

## AQUACULTURE DRUG APPROVAL DEVELOPMENT STATUS

### **FORMALIN (FORMALIN-F®, PARASITE-S®, and FORMACIDE-B®): RESEARCH AND DEVELOPMENT PLAN AND LABEL CLAIM MATRICES FOR SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA) APPROVALS**

1. [Formalin \(PARASITE-S®, FORMALIN-F®, and FORMACIDE-B®\)  
NADA approvals \(7/16/98, 11/25/02, 7/17/07\)](#)
2. [Status of Technical Sections that support all supplemental  
NADA approvals](#)
3. [Label Claim #1: For the control of mortality in freshwater-reared  
finfish due to saprolegniasis](#)

**DEVELOPED UNDER THE FEDERAL-STATE AQUACULTURE DRUG  
APPROVAL PARTNERSHIP PROJECT, A PROJECT OF THE  
ASSOCIATION OF FISH AND WILDLIFE AGENCIES**

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**FORMALIN (PARASITE-S®, FORMALIN-F®, and FORMACIDE-B®)  
(Version 2, March 2008)**

### ABBREVIATIONS, ACRONYMS, & CONTACT INFORMATION FOR ENTITIES IN TABLE

AOI	All Other Information Technical Section, not included in any of the other sections, that is pertinent to an evaluation of effectiveness or safety [21 CFR § 514.1(b)(8)(iv)]
CVM	Aquaculture Drugs Team (HFV-131), Division of Therapeutic Drugs for Food Animals, Office of New Animal Drug Evaluations, Center for Veterinary Medicine, U.S. Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855; Dr. Donald Prater; Phone: 240-276-8343; E-mail: <a href="mailto:Donald.Prater@fda.hhs.gov">Donald.Prater@fda.hhs.gov</a>
CVM-OR	Division of Animal Research (HFV-520), Office of Research, Center for Veterinary Medicine, U.S. Food and Drug Administration, Dr. Renate Reimschuessel; Phone: 301-210-4024; E-mail: <a href="mailto:renate.reimschuessel@fda.hhs.gov">renate.reimschuessel@fda.hhs.gov</a>
Efficacy	Effectiveness Technical Section includes pivotal & supportive studies that show whether or not a drug is effective for its intended use [21 CFR § 514.1(b)(8)(i)]
FOI	Final Freedom of Information summary generated by CVM based on draft FOIs developed by researchers for each study [21 CFR § 514.11(e)(2)(ii)]
INAD	Investigational New Animal Drug exemption [21 CFR 511]
Label	Labeling Technical Section includes labeling and package inserts [21 CFR § 514.1(b)(3)]
NADA	New Animal Drug Application [21 CFR 514]
NADA Coordinator	Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, 3039 Edgewater Lane, La Crosse, Wisconsin 54603-1088; Phone: 608-781-2205; Fax: 608-783-3507; E-mail: <a href="mailto:RozSchnick@centurytel.net">RozSchnick@centurytel.net</a>
Product Chemistry	Product Chemistry Technical Section includes chemistry, manufacturing, and controls [21 CFR § 514.1(b)(4-6)]
PMF	Public Master File can contain safety and efficacy data and information generated with public funds (Guidance Document #57)
SPONSORS	Sponsors of formalin: <b>FORMALIN-F® (NADA #137-687)</b> —Natchez Animal Supply Company, 201 John R. Junkin Drive, Natchez, MS 39120; E-mail address: <a href="mailto:drajhall@bellsouth.net">drajhall@bellsouth.net</a> <b>PARASITE-S® (NADA #140-989)</b> —Western Chemical Inc., 1269 Latimore Road, Ferndale, Washington 98248; Phone: 360-384-5898; Fax: 206-384-0270; E-mail: <a href="mailto:WCI@Premier1.net">WCI@Premier1.net</a> <b>FORMACIDE-B® (NADA #200-414)</b> —B.L. Mitchell, Inc., 103 Highway 82 E., Leland, MS 38756; Phone: 662-686-9002; Fax: 662-686-9020; E-mail: <a href="mailto:blmitch@bellsouth.net">blmitch@bellsouth.net</a>
Toxicology	Part of Human Food Safety Technical Section, toxicological testing includes genetic toxicity tests and mammalian safety studies (e.g., acute, subchronic) (Guidance Document #3)
UMESC	Upper Midwest Environmental Sciences Center—Mark Gaikowski, 2630 Fanta Reed Road, La Crosse, Wisconsin 54603; Phone: 608-783-6451; Fax: 608-783-6066; E-mail: <a href="mailto:MGaikowski@usgs.gov">MGaikowski@usgs.gov</a>

### KEY TO COLOR CODING

COLOR	STATUS
	No current plans and/or funds
	In progress or planned; funded
	Submitted to CVM
	Accepted by CVM

**FORMALIN (PARASITE-S®, FORMALIN-F®, and FORMACIDE-B®)**

**Formalin (PARASITE-S®, FORMALIN-F®, and FORMACIDE-B®) NADA approvals (7/16/98, 11/25/02, 7/17/07)**

**INDICATIONS FOR USE**

PARASITE-S®, FORMALIN-F®, and FORMACIDE-B® 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 protozoan parasites (*Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.) on penaeid shrimp.

**DOSAGE FORM, ROUTE OF ADMINISTRATION AND RECOMMENDED DOSAGE**

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

B. Route of Administration: In the environmental water

C. Recommended Concentrations: as shown in Tables 3.1 to 3.3.

1. For the Control of External Parasites on Finfish

**TABLE 3.1** Concentrations of Formalin

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

\* 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. Alternately, 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 3.2** Concentrations of Formalin

<b>Aquatic Species</b>	<b>Administer in Hatchery Systems (µL/L)*</b>
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 sub sample 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 Control of External Protozoan Parasites on Penaeid Shrimp

**Table 3.3** Concentrations of Formalin

<b>Aquatic Species</b>	<b>Administer in Tanks and Raceways for up to 4 hours (<math>\mu\text{L/L}</math>)*</b>	<b>Administer in Earthen Ponds Indefinitely (<math>\mu\text{L/L}</math>)*</b>
Shrimp	50 to 100**	25***

\*Microliter per liter  $\mu\text{L/L}$  = 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.

**FORMALIN (PARASITE-S®, FORMALIN-F®, and FORMACIDE-B®)**

Status of Technical Sections that support all supplemental NADA approvals

Technical Section	Entity—Data—Action	Impediments or Cost—Action
<b>Product Chemistry</b>	<b>SPONSORS—Product chemistry—previously accepted</b>	<b>None</b>
<b>Environmental Safety</b>	<b>UMESC (PMF #5639)—Environmental Safety—previously accepted</b>	<b>None</b>
<b>Human Food Safety (toxicology)</b>	<b>SPONSORS—Human Food Safety/toxicology—Previously accepted</b>	<b>None</b>
<b>Human Food Safety (residue chemistry)</b>	<b>UMESC (PMF #5639)—Human Food Safety/residue chemistry—previously accepted</b>	<b>None</b>
<b>Target Animal Safety (all finfish eggs)</b>	<b>UMESC (PMF #5639)—Target Animal Safety/finfish eggs —accepted 7/18/96; Sponsors—supplemental NADA approved 7/16/98, 11/25/02, &amp; 7/17/07</b>	<b>None</b>
<b>Target Animal Safety (all finfish)</b>	<b>UMESC (PMF #5639)—Target Animal Safety/certain species—previously accepted; Other entities/hybrid striped bass—accepted; Sponsors—supplemental NADAs approved 7/16/98, 11/25/02, &amp; 7/17/07</b>	<b>None</b>

**FORMALIN (PARASITE-S®, FORMALIN-F®, and FORMACIDE-B®)**

**LABEL CLAIM #1**

**SPECIES: FRESHWATER-REARED FINFISH**

**INDICATIONS:** For the control of mortality in freshwater-reared finfish due to saprolegniasis

**DIRECTIONS FOR USE:** Apply formalin at a rate of 75 to 150 milligrams formalin per liter [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply of finfish culture units or as a static bath for 60 minutes once per day on alternate days for a total of three treatments.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (Saprolegniasis/all finfish eggs)	UMESC (PMF #5639)—Efficacy/Saprolegniasis/all fish eggs—accepted 7/18/96; Sponsors—supplemental NADAs approved 7/16/98, 11/25/02, & 7/17/07	None
Efficacy (Saprolegniasis/all finfish)	UMESC (PMF #5639 & 5228) & AADAP (INAD #9013)—Efficacy/Saprolegniasis/all fish—accepted as supportive—1998	None
Efficacy (Saprolegniasis/channel catfish)	UMESC (INAD #11-365 & PMF #5639)—Efficacy/Saprolegniasis/channel catfish—accepted as supportive 11/16/04	None
Efficacy (Saprolegniasis/channel catfish)	CVM-OR—Pivotal efficacy/Saprolegniasis/channel catfish—in progress	None—pending acceptance
Efficacy (Saprolegniasis/rainbow trout)	CVM-OR—Pivotal efficacy/Saprolegniasis/rainbow trout—accepted as pivotal 7/25/05	None
Label	SPONSORS—Label/Saprolegniasis/all freshwater-reared finfish—planned in the future	None—pending acceptance
FOI	CVM--FOI—planned in the future	None—pending acceptance
AOI	SPONSORS—AOI/Saprolegniasis/all freshwater-reared finfish—planned in the future	None—pending acceptance
NADA Package	SPONSORS—NADA Package/Saprolegniasis/all freshwater-reared finfish—planned in the future	None—pending acceptance