

On August 30, 2016, a Human Food Safety technical section incomplete letter, I-006013-P-0126-HF, was issued to the National Research Support Program No. 7 (NRSP-7). The Human Food Safety technical section was considered to be incomplete for the use of AQUAMYCIN 100 (erythromycin thiocyanate) Type A medicated article in juvenile salmonids (< 60 g). The proposed use is to administer, *via* feed, 100 mg erythromycin thiocyanate/kg bw/day for 28 consecutive days.

CVM concluded that based on the evaluation of publicly available information and conditions of the proposed use in juvenile salmonids (<60 g), CVM has no toxicological concerns at the tolerance of 0.1 ppm for erythromycin residues in muscle with adhering skin. This tolerance is currently codified for tissues of cattle and swine (21 CFR 556.230) and would be applied to salmonids.

Status of the Human Food Safety Technical Section for erythromycin thiocyanate Type A medicated article in juvenile salmonids.

<i>Components of the Human Food Safety Assessment</i>	<i>Status</i>
Microbial Food Safety (Antimicrobial Resistance)	Complete P-0092 November 22, 2005 [#]
Impact of Residues on Human Intestinal Flora	Complete P-0104 January 11, 2007
Toxicology	Complete, current submission*
Residue Chemistry	Complete P-0104 [†] January 11, 2007

(# indicates that the antimicrobial resistance evaluation for erythromycin was completed, but any sponsors interested in pursuing an NADA for this indication will need to provide CVM with updated information for evaluation.)

(* indicates that the toxicological evaluation for erythromycin is complete, but any sponsors interested in pursuing an NADA for this indication will need to provide CVM with the final product formulation so CVM can confirm that all the non-active ingredients have been adequately evaluated for human food safety.)

(† indicates that the residue chemistry evaluation for erythromycin is complete, but any sponsors interested in pursuing an NADA for this indication will need to provide CVM with the final product formulation so CVM can confirm that the sponsors' product is the same as the product tested under the INAD.)

Human food safety requirements for the use of AQUAMYCIN 100 (erythromycin thiocyanate) Type A medicated article in juvenile salmonids (< 60 g) have been satisfied for microbial food safety (antimicrobial resistance), impact on human intestinal flora, toxicology, and residue chemistry.

CVM's acceptance of completeness of the components of the human food safety evaluation with three exceptions^{#**†} only applies to the use of this erythromycin product in juvenile salmonids (< 60 g), and a labeling restriction addressing this limitation is necessary. If a sponsor pursues approval of the use of erythromycin in adult salmonids, additional information supporting its use in adults will need to be submitted and evaluated.

The following human food safety parameters describe this product:

Acceptable Daily Intake (ADI)

- Neither a microbiological nor a toxicological ADI for total residues of erythromycin is needed for this application.

Tolerance

- Erythromycin: 0.1 ppm for muscle with adhering skin

Withdrawal Period

- A withdrawal period of 60 days is assigned for juvenile salmonids (< 60 g) treated with erythromycin thiocyanate at 100 mg erythromycin thiocyanate/kg bw/day for 28 consecutive days in feed.

Analytical Method for Residue Detection

- The analytical method for detection of residues of erythromycin is a microbiological cylinder plate assay.

Microbial Food Safety (Antimicrobial Resistance)

- The antimicrobial resistance portion of microbial food safety is complete; however, the component will need to be updated by the drug sponsor with a revised evaluation.