From:

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Re: Uniprim® Oral Granules
Case Id: ON-121021-24015
Date of Response: Dec 13, 2021 11:27:16 AM

Case Information:

Date Submitted	Dec 10, 2021 2:42:44 PM
Species	Chickens/Broilers
Number of Animals	20000
Location of Animals	[redacted]
Reason for Use	Treatment
Additional Information	750ppm = 249.75ppm of Sulfadiazine and 50.25 ppm Trimethoprim

Drugs Administered

Drug Trade Name	Generics	Route	Dose	Diseases
Uniprim® Oral Granules	• sulfadiazine • trimethoprim	Oral - Feed	750 ppm of Uniprim Oral Granules per tonne of feed (249.75 ppm of sulfadiazine and 50.25 ppm trimethoprim) continuously for 7 days.	• **Alimentary:** colibacillosis

Response and Recommendation: *3 days*

As sulfadiazine and trimethoprim are not approved for poultry in Canada, there are no MRLs for these drugs in poultry. Therefore, any amount of sulfadiazine or trimethoprim detected in the tissues of chickens is a residue violation. Trimethoprim is usually administered with a sulfonamide but is excreted faster. Consequently if no residues of sulfonamide are detectable, no residues of trimethoprim would be expected. So, CFIA's detection program focuses on sulfonamides. We have been provided with depletion data for sulfadiazine/ trimethoprim in chickens at a dose of 25-30 mg/kg from the US manufacturer of Uniprim. The methodology of the analysis is unknown and may not be as accurate as the methodology employed by the CFIA, but it does give us data to

model the elimination of sulfadiazine from chickens and we use the means plus 3 standard deviations. We find a liver elimination half-life of 4 hours, which corresponds to a literature reference of a plasma elimination half-life of 2 hours. By modelling the US data from the highest tissue levels (liver), we believe that a 72 hour (3 days) withdrawal interval for meat will be sufficient to prevent detectable residues of sulfadiazine in chickens at this dose.

Therefore, the Canadian gFARAD recommends a withdrawal interval of 3 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=24015&langen