United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Document Type:

☒ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☐ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

PETITION

To the
U.S. Department of Agriculture
National Organic Program

To Amend 7 CFR §205.603(a)(23)
To Include Fenbendazole
As A Synthetic Substance Allowed
For Use in Organic Livestock Production

Submitted July 5, 2019

By Merck Animal Health
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Contents

1. The Substance's Common Name

Common Name: Fenbendazole (Safe-Guard® AquaSol®)
Chemical Name: methyl N-(5-phenylsulfanyl-3H-benzoimidazol-2-yl)carbamate
Chemical Formula: $C_{15}H_{13}N_3O_2S$

2. The Official Name, Address, And Telephone Number for Merck Animal Health

Intervet Inc.
(d/b/a Merck Animal Health)
c/o Dr. Allison Flinn
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Website: https://www.merck-animal-health-usa.com/

Intervet, doing business as Merck Animal Health which is a subsidiary of Merck & Co., Inc.

3. The intended or current use of the substance

Fenbendazole was first approved in 1983 for use in cattle, including beef animals and dairy cows, as a treatment and control of several types of gastronomical worms, including: lungworms (ductyocaulus viviparous), stomach worms (brown stomach worm, barberpole worm and small stomach worm), and intestinal worms (hookworm, threadnecked intestinal worm, small intestinal worm, bankrupt worm, and nodular worm).

In May 2012, fenbendazole was added to the National List of organic materials for use in organic livestock, as specified in 7 CFR §205.603:

> (23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.
>
> > (i) Fenbendazole (CAS #43210-67-9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following

treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

Since that time, Merck Animal Health has developed Safe-Guard® AquaSol® as an anthelmintic, i.e.: a medication capable of causing the evacuation of parasitic intestinal worms in poultry.

In October 2015, the FDA gave formal approval for the use of fenbendazole under the trade name of AquaSol for use for the treatment and control of adult *A. galli* in broiler chickens and replacement chickens intended to become breeding chickens and for the treatment and control of adult *A. galli* and *H. gallinarum* in breeding chickens. In January 2018, that approval was extended for the use of fenbendazole under the trade name of AquaSol for use in laying hens and replacement chickens intended to become laying hens.

This petition requests an annotation to 7 CFR §205.603 (23)(i) to include laying hens and replacement chickens intended to become laying hens.

4. Intended Activities and Application Rate

The substance is approved for use in conventional poultry production the following manners:

- 200 mg of fenbendazole/ml for oral administration via drinking water
- Safe-Guard® Safe-Guard® AquaSol must be administered orally to chickens via the drinking water at a daily dose of 1.0 mg/kg BW (0.454 mg/lb.) for 5 consecutive days.

Mode of action: Fenbendazole binds to β-tubulin, inhibiting assembly of microtubules, resulting in cell and parasite death. According to the Merck Veterinary Manual, "The wide safety margin of benzimidazoles is due to their greater selective affinity for parasitic β-tubulin than for mammalian tissues." (Merck, 2006)

It is being petitioned for inclusion on §205.603(a)(23)(i) of the National List of Synthetic Livestock Materials Allowed.

5. Manufacturing Process

The manufacturing process for fenbendazole was included in the March 2007 petition requesting the addition of fenbendazole as an approved material under §205.603(a)(23)(i) of the National List.

The fenbendazole in AquaSol is now further processed whereby it is reduced in particle size to create a more stable suspension in drinking water. This further processing subjects the

fenbendazole to a wet-milling process whereby a 40 percent fenbendazole suspension is recirculated between a mixing vessel and wet-mill.

Utilizing a rotating axis and milling beads, the wet-mill subjects the fenbendazole particles to impaction and sheer forces, reducing the particle to a submicron size. Moreover, at the end of the manufacturing process Panacur AquaSol is a 20 percent fenbendazole suspension whereas Panacur Suspension 10% (Safe Guard in the US) is a 10 percent suspension.

6. Ancillary Substances

The ancillary substances in fenbendazole were included in the March 2007 petition requesting the addition of fenbendazole as an approved material under §205.603(a)(23)(i) of the National List. The manufacturing process has not changed since the material was added to the National List in 2012.

7. Previous Reviews

Fenbendazole has undergone at least the following reviews:

1. Technical Advisory Panel Report, NOSB Materials Database, November 25,1999. https://www.ams.usda.gov/sites/default/files/media/Fenbendazole%20TR%201999.pdf
2. Technical Evaluation Report, Compiled by USDA AMS, Agricultural Analytics Division for the USDA National Organic Program, June 3, 2015. https://www.ams.usda.gov/sites/default/files/media/Fenbendazole%20TR%202015.pdf

8. Regulatory Authority

Products containing fenbendazole are regulated by the Food and Drug Administration's Center for Veterinary Medicine (CVM). The New Animal Drug Application designation (NADA number) is: Safe-Guard® AquaSol 200/mg/mL (Suspension) NADA #141-449

9. Chemical Abstracts Service CAS Number and Product Labels

The CAS No. for fenbendazole is: 43210-67-9

Product labels are attached as Attachment A.

10. Physical and Chemical Properties

The physical and chemical properties were included in the March 2007 petition requesting the addition of fenbendazole as an approved material under §205.603(a)(23)(i) of the National List. The manufacturing process has not changed since the material was added to the National List in 2012.

The March 2007 petition can be accessed at:
https://www.ams.usda.gov/sites/default/files/media/Fenbendazole%20Petition.pdf

The June 3, 2015 Technical Evaluation Report, Compiled by USDA AMS, Agricultural Analytics Division for the USDA National Organic Program can be accessed at:
https://www.ams.usda.gov/sites/default/files/media/Fenbendazole%20TR%202015.pdf

11. Safety Information

The safety information for fenbendazole was included in the March 2007 petition requesting the addition of fenbendazole as an approved material under §205.603(a)(23)(i) of the National List. That information has not changed since the material was added to the National List in 2012.

The Material Safety Data Sheet for this material is included with this petition as **Attachment B.**

12. Research Information

A listing of relevant research information and literature concerning fenbendazole is included as **Attachment C** with this petition.

13. Petition Justification Statement

A. Why this synthetic substance is necessary for the production of organic laying poultry.

The National Organic Standards specify that organic livestock living conditions allow for "exercise, freedom of movement, and reduction of stress appropriate to the species."[1] These standards provide the foundation for customer expectations over the manner in which organic flocks are raised. Through the years, those expectations have increased to include more outdoor access, including direct contact with soil. Responsible organic producers strive to fulfill those expectations.

This consumer-driven shift in organic poultry production has significantly increased the flocks' exposure to internal parasites, resulting in increased sickness and mortality.

As noted in the 2015 Technical Evaluation Report on Fenbendazole, Ivermectin and Moxidectin, "Parasitism may be the weakest link in organic livestock production (Karreman, 2004). Outbreaks of disease due to nematode parasites can happen even in well managed flocks. When changes in a production system occur as a result of land use,

[1] 7CFR§205.238 (a)(4)

weather, or transient exposure of susceptible animals to parasites the natural imbalance favors parasite infestation."[2]

Organic standards—and organic philosophy—require that synthetic materials can be allowed only when organic herd health practices and natural controls are ineffective. Organic producers actively work to provide appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites. Yet, those producers are still experiencing significant losses to their flocks.

The vast majority of hens are subclinically infected with at least one helminth species. The prevalence as well as intensity of the helminth infections, particularly with tapeworms, considerably increases in summer.[3]
There are several reports showing that outdoor runs act as an important infection source for virtually all poultry helminths including *Ascaridia galli (A. galli)* (Heckendorn et al., 2009; Permin et al., 1999).[4]

Studies on sustainable worm control strategies in commercial laying hen flocks, though, are scarce.[5]

One study conducted in Denmark in 2010 compared a randomly selected group of organic chicken flocks with conventional confinement flocks in deep litter. From 1995 to 2007, the average total mortality for flocks registered by the Danish efficiency control program ranged from 4.0% to 5.9% for caged layers; from 9.0% to 12.1% for confined deep litter production; and from 6.6% to 11.4% for free-range production, whereas the mortality rate for organic table egg production ranged from 9.0% to 18.4%.[6]

That study concluded, "Thus, vaccination and use of anthelmintics to control bacterial infections and parasites and proper disease surveillance must be combined to prevent the reemergence of classical poultry diseases in free-range flocks."[7]

A separate study, conducted in the United States, concluded, "Prevalence studies have shown that almost 100% of free-range chickens are infected with a wide range of parasites. The infections are mostly subclinical in nature, resulting in production losses

[2] USDA AMS (2015) Technical Evaluation Report, Parasiticides: Fenbendazole, Ivermectin, Moxidectin, June 3.
[3] Kaufmann, Falko (2011) Helminth infections in laying hens kept in organic free range systems in Germany. Department of Animal Sciences, Livestock Production Systems, Georg August, University, Göttingen, 37075 Göttingen, Germany
[4] Hoglund, Johan, et al (2011*) Infection dynamics of Ascaridia galli in non-caged laying hens*. Veterinary Parasitology, March
[5] Tarbait, B; et al (2016) Comparison between anthelmintic treatment strategies against Ascaridia falli in commercial laying hens. Department of Biomedical Sciences and Veterinary Public Health, Section for Parasitology, Swedish University of Agricultural Sciences
[6] Stokholm, A A. Permin, B M. Bisgaard, A and J. P. Christensen AC (2010) *Causes of Mortality in Commercial Organic Layers in Denmark N. M.* AVIAN DISEASES 54:1241-1250
[7] IBID

and occasionally mortality. Newcastle disease (ND) on the other hand, results in high mortality rates during epidemics."[8]

Yet another study concludes, "As shown by our survey, chickens from organic farms not only harbor a large spectrum of helminths, but also the intensity of infections is high. The large spectrum and intense helminth infections cannot only be attributed to poor biosecurity in free range systems, but also to the distinctive properties of organic farming that appear to provide favorable conditions for helminth infections. Organic egg production systems imply different housing and feeding conditions for the animals. The obligate outdoor access increases the risk of infection with several parasites, as hens are exposed to a natural environment that allows helminths to complete their life cycles (Norton and Ruff, 2003)."[9]

Jonathan LaFoe, live operations manager at Braswell Family Farms, reports, "We have had an increase in roundworms and fecal worms that are positive for Blackhead disease. With that increase in parasitic infestation we have seen an increase in pullet mortality from 3-8 weeks that ranges from a 2-3% increase which equates to roughly 98,000 eggs lost in mortality. We see anywhere from 5-15% reduction in overall production in these flocks as well, which equates to roughly 326,700 eggs once the hens are in the hen house. These figures are based off of a 9,000-hen placement, production percentage used was 10% to be an average."[10]

Falko Kaufmann notes that the lack of access to effective parasite control represents an animal welfare issue. "Organic production systems are supposed to offer the very highest animal welfare standards. Yet, hens in organic flocks are intensively infected with a large spectrum of helminths. Effects of parasitic infections on animal welfare, performance as well as on the farm economy remain to be further investigated. Losses due to a high morbidity might be considered of greater economic impact than high worm counts that cause mortality in a few birds.[11]

Deidre Hess of Powl Associates agrees: "Worm infestation is an animal welfare and feed efficiency issue that results in less eggs produced per hen housed, and likely has negative impacts on the quality of life of the egg laying hen."[12]

According to Kaufmann, "One major challenge in nematode control in general including non-cage housing systems for laying hens, is to reduce environmental fecal contamination and thereby minimize the exposure to infectious parasite eggs. In this study, the mean EPGs in pooled fecal samples remained significantly lower in the TT

[8] Hørning G[1], Rasmussen S, Permin A, Bisgaard M. (2003) *Investigations on the influence of helminth parasites on vaccination of chickens against Newcastle disease virus under village conditions*
[9] Kaufmann, F., et al (2011) Helminth infections in laying hens kept inorganic free range system in Germany, Life Science magazine.
[10] LaFoe, Jonathan (2018) Communication with Dave Carter, dated June 12, 2018
[11] Kaufmann, F., et al (2011) Helminth infections in laying hens kept inorganic free range system in Germany, Life Science magazine.
[12] Hess, Deidre (2018) Communication with Dave Carter, dated June 20, 2018

compared to the other treatment protocols on all sampling occasions except for week 22 and 24 (Fig. B). This was possibly due to the temporary effect of the FBZ fenbendazole) treatment on the egg expulsion (Martinet al., 1985)."

B. Nonsynthetic substances, synthetic substances on the National List, or alternative cultural method that could be used in place of the petitioned synthetic substance.

While diatomaceous earth (DE) is utilized widely and effectively as a control for external parasites, its effectiveness as an internal control has not been reputably documented. Diatomaceous earth has no effect on lungworm and is not very appetizing to poultry. It may also be a lung irritant. Given that the level of dust is already quite high in barns, diatomaceous earth does not seem appropriate when the animals are fed indoors. The main motivation for adding diatomaceous earth to rations should not be to control internal parasites.[13]

One investigation tested the effectiveness of DE on Boban Brown (BB) and Lohmann breeds of poultry. That study concluded, "BB hens treated with dietary DE had significantly lower Capillaria FEC, slightly lower Eimeria FEC, fewer birds infected by Heterakis, and a significantly lower Heterakis worm burden than control BB hens. Each individual parameter may not be strong, but together they provide convincing evidence. We therefore conclude that the effect of DE on internal parasites was not robust. It did not improve resistance in birds that were genetically more resistant but may help birds that were less resistant to lower their parasite load." (Emphasis added)[14]

Organic producers employ a variety of other allowable materials to manage parasite infestations in organic flocks. Those materials include:
Arctium lappa (burdock);
Artemisia sp. (wormwood);
Chenopodium album (lambsquarters) and C. ambrosioides (epazote);
Cirsium arvense (Canada thistle);
Juniperus spp. (juniper);
Mentha piperita (peppermint);
Nicotiana sp. (tobacco);
Papaver somniferum (opium poppy);
Rubus spp. (blackberry and raspberry relatives);
Symphytum officinale (comfrey);
Taraxacum officinale (common dandelion);
Thuja plicata (western red cedar); and

[13] Intervet (2007) Petition to the USDA to include Fenbendazole as a Synthetic Substance Allowed for Use in Organic Livestock production Pg. 25
[14] Bennerr, D.C.; et al. (2011) Effect of diatomaceous earth on parasite load, egg production and eff quality of free-range organic laying hens. Avian Research Centre, University of British Columbia. https://pdfs.semanticscholar.org/05b3/56ec1f5ade12ad71c0a72be0d720a3d75b9e.pdf?_ga=2.189172907.1864391858.1529877060-941771993.1529877060

Urtica dioica (stinging nettle).[15]

The effectiveness of these alternative materials has not been documented.

Information provided by veterinarians and livestock health officials during this analysis indicate viable alternatives are lacking for the treatment of parasite infestations in organic poultry flocks.

Some of that information includes:

Diedra Hess of Powl Associates wrote, "Our company has experimented with several organic additives including diatomaceous earth (DE), feed grade oregano, and liquid oregano. High doses of liquid oregano were shown to improve, but not remedy worm issues."[16]

Alexander W. Strauch, DVM, the company veterinarian for Herbruck's Poultry Ranch, Inc., reports, "The currently available organic methods of intestinal worm control do not work. In-feed diatomaceous earth (DE) powder, environmental DE powder, and oregano extract to not prevent or treat helminthiasis. I've personally run multiple field studies on "natural" de-wormers and have not only seen their ineffectiveness, but have seen the decreases in feed consumption and egg production that directly follow some of their uses. I have discontinued the practice of in-feed DE altogether at organic laying farms for those exact reasons."[17]

Johathan LaFoe, live operations manager for Braswell Family Farms, adds, "We've implemented bleach, virkon, trialing natustat right now, increasing cleanouts to every flock for pullets. We haven't seen positive results from these implemented practices. Will see how the natustat works for this trial."[18]

C. The beneficial effects to the environment, human health, or farm ecosystem from the use of the synthetic substance that support its use instead of the use of the nonsynthetic substance or alternative cultural method.

Fenbendazole is insoluble in water, and only slightly soluble with the usual solvents. The substance binds with soil, and thus does not impact other substances used in organic production.

Specific studies have been conducted on fenbendazole concerning impact on earthworms (both *Eisenia foetida* and *Lumbricus terrestris*). The studies (detailed in section 9(e)(iv))

[15] Lans, C, and Turner, N (2011) *Organic parasite control for poultry and rabbits in British, Columbia, Canada.* Joournal of Ethnobiology and Ethnomedicine
[16] Hess, Deidre (2018) Communication with Dave Carter, dated June 20, 2018
[17] Strauch, Alexander (2019) Written communication with Dave Carter May 15, 2018
[18] LaFoe, Jonathan (2018) Communication with Dave Carter dated June 12, 2018

demonstrated the absence of an acute lethal effect of fenbendazole on *Eisenia foetida* at concentrations below 100 ppm. On a separate study on *Lumbricus terrestris*, the LC_{50} for earthworms exposed to fenbendazole for 28 days was calculated by moving average angle analysis to be 180 ppm fenbendazole. The concentration of fenbendazole in soil with waste from treated animals would be significantly lower (390 ppb).

Dung beetles *(Onthophagus gazelle)* are considered an important tool in organic livestock production and pasture management. A toxicity investigation on exposure of dung beetles to fenbendazole was conducted by Springborn Laboratories, Inc. That investigation (explained in greater detail in Section 9(e)(iv)) determined no detectible impact on dung beetles.

Fenbendazole is non-toxic

This product is not considered a carcinogen and is not listed by OSHA, IRAC or NTP.

Acute toxicity studies were conducted for evaluation by the Joint FAO/WHO Expert Committee on Food Additives. Doses of fenbendazole were administered to mice, rats, rabbits, dogs, swine and sheep. (Scholz & Schultes, 1973)

Toxicity studies were reviewed also by the European Medicines Agency. Fenbendazole was shown to be of low acute toxicity. Oral LD50 values in laboratory rats and mice were greater than 10000 mg/kg.

Fenbendazole Lacks Environmental Persistence

Rapid Photolytic Decomposition

A study designed to conform to Method 3.10 of the FDA Environmental Assessment Technical Assistance Document was conducted by Springborn Laboratories, Inc. to measure the photo-degradation of fenbendazole in aqueous solution.

Photolytic decomposition is a known degradative pathway for benzimidazoles. The effect of simulated sunlight on the photolytic degradation of aqueous solutions of fenbendazole was tested at pH 5, 7 and 9. Actinometer (reference material) solutions of paranitroacetophenone (PNAP) were analyzed concurrently with the pH 5, 7 and 9 test solutions.

Sampling and analysis for [14 C] fenbendazole consisted of an extraction method where 4- 5 separate tubes for the light-exposed and dark control solutions were separately combined, each containing approximately 12-mL. to provide triplicate replicates for solid phase extraction (SPE). Eluent from the solid phase columns were analyzed utilizing high performance liquid chromatography (HPLC) with fraction

collection and subsequent radioassay. Radiochromatograms (histograms) were conducted to quantify the concentration of fenbendazole present and to determine its degradation rate. Samples for PNAP were analyzed by high performance liquid chromatographic analysis with UV detection.

Since degradation was so rapid, insufficient quantities of photolyzed samples existed for identification of degradates. Additional exposures at pH 5, 7 and 9 were conducted upon completion of the definitive portion of the study, with a large number of replicates, to provide enough volume for photodegradate identification. The combined volume of these replicates was extracted using a solid phase system and a photodegradate profile determined based on chromatographic comparison of retention times with supplied standards. None of the degradation products comprised more than 10% of the original concentration of fenbendazole, indicating that photolysis was severely destructive to the molecule.

The half-life ($T^1/_2$, days) of fenbendazole at pH 5, 7 and 9 are presented below.

pH	**$T^1/_2$ days**
5	0.713
7	0.527
9	0.471

This study conclusively demonstrates a rapid degradation process for fenbendazole exists (less than one day) with photolysis proceeding to many insignificant degradate compounds in which none comprise more than 10% of the original concentration.

Fenbendazole has No Migration to Runoff or Leachate Water

In one study researchers assumed there will be two inches of rainfall over an acre of land during the year. Two inches of rainfall on an acre of land weighs approximately 205,500 kilograms. The study assumed 10 animals per acre per year. Therefore, the amount of fenbendazole on one acre would equal:

10 dairy cows x 3.4 g/cow x 3 treatments/year = 102 g fenbendazole per acre per year.

Fenbendazole is not soluble in water. If it is possible to have the entire residue in the run-off, the maximum concentration of fenbendazole in the run-off, assuming no degradation, equals:

$$\frac{102 \text{ grams}}{205{,}500 \text{ kg of water}} = .496 \text{ mg/kg (496 ppb) FBZ in runoff}$$

It would be expected that the amount of fenbendazole released into water runoff would be very much lower than 496 ppb because fenbendazole is very insoluble in water and absorbs tightly to soil particles. Therefore, fenbendazole is not expected to

migrate from application sites into runoff or leachate water, and hence, is not expected to be available to aquatic species. Exposure would be limited by adsorption and available pathways for rapid degradation (e.g. photolysis).

No Runoff from Fecal Matter

Separate studies have shown that the same metabolites are found in the feces of swine and cattle treated with fenbendazole. Feces from pigs treated with 14C fenbendazole were mixed with soil to a final concentration equivalent to 11.07 micrograms of 14C fenbendazole/g of soil. The soil feces mixture was incubated with a 10-fold excess of distilled water for 72 hours with constant shaking to achieve an equilibrium distribution of fenbendazole ÷ metabolites between the soil and the aqueous phase. The final concentration of 14C fenbendazole in the aqueous phase was .045 micrograms/mL which represented 3.19% of the initial 14C activity.

The result of this study shows that fenbendazole metabolites just as fenbendazole parent substance is bound tightly to particulate matter and do not migrate into surface waters. (Bio/dynamics, Bound Brook, NJ.)

No significant Impact on Aquatic Environment

Under "worst case" conditions (assuming that all fenbendazole administered to dairy cattle is excreted via their manure, is extracted from the manure by two-inch rainfall and enters into water run-off), the estimated water run-off concentration of fenbendazole is 496 ppb. This would be the highest concentration of fenbendazole in any aquatic environment since it assumes three treatment periods per year which are not consecutive, does not account for dilution as it enters bodies of water such as streams, rivers, ponds and lakes (secondary aquatic environments), does not account for the fact that fenbendazole and fenbendazole metabolites are bound tightly to the soil and do not migrate into surface waters, and that upon entry into these secondary aquatic environments, fenbendazole and fenbendazole metabolites rapidly decompose through the process of photo-degradation. The half-life in water is less than one day. Dilution and photochemical decomposition in the secondary aquatic environments reduces the environmental concentrations of fenbendazole and its metabolites such that the effects from fenbendazole on vertebrate and invertebrate populations are expected to be transient and would not be considered to be significant.

No Significant Impact on Soil Resources

In one study, researchers assumed that:

a. No degradation in the manure before applying to the soil.
b. Manure is added to the soil at the rate of 40.0 metric tons per acre. Amount of fenbendazole in 40 metric tons equals 0.356 kg.
c. (3.4 g fenbendazole/380.8 kg manure per week) X 40,000 kg per acre = 0.356 kg
d. Fenbendazole in 40 metric tons manure or 8.9 mg/kg (ppm) manure.

e. The manure will be incorporated into the top 6" of soil (weight of the top 6” of soil in one acre equals 909,000 kg).

The amount of fenbendazole in the top six (6) inches of soil would equal:

Drug Conc. In soil (mg/kg)	=	Drug conc. in manure (mg/kg)	x	Kg manure applied to soil / acre of soil	x	acre of soil kgs in top 6” of soil

Drug Conc. In soil	= 8.9 mg/kg x	40,000 kg manure / 1 acre	x	acre = 0.39 mg/kg (390 ppb) FBZ in soil 9.09×10^5 kg

As demonstrated above, the amount of fenbendazole (assuming no degradation) released into the soil would be extremely minimal.

No significant Impact on Plant Health

Another study was conducted to determine if fenbendazole is accumulated in plants. Feces from a cow which had been treated with 14C fenbendazole at a dose level of 5 mg fenbendazole/kg body weight were used to determine if fenbendazole or its metabolites are taken up by plants.

Barley and bean plants were raised under laboratory conditions on sandy loam soil to which 3.5% of a mixture of urine and feces had been added. The plants and new crop, tested for their radioactive content at various times after sowing 6 days, 14 days, 11 weeks - showed concentrations varying between the level of detection and twice the level of detection of ppb. The comparative value for the soil was 490 ppb.

No Impact on Micro-Organisms (Including Soil Organisms)

A number of micro-organisms were exposed to fenbendazole and no activity of fenbendazole was found. The micro-organisms included:

Gram positive aerobic bacteria:
Staphylococcus aureus S.G. 511
Streptococcus pyogenes A (308)
Streptococcus faecium D

Gram negative bacteria:
Escherichia coli 055
Proteus mirabilis

Pseudomonas aeruginosa

Mycoplasma:
Mycoplasma gallisepticum 15302

The test method was a bacteriostatic (growth inhibition) test. Serial dilutions in Mueller-Hinton-Broth were used. The inoculum per ml medium was .05 ml of a 24-hour stationary fluid culture of the respective organism diluted 1:100. The minimum inhibitory concentration (MIC) was determined after an incubation of 18 hours at 37°C. MIC was the concentration of the last test tube in which no macroscopically visual bacterial growth was observed. The highest tested concentration of fenbendazole was 100 micrograms/mL. No antibacterial effect could be found against any of the tested aerobic bacteria.

In addition to these aerobic bacteria, anaerobic bacteria were also tested as follows:

Several strains of *Bacteroides fragilis*
Bacteroides ovatus
Bacteroides thetajotaomicron
Sphaerophorus varius
Sphaerophorus freundii
Peptococcus anaeroblus and *variabilis*
Peptostreptococcus anaerobius and *variabilis*
Propionibacterium acnes as well as several clostridia strains including
Clostridium erfringens
Clostridium septicum.

The highest tested concentration of fenbendazole was 100 micrograms/mL agar. No antibacterial effect could be found against any of the tested anaerobic bacteria.

Fenbendazole was further evaluated for in-vitro activity against *Trichomonas vaginalis* and *Entamoeba histolytica.* The study was done as an in-vitro model for activity against *Histomonas meleagridis.* No in-vitro effect was seen at concentrations of up to 200 micrograms/mL in-vitro.

Fenbendazole was tested against these protozoa in in-vivo experiments:
Eimeria tenella
Entamoeba histolytica
Trichomonas foetus
Aegyptianella pullorum
Trypanosoma brucei
Plasmodium vinckei
Babesia rodhaini

No activity was found in any of the experiments.

An antifungal test was also performed against:

Trichophyton mentagrophytes
Trichophyton rubrum
Microsporum canis
Candida alblcans
Aspergillus niger

Two test media were used: malt extract peptone glucose agar and serum glucose agar. The concentration of fenbendazole was up to 100 micrograms/mi. No inhibition of fungi was observed in this study.

We conclude from the available information that fenbendazole would not have any effect on soil microbes because no growth inhibition could be demonstrated at the 100 and 200 ppm concentrations which are greater than the maximum solubility of the compound (10-40 ppb).

Dung Beetle Toxicity (*Onthophagus gazelle)*

An investigation was conducted by Springborn Laboratories, Inc. to determine the NOEC and LD_{50} of fenbendazole to dung beetles. The 7-day toxicity test with dung beetles *(Onthophagus gazelle)* included a single measured fenbendazole concentration of 770 mg/kg and a control. Five replicate vessels were maintained for the treatment and control. Treated cattle manure (1000 mg/kg, nominal) was divided into five 300 g aliquots formed into oval shaped patties and placed in the plastic pail vessels, each containing 2.4 kg of moistened artificial soil. Five replicates of 300 g aliquots of untreated cattle manure (control) were also maintained. Test vessels were randomly positioned in a temperature-controlled water bath designed to maintain temperature at 28 ± 2° C. Relative humidity was maintained at 58 to 66%. Light intensity was 60-foot candles with a photoperiod of 18 hours light and 8 hours darkness. Each vessel was misted with deionized water once daily. Two male-female pair of dung beetles were placed in each replicate vessel. Survival rate, physical or behavioral abnormalities (e.g. lethargy) and presence of dung balls were recorded at test termination (day 7).

At test initiation (day 0) and test termination manure samples for the treatment level and the control were analyzed for fenbendazole concentration. The mean of the day 0 and the normalized day 7 concentrations defined the measured treatment level to be 770 mg/kg.

Mean survival among dung beetles exposed to the treatment level of fenbendazole tested (770 mg/kg, measured) was 100%. Based on the absence of mortality and sublethal-effects during the study, the 7-day LO_{50} was empirically estimated to be greater than 770 mg/kg. The No-Observed-Effect Level was determined to be 770

mg/kg. The concentration of fenbendazole in waste manure from treated animals would be significantly lower (8.9 ppm) than the NOEC of 770 ppm.

Earthworm Toxicity *(Eisenia foetida & Lumbricus terrestris)*

Eisenia foetida

A preliminary range-finding test using earthworms *(Eisenia foetida)* tested the toxicity of fenbendazole doses of 1,000, 500 and 100 mg drug/kg soil. Worm mortality was not observed until 14 days and then only in the 1,000 and 500 mg/kg groups. The 14-day LC_{50} was calculated to be 1,068 mg/kg with the 95% confidence interval being from about 900-1600 mg/kg. The worms at 100 mg/kg suffered no mortalities.

The study demonstrated the absence of an acute lethal effect of fenbendazole on earthworms at concentrations below 100 ppm. It did not determine the minimum effect level for sublethal effects since doses lower than 100 mg/kg were not tested.

Lumbricus terrestris

The subacute toxicity of fenbendazole on earthworms *(Lumbricus terrestris)* was evaluated in a study conducted by Springborn Laboratories, Inc. in accordance with "FDA Environmental Assessment Technical Document 4.12.

A preliminary range-finding test, consisting of two replicate test vessels per concentration and control, using earthworms *(Lumbricus terrestris)* tested the toxicity of fenbendazole doses of 1,000, 100, 10, 1.0. 0.10 and 0 (control) mg drug/kg artificial soil (dry weight basis). Percent survival was 95% or greater at all levels tested except 1000 mg/kg where 5% survival rate was observed. Definitive test concentrations were then established to be 960, 500, 240, 120, 56 and 0 (control) mg fenbendazole/kg artificial soil (dry weight basis). For each exposure concentration and control, four replicate test vessels were utilized during the definitive test. When compared with burrowing time and percent weight change, statistical analysis of the data determined that earthworm survival was the most sensitive parameter to the toxicity of fenbendazole. At test termination survival in 960, 500, 240, 120, 56 and 0 (control) mg fenbendazole/kg artificial soil was 0, 25, 35, 53, 93, and 100%, respectively. Therefore, earthworm survival was used to establish the LC_{50}, LOEC and NOEC.

The LC_{50} for earthworms exposed to fenbendazole for 28 days was calculated by moving average angle analysis to be 180 ppm fenbendazole. The Lowest-Observed-Effect Concentration (LOEC) was determined to be 120 ppm fenbendazole, and the No-Observed-Effect Concentration (NOEC) was determined to be 56 ppm fenbendazole in artificial soil containing 50 g cattle manure per kg dry artificial soil.

The concentration of fenbendazole in soil with waste from treated animals would be significantly lower (390. ppb) than the NOEC of 56,000 ppb.

Internal Parasites Create a Risk to Food Quality

The inability to treat parasite outbreaks poses a risk to food quality that can undermine consumer confidence in the organic seal.

Strauch of Herbruck's Poultry Ranch reports, "Unfortunately, organic laying hens will always run the risk of passing adult worms into their eggs. While extremely rare, it is possible to have adult roundworms expelled from the rectum and ascend retrograde into the uterus while eggs are developing. Quality assurance technologies can pick out these intruders during processing, but roundworms can become effaced along the edge of the yolks and make their way into saleable egg cartons. While the presence of an accidental avian roundworm in a cooked egg is not a public health issue as worms are species specific, it certainly upsets customers and sullies the confidence of the organic label."[19]

D. Approval will provide U.S. organic poultry producers with a management resource already available to organic producers in Canada, the European Union and Japan

The organic standards in Canada and the European Union already allow poultry producers to utilize parasiticides as an emergency treatment when all other preventative measures fail. Specifically, the international standards include:

Canada

The Canadian Organic Production Systems General Principles and Management Standards (CAN/CGSB-433 32.310-2006) generally prohibit the use of parasiticides but allow emergency treatment. And, poultry flocks can be treated, but laying hens with more than one treatment per 12 months lose organic status.

European Union

European Economic Community (EEC) Council Regulations, EC No. 834/2007 and 889/2008 specify that preventive use of chemically synthesized allopathic medicinal products is not permitted in organic farming. However, in the case of a sick animal requiring an immediate treatment, the use of chemically synthesized allopathic medicinal products is limited to a strict minimum. Doubling withdrawal periods after use of chemically synthesized allopathic medicinal products is suggested to guarantee the integrity of organic production for consumers.

[19] Strauch, Alexander (2019) Written communication with Dave Carter May 15, 2018

Japan

The organic standards of Japan do not specify which parasiticides may be used. The withdrawal period is two days prior to slaughter for foods, milk or egg collection or twice the period of drug withdrawal.

E. Conclusion

Fenbendazole clearly meets the three major criteria specified in this section:

1. Why the synthetic substance is necessary?

   Internal parasites cannot always be controlled through species selection and management practices. The ineffectiveness of non-synthetic parasite control measures is a major inhibitor to the growth of the organic sector. In addition, the inability to effectively control parasites through non-synthetic means results in suffering--and even mortality--among livestock populations.

   Additionally, exposure to parasites increases significantly when flocks are managed on soil, rather than in barns.

   Fenbendazole provides a solution which will effectively address the target nematodes without causing harm to the environment.

2. Alternative methods currently available are not effective, and the only allowed synthetic materials are incompatible with organic livestock production.

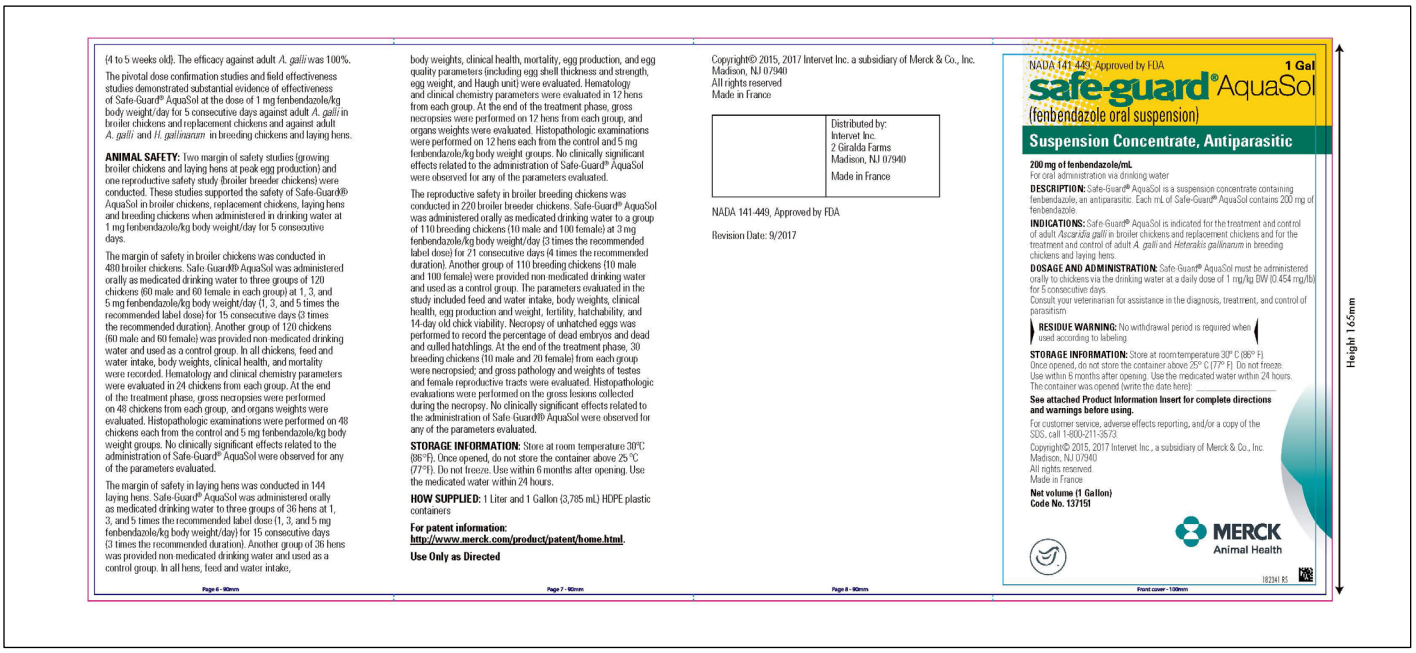
   Current non-synthetic substances, synthetic substances on the National List, and alternative cultural practices are not adequate. For example, diatomaceous earth has not been demonstrated to be effective on internal parasites.

3. Fenbendazole is benign in terms of impact on environment, human health, or farm ecosystems.

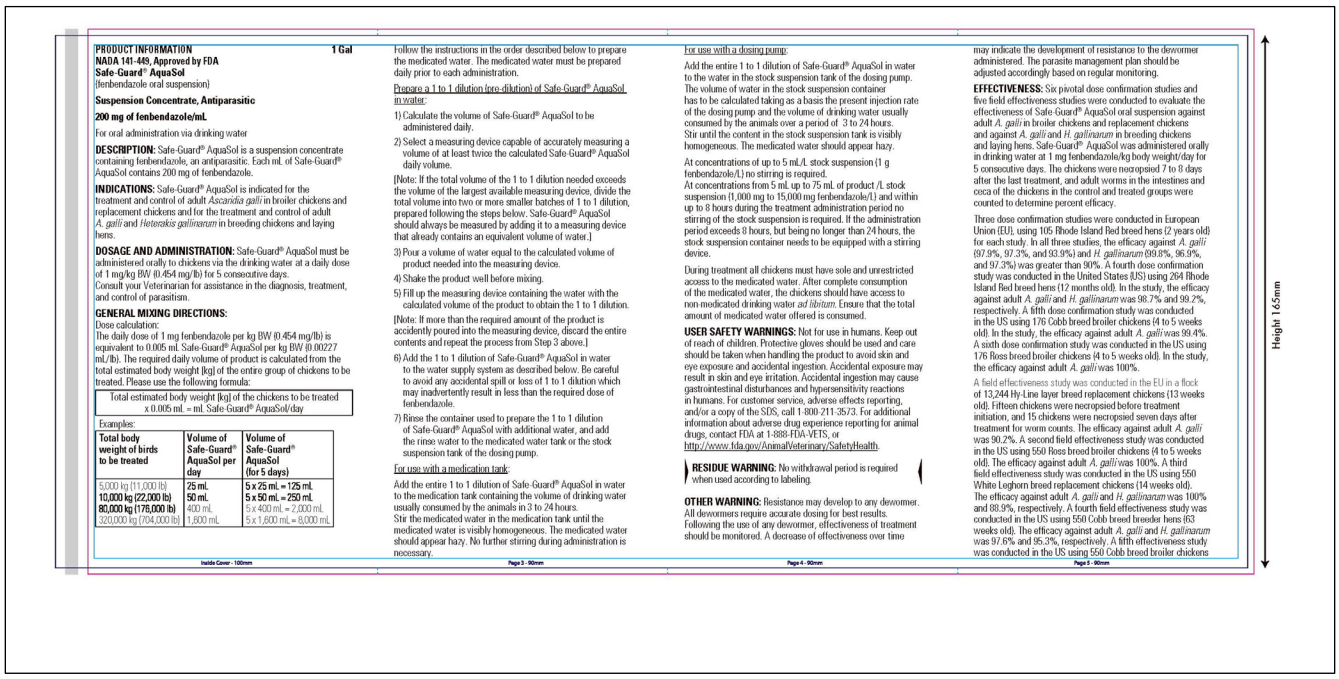
   Studies referenced above have demonstrated that fenbendazole will not have negative impact on dung beetles, earthworms or plant life. The National Organic Standards clearly specify that synthetic parasiticides are not to be used as a substitute for cultural methods. Fenbendazole, however, will provide certified organic poultry producers with a viable material that can be utilized when cultural methods fail to prevent parasitic infestations.

   Fenbendazol was approved for use in 1983, and therefore has a proven track record of more than 20 years. During this time period, a significant body of evidence has been developed to demonstrate the efficacy of fenbendazole, as well as its lack of negative affects on the environment.

Attachment A - Product Labels



Attachment A (Cont.) - Product Labels



PRODUCT INFORMATION **1 Gal**
NADA 141-449, Approved by FDA
Safe-Guard® AquaSol
(fenbendazole oral suspension)

Suspension Concentrate, Antiparasitic

200 mg of fenbendazole/mL

For oral administration via drinking water

DESCRIPTION: Safe-Guard® AquaSol is a suspension concentrate containing fenbendazole, an antiparasitic. Each mL of Safe-Guard® AquaSol contains 200 mg of fenbendazole.

INDICATIONS: Safe-Guard® AquaSol is indicated for the treatment and control of adult *Ascaridia galli* in broiler chickens and replacement chickens and for the treatment and control of adult *A. galli* and *Heterakis gallinarum* in breeding chickens and laying hens.

DOSAGE AND ADMINISTRATION: Safe-Guard® AquaSol must be administered orally to chickens via the drinking water at a daily dose of 1 mg/kg BW (0.454 mg/lb) for 5 consecutive days.
Consult your Veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

GENERAL MIXING DIRECTIONS:
Dose calculation:
The daily dose of 1 mg fenbendazole per kg BW (0.454 mg/lb) is equivalent to 0.005 mL Safe-Guard® AquaSol per kg BW (0.00227 mL/lb). The required daily volume of product is calculated from the total estimated body weight [kg] of the entire group of chickens to be treated. Please use the following formula:

Total estimated body weight [kg] of the chickens to be treated x 0.005 mL = mL Safe-Guard® AquaSol/day

Examples:

Total body weight of birds to be treated	Volume of Safe-Guard® AquaSol per day	Volume of Safe-Guard® AquaSol (for 5 days)
5,000 kg (11,000 lb)	**25 mL**	**5 x 25 mL = 125 mL**
10,000 kg (22,000 lb)	**50 mL**	**5 x 50 mL = 250 mL**
80,000 kg (176,000 lb)	400 mL	5 x 400 mL = 2,000 mL
320,000 kg (704,000 lb)	1,600 mL	5 x 1,600 mL = 8,000 mL

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Follow the instructions in the order described below to prepare the medicated water. The medicated water must be prepared daily prior to each administration.

Prepare a 1 to 1 dilution (pre-dilution) of Safe-Guard® AquaSol in water:

1) Calculate the volume of Safe-Guard® AquaSol to be administered daily.

2) Select a measuring device capable of accurately measuring a volume of at least twice the calculated Safe-Guard® AquaSol daily volume.

[Note: If the total volume of the 1 to 1 dilution needed exceeds the volume of the largest available measuring device, divide the total volume into two or more smaller batches of 1 to 1 dilution, prepared following the steps below. Safe-Guard® AquaSol should always be measured by adding it to a measuring device that already contains an equivalent volume of water.]

3) Pour a volume of water equal to the calculated volume of product needed into the measuring device.

4) Shake the product well before mixing.

5) Fill up the measuring device containing the water with the calculated volume of the product to obtain the 1 to 1 dilution.

[Note: If more than the required amount of the product is accidently poured into the measuring device, discard the entire contents and repeat the process from Step 3 above.]

6) Add the 1 to 1 dilution of Safe-Guard® AquaSol in water to the water supply system as described below. Be careful to avoid any accidental spill or less of 1 to 1 dilution which may inadvertently result in less than the required dose of fenbendazole.

7) Rinse the container used to prepare the 1 to 1 dilution of Safe-Guard® AquaSol with additional water, and add the rinse water to the medicated water tank or the stock suspension tank of the dosing pump.

For use with a medication tank:

Add the entire 1 to 1 dilution of Safe-Guard® AquaSol in water to the medication tank containing the volume of drinking water usually consumed by the animals in 3 to 24 hours.
Stir the medicated water in the medication tank until the medicated water is visibly homogeneous. The medicated water should appear hazy. No further stirring during administration is necessary.

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For use with a dosing pump:

Add the entire 1 to 1 dilution of Safe-Guard® AquaSol in water to the water in the stock suspension tank of the dosing pump. The volume of water in the stock suspension container has to be calculated taking as a basis the present injection rate of the dosing pump and the volume of drinking water usually consumed by the animals over a period of 3 to 24 hours. Stir until the content in the stock suspension tank is visibly homogeneous. The medicated water should appear hazy.

At concentrations of up to 5 mL/L stock suspension (1 g fenbendazole/L) no stirring is required.
At concentrations from 5 mL up to 75 mL of product /L stock suspension (1,000 mg to 15,000 mg fenbendazole/L) and within up to 8 hours during the treatment administration period no stirring of the stock suspension is required. If the administration period exceeds 8 hours, but being no longer than 24 hours, the stock suspension container needs to be equipped with a stirring device.

During treatment all chickens must have sole and unrestricted access to the medicated water. After complete consumption of the medicated water, the chickens should have access to non-medicated drinking water *ad libitum*. Ensure that the total amount of medicated water offered is consumed.

USER SAFETY WARNINGS: Not for use in humans. Keep out of reach of children. Protective gloves should be used and care should be taken when handling the product to avoid skin and eye exposure and accidental ingestion. Accidental exposure may result in skin and eye irritation. Accidental ingestion may cause gastrointestinal disturbances and hypersensitivity reactions in humans. For customer service, adverse effects reporting, and/or a copy of the SDS, call 1-800-211-3573. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or http://www.fda.gov/AnimalVeterinary/SafetyHealth.

RESIDUE WARNING: No withdrawal period is required when used according to labeling.

OTHER WARNING: Resistance may develop to any dewormer. All dewormers require accurate dosing for best results. Following the use of any dewormer, effectiveness of treatment should be monitored. A decrease of effectiveness over time may indicate the development of resistance to the dewormer administered. The parasite management plan should be adjusted accordingly based on regular monitoring.

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EFFECTIVENESS: Six pivotal dose confirmation studies and five field effectiveness studies were conducted to evaluate the effectiveness of Safe-Guard® AquaSol oral suspension against adult *A. galli* in broiler chickens and replacement chickens and against *A. galli* and *H. gallinarum* in breeding chickens and laying hens. Safe-Guard® AquaSol was administered orally in drinking water at 1 mg fenbendazole/kg body weight/day for 5 consecutive days. The chickens were necropsied 7 to 8 days after the last treatment, and adult worms in the intestines and ceca of the chickens in the control and treated groups were counted to determine percent efficacy.

Three dose confirmation studies were conducted in European Union (EU), using 105 Rhode Island Red breed hens (2 years old) for each study. In all three studies, the efficacy against *A. galli* (97.9%, 97.3%, and 93.9%) and *H. gallinarum* (99.8%, 96.9%, and 97.3%) was greater than 90%. A fourth dose confirmation study was conducted in the United States (US) using 264 Rhode Island Red breed hens (12 months old). In the study, the efficacy against adult *A. galli* and *H. gallinarum* was 98.7% and 99.2%, respectively. A fifth dose confirmation study was conducted in the US using 176 Cobb breed broiler chickens (4 to 5 weeks old). In the study, the efficacy against adult *A. galli* was 99.4%. A sixth dose confirmation study was conducted in the US using 176 Ross breed broiler chickens (4 to 5 weeks old). In the study, the efficacy against adult *A. galli* was 100%.

A field effectiveness study was conducted in the EU in a flock of 13,244 Hy-Line layer breed replacement chickens (13 weeks old). Fifteen chickens were necropsied before treatment initiation, and 15 chickens were necropsied seven days after treatment for worm counts. The efficacy against adult *A. galli* was 90.2%. A second field effectiveness study was conducted in the US using 550 Ross breed broiler chickens (4 to 5 weeks old). The efficacy against adult *A. galli* was 100%. A third field effectiveness study was conducted in the US using 550 White Leghorn breed replacement chickens (14 weeks old). The efficacy against adult *A. galli* and *H. gallinarum* was 100% and 98.9%, respectively. A fourth field effectiveness study was conducted in the US using 550 Cobb breed breeder hens (63 weeks old). The efficacy against adult *A. galli* and *H. gallinarum* was 97.6% and 95.3%, respectively. A fifth effectiveness study was conducted in the US using 550 Cobb breed broiler chickens

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Height 165mm

Attachment B – Material Safety Data Sheet

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 vP vB.

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 (CO_2), 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)

Attachment C - Research Information

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