I. GENERAL INFORMATION

NADA Number: NADA 140-989

Sponsor: WESTERN CHEMICAL INC.
1269 Lattimore Road
Ferndale, WA. 98248

Accepted Name: Formalin

Trade Name: PARASITE-S

Marketing Status: Over-the-counter

Supplemental Effects: The approval will allow for the use of formalin to be expanded, as a parasiticide, to all finfish, and, as a fungicide, to the eggs of all finfish.

II. INDICATIONS FOR USE

PARASITE-S is added to the environmental water as follows: (a) for the control of external protozoa (*Chilodonella* spp., Costia spp., *Epistylis* spp., *Ichthyophthirius* spp., *Scyphidia* spp. and *Trichodina* spp.), and the monogenetic trematode parasites (*Cleidodiscus* spp., *Dactylogyrus* spp., and *Gyrodactylus* spp.) on all finfish, (b) for the control of fungi of the family Saprolegniaceae on all finfish eggs and (c) for the control of external protozoan parasites (*Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.) on penaeid shrimp.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND RECOMMENDED DOSAGE

A. Dosage Form: Formalin is a solution of about 37% by weight of formaldehyde gas in water. (This is equivalent to formalin 37, or 37 grams of formaldehyde in 100 ml of solution.)

B. Route of Administration: In the environmental water

C. Recommended Concentrations: as represented in Table 1-3 below.

1. For the Control of External Parasites on Finfish

TABLE 1
Concentrations of Formalin

Aquatic Species	Administer in Tanks and Raceways for up to 1 hour (µL/L)*	Administer in Earthen Ponds Indefinitely (µL/L)*
Salmon & trout		
above 50°F	up to 170	15 to 25**, ***
below 50°F	up to 250	15 to 25**, ***
All other finfish	up to 250	15 to 25**, ***

* Microliter per liter (µL/L) = parts per million (ppm).

** Use the lower concentration when ponds, tanks or raceways are heavily loaded with phytoplankton, or finfish, to avoid oxygen depletion due to the biological oxygen demand created by decay of dead phytoplankton. Alternatively, a higher concentration might be used if dissolved oxygen is strictly monitored.

*** Although the indicated concentrations are considered safe for cold and warm water finfish, a small number of each lot or pond to be treated should always be used to check for any unusual sensitivity to formalin before proceeding.

2. For the Control of Fungi of the Family Saprolegniaceae on Finfish Eggs

TABLE 2
Concentrations of Formalin

Aquatic Species	Administer in Hatchery Systems (µL/L)*
Eggs of all finfish except Acipenseriformes	1000 to 2000 for 15 minutes**
Eggs of Acipenseriformes	up to 1500 for 15 minutes**

* Microliter per liter (µL/L) = parts per million (ppm).

** Apply in constant flow water supply of incubating facilities. A preliminary bioassay should be conducted on a small subsample of finfish eggs to determine sensitivity before treating an entire group. This is necessary for all species because egg sensitivity can vary with species or strain and the unique conditions at each facility.

3. For the Control of External Protozoan Parasites on Penaeid Shrimp

TABLE 3
Concentrations of Formalin

Aquatic Species	Administer in Tanks and Raceways for up to 4 hours (µL/L)*	Administer in Earthen Ponds Indefinitely (µL/L)*
Shrimp	50 to 100**	25***

* Microliter per liter (µL/L) = parts per million (ppm).

** Treat for up to 4 hours daily. Treatment may be repeated daily until parasite control is achieved. Use the lower concentration when tanks or raceways are heavily loaded with phytoplankton, or shrimp, to avoid oxygen depletion due to the biological oxygen demand created by decay of dead phytoplankton. Alternatively, a higher concentration might be used if dissolved oxygen is strictly monitored.

*** Treatment may be repeated in 5 to 10 days, if needed.

IV. PREVIOUS APPROVAL

Fish are minor species of animals defined under 21 CFR 514.1 (d). Formalin is presently approved for use as a parasiticide on catfish, largemouth bass, bluegill, salmon, trout, and shrimp, and a fungicide on salmon, trout and esocid eggs (21 CFR 529.1030).

V. EFFECTIVENESS

A. Striped Bass and all other Finfish

The need for additional efficacy studies has been waived because it was determined that interspecies extrapolation is appropriate to demonstrate the efficacy of formalin in striped bass (*Morone saxatilis*) and all other finfish for the control of the same ectoparasites for which the drug is currently approved.

Formalin is a water treatment where the primary effect results from localized action at the topical site of administration. The concentration of active drug at the topical site is a function of the administered concentration and water conditions. These latter two conditions and the pathogen's drug sensitivity are considered the primary determinants of efficacy. Although the drug may be slightly absorbed, systemic absorption is not believed to play a significant role in the drug's effectiveness at the topical site. Thus, drug concentration and the effects of the pathogen are considered to be the primary determinants of effectiveness, while differences in drug/host response among species is considered to be an insignificant factor.

Formalin is currently approved for its effectiveness against external protozoa (*Chilodonella* spp., *Costia* spp., *Epistylis* spp., *Icthyophthirius* spp., *Scyphidia* spp., and *Trichodina* spp.) and monogenetic trematode parasites (*Cleidodiscus* spp., *Dactylogyrus* spp., and *Gyrodactylus* spp.), in a wide range of cold and warm freshwater finfish (see 21 CFR 529.1030). Since, as discussed above, formalin's effectiveness is based on drug concentration and the drug effects on potentially pathogenic external protozoans rather than the *in vivo* drug/host response in various species, the effectiveness of formalin against these pathogens would be the same in all species of finfish. Therefore, the efficacy data summarized in the attached Public Master File (PMF) 3543 and PMF 5228 are adequate to support formalin's effectiveness against the same ectoparasites on striped bass and on all other finfish.

B. Eggs of all Finfish

The need for additional efficacy studies has been waived because it has been determined that interspecies extrapolation is appropriate to demonstrate the efficacy of formalin on the eggs of all finfish for the control of the same family of fungi (Saprolegniaceae) for which the drug is currently approved.

Formalin is a water treatment where the primary effect results from localized action at the topical site of administration. The concentration of active drug at the topical site is a function of the administered concentration and water conditions. Although the drug may be slightly absorbed, absorption of formalin by the eggs is not believed to play a significant role in the drug's effectiveness at the topical site. Thus, drug concentration and the effects on the fungi are considered to be the primary determinants of effectiveness, while differences in drug/host response among species is considered to be an insignificant factor.

Formalin is currently approved for its effectiveness against fungi of the family Saprolegniaceae on salmon, trout and esocid eggs (see 21 CFR 529.1030). Since, as discussed above, formalin's effectiveness is based on drug concentration and the drug effects on eggs rather than the individual drug/host response in various species, the effectiveness of formalin against the fungi would be the same in all species of eggs. Therefore, the efficacy data in PMF 3543 (attached) and data existing in the publicly-disclosable Investigational New Animal Drug (INAD) file 8886 are adequate to support formalin's effectiveness against the same fungi on all finfish eggs. Studies within INAD file 8886 address the safety of formalin when used on the eggs of several finfish species representing five families, including: walleye, common carp, channel catfish, white sucker and lake sturgeon. These same studies indirectly address the effectiveness of the treatment as measured by egg hatchability, because the presence of significant fungi on finfish eggs can severely reduce hatchability.

VI. ANIMAL SAFETY

A. Finfish

The data in PMF 3543 (attached) addressed the safety of formalin in salmon, trout, catfish, largemouth bass, bluegill (the originally approved set of species), as well as smallmouth bass, black bullhead and green sunfish. The results of additional studies (contained in PMF 5228)

demonstrating the safety of short-term and indefinite use of formalin in striped bass, a species known to be sensitive to formalin, are described below. The data in these studies show that use of the drug at the recommended concentration is safe in a wide range of cold and warm water finfish, including striped bass, the most sensitive species. Since, as discussed above, formalin safety has been demonstrated in a wide variety of species (nine species from four of the most important North American families of cultured finfish: Ictaluridae, Salmonidae, Centrarchidae and Percichthyidae), one species (striped bass) of which has been documented as an extremely sensitive species, the safety of formalin would be the same for all finfish species. Therefore, these studies are adequate to demonstrate that use of the drug at recommended concentrations is safe in all finfish.

As noted in the Freedom of Information summary for PMF 3543, tolerances to formalin may vary with strains and species of finfish. Health status may also affect formalin tolerance. Although the indicated concentrations are considered safe for cold and warm water finfish, a small number of each lot or pond to be treated should always be used to check for any unusual sensitivity to formalin before proceeding.

In addition, formalin may be harmful to biofilters, and care should be taken to avoid contamination of the biofilter with treatment solution.

1. Target Animal Safety Study #1

a. Name and Address of Investigator:

Wilmer A. Rogers, Ph.D.
Department of Fisheries and Allied Aquacultures
Auburn University, Alabama 36849

b. General Design of the Investigation:

i. Purpose of the study: To determine if formalin is safe when administered to healthy striped bass.

ii. Test Animals: Striped bass (*Morone saxatilis*) fingerlings averaging 46.7 mm in length and 0.9 g in body weight were used for this set of studies. One study was conducted at 18ºC, while the other was conducted at 25ºC. Sixteen aquaria (eight aerated and eight not aerated), with 20 fingerlings in each, were used in the study.

iii. Dosage form: Formalin solution

iv. Route of Administration: In the environmental water

v. Dosages Used: Untreated control, 250, 500, and 750 ppm formalin, respectively (1X, 2X, and 3X the maximum proposed concentration)

vi. Test Duration: 3 hours

vii. Parameters: Mortality at 0.5, 1.0, 1.5, 2.0, 2.5, and 3.0 hours of treatment

c. Results: Refer to Tables 4 and 5 below. No mortality occurred in fish exposed to 250 ppm formalin for up to 1.5 hour.

TABLE 4
Safety of Formalin in Striped Bass at 25ºC

Formalin Concentration (ppm)	Mortalities (%), with/without Aeration					
	0.5 hr	1.0 hr	1.5 hr	2.0 hr	2.5 hr	3.0 hr
0	0/0	0/0	0/0	0/0	0/0	0/0
250	0/0	0/0	0/0	50/25	50/30	65/45
500	0/0	0/0	20/45	70/90	80/100	80/100
750	10/5	75/50	100/80	100/100	100/100	100/100

TABLE 5
Safety of Formalin in Striped Bass at 18ºC

Formalin Concentration (ppm)	Mortalities (%), with/without Aeration					
	0.5 hr	1.0 hr	1.5 hr	2.0 hr	2.5 hr	3.0 hr
0	0/0	0/0	0/0	0/0	0/0	0/0
250	0/0	0/0	0/0	0/15	5/25	15/35
500	0/0	0/0	25/40	55/65	80/85	100/100
750	0/5	35/10	80/70	95/100	100/100	100/100

2. Target Animal Safety Study #2

a. Name and Address of Investigator:

Wilmer A. Rogers, Ph.D.
Department of Fisheries and Allied Aquacultures
Auburn University, Alabama 36849

b. General Design of the Investigation:

i. Purpose of the study: To determine if formalin is safe when administered to healthy striped bass.

ii. Test animals: Striped bass fingerlings averaging 46.5 mm in length and 0.9 g in body weight were used for this study. Twenty fish were allotted to each of six treatment groups. The study was conducted at 22ºC.

iii. Dosage form: Formalin solution

iv. Route of Administration: In the environmental water

v. Dosages Used: Untreated control, 55.0, 57.5, 60.0, 62.5, and 65.0 ppm formalin. Formalin administered in flow-through aquaria with aeration.

vi. Test Duration: 96 hours

vii. Parameters: Cumulative mortality at 24, 48, 72, and 96 hours of treatment

c. Results: The 96-hour LC_{50} was 60.1 ppm. Refer to Table 6 below for mortality patterns.

TABLE 6
Safety of Formalin in Striped Bass at 22ºC

Formalin Concentration (ppm)	Cumulative Mortalities (%) at Different Times after Formalin Application			
	24 hr	48 hr	72 hr	96 hr
0	0	0	0	0
55.0	0	0	0	0
57.5	5	40	40	40
60.0	20	45	55	55
62.5	15	35	55	60
65.0	5	70	90	90

3. Target Animal Safety Study #3

Bills, T.D., L.L. Marking, G.E. Howe. 1993. Sensitivity of juvenile striped bass to chemicals used in aquaculture. United States Department of the Interior, Fish and Wildlife Service, *Resource Publication 192*.

These studies determined LC_{50}'s (concentrations producing 50% mortality in a population) of formalin in striped bass. Ten juvenile (1.0 g) striped bass were exposed to each test concentration of formalin in 15 L glass jars. Tests were conducted at a water temperature of 12ºC and at varying levels of water hardness. Observations on mortality were made at 1, 3, and 6 hours during the first day of exposure, and then once daily for 4 days. Tests were duplicated in different year class fish in waters of different temperature (12, 17, and 22ºC), hardness, and pH. Mean LC_{50}'s in soft water of pH 7.5 at 12ºC were as represented in Table 7:

TABLE 7
Mean 50% Lethal Concentrations (LC50's) of Formalin to Striped Bass (ppm)

Time (hours)	Test 1	Test 2
1	1230	>1000
3	1410	>1000
6	940	760
24	211	120
96	75	56

Toxicity of formalin was not affected by water hardness or pH. However, toxicity was greater in warm water than in cold water. Mean LC_{50}'s in soft water of pH 7.5 at three temperatures were as represented in Table 8.

TABLE 8
Mean 50% Lethal Concentrations (LC50's) of Formalin to Striped Bass (ppm)

Time (hours)	12°C	17°C	22°C
1	>1000	>1000	>1000
3	>1000	>1000	750
6	760	455	210
24	120	86	82
96	56	48	30

B. Eggs of Finfish

Formalin is currently approved for the control of fungi of the family Saprolegniaceae on salmon, trout, and esocid eggs (see 21 CFR 529.1030). Additional safety studies for the control of fungi of the family Saprolegniaceae on other finfish eggs are provided in INAD file 8886. The sponsor, U.S. National Biological Service, Upper Mississippi Science Center, La Crosse, Wisconsin, has authorized the public disclosure of all information within their INAD file 8886.

The data in these studies show that use of the drug at the recommended concentration is safe on the eggs of a wide range of cold and warm water fish. Since, as discussed above, formalin safety has been demonstrated in finfish eggs from a wide variety of species, the safety of formalin would be the same for the eggs of all finfish species. Therefore, these studies are adequate to demonstrate that use of the drug at the recommended concentration is safe on the eggs of all finfish. The following summarizes the finfish egg safety study in INAD 8886.

1. Name and Address of Investigator:

National Fisheries Research Center
National Biological Service
Department of the Interior
La Crosse, Wisconsin 54602-0818

2. General Design of the Investigation:

a. Purpose of the study: To determine if formalin is safe when administered to finfish eggs of representative finfish species.

b. Test Animals: Green eggs of walleye (*Stizostedion vitreum*), channel catfish (*Ictalurus punctatus*), white sucker (*Catostomus commersoni*), common carp (*Cyprinus carpio*) and lake sturgeon (*Acipenser transmontanus*) were tested. The study was conducted at 12±2ºC for walleye and white sucker, at 17±2ºC for common carp and lake sturgeon and at 22±2ºC for channel catfish.

c. Dosage form: Formalin solution

d. Route of Administration: In the environmental water

e. Dosages Used: 1500, 4500, and 7500 ppm formalin

f. Test Duration: 45 minutes

g. Parameters: percent hatch was calculated by the following formula:

% hatch = (number of hatched fry ÷ initial number of eggs) x 100

3. Results:

This study demonstrated that standard formalin treatment, at a concentration of 1000 to 2000 ppm, is safe for finfish eggs of the orders Cypriniformes (common carp and white sucker), Perciformes (walleye) and Siluriformes (channel catfish) for 15 minutes daily, if necessary. Formalin is also safe, at a concentration of 1500 ppm or less, for finfish eggs of the order Acipenseriformes (lake sturgeon) for 15 minutes daily, if necessary. Because the species of finfish eggs treated in the study are representative of the variety of species of finfish eggs, it is determined that formalin is safe for other finfish eggs. Due to the varying sensitivity of finfish eggs, however, the following statement is included in the labeling.

> "A preliminary bioassay should be conducted on a small subsample of finfish eggs to determine sensitivity before treating an entire group. This

is necessary for all species because egg sensitivity can vary with species or strain and the unique conditions at each facility."

VII. HUMAN FOOD SAFETY

Human food safety data for the use of formalin in salmon, trout, catfish, largemouth bass, and shrimp are found in PMF 3543. The results of four residue depletion studies of formalin in striped bass are summarized below (and found in PMF 5228). The use of formalin has not been shown by these studies to result in the accumulation of formaldehyde above naturally occurring levels in the edible tissue of any of these aquatic species. Because formalin treatment of this wide variety of aquatic species does not result in levels of formaldehyde in the edible tissue above the normal range of endogenous formaldehyde, formaldehyde is not expected to accumulate in additional finfish species which have not been specifically tested.

The studies summarized below (and found in detail in PMF 5228) were all conducted by Wilmer A. Rogers, Ph.D. at Auburn University, Auburn, Alabama. Formalin was administered in the environmental water in all studies and the following method of tissue analysis was used in all studies. Formaldehyde was measured in the muscle of treated and control fish by the Nash test (described in Castell and Smith, *J. Fisheries Research Board of Canada* 30:91, 1973). The Nash test also was used in the residue studies to support the prior approvals for formalin in salmon, trout, catfish, largemouth bass, and shrimp. The recovery of formaldehyde in striped bass muscle samples fortified with 5, 20, and 40 mg/kg formalin was 106.9%, 78.0%, and 70.9%, respectively. The limit of quantitation was 5 mg/kg formalin (1.85 mg formaldehyde/kg fish).

The studies differed from each other as follows:

A. Juvenile/Indefinite Exposure Period Study - a two-part experiment in which striped bass in tanks were exposed to formalin for an indefinite period of time at two water temperatures.

1. **Test Animal:** Striped bass; body weight was 23 grams for Part 1 and 39 grams for Part 2
2. **Water Temperature:** 12 to 14ºC for Part 1 and 21 to 22ºC for Part 2
3. **Dose Levels and Treatment Duration:** 0 (control) and 25 ppm formalin indefinitely.
4. **Results:** as represented in Table 9

TABLE 9
Mean Formaldehyde Residues (mg/kg) in Muscle of Juvenile Striped Bass

Hours of Exposure to 25 ppm Formalin	Part 1: 12-14 C		Part 2: 21-22 C	
	Treated Fish n= 2	Control Fish n = 2	Treated Fish n = 5	Control Fish n = 5
0	4.67	3.74	3.26	3.32
12	4.42	4.02	not collected	not collected
24	4.40	3.85	6.63	5.52
48	4.22	1.67	6.64	3.39
72	5.12	3.84	7.60	5.34
96	4.12	3.63	5.61	4.41
120	2.36	2.71	4.02	4.03
144	1.76	1.76	4.63	4.58
168	3.60	3.74	4.04	3.86

B. Fingerling/Short Duration Bath Study - striped bass in tanks were exposed to formalin for one hour.

1. **Test Animal:** Striped bass; body weight was 26 grams
2. **Water Temperature:** 21ºC
3. **Dose Levels and Treatment Duration:** 0 ppm (control) and 250 ppm formalin for 1 hour
4. **Results:** as represented in Table 10

TABLE 10
Mean Formaldehyde Residues (mg/kg) in Muscle of Fingerling Striped Bass

Hours After Addition of 250 ppm Formalin	Treated Fish n = 4	Control Fish n = 4
0	2.86	3.57
12	3.67	3.17
24	3.73	3.61
48	2.65	2.97
72	3.37	3.38

C. Market size/Indefinite Exposure Period Study - market size striped bass in tanks were exposed to formalin indefinitely.

1. **Test Animal:** Striped bass; body weight was 435 grams
2. **Water Temperature:** 24ºC
3. **Dose Levels and Treatment Duration:** 0 ppm (control) and 25 ppm formalin indefinitely
4. **Results:** as represented in Table 11

TABLE 11
Mean Formaldehyde Residues (mg/kg) in Muscle of Market-size Striped Bass

Hours of Exposure to 25 ppm Formalin	Treated Fish n = 2	Control Fish n = 2
0	3.29	4.00
48	3.98	4.42
96	3.85	3.85

D. Juvenile/Indefinite Exposure Study - striped bass in ponds were exposed to formalin indefinitely.

1. **Test Animal:** Striped bass; body weight was 137 grams
2. **Water Temperature:** 26 to 30ºC
3. **Dose Levels and Treatment Duration:** 0 ppm (control) and 25 ppm formalin indefinitely
4. **Results:** as represented in Table 12

TABLE 12
Mean Formaldehyde Residues (mg/kg) in Muscle of Juvenile Striped Bass

Hours of Exposure to 25 ppm Formalin	Treated Fish n = 8	Control Fish n = 8
24	3.60	3.78
48	3.50	3.43
72	3.53	3.50
96	3.43	3.37
120	3.63	3.53

E. Human Food Safety Conclusions: Formaldehyde residues in striped bass muscle did not differ between any of the test groups. Formaldehyde did not accumulate as a result of formalin treatment in juvenile or adult striped bass. Residue accumulation was not affected by dose or duration of exposure. Water temperatures between 12 and 30ºC did not appear to affect accumulation of formaldehyde residues in striped bass muscle exposed to formalin.

By the studies in PMF 3543 and PMF 5528, the use of formalin at the recommended concentration has not been shown to result in the accumulation of formaldehyde above naturally occurring levels in the edible tissue of a wide range of cold and warm water fish, including striped bass, the most sensitive species. Therefore, these studies are considered adequate to demonstrate that use of the drug in all finfish and on all finfish eggs at the recommended concentration will not result in the accumulation of formaldehyde above naturally occurring levels in their edible tissue.

VIII. ENVIRONMENTAL SAFETY

The Center for Veterinary Medicine has considered the potential environmental impact of this action and has concluded that this action will not have a significant impact on the quality of the human environment and that, therefore, an environmental impact statement will not be prepared.

The EA provides information on the potential environmental effects from the use of the product in all species of finfish. An amendment to the EA dated September 6, 1995, was prepared by the Environmental Staff of the Center for Veterinary Medicine to analyze the potential for environmental impacts from the use of formaldehyde to treat fungus on the eggs of all species of finfish.

The EA and the amendment to the EA, indicate that no environmental impact are expected provided that the finfish and penaeid shrimp treatment water is diluted 10-fold and the finfish egg treatment water is diluted 100-fold. These directions for the dilution of treatment water and additional environmental precautions are contained on the labeling of the product.

The EA, the amendment to the EA and the labeling provides adequate information to determine that the use of PARASITE-S is not expected to cause a significant impact on the environment.

IX. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfies the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The sponsor of this NADA has referenced PMF 5228, PMF 3543, and publicly-disclosable INAD file 8886 to support the addition of the new claims to their existing NADA. The data demonstrate that formalin, when used as recommended, is effective for the control of external parasites (*Chilodonella* spp., *Costia* spp., *Epistylis* spp., *Icthyophthirius* spp., *Scyphidia* spp., and *Trichodina* spp.) and

monogenetic trematode parasites (*Cleidodiscus* spp., *Dactylogyrus* spp., and *Gyrodactylus* spp.) on all finfish, and for the control of fungi of the family Saprolegniaceae on the eggs of all finfish.

According to the Center's supplemental approval policy, 21 CFR 514.106(b)(2)(vii) and (ix), this is a Category II change that did not require a reevaluation of the safety and effectiveness data in the parent application.

This product remains an over-the-counter drug for use by a lay-person. Adequate instructions have been provided for its safe and effective use for the label indications.

Fish are minor animal species as defined under 21 CFR 514.1(d). The data submitted (in PMF 5228 and INAD 8886) meet the requirements of that regulation and FDA's "Guidelines for the Preparation of Data to Satisfy the Requirements of Section 512 of the Act Regarding Minor use of Animal Drugs" (April 1986). FDA has considered these data, along with other required data, as support for this supplemental NADA (140-989) which was filed for the expansion of the use of formalin as a parasiticide in all finfish, and as a fungicide on the eggs of all finfish.

Additional efficacy studies in other species of finfish were not necessary because interspecies extrapolation is appropriate to demonstrate the efficacy of formalin on all finfish for the control of the same ectoparasites on a select group of finfish for which the drug is currently approved (see 21 CFR 529.1030). Similarly, additional efficacy studies were not needed to demonstrate efficacy of formalin on the eggs of all finfish for the control of the same fungi (Saprolegniaceae) found on the eggs of the previously approved finfish species (see 21 CFR 529.1030).

Additional target safety studies on other finfish species were not needed because interspecies extrapolation is appropriate to demonstrate the safety of formalin on all finfish for the control of the same ectoparasites on a select group of finfish for which the drug is currently approved (see 29 CFR 529.1030) and demonstrated to be safe for use in striped bass, as reported in PMF 5228. Similarly, additional target safety studies on the eggs of other finfish species were not needed, because interspecies extrapolation is appropriate to demonstrate its control of the same fungi (Saprolegniaceae) found on the eggs of the previously approved finfish species (see 21 CFR 529.1030) and demonstrated to be safe for use on the eggs of finfish species, as reported in publicly-disclosable INAD file 8886.

Data found within PMF 5228 demonstrate that formaldehyde residues in the muscle of striped bass juveniles and adults did not differ between those treated with formalin and non-treated controls. By the studies in PMF 3543 and PMF 5528, the use of formalin at the recommended concentration has not been shown to result in the accumulation of formaldehyde in the muscle of striped bass, salmon, trout, catfish, largemouth bass, or shrimp. Therefore, additional residue depletion studies for other finfish species are not necessary, because these studies are considered adequate to demonstrate that use of the drug in all finfish at the recommended concentration will not result in the accumulation of formaldehyde.

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) has been prepared, which, along with the evidence supporting that finding contained within an environmental assessment, will be placed on display in the Dockets Management Branch

(HFA-305), Park Building (Room 1-23), 12420 Parklawn Dr., Rockville, Maryland 20857 at the time of publication of approval in the FEDERAL REGISTER.

PARASITE-S is not under any unexpired U.S. patents.

X. APPROVED PRODUCT LABELING: See attached draft package insert and drum labeling.