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: **PANACUR Paste**

SYNONYM(S):
Panacure Paste 10% (Flavored)
Safe-Guard Paste 10% (Flavored)
Panacure Paste 18.75%
Panacure Pet Paste
Axilure Paste
Panacure Paste 18.75% (Flavored)
Equiworm
Axilur Paste (Flavored)
Panacur Equinos
Panacure PA 10% FLAV
Panacure PA 18.75%
Panacure PA 18.75% Aromatise
Panacure Paste

MSDS NUMBER: SP002089

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

Paste
White to off-white
Apple Cinnamon
May be irritating to skin and eyes.
May cause skin sensitization in sensitive individuals.
May cause effects to:
liver
kidney
gastrointestinal tract
stomach
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). Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) are presented.

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.

Propylene glycol is considered to be relatively non-toxic. It is a mild irritant to the eyes and has been reported to irritate the skin. It may cause skin sensitization resulting in allergic contact dermatitis in susceptible individuals. Inhalation exposure to saturated and supersaturated atmospheres of propylene glycol for prolonged periods of time produced no adverse effects. Propylene glycol may cause nervous system depression, acidosis, stupor, and seizures after chronic ingestion.

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

CHEMICAL FAMILY: Anthelmintic

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.

This formulation may contain some sodium hydroxide for pH adjustment.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT

Propylene Glycol	57-55-6	10-20
Glycerin	56-81-5	<10
Sorbitol	50-70-4	<10
Fenbendazole	43210-67-9	10-18.75

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. This material has been shown by standard laboratory testing to exhibit a low sensitivity to ignition by electrostatic discharges. However, all large conductive items used during processing of 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 (CO2), 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.

STORAGE:
Store below 25 deg C. Store in adequately sealed container.

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.

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 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):

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.
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.
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.
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.

EXPOSURE LIMIT VALUES

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Glycerin	56-81-5	10 mg/m^3	15 mg/m^3

See Internal Occupational Exposure Limit listed above.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Paste
COLOR: White to off-white
ODOR: Apple Cinnamon
pH: 6-8
SOLUBILITY:
Water: Insoluble

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
Strong Oxidizers.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Carbon oxides (COx).

SECTION 11. TOXICOLOGICAL INFORMATION

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

ACUTE TOXICITY DATA

INHALATION:
Propylene glycol caused no adverse effects in monkeys or rats following exposure to saturated atmospheres for prolonged periods of time.

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

Propylene glycol: Dermal LD50: 20.8 g/kg (rabbit)
Propylene glycol was irritating in a human patch test. Propylene glycol was not irritating to the skin of rabbits, guinea pigs and swine.

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

Propylene glycol was slightly irritating to the eyes of rabbits.

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

Propylene glycol: Oral LD50: 21 to 33.7 g/kg (rat), 10 to 20 g/kg (dog)
Propylene glycol caused dyspnea, cramps, loss of equilibrium, depression, analgesia, and death after prolonged moribund state in mice at doses ranging from 23.9 to 31.8 g/kg. In rabbits, 1 to 1.5 g/kg propylene glycol reduced intraocular pressure by raising the osmotic pressure of blood.

DERMAL AND RESPIRATORY SENSITIZATION:
Propylene glycol did not cause sensitization in a human patch test.

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]

Propylene glycol caused no adverse effects in monkeys or rats exposed to saturated vapor concentrations for 12 to 18 months. Rats exposed to 25 or 50% (7.7 and 13.2 g/kg/day) propylene glycol in water died within 69 days in a 140 day study. In a separate study, a diet of 30% propylene glycol was not well tolerated in young rats, and dams could not bring their young to weaning; diets containing 40, 50, or 60% propylene glycol were lethal after a few days.

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.

Propylene glycol caused decreased food consumption, retarded growth, smaller litters, changes in breeding patterns, and inhibited weaning in rats that were fed 30% propylene glycol through six generations; however, this may have been due to nutritional insufficiency. Propylene glycol was not teratogenic in rabbits, monkeys or chickens.

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.

Propylene glycol was negative in a bacterial mutagenicity study (Ames).

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. Propylene glycol was not carcinogenic when applied to the skin, or when given orally in mice and rats.

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

Propylene glycol: 96-hr LC50 (sheepshead minnow): 23,800 mg/L
Propylene glycol: 48-hr EC50 (daphnid): >43,500 mg/L
Propylene glycol: 72-hr EC50 (green algae): >19,000 mg/L
Propylene glycol is expected to be readily biodegradable.

ENVIRONMENTAL DATA

Partition Coefficient (log Pow) Results:	Fenbendazole: 2.3
Biodegradation Results:	Fenbendazole: Expected to degrade.

OTHER INGREDIENT ENVIRONMENTAL DATA: Propylene glycol is expected to be readily biodegradable.

SECTION 13. DISPOSAL CONSIDERATIONS

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.

DOT CLASSIFICATION:

Non-regulated per 49 CFR 171.4(c) for ground shipment.

IATA/ICAO CLASSIFICATION:

This classification only applies in a transport chain to/from a country which regulates this material as an environmentally hazardous substance. For all other air shipments, this material is non-regulated.

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

ADR CLASSIFICATION:

ADR Special Provision 601 exempts pharmaceutical products which are also environmentally hazardous substances from all ADR regulation.

Per ADR special provision 601, as a pharmaceutical product (medicine) ready for use, this material is not regulated as a dangerous good for transport within Europe.

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

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

INGREDIENT	TSCA
Propylene Glycol	X
Glycerin	X
Sorbitol	X

Substances not included in the table above are TSCA exempt or not regulated under TSCA.

U.S. STATE REGULATIONS

INGREDIENT	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Propylene Glycol			3595		
Glycerin			3319		X

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Propylene Glycol	X	X		X
Glycerin	X	X		X

Fields in the above tables that do not contain data indicate that those materials have not been listed by local regulations.

X: Listed on applicable state hazardous substance or right-to-know lists.

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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