SAFETY DATA SHEETS

This SDS packet was issued with item:

078056510

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078392681

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078056536 078791320

MSD Animal Health
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

SAFETY DATA SHEET

MSD 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

SDS 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

SDS Number: SP002089

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)

INFORMATION: +31 (0) 485-587600 (MSD Animal Health - Boxmeer, Netherlands)

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

SDS EMAIL: spmsds@spcorp.com

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SECTION 2. HAZARDS IDENTIFICATION

EU CLASSIFICATION(S): Repr.Cat.3;R63 N;R50/53

EMERGENCY OVERVIEW

White to off-white
Paste
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 IARC or EU Directive 90/394 (Annex I) 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.

This formulation may contain some sodium hydroxide for pH adjustment.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EC NUMBER	EU CLASSIFICATION	PERCENT
Sorbitol	50-70-4	200-061-5		<10
Glycerin	56-81-5	200-289-5	Not Classified	<10
Propylene Glycol	57-55-6	200-338-0		10-20

INGREDIENT	CAS NUMBER	EC NUMBER	EU CLASSIFICATION	PERCENT
Fenbendazole	43210-67-9	256-145-7	Repr. Cat.3;R63 N;R50-53	10-18.75

Fields in the above table that do not contain data indicate that the substance(s) have not been listed or classified according to EU criteria.

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 15 for EU hazard classification symbols and risk and safety phrases.

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.

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 below 25 deg C. Store in adequately sealed container.

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

OCCUPATIONAL EXPOSURE GUIDELINE (OEG):
An Occupational Exposure Guideline (OEG) of 100 mcg/m^3 (8-hr. TWA) has been established for fenbendazole.

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)	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)
Glycerin	56-81-5	10 mg/m^3		

Fields in the above table(s) that do not contain data indicate that exposure limits are not available for those endpoints.

INGREDIENT	CAS NUMBER	EU	Austria	Belgium	Denmark	France
Glycerin	56-81-5			TWA 10 mg/m^3		VME 10 mg/m^3

INGREDIENT	CAS NUMBER	Germany	Ireland	Italy	Netherlands
Glycerin	56-81-5	MAK 50 mg/m^3 Peak 100 mg/m^3	TWA 10 mg/m^3		
Propylene Glycol	57-55-6		TWA 150 ppm TWA 470 mg/m^3 TWA 10 mg/m^3		

INGREDIENT	CAS NUMBER	Norway	Portugal	Spain	Switzerland	UK:
Glycerin	56-81-5		TWA 10 mg/m^3	VLA-ED 10 mg/m^3	STEL 100 mg/m^3 MAK 50 mg/m^3	STEL 30 mg/m^3 TWA 10 mg/m^3
Propylene Glycol	57-55-6	STEL 37.5 ppm STEL 118.5 mg/m^3 TWA 25 ppm TWA 79 mg/m^3				STEL 450 ppm STEL 1422 mg/m^3 STEL 30 mg/m^3 TWA 150 ppm TWA 474 mg/m^3 TWA 10 mg/m^3

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 conditions specified in Section 7 of this SDS. No hazardous reactions known.

CONDITIONS AND MATERIALS TO AVOID:
None known.

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). Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) is presented.

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 (trout): 0.04 mg/L
48-hr LC50 (daphnia): 0.009-0.012 mg/L
96-hr LC50 (zebra fish): >500 mg/kg
21-day LC50 (bluegill sunfish): >0.019 mg/L
96-hr LC50 fish (Lepomis macrochirus): 1000 mg/L (highest concentration tested)
96-hr fish (Salmo gardneri): 7.5 mg/L (highest concentration tested)
Earthworm toxicity (LC50): 180 mg/kg (28 days)
Dung beetle toxicity (LD50): >770 mg/kg (7 days)

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

ENVIRONMENTAL DATA

OTHER INGREDIENT ENVIRONMENTAL DATA:

Fenbendazole: Partition Coefficient (log Pow): 3.3
Fenbendazole: Aerobic Biodegradation (soil) Results: DT50 between 4 and 12 days (for three types of soil)
Fenbendazole: Not readily biodegradable.

Propylene glycol is expected to be readily biodegradable.

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:

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

The following classification is based on available data and is in accordance with European Union criteria.

EUROPEAN UNION REGULATIONS:

The classification presented below is based on the active ingredient(s) and individual hazardous ingredients in the product formulation.

Indication of Danger:
Xn - Harmful.
N - Dangerous For The Environment.

Risk Phrases:
R63 - Possible risk of harm to the unborn child.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety Phrases:
S29 - Do not empty into drains.
S46 - If swallowed, seek medical advice immediately and show this container or label.
S61 - Avoid release to the environment. Refer to special instructions/Safety data sheets.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 1/2 - Keep locked-up and out of the reach of children.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.
S24/25 - Avoid contact with skin and eyes.

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).

DEPARTMENT ISSUING MSDS:	Global Safety & the Environment Merck & Co., Inc. One Merck Drive Whitehouse Station, NJ 08889
MERCK SDS HELPLINE:	+1 (908) 473-3371 (Worldwide) Monday to Friday, 9am to 5pm (US Eastern Time)
MSDS CREATION DATE:	13-Jan-2011
SUPERSEDES DATE:	13-Oct-2011
SIGNIFICANT CHANGES (EU SUBFORMAT):	OEB

Fenbendazole

Version	Revision Date:	SDS Number:	Date of last issue: 09/22/2015
4.5	01/15/2016	18150-00007	Date of first issue: 10/02/2014

SECTION 1. IDENTIFICATION

Product name : Fenbendazole

Product code : Fenbendazole

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : One Merck Drive
Whitehouse Station - New Jersey - USA 08889

Telephone : 908-423-1000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Combustible dust

Reproductive toxicity : Category 2

Specific target organ systemic toxicity - repeated exposure (Oral) : Category 2 (Liver, lymph node, Stomach, Nervous system)

GHS label elements

Hazard pictograms :

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H361 Suspected of damaging fertility or the unborn child.
H373 May cause damage to organs (Liver, lymph node, Stomach, Nervous system) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance

Substance name : Fenbendazole

CAS-No. : 43210-67-9

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Fenbendazole	43210-67-9	>= 90 - <= 100

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. Suspected of damaging fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Fenbendazole	43210-67-9	TWA	100 µg/m3	Merck

Engineering measures : Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
Material : Impervious gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:
Safety goggles

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : off-white

Odor	:	odorless
Odor Threshold	:	No data available
pH	:	7 - 7.5
Melting point/freezing point	:	233 °C
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	0.2 mg/l
Partition coefficient: n-octanol/water	:	log Pow: 2.3
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.

Possibility of hazardous reactions	:	Dust can form an explosive mixture in air. Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Ingredients:

Fenbendazole:

Acute oral toxicity	:	LD50 (Rat): > 10,000 mg/kg LD50 (Mouse): > 10,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Ingredients:

Fenbendazole:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:

Fenbendazole:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitization

Skin sensitization: Not classified based on available information.
Respiratory sensitization: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Ingredients:

Fenbendazole:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative

: Test Type: DNA Repair
Result: negative

: Test Type: Chromosomal aberration
Result: negative

: Test Type: in vitro test
Species: mouse lymphoma cells
Metabolic activation: Metabolic activation
Result: Equivocal

Carcinogenicity

Not classified based on available information.

Ingredients:

Fenbendazole:
Species: Mouse
Application Route: oral (feed)
Exposure time: 2 Years
NOAEL: NOAEL (No observed adverse effect level): 405 mg/kg body weight

Result: negative

Species: Rat
Application Route: Oral
Exposure time: 2 Years
NOAEL: NOAEL (No observed adverse effect level): 5 mg/kg body weight

Result: negative
Target Organs: Lymph nodes, Liver

IARC	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
NTP	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Ingredients:

Fenbendazole:
Effects on fertility : Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: oral (feed)
General Toxicity Parent: NOAEL (No observed adverse effect level): 15 mg/kg body weight

Fertility: LOAEL (Lowest observed adverse effect level): 45 mg/kg body weight
Result: Effects on fertility.

Effects on fetal development : Test Type: Development
Species: Dog, female
Application Route: Oral
Developmental Toxicity: LOAEL (Lowest observed adverse effect level): 100 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL (No observed adverse effect level): 25 mg/kg body weight
Result: Fetotoxicity.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL (Lowest observed adverse effect level): 63 mg/kg body weight

Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL (No observed adverse effect level): 120 mg/kg body weight
Result: No effects on fetal development.

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Liver, lymph node, Stomach, Nervous system) through prolonged or repeated exposure if swallowed.

Ingredients:

Fenbendazole:
Routes of exposure: Ingestion
Target Organs: Liver, lymph node, Stomach, Nervous system
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Ingredients:

Fenbendazole:

Species: Rat
LOAEL: 500 mg/kg
Application Route: Oral
Exposure time: 2 Weeks
Target Organs: Kidney, Liver

Species: Rat
NOAEL: > 2,500 mg/kg
Application Route: Oral
Exposure time: 30 Days
Remarks: No significant adverse effects were reported

Species: Rat
LOAEL: 1,600 mg/kg
Application Route: Oral
Exposure time: 90 Days
Target Organs: Central nervous system
Symptoms: Tremors

Species: Dog
NOAEL: 4 mg/kg
LOAEL: 8 mg/kg
Exposure time: 6 Months
Target Organs: Stomach, lymph node, Nervous system

Aspiration toxicity

Not classified based on available information.

Ingredients:

Fenbendazole:
No aspiration toxicity classification

Experience with human exposure

Ingredients:

Fenbendazole:
Ingestion : Symptoms: Rapid respiration, Salivation, anorexia, Diarrhea

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Ingredients:

Fenbendazole:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 7.5 mg/l Exposure time: 96 h Remarks: No toxicity at the limit of solubility.
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0.008 mg/l Exposure time: 48 h Method: OECD Test Guideline 202

M-Factor (Acute aquatic toxicity)	:	100
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.0015 mg/l Exposure time: 21 Days Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	10

Persistence and degradability

No data available

Bioaccumulative potential

Ingredients:

Fenbendazole:

Bioaccumulation	:	Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 240
Partition coefficient: n-octanol/water	:	log Pow: 2.3

Mobility in soil

Ingredients:

Fenbendazole:

Distribution among environmental compartments	:	log Koc: 4.73

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulation

UNRTDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(Fenbendazole)

Class	:	9
Packing group	:	III
Labels	:	9

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Fenbendazole)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956

IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fenbendazole)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fenbendazole)
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes (Fenbendazole)
Remarks	:	Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards : Chronic Health Hazard
Fire Hazard

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Fenbendazole	43210-67-9	90 - 100 %

New Jersey Right To Know

Fenbendazole	43210-67-9	90 - 100 %

California Prop. 65 This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

The ingredients of this product are reported in the following inventories:

AICS : not determined

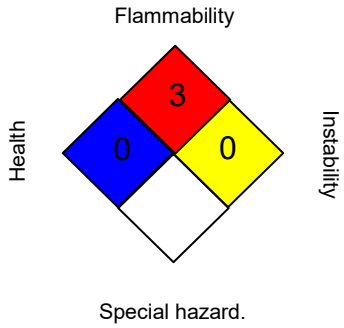
DSL : not determined

IECSC : not determined

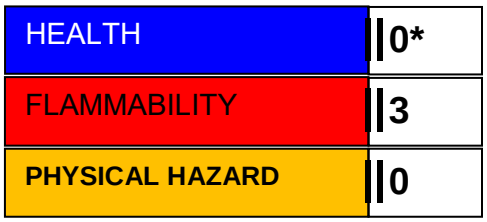
SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:



0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations;

UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Revision Date	:	01/15/2016

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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