

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 140-989

B. Sponsor

Western Chemical, Inc.
1269 Lattimore Road
Ferndale, Washington 98248

C. Proprietary Name

PARASITE-S®

D. Established Name

formalin

E. Dispensing Status

OTC

F. Indication

Formalin is indicated for the control of external parasites on cultured food fishes: salmon, trout, catfish, largemouth bass, and bluegill sunfish. Organisms controlled include the protozoa: Ichthyophthirius spp. ("Ich"), Chilodonella spp., Costia spp., Scyphidia spp., Epistylis spp., and Trichodina spp. and monogenetic trematodes: Cleidodiscus spp., Gyrodactylus spp., and Dactylogyrus spp.

For control of fungi of the family Saprolegniaceae on salmon, trout, and esocid eggs.

II. EFFECTIVENESS

Animal efficacy is discussed in the FOI Summary for PMF 3543.

III. TARGET ANIMAL SAFETY

Animal safety is discussed in the FOI Summary for PMF 3543.

IV. HUMAN FOOD SAFETY

Human food safety is discussed in the FOI Summary for PMF 3543.

V. AGENCY CONCLUSIONS

The data submitted in support of this NADA satisfy the requirements of 512 of the Act and demonstrate that formalin, when used under its proposed conditions of use, is safe and effective for the control of external protozoa and monogenetic trematodes on salmon, trout, catfish, largemouth bass, and bluegill sunfish, and for the control of fungi on salmon, trout, and esocid eggs.

A tolerance is not required for fish because total residue data showed that mean concentrations of formalin residues at 12 hours after the last treatment (zero withdrawal) were not different from naturally-occurring formaldehyde, which is a product of autolysis.

The proposed labeling is adequate to ensure the safe use of formalin by lay persons. Therefore, this product is an over-the-counter (OTC) product.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.