



United States Department of the Interior

U.S. FISH & WILDLIFE SERVICE
AQUATIC ANIMAL DRUG APPROVAL PARTNERSHIP PROGRAM
4050 BRIDGER CANYON ROAD
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May 24, 2007

Dr. Joan Gotthardt
Director, Division of Therapeutic Drugs
for Food Animals
Document Control Unit, HFV-199
Center for Veterinary Medicine
7500 Standish Place, MPN-2
Rockville, MD 20855

Dear Dr. Gotthardt:

The purpose of this letter is to request that CVM, on behalf of the U. S. Fish and Wildlife Service (Service), establish a Public Master File (PMF) for the use of chloramine-T as an immersion treatment to control mortality caused by external bacterial pathogens in a variety of fish species. We also request that the attached information be placed in the PMF. The purpose of the Service's PMF will be to serve as a repository for efficacy and target animal safety information and data required to support a sponsor's New Animal Drug Application (NADA) for chloramine-T. All information and data, including Freedom of Information (FOI) Summaries, submitted to the PMF have been reviewed by CVM and issued Technical Section Complete letters.

This submission includes three copies each of (1) an efficacy protocol, (2) a target animal safety protocol, (3) a chloramine-T dose confirmation protocol, (4) abstracts from three effectiveness final study reports summarizing the use of 12 mg/L chloramine-T administered daily as a 60 min bath on three alternate or consecutive days to control mortality in rainbow trout, chum salmon, and Apache trout, (5) executive summaries for ten target animal safety studies demonstrating that the highest proposed efficacious therapeutic concentration of 20 mg/L chloramine-T is safe to various life stages of rainbow trout, (6) an abstract from a final study report summarizing the results from a chloramine-T flow-through dose confirmation study, and (7) CVM correspondence related to completion of Technical Sections from the Service's INAD file #4000. Also included is a Freedom of Information (FOI) Summary of these data, as well as the Table of Contents for the PMF. An electronic copy of all attachments is provided for your convenience.

We request that the availability of this information and these data be announced in the FEDERAL REGISTER so that a commercial sponsor may use them by reference to support these components of an NADA.

The information in this PMF supports the following label claim:

For use to control mortality caused by bacterial gill disease in freshwater-reared salmonids. Treat fish one time per day at 12 – 20 mg/L for 60 min in a static or flow-through bath on three alternate or consecutive days.

If you have questions regarding the above-described request, please contact Dr. David Erdahl, Branch Chief, U. S. Fish and Wildlife Service, AADAP Program at (406)-994-9904. We would like to thank you in advance for your time and consideration with respect to the above-described request.

Sincerely,



Dr. David Erdahl
Branch Chief, AADAP Program

Attachments (3 copies of each)

1. Protocols

- a. Efficacy of chloramine-T for control of mortality associated with bacterial gill disease and flexibacteriosis in a variety of fish species
- b. The safety of chloramine-T (trihydrate) to various rainbow trout life stages
- c. Analytical verification of chloramine-T to confirm target dosage in a bath solution administered using a flow-through treatment method

2. Efficacy Final Study Reports

- a. Abstract - Efficacy of chloramine-T to control mortality caused by bacterial gill disease associated with flavobacters in fall chum salmon fingerling (Study Number 4000-1-02)
- b. Abstract - Efficacy of chloramine-T to control mortality caused by bacterial gill disease in fingerling rainbow trout (Study Number 4000-1-04)
- c. Abstract - Efficacy of chloramine-T to control mortality caused by bacterial gill disease in Apache trout fry (Study Number 4000-1-05)
- d. Abstract – Analytical verification of chloramine-T to confirm target dosage in a bath solution administered using a flow-through treatment method (Study Number BFTC-01-CHLT-FT-01)

3. Target Animal Safety Final Study Reports

a. Executive Summary for TAS Experiments 1 – 8, and 10 (Acute Toxicity)

- i. Exp. #1 - The safety of chloramine-T to rainbow trout (RBT) fry at 8°C administered on alternate days
- ii. Exp. #2 - The safety of chloramine-T to RBT fry at 14°C administered on alternate days
- iii. Exp. #3 - The safety of chloramine-T to juvenile RBT fry at 8°C administered on alternate days
- iv. Exp. #4 - The safety of chloramine-T to juvenile RBT fry at 14°C administered on alternate days
- v. Exp. #5 - The safety of chloramine-T to fingerling RBT fry at 8°C administered on alternate days
- vi. Exp. #6 - The safety of chloramine-T to fingerling RBT fry at 14°C administered on alternate days
- vii. Exp. #7 - The safety of chloramine-T to juvenile RBT fry at 14°C administered on alternate days
- viii. Exp. #8 - The safety of chloramine-T to juvenile RBT fry at 14°C administered on alternate days
- ix. Exp. #10 - The safety of chloramine-T to juvenile RBT fry at 14°C administered on consecutive days

b. Executive Summary for TAS Experiment 9 (Pathologies)

- i. Exp. #9 - The safety of chloramine-T to juvenile RBT fry at 14°C administered on alternate days

4. CVM correspondence related to Technical Section completion

5. Freedom of Information (FOI) Summary

6. PMF Table of Contents