



U.S. Fish & Wildlife Service

The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: Oxytetracycline Medicated Feed INAD 9332

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of oxytetracycline (OTC) when fed as a feed additive to 1) control mortality caused by bacterial diseases in a variety of freshwater and marine fish, and abalone; and 2) mark skeletal tissue of finfish.
Drug name:	Oxytetracycline dihydrate (Terramycin 200 [®] for Fish; TM200)
Source of drug:	Phibro Animal Health Corporation
Address:	Glenpointe Centre East, 3 rd Fl, 300 Frank W. Burr Blvd., Ste 21, Teaneck, NJ 07666
Contact:	Etan Bendheim; Phone: 201-329-7351; email: Etan.Bendheim@pahc.com
Target pathogen(s):	Bacterial pathogens susceptible to oxytetracycline, exclusive of already approved claims.
Method of administration:	Medicated-feed treatment
Treatment dosage:	Standard therapeutic finfish dose: 2.5 - 3.75 g OTC per 100 pounds fish per day. High therapeutic finfish dose: 10 g OTC per 100 pounds fish body weight per day. Standard abalone dose: up to 6.0 g OTC per 100 pound abalone body weight per day. Skeletal marking dose: same as standard or high therapeutic finfish dose.
Treatment regimen:	Option A: standard therapeutic finfish dose; 10-day treatment duration (all salmonids). Option B: high therapeutic finfish dose; 14-day treatment duration; temp > 4°C (all finfish). Option C: standard therapeutic finfish dose; 10-day treatment duration (non-salmonid freshwater and marine fish). Option D: standard abalone dose; 14-day treatment duration. Option E: skeletal marking at standard therapeutic dose, 10-day treatment duration; skeletal marking at high therapeutic dose, 14-day treatment duration.
Withdrawal period:	Option A: 21 days. Option B: 70 days. Option C: 40 days. Option D: 35 days. Option E (standard dose): 21 days (salmonids); 40 days (non-salmonids). Option E (high dose): 70 days (all finfish). No withdrawal period is required for treated fish that will not be susceptible to legal harvest or slaughtered for market for the appropriate number of days as specified in the Options listed above.
Required test parameters:	Investigator must collect mortality data throughout the 5 day pre-treatment, treatment, and 10 day post-treatment periods. Investigator should also report general fish behavior and any possible adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Not for use for existing FDA-approved claims for TM200. Investigator must follow all instructions in the Study Protocol for INAD 9332 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Drug discharge must be in compliance with local NPDES permitting requirements.
Required INAD fee:	\$700.00/facility/year
AADAP Contact Information:	Ms. Bonnie Johnson, FWS-AADAP Phone: 406-994-9905 Fax: 406-582-0242 email: bonnie_johnson@fws.gov