPOSURE BAND (OEB):
OEB 2: >=100<1000 mcg/m^3. Materials in an OEB 2 category are considered to be slight health hazards. The OEB is a range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

INTERNAL OCCUPATIONAL EXPOSURE LIMIT (8-hr TWA):
Fenbendazole: 100 mcg/m^3

EXPOSURE LIMIT VALUES:

INGREDIENT	Greece	Poland	Hungary	Croatia	Turkey
Benzyl Alcohol		NDS 240 mg/m^3			

EXPOSURE CONTROLS
The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Body Protection:	In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance. In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.
Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Eye Protection:	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

FORM:	Suspension
COLOR:	White to off-white
ODOR:	Odor unknown
ODOR THRESHOLD:	Not determined
pH:	6-8
BOILING POINT / RANGE:	Not determined
MELTING POINT / RANGE:	Not determined
DECOMPOSITION TEMPERATURE:	Not determined
VAPOR PRESSURE:	Not determined
VAPOR DENSITY:	Not determined
SPECIFIC GRAVITY:	Not determined
SOLUBILITY:	
Water:	Not determined
PARTITION COEFFICIENT (log Pow):	Not determined
VISCOSITY:	Not determined
EVAPORATION RATE:	Not determined
FLAMMABILITY DATA:	
Flash Point:	Not determined (liquids) or not applicable (solids).
Flammability (solid, gas):	Not determined
UEL:	Not determined
LEL:	Not determined
Autoignition Temperature:	Not determined

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under conditions specified in Section 7 of this SDS. No hazardous reactions known.

CONDITIONS AND MATERIALS TO AVOID:
None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

LIKELY ROUTES OF EXPOSURE:
Skin, eye, inhalation, and ingestion.

ACUTE TOXICITY DATA

INHALATION:
No data available.

ORAL:
Fenbendazole: Oral LD50: > 10 g/kg (rat)

Benzyl alcohol: Oral LD50: 1230 mg/kg (rat)

EYE:
Fenbendazole was not irritating to the eyes of rabbits.

Benzyl alcohol was severely irritating to the eyes of rabbits.

SKIN:
Fenbendazole was not irritating to the skin of rabbits.

Benzyl alcohol: Dermal LD50: 2000 mg/kg (rabbit)
Benzyl alcohol was moderately irritating to the skin of guinea pigs and rabbits.

ASPIRATION:
No data available.

DERMAL AND RESPIRATORY SENSITIZATION:
Benzyl alcohol was not a skin sensitizer in guinea pigs.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
A number of oral subchronic and chronic animal studies have been conducted with fenbendazole and have demonstrated that the liver is the main target tissue. In addition, stomach, kidneys, blood, immune system, and central nervous system are also affected by treatment with fenbendazole.

Data in some animal species indicate that the ability of T and B lymphocytes to proliferate in the secondary immune response may be suppressed during treatment with fenbendazole.

High oral dosages (500-3000 mg/kg/day) during 2-week dosing in rats caused reduced body weight gain, and severe renal and liver toxicity. Fenbendazole did not cause treatment-related effects when administered via stomach tube to immature rats at the rate of 0, 25, 250, and 2500 mg/kg b.w./day for 30 days. In a 90- day study, rats administered fenbendazole at 1600 to 2500 mg/kg /day showed tremors. No other treatment-related findings were reported.

Fenbendazole did not cause treatment-related effects in dogs administered oral dosages ranging from 50 to 250 mg/kg/day in a 6-day study, 20 to 125 mg/kg/day in a 90-day study, or 1 to 10 mg/kg/day in a 14-week study. At higher dosages, or in longer term studies, treatment-related effects were observed. Common effects observed in these additional studies include lymph follicle proliferation or nodules in the gastric mucosa. These effects were observed in dogs administered 250 mg/kg/day in a 30-day study, and in dogs given 8 to 20 mg/kg/day in one 6-month study and 20 to 125 mg/kg/day in another 6-month study. In addition to these effects, focal encephalomalacia, satellitosis, neuronophagia, perivascular inflammation or gliosis were observed in the cerebra of three dogs given 125 mg/kg/day for 6 months, and hyperplasia and congestion of the mesenteric lymph nodes were noted in dogs administered 8 to 20 mg/kg/day in the other 6-month study. [NOELS: 30-day Study: 25 mg/kg/day, 6-month Study (high-dose): none established, and 6-month Study (low-dose): 4 mg/kg/day]

Benzyl alcohol caused dose-related effects in rats given oral dosages of 50 to 800 mg/kg/day for 13 weeks. Rats showed reductions in weight gain and also signs of staggering, lethargy, and respiratory difficulty, indicating neurotoxicity at the high dosage. Hemorrhages around the mouth and nose, and histological lesions in the brain, thymus, skeletal muscle, and kidney were also noted. Mice tested under similar conditions exhibited similar effects.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Fenbendazole was found not to be teratogenic when tested in rats, dogs, or rabbits. Developmental effects (abortions, resorptions, and decreased fetal weights) were observed in the absence of maternal toxicity only in rabbits. When used in pigs, sheep, horses, and cattle, no relevant adverse effects on reproductive ability or offspring survival have been noted.

Fendbendazole was administered to rats at dietary dosages ranging from 5 to 135 mg/kg/day in a three-generation reproduction study. Reproductive and/or developmental effects observed in the 45 and 135 and 45 mg/kg/day dosage groups include reduced fertility indices, survival indices, pup weight, and pup growth, as well as diarrhea, yellow color, reduced activity, bloated stomach, and alopecia. These effects were more pronounced in the high-dose group. The NOEL for this study was 15 mg/kg/day for maternal and reproductive toxicity.

The potential embryotoxicity of fenbendazole was evaluated in pregnant rabbits, administered doses via stomach tube of 0, 10, 25, and 63 mg/kg/day on gestation days 7-19. Abortion or resorption of litters was observed in the 63 and 25 mg/kg/day dose groups. An increase in skeletal anomalies (13th rib) and delayed ossification of cranial bones also occurred in the high dose group. The NOEL for this study was 25 mg/kg/day.

Fenbendazole was administered to 2 groups of 12 female dogs at oral doses of 100 mg/kg/day, on gestation days 14-22 or 22-30. Developmental toxicity (stillborn pups and survival indices) were observed. About half the dogs in each group produced litters. No macroscopic abnormalities were observed in pups that died during the study.

Benzyl alcohol did not affect the gestation index, reproductive index, litter size, average litter weight, or postnatal weight gain or survival when given to rats by gavage during days 6 to15 of gestation.

MUTAGENICITY / GENOTOXICITY:
Fenbendazole was negative in a bacterial mutagenicity assay,a chromosomal aberration study, micronucleus, and DNA repair assay. It was weakly positive in the mouse lymphoma assay. Fenbendazole increased the mitotic index of HeLa cells in vitro, an effect that could be related to the ability of benzimidazoles to interfere with tubulin polymerization and thus inhibit spindle formation.

Benzyl alcohol was negative in bacterial mutagenicity study (Ames) and was positive in a mammalian mutagenicity study (mouse lymphoma).

CARCINOGENICITY:
Fenbendazole was not carcinogenic in mice receiving 45 to 405 mg/kg fenbendazole in the diet for 2 years.

A two-year oral carcinogenicity study has been conducted in rats at dose levels of 0, 5, 15, 45, and 135 mg/kg/day. Treatment-related signs reported included diarrhea and red feces (45 mg/kg/day and 135 mg/kg/day) and reddish-brown urine (15, 45, and 135 mg/kg/day). Mortality was not statistically different from controls for any treatment group. Body weights and weight gains at study termination were significantly lower for the 45 and 135 mg/kg/day groups compared with controls. The alkaline phosphatase in all dose groups and SGOT in the high dose group were consistently elevated. Necropsy revealed enlargement or cyst formation in lymph nodes of rats in the two highest dose groups.liver mass and/or nodule formation, cyst formation in the liver of females, and testicular masses among males were reported at the 135 mg/kg/day dose-level.

Further treatment-related effects included sinus ectasia and hyperplasia of the mesenteric lymph nodes in all but the low dose group; Additionally, liver hypertrophy and hyperplasia, hepatocellular cytoplasmic vacuolation, bile duct proliferation, biliary cyst formation , and nodular hepatocellular hyperplasia were reported in female rats at the two highest dose levels. Testicular interstitial cell adenomas in the 135 mg/kg/day male rats were observed. The NOEL for this study was 5 mg/kg/day. Benzyl alcohol was not carcinogenic in a 2 year oral gavage study in rats administered doses of up to 400 mg/kg/day for 5 days a week or in mice at doses up to 200 mg/kg/day for 5 days per week.

Classification according to EC Directive 1272/2008:
Repr. 2 (H361d). Aquatic Acute 1 (H400). Aquatic Chronic 2 (H411).

Classification criteria have not been met for the following endpoints due to lack of data, inconclusive data, technical impossibility to obtain the data, or data which are conclusive although insufficient for classification (available information to support classification criteria is given in Section 4 or Section 11 of this data sheet):
Inhalation toxicity. Dermal toxicity. Eye damage or irritation. Oral toxicity. Skin sensitization. Skin corrosion or irritation. Respiratory sensitization. Mutagenicity. Carcinogenicity. Specific target organ toxicity (STOT) - Single Exposure. Specific target organ toxicity (STOT) - Repeated Exposure. Aspiration hazard.

See Section 4 for human health symptoms and effects.

SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Fenbendazole:
96-hr LC50 (Rainbow trout): >7.5 mg/L
96-hr LC50 (Bluegill sunfish): >1000 mg/L
48-hr EC50 (Daphnia magna): 0.008 - 0.012 mg/L
21-days LC50 (Bluegill sunfish): 0.019 - 0.028 mg/L
BCF (Bluegill sunfish): 240

Benzyl alcohol: 96-hr LC50 (fathead minnow): 460 mg/L
Benzyl alcohol: 96-hr LC50 (bluegill): 10 mg/L
Benzyl alcohol: 48-hr EC50 (daphnid): 400 mg/L
Benzyl alcohol: 96-hr NOEL (E. coli): 1000 ppm

PERSISTENCE AND DEGRADABILITY

Biodegradation Results: Fenbendazole: Expected to degrade.

BIOACCUMULATIVE POTENTIAL

Fenbendazole: Not expected to bioaccumulate.

Partition Coefficient (log Pow) Results: Fenbendazole: 2.3

MOBILITY IN SOIL

This product is expected to be immobile in soil.

Soil Adsorption/Desorption Results: No data available.

PBT and vPvB ASSESSMENT

This product is not expected to be a PBT or vPVB compound..

OTHER ADVERSE EFFECTS

ENVIRONMENTAL FATE AND EFFECTS: No data available.

OTHER INGREDIENT ENVIRONMENTAL DATA: Benzyl alcohol is expected to be readily biodegradable. Benzyl alcohol is characterized as a high risk air pollutant because it may emit toxic vapors when heated.

SECTION 13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT METHODS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

Refer to site-specific procedures and requirements for additional guidance.

IATA/ICAO CLASSIFICATION:

Proper Shipping Name:	Environmentally hazardous substance, liquid, n.o.s. (fenbendazole)
Hazard Class:	9
UN Number:	UN 3082
Packing Group:	III

ADR CLASSIFICATION:

Proper Shipping Name:	Environmentally hazardous substance, liquid, n.o.s. (fenbendazole)

Hazard Class:	9
UN Number:	UN 3082
Packing Group:	III
Classification Code:	M6

IMDG/IMO CLASSIFICATION:

Proper Shipping Name:	Environmentally hazardous substance, liquid, n.o.s. (fenbendazole)
Hazard Class:	9
UN Number:	UN 3082
Packing Group:	III

ADDITIONAL INFORMATION:
Shipment by ground under DOT is non-regulated, however, may be shipped per hazard classification above to facilitate multi-modal transport involving ICAO or IMO.

SECTION 15. REGULATORY INFORMATION

SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Germany, Water Endangering Classes (WGK)

INGREDIENT	Annex 1	Annex 2 - Water Hazard Classes	Annex 3
Fenbendazole	Not listed.	Not listed.	Not listed.
Benzyl Alcohol	Not listed.	216	Not listed.

Ozone Depleting Substance(s)

INGREDIENT	Listing
Fenbendazole	Not listed.
Benzyl Alcohol	Not listed.

Persistent Organic Pollutants

INGREDIENT	Listing
Fenbendazole	Not listed.
Benzyl Alcohol	Not listed.

EU Import and Export Restrictions

INGREDIENT	Requires PIC Notification	Requires Export Notification	Export Ban
Fenbendazole	Not listed.	Not listed.	Not listed.
Benzyl Alcohol	Not listed.	Not listed.	Not listed.

SEVESO II EU Directive

INGREDIENT	Listing
Fenbendazole	Not listed.
Benzyl Alcohol	Not listed.

REACH

INGREDIENT	Subject to Authorization	Candidate List for Authorization	Potential Substances of High Concern	Restrictions
Fenbendazole	Not listed.	Not listed.	Not listed.	Not listed.
Benzyl Alcohol	Not listed.	Not listed.	Not listed.	Not listed.

CHEMICAL SAFETY ASSESSMENT

A Chemical Safety Assessment has not been done.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

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SUPERSEDES DATE: 07-May-2009

SIGNIFICANT CHANGES (EU SUBFORMAT): New regional format

DEFINITIONS (referred to under Sections 2 and 3):

CLP Classifications:	• Repr. 2 (H361d) • Aquatic Acute 1 (H400) • Aquatic Chronic 2 (H411) • Acute Tox. 4 (H302) - Harmful if swallowed. • Acute Tox. 4 (H332) - Harmful if inhaled. • Aquatic Chronic 1 (H410) - Very toxic to aquatic life with long lasting effects.	• Suspected of damaging the unborn child • Very toxic to aquatic life • Toxic to aquatic life with long lasting effects
Risk Phrases:	• R63 - Possible risk of harm to the unborn child. • R20/22 - Harmful by inhalation and if swallowed. • R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. • R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	

GLOSSARY:
IARC - International Agency for Research on Cancer, IARC Group 1 or 2A.
NTP - National Toxicology Program
ACGIH - American Conference of Governmental Industrial Hygienists
ADR - International Carriage of Dangerous Goods by Road
API - Active Pharmaceutical Ingredient
CAS - Chemical Abstract Service
CLP - Classification, Labeling and Packaging
DOT - Department of Transportation
EC - European Council
ETAC - Estimated Target Airborne Concentration
GHS - Globally Harmonized System
HEPA - High Efficiency Particulate Arresting
HHC - Health Hazard Category
HPA - Hypothalamic Pituitary Adrenal
IATA - International Air Transport Association
IMO - International Maritime Organization
IP - Intraperitoneal Injection
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%
LOEL - Lowest Observed Effect Level
NEL - No Effect Level
NOAEL - No Adverse Effect Level
NOEL - No Observe Effect Level
OEG - Occupational Exposure Guideline
PBT - Persistent BioaccumulativeToxic
PG - Packing Group
PIC - Prior Informed Consent
PPE - Personal Protective Equipment
REACH - Registration, Evaluation, Authorization and Restriction of Chemical Substances
RPE - Respiratory Protective Equipment
SCBA - Self Contained Breathing Apparatus
STOT - Specific Target Organ Toxicity
TSCA - Toxic Substances Control Act
TWA - Time Weighted Average
UN - United Nations
vPvB - Very Persistent andVery Bioaccumulative
WGK - Water Hazard Class (Germany)