



**PHIBRO ANIMAL HEALTH CORPORATION**

**AVIAX® PLUS**

**Public summary according to Article 7(3)(h) of  
Regulation (EC) No 1831/2003**

**April 2023**

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***HEALTHY ANIMALS. HEALTHY FOOD. HEALTHY WORLD.®***

Glenpointe Centre East / 3<sup>rd</sup> Floor / 300 Frank W. Burr Blvd., Ste. 21 / Teaneck, NJ 07666-6712  
Direct: 201-329-7300 / Fax: 201-329-7399

**Public summary according to Article 7(3)(h) of Regulation (EC) No 1831/2003**

**1.1.1. Contents**

- (a) name of the applicant(s);*
- (b) identification of the additive;*
- (c) method of production and method of analysis;*
- (d) studies on safety and efficacy of the additive;*
- (e) proposed conditions for use; and*
- (f) proposal for post-market monitoring*

**1.1.2. Description**

- (a) name and address of the applicant(s)

Phibro Animal Health Corporation, 300 Frank W. Burr Blvd., Teaneck, NJ 07666

- (b) identification of the additive

Aviax Plus, an anticoccidial agent, is a combination of semduramicin, a polyether ionophore plus nicarbazin. In combination, both active ingredients have a better control of at least one strain of Eimeria in broiler chickens, including strains that are resistant to ionophores used alone.

Target species: Broiler chickens

Level of inclusion in feeds: Mix in the feed at a ratio of 500 to 600 grams per ton, as to obtain a final concentration from 15ppm of Semduramicin + 40ppm of Nicarbazin to 18ppm of Semduramicin + 48ppm of Nicarbazin.

- (c) method of production and method of analysis

Aviax Plus is manufactured from a mixture of the two active ingredients, semduramicin (3%) and nicarbazin (8%), and the excipients in a horizontal mixer. Aviax Plus is a product in granular form, of a light to dark mustard color, with the occasional presence of white particles.

Each 100g of Aviax Plus contains:

Active substances:

Nicarbazin - 8.0g

Semduramicin - 3.0g

Excipients:

Soybean oil

Sodium Carbonate

Antioxidant

Stearic Acid

Corn grits (q.s)

Semduramicin is analyzed using liquid chromatography in reversed phase column C18 with detection by refraction index.

Nicarbazin is analyzed using liquid chromatography with UV detection with UV detection at 298 nm.

(d) studies on safety and efficacy of the additive

Human food safety:

A study assessed the concentrations of semduramicin and nicarbazin in tissues of broiler chickens raised in a floor-pen facility. The chickens were fed Aviax Plus at the inclusion rate of 600 grams/metric ton of food (18 ppm semduramicin and 48 ppm nicarbazin) until the birds were 39 days old. Samples of muscle (breast+thigh in equal proportions), liver, kidney, and skin+fat (in equal proportions) were collected daily from Day 39 to Day 49. The tissue samples were analyzed via LC-MSMS method.

The average semduramicin concentrations in each organ at zero day withdrawal for Replicate 1 and Replicate 2 respectively were: 0.022 mg/kg and 0.022 mg/kg for muscle, 0.186 mg/kg and 0.183 mg/kg for skin/fat, 0.235 mg/kg and 0.228 mg/g for liver, and the samples for kidney were below the quantification limit.

The average nicarbazin concentrations in each organ at zero day withdrawal for Replicate 1 and Replicate 2 respectively were: 0.947 mg/kg and 1.000 mg/kg for muscle, 1.358 mg/kg and 1.379 mg/kg for skin/fat, 12.354 mg/kg and 12.870 mg/kg for liver and 1.879 mg/kg and 1.895 mg/kg for kidneys.

**Efficacy:**

A study showed that the treatment of semduramicin 15 ppm and nicarbazin 40 ppm promoted the best performance rates and control of coccidiosis and lowest mortality during the entire period of the experiment (42 days). The individual treatments of semduramicin (15 ppm) and nicarbazin (40 ppm) were sufficient to control mortality, but were not efficient at restoring weight gain or controlling injury in the same way as the combination of semduramicin and nicarbazin, 15 ppm and 40 ppm, respectively.

The efficacy of different levels of recommended dose of Aviax Plus was evaluated in a study. The efficacy of 15 ppm semduramicin and 40 ppm nicarbazin (group 2), 16.5 ppm semduramicin and 44 ppm nicarbazin (group 3), and 18 ppm semduramicin and 48 ppm nicarbazin (group 4) were compared to the control group. The results confirm that broilers treated with Aviax Plus had better weights, increased weight gain, and lower lesions scores compared to the control animals.

(e) proposed conditions for use

Target species: Broiler chickens

Method of administration: oral in feed

Level of inclusion in feeds: 500 to 600 grams per ton of Aviax Plus to obtain a final concentration from 15ppm of Semduramicin + 40ppm of Nicarbazin to 18ppm of Semduramicin + 48ppm of Nicarbazin.

Possible interactions: This product contains an ionophore; its concurrent use with certain drug products may be contraindicated. Broiler chickens receiving Nicarbazin may show low tolerance to heat and humidity. Addition of tiamulin in feeds containing Aviax Plus can cause some degree of depression in feed intake.

Proposed duration of administration: Aviax Plus is indicated for broilers from one day of age up to one day before slaughter.

(f) proposal for post-market monitoring

The applicant also confirms a pharmacovigilance system will be used to trace and identify any direct or indirect, immediate, delayed or unforeseen effects resulting from the use of the additive on human or animal health or the environment.