



From:

Saad Enouri, BVSc, MSc, PhD
Research Associate, Canadian gFARAD
Ontario Veterinary College
senouri@uoguelph.ca
Telephone: 519-824-4120 ext. 54984

To: [REDACTED]
Telephone: [REDACTED]
Fax: [REDACTED]
Email: [REDACTED]

Re: Chlor 100 Premix
Case Id: ON-032321-22791
Date of Response: Mar 31, 2021 8:01:12 AM

Case Information:

Date Submitted Mar 23, 2021 2:49:49 PM
Species Chickens/Broiler Breeder
Number of Animals 25000
Location of Animals [REDACTED]
Reason for Use Treatment
Additional Information Please provide meat withdrawal recommendations.

Drugs Administered

Drug Trade Name	Generics	Route	Dose	Diseases
Chlor 100 Premix	• chlortetracycline	Oral - Feed	220 ppm (in feed) Continuously for 70 days	• Alimentary: colibacillosis

Response and Recommendation: 13 days

Chlortetracycline was approved for use in broiler chickens at doses up to 220 ppm with a 7 day meat withdrawal time. Recent changes in legislation removed all growth promotion claims on feed additive drugs in Canada. These changes resulted in no "on label" claims for oxytetracycline or chlortetracycline in any class of chickens. In concurrence with the US codified regulations regarding ELDU, the CgFARAD™ has a policy of recommending a greatly extended withdrawal interval when drugs are used extra label in food producing animals. Therefore, CgFARAD™ will now recommend an 8 day meat withdrawal interval for oxytetracycline or chlortetracycline administered at concentrations consistent with the old approved labelling. In your case however chlortetracycline will be fed to these birds for a long duration (70 days). In Canada, the MRLs for chlortetracycline in chickens are 0.2 ppm in muscle, 0.6 ppm in liver and 1.2 ppm in kidney. In the United States, chlortetracycline is approved as a feed additive in chickens with a zero meat withdrawal time when fed up to 400 g/ton (or 441 ppm) and with a 24 hours withdrawal interval

when used at 500 g/ton (or 551 ppm). This discrepancy in withdrawal times is partly due to the higher MRLs for chlortetracycline in the United States (2 ppm in muscle, 6 ppm in liver and 12 ppm in kidney). The United States currently has the highest tetracycline tolerances in the world. Data obtained from the FOI for Aureomycin in the United States showed that all tissues contained chlortetracycline residues well below the United States MRL's immediately following administration to justify a zero withdrawal time. The depletion studies identified the kidney as the slowest eliminating organ for chlortetracycline residues. The half-life in the kidney should; therefore, be used rather than the muscle or serum half-lives, in order to determine an acceptable withdrawal interval. The data from the depletion studies described in the United States FOI (NADA 048-761) indicate that the elimination half-life of chlortetracycline residues in chicken kidneys is approximately 4.11 days. By convention, we add a half-life to the withdrawal time for every increasing/doubling of the drug dose under the assumption that the elimination mechanisms have not become saturated. This also applies when the duration of treatment is extended. Therefore, we recommend following a minimum meat withdrawal interval of 13 days for these birds.

Therefore, the Canadian gFARAD recommends a withdrawal interval of 13 days, 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=22791&langen>