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Another group of 120 chickens (60 male and 60 female) was provided non-medicated drinking water and used as a control group. In all chickens, feed and water intake, body weights, clinical health, and mortality were recorded. Hematology and clinical chemistry parameters were evaluated in 24 chickens from each group. At the end of the treatment phase, gross necropsies were performed on 48 chickens from each group, and organs weights were evaluated. Histopathologic examinations were performed on 48 chickens each from the control and 5 mg fenbendazole/kg body weight groups. No clinically significant effects related to the administration of Safe-Guard® AquaSol were observed for any of the parameters evaluated.

The margin of safety in laying hens was conducted in 144 laying hens. Safe-Guard® AquaSol was administered orally as medicated drinking water to three groups of 36 hens at 1, 3, and 5 times the recommended label dose (1, 3, and 5 mg fenbendazole/kg body weight/day) for 15 consecutive days (3 times the recommended duration). Another group of 36 hens was provided non-medicated drinking water and used as a control group. In all hens, feed and water intake, body weights, clinical health, mortality, egg production, and egg quality parameters (including egg shell thickness and strength, egg weight, and Haugh unit) were evaluated. Hematology and clinical chemistry parameters were evaluated in 12 hens from each group. At the end of the treatment phase, gross necropsies were performed on 12 hens from each group, and organs weights were evaluated. Histopathologic examinations were performed on 12 hens each from the control and 5 mg fenbendazole/kg body weight groups. No clinically significant effects related to the administration of Safe-Guard® AquaSol were observed for any of the parameters evaluated.

The reproductive safety in broiler breeder chickens was conducted in 220 broiler breeder chickens. Safe-Guard® AquaSol was administered orally as medicated drinking water to a group of 110 breeder chickens (10 male and 100 female) at 3 mg fenbendazole/kg body weight/day (3 times the recommended label dose) for 21 consecutive days (4 times the recommended duration). Another group of 110 breeder chickens (10 male and 100 female) were provided non-medicated drinking water and used as a control group. The parameters evaluated in the study included feed and water intake, body weights, clinical health, egg production and weight, fertility, hatchability, and 14-day old chick viability. Necropsy of unhatched eggs was performed to record the percentage of dead embryos and dead and culled hatchlings.

At the end of the treatment phase, 30 breeder chickens (10 male and 20 female) from each group were necropsied, and gross pathology and weights of testes and female reproductive tracts were evaluated. Histopathologic evaluations were performed on the gross lesions collected during the necropsy. No clinically significant effects related to the administration of Safe-Guard® AquaSol were observed for any of the parameters evaluated.

STORAGE INFORMATION: Store at room temperature 30°C. Once opened, do not store the container above 25°C. Do not freeze. Protect from light. Use within 6 months after opening. Use the medicated water within 24 hours.

HOW SUPPLIED: 1 liter and 1 gallon (3,785 mL) HDPE plastic containers

For patent information: <http://www.merck.com/product/patent/home.html>.

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NADA 141-449, Approved by FDA

Rev. 2/2015

NADA 141-449 Approved by FDA
safe-guard® AquaSol
(fenbendazole suspension for oral suspension)
Suspension Concentrate, An 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 intended to become breeding chickens and for the treatment and control of adult *A. galli* and *Heterakis gallinarum* in breeding chickens.

DOSAGE AND ADMINISTRATION: 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.

RESIDUE WARNING: There is no pre-slaughter withdrawal period as Safe-Guard AquaSol can be administered to chickens to day of slaughter. Because a withdrawal time in eggs has not been established, do not use in laying hens.

STORAGE INFORMATION: Store at room temperature 30°C. Once opened, do not store the container above 25°C. Do not freeze. Protect from light. Use within 6 months after opening. Use the medicated water within 24 hours.

See attached Product Information Insert for complete directions and warnings before using.

For customer service, adverse effects reporting, and/or a copy of the MSDS, call 1-800-211-3573.

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Made in France
Net volume (1 Gallon)

Code No.

143540 R5

PRODUCT INFORMATION

NADA 141-449, Approved by FDA

Safe-Guard® AquaSol
(fenbendazole suspension for oral suspension)

Suspension Concentrate,
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GENERAL MIXING DIRECTIONS:

Dose calculation:

The daily dose of 1.0 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

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 container with a volume of at least twice the calculated Safe-Guard® AquaSol daily volume.
- 3 Pour the calculated Safe-Guard® AquaSol daily volume in the container and add half of the equivalent volume of water in the container. Using the remaining half of water, rinse the container used to measure the Safe-Guard AquaSol and add the rinse water to the container to obtain a 1 to 1 dilution of Safe-Guard® AquaSol in water.
- 4 Mix the 1 to 1 dilution of Safe-Guard® AquaSol in water thoroughly.
- 5 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 loss of 1 to 1 dilution which may inadvertently result in less than the required dose of fenbendazole.
- 6 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.

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 4 to 6 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.

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 preset injection rate of the dosing pump and the volume of drinking water usually consumed by the animals over a period of 4 to 6 hours. Stir until the content in the stock suspension tank is visibly homogeneous. The medicated water should appear hazy.

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 6 hours during the treatment administration period stirring of the stock suspension is required.

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*.

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 MSDS, 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/Animal/Veterinary/SafetyHealth>.

CAUTION: Not for use in laying hens and replacement chickens intended to become laying hens.

RESIDUE WARNING: There is no pre-slaughter withdrawal period as Safe-Guard AquaSol can be administered to chickens to day of slaughter. Because a withdrawal time in eggs has not been established, do not use in laying hens.

ADVERSE REACTIONS: There are no known adverse effects and contraindications for the use of fenbendazole in chickens.

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* and *H. gallinarum* in broiler chickens, replacement chickens, laying hens, and breeder chickens. 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 adult *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.

The pivotal dose confirmation studies and field effectiveness studies demonstrated substantial evidence of effectiveness of Safe-Guard® AquaSol at the dose of 1 mg fenbendazole/kg body weight/day for 5 consecutive days. The margin of safety in broiler chickens was conducted in 480 broiler chickens. Safe-Guard® AquaSol was administered orally as medicated drinking water to three groups of 120 chickens (60 male and 60 female in each group) at 1, 3, and 5 mg fenbendazole/kg body weight/day (1, 3, and 5 times the recommended label dose) for 15 consecutive days (3 times the recommended duration).

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 88.9%, respectively. A fourth field effectiveness study was conducted in the US using 550 Cobb breed broiler hens (63 weeks old). The efficacy against adult *A. galli* and *H. gallinarum* was 97.6% and 95.3%, respectively. A fifth field effectiveness study was conducted in the US using 550 Cobb breed broiler chickens (4 to 5 weeks old). The efficacy against adult *A. galli* was 100%.

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