



From:

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| <p>To: [REDACTED]</p> <p>Telephone: [REDACTED]</p> <p>Fax: [REDACTED]</p> <p>Email: [REDACTED]</p> | <p>Re: Surmax™ Premix, Avatec® Medicated Premix, Safe-Guard Premix</p> <p>Case Id: ON-090721-23577</p> <p>Date of Response: Sep 7, 2021 2:19:26 PM</p> |
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Case Information:

Date Submitted Sep 7, 2021 11:30:16 AM
Species Turkeys
Number of Animals 23500
Location of Animals [REDACTED]
Reason for Use Prophylaxis
Additional Information The total length of time that Avilamycin is in the feed is greater than 21 days.

Drugs Administered

| Drug Trade Name | Generics | Route | Dose | Diseases |
|--------------------------|--------------------|-------------|--|---|
| Surmax™ Premix | • avilamycin | Oral - Feed | 20 ppm (in feed) Continuously for 7 days | • Alimentary: necrotic enteritis - clostridium perfringens |
| Avatec® Medicated Premix | • lasalocid sodium | Oral - Feed | 100 ppm (in feed) Continuously for 7 days | • Alimentary: coccidiosis |
| Safe-Guard Premix | • fenbendazole | Oral - Feed | 30 ppm (in feed) Continuously for 7 days | • Alimentary: endoparasites - ascarids • Alimentary: endoparasites - heterakis |

Response and Recommendation: 72 hours

Avilamycin is not approved for use in turkeys in Canada, and there are no maximum residue limits for turkeys. Therefore, any amount detected at slaughter will constitute a violative residue. The CgFARAD™ was able to obtain tissue depletion data for avilamycin used at 45 ppm for 21 days in turkeys from Elanco. Based on the results of the Elanco study, following a withdrawal interval of 24 hours should be sufficient for the use of avilamycin up to 45 ppm for 21 days in turkeys. Due to concerns regarding antimicrobial resistance, the Veterinary Drugs Directorate will no longer approve antimicrobials for continuous use throughout the production cycle and they strongly discourage extended durations of therapy. Therefore, we suggest that extended treatments with avilamycin should be avoided whenever possible and if used beyond 21 days, we recommend extending the above recommendation to at least 48 hours. Lasalocid is approved for use in turkey feeds for the prevention of coccidiosis at 100 ppm to be fed continuously “from day one (1) for sixteen (16) weeks for males and fourteen (14) weeks for females” with a zero day withdrawal time. Fenbendazole has just been approved as a dewormer for growing turkeys in Canada at 16 ppm to be fed for 6 days with a withdrawal time of 24 hours. The VDD has just set an MRL for turkeys at 3 ppm for liver and 2 ppm for kidney, muscle & skin-fat. In your case, fenbendazole will be used at approximately 2X the approved dose for 7 days. By convention, we add an elimination half-life for every doubling of the drug dose. This also applies when the duration of therapy is extended. Given that the label withdrawal time is 24 hours and to comply with CgFARAD™ policy of recommending a "greatly extended" withdrawal interval for any extralabel drug use in food animals, we recommend following a withdrawal interval of at least 72 hours for this extralabel use of fenbendazole in turkeys. We are not aware of any interaction between these drugs that would require further extension of the withdrawal intervals. Therefore, we recommend following a withdrawal interval of at least 72 hours for this combination.

Therefore, the Canadian gFARAD recommends a withdrawal interval of 72 hours, which should be sufficient so that detectable residues are not found. Furthermore, this recommendation for residue avoidance does not address the risks of developing or transmitting antimicrobial resistance from treated animals to other animals or humans following the extralabel use of this antimicrobial. Because the Canadian gFARAD withdrawal recommendation is not an official withdrawal time and is based on data that has not been reviewed nor approved by the Veterinary Drugs Directorate or the Canadian Food Inspection Agency, responsibility for residue violations rests with the attending veterinarian.

To review this request in CgFARAD:

<https://farad.usask.ca/cgfarad/vet/viewRequest?id=23577&langen>