Approval Date: September 30, 1993

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 140-989

B. Sponsor

Western Chemical Inc.
1269 Lattimore Road
Ferndale, WA 98248

C. Proprietary Name

PARASITE-S®

D. Established Name

formalin

E. Dosage Form

formalin, formol

F. Amount of Active Ingredient

A solution of about 37% by weight of formaldehyde gas in water, usually with 10 to 15% methanol added to prevent polymerization. The solution is the same strength as formalin 40% which signifies that it contains 40 grams in 100 mL of the solution and which is equivalent to 37% by weight.

G. Dispensing Status

OTC

H. Dosage Regimen

1. Concentration used for treatment are summarized in Table 1 below. Concentrations used for treatment are expressed as microliters (µL) of formalin (37% formaldehyde) per liter (L) of water which is equivalent to parts per million (ppm) as follows:

Table 1. Concentrations used for control of external parasites on penaeid shrimp. Concentration of formalin (µL/L)+ in ppm

Species	Tanks and raceways (for up to 4 hours daily)*	Earthen ponds (single treatment)**
Penaeid Shrimp	50 to 100***	25

+ µL/L: Microliters per liter (equal to parts per million, ppm).
* May be repeated daily until parasite control is achieved.
** May be repeated in 5 to 10 days if needed.
*** Use the lower concentrations when tanks and raceways are heavily loaded with shrimp.

2. Duration of drug treatment proposed: For external protozoan parasites of penaeid shrimp specified above, a 4-hour exposure from 50 to 100 ppm of formalin daily until parasite control is achieved or a single treatment in ponds at 25 ppm (may be repeated in 5 to 10 days if needed).

I. Route of Administration

In the environmental water.

J. Indication

For control of external protozoan parasites (*Bodo* spp., *Epistylis* spp., and *Zoothamnium*) on cultured shrimp.

K. Effect of Supplement

To add a new species, new claims, new dosages, and new treatment regimens.

II. EFFECTIVENESS

Efficacy data from the Freedom of Information (FOI) summary for PMF 3543, 56 FR 20618, May 6, 1991, demonstrated that formalin, when used as directed, is effective in the treatment and control of external protozoan parasites on shrimp.

III. TARGET ANIMAL SAFETY

Target animal safety data from the Freedom of Information (FOI) summary for PMF 3543, 56 FR 20618, May 6, 1991, demonstrated that an adequate margin of animal safety is inherent to formalin when it is used as directed by labeling in penaeid shrimp.

IV. HUMAN FOOD SAFETY

A. Toxicity Testing:

These have been adequately addressed in the FOI summary for PMF 3543.

B. Withdrawal Time:

Residue depletion data submitted under PMF 3543, 56 FR 20618, May 6, 1991, support a zero-hour pre-harvest withdrawal time for penaeid shrimp treated with the recommended dose of formalin.

V. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA comply with the requirements of Section 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 protozoan parasites on penaeid shrimp.

A tolerance is not required for shrimp because total residue data submitted under PMF 3543, 56 FR 20618, May 6, 1991, indicate that mean concentrations of formalin residues at 12 hours after the last treatment (zero-hour withdrawal) were not different from naturally-occurring formaldehyde, which is a product of autolysis.

The proposed labeling is adequate to assure the safe use of formalin by aquaculturists. Therefore, this product can be marketed Over-the-Counter (OTC).

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact (FONSI) and the evidence supporting that finding are contained in an environmental assessment, which may be seen in the Docket Management Branch (HFV-305), Park Building (Room 1-23), 12420 Parklawn Dr., Rockville, Maryland 20855.

Under the Center's supplemental approval policy, 21 CFR 514.106(b)(2), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

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.