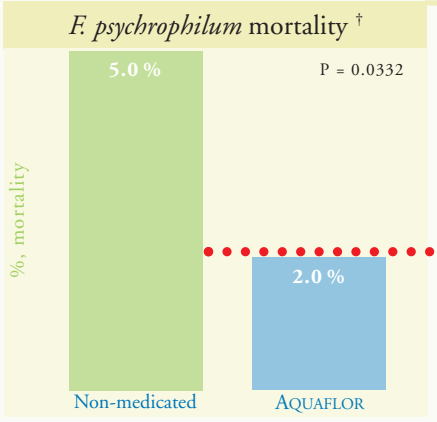
NATURAL DISEASE CHALLENGE

The results of these trials show the value of using AQUAFLOR (florfenicol) — the first and only antibiotic approved for controlling mortality in freshwater-reared salmonids due to coldwater disease associated with *Flavobacterium psychrophilum* — in natural disease challenge conditions.



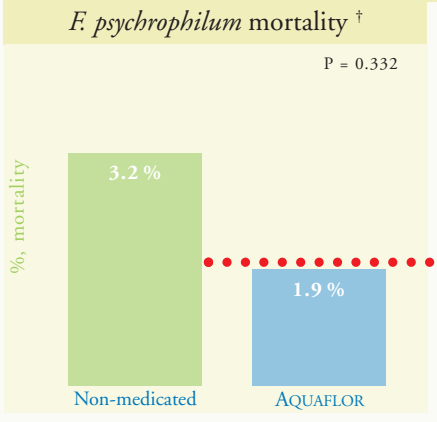
STEELHEAD TROUT FINGERLINGS

Natural disease challenge / 2,640 fish

Treating with AQUAFLOR reduced mortality

60 %

- AQUAFLOR demonstrated a statistically significant difference in mortality versus untreated controls.
- No moribund fish were observed in treated tanks during the post-treatment observation period, indicating that AQUAFLOR effectively controlled the coldwater disease outbreak.



CUTTHROAT TROUT FINGERLINGS

Natural disease challenge / 29,560 fish

Treating with AQUAFLOR reduced mortality

41 %

- Mean mortality was controlled by AQUAFLOR within 4-5 days post-treatment versus 29 days in the untreated group.

† Cumulative mortality (Days 1-24) of fingerlings afflicted with naturally occurring coldwater disease and treated with AQUAFLOR (treated 10 days, 14 days non-medicated) vs non-medicated controls.

NDC 0061-1355-01

2.0 kg (4.4 lb)

AQUAFLOR® (florfenicol)

TYPE A MEDICATED ARTICLE

FOR USE IN CATFISH AND SALMONID FEEDS ONLY

DO NOT FEED UNDILUTED

CAUTION: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive (VFD) issued by a licensed veterinarian in the course of the veterinarian's professional practice.

Active Drug Ingredient: Florfenicol 500 g per kg (227.27 g per lb)

Inert Ingredients: Lactose and Povidone.

Description: Each kg of AQUAFLOR® (florfenicol) contains 500 grams (1.1 lb) of the antibiotic florfenicol in a palatable base.

Activity:

Catfish: *In vitro* and *in vivo* investigations in catfish have established florfenicol's activity against *Edwardsiella ictaluri* (Table 1).

Table 1: Minimum inhibitory concentration (MIC) of florfenicol against *Edwardsiella ictaluri* isolated from channel catfish, between 1998-2001.

ORGANISM	NO. OF ISOLATES	MIC_{90} (µg/ml)	MIC_{90} MIC RANGE (µg/ml)
Edwardsiella ictaluri	95	0.25	0.25

Indications:

Catfish: For the control of mortality in catfish due to enteric septicemia of catfish associated with *Edwardsiella ictaluri*.

Freshwater-reared Salmonids: For the control of mortality in freshwater-reared salmonids due to coldwater disease associated with *Flavobacterium psychrophilum*.

Caution: The effects of AQUAFLOR® (florfenicol) on reproductive performance have not been determined. For catfish, a dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for the hematopoietic/lymphopoietic tissues to regenerate was not evaluated.

WARNING: Catfish: Feeds containing AQUAFLOR® (florfenicol) must be withdrawn 12 days prior to slaughter.

WARNING: Salmonids: Feeds containing AQUAFLOR® (florfenicol) must be withdrawn 15 days prior to slaughter.

Important: Must be thoroughly mixed in feeds or surface-coated (top-coated) onto the feeds before use.

Mixing Instructions:

For incorporation inside pellets: For making AQUAFLOR® Type C Medicated Feed for catfish and freshwater-reared salmonids: a) AQUAFLOR® (florfenicol) is added to other feed ingredients in the mixer prior to extrusion, b) the medicated feed is mixed thoroughly to insure homogeneity, c) the mixture is extruded and pellets are dried, d) the pellets are dry-mixed/coated with a predetermined amount of fish or vegetable oil, and e) at the completion of mixing, the product is transferred to a storage tank for packaging or transport.

For surface-coating (top-coating): For making AQUAFLOR® Type C Medicated Feed for freshwater-reared salmonids only: a) add a known quantity of fish feed into a mixer, b) weigh out AQUAFLOR® (florfenicol), c) weigh out fish oil or vegetable oil into a bucket, d) mix AQUAFLOR® (florfenicol) and oil thoroughly in the bucket, e) add the AQUAFLOR® (florfenicol) and oil mixture to the feed in the mixer, slowly, while the mixer is running at low speed, f) at the completion of mixing, the product is transferred to a storage tank for packaging or transport.

Recommended AQUAFLOR® (florfenicol) Inclusion Rates for Preparation of Type C Medicated Feed for Catfish and Freshwater-reared Salmonids

Feeding Rate	Florfenicol Composition in Feed	Amount of AQUAFLOR® (florfenicol) per Ton	Biomass of Fish Medicated per Ton of Feed per 10-day Treatment Period
% Biomass	Grams / ton	lbs	lbs
0.5	1,816	8.00	40,000
1.0	908	4.00	20,000
2.0	454	2.00	10,000
3.0	300	1.32	6,666
5.0	182	0.80	4,000

Feeding Directions:

Catfish: Feed as the sole ration for 10 consecutive days. AQUAFLOR® (florfenicol) medicated feed should only be administered once disease associated with *Edwardsiella ictaluri* in catfish has been appropriately diagnosed. Feeding fish at a percent of biomass and corresponding florfenicol concentration included in the table above will deliver 10 mg florfenicol per kg of fish.

Freshwater-reared salmonids: Feed as the sole ration for 10 consecutive days. AQUAFLOR® (florfenicol) medicated feed should only be administered once disease associated with *Flavobacterium psychrophilum* in freshwater-reared salmonids has been appropriately diagnosed. Feeding fish at a percent of biomass and corresponding florfenicol concentration included in the table above will deliver 10 mg florfenicol per kg of fish.

Caution: Feed containing AQUAFLOR® (florfenicol) shall not be fed to catfish or freshwater-reared salmonids for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The expiration date for VFD for AQUAFLOR® (florfenicol) must not exceed 15 days from the date of issuance. VFD for AQUAFLOR® (florfenicol) shall not be refilled.

WARNING: Avoid inhalation, oral exposure, and direct contact with skin or eyes. Operators mixing and handling AQUAFLOR® should use protective clothing, gloves, goggles and NIOSH-approved dust mask. Wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water. If irritation persists, seek medical attention. Not for human consumption. Keep out of reach of children. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. For more information or to report adverse effects, call 1-800-224-5318. For customer service, call 1-800-521-5767. For a copy of MSDS sheet, call 1-800-770-8878.

STORAGE CONDITIONS: Store at 2-30°C (36-86°F).

NADA #141-246, Approved by FDA.

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Schering-Plough

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TAKE TIME TO OBSERVE LABEL DIRECTIONS.

COLDWATER DISEASE