



The following documentation is an electronically-submitted vendor response to an advertised solicitation from the *West Virginia Purchasing Bulletin* within the Vendor Self-Service portal at ***wvOASIS.gov***. As part of the State of West Virginia's procurement process, and to maintain the transparency of the bid-opening process, this documentation submitted online is publicly posted by the West Virginia Purchasing Division at ***WVPurchasing.gov*** with any other vendor responses to this solicitation submitted to the Purchasing Division in hard copy format.

Jump to: FORMS

Go

Home

Personalize

Accessibility

App Help

About

Welcome, Lu Anne Cottrill

Procurement

Budgeting

Accounts Receivable

Accounts Payable

Solicitation Response(SR) Dept: 0310 ID: ESR12191600000002817 Ver.: 1 Function: New Phase: Final Modified by batch , 12/20/2016

Header 4

List View

General Information

Contact

Default Values

Discount

Document Information

Procurement Folder: 267029

Procurement Type: Central Master Agreement

Vendor ID: 000000230225

Legal Name: WESTERN CHEMICAL INC.

Alias/DBA:

Total Bid: \$22,029.00

Response Date: 12/19/2016

Response Time: 12:11

SO Doc Code: CRFQ

SO Dept: 0310

SO Doc ID: DNR1700000023

Published Date: 12/13/16

Close Date: 12/20/16

Close Time: 13:30

Status: Closed

Solicitation Description: Addendum No.01 OpenEnd  
Contract Formaldehyde-55 Gallon

Total of Header Attachments: 4

Total of All Attachments: 4



Purchasing Division  
2019 Washington Street East  
Post Office Box 50130  
Charleston, WV 25305-0130

State of West Virginia  
Solicitation Response

Proc Folder : 267029

Solicitation Description : Addendum No.01 OpenEnd Contract Formaldehyde-55 Gallon Drums

Proc Type : Central Master Agreement

Date issued	Solicitation Closes	Solicitation Response	Version
	2016-12-20 13:30:00	SR 0310 ESR12191600000002817	1

VENDOR

000000230225

WESTERN CHEMICAL INC.

Solicitation Number: CRFQ 0310 DNR1700000023

Total Bid : \$22,029.00

Response Date: 2016-12-19

Response Time: 12:11:11

Comments:

FOR INFORMATION CONTACT THE BUYER

Brittany E Ingraham

(304) 558-2157

brittany.e.ingraham@wv.gov

Signature on File

FEIN #

DATE

All offers subject to all terms and conditions contained in this solicitation

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
1	Formaldehyde-55 Gallon Drum for Petersburg Hatchery	1.00000	EA	\$467.000000	\$467.00

Comm Code	Manufacturer	Specification	Model #
12352501			

Extended Description :	Formaldehyde-55 Gallon Drum for Petersburg Hatchery
------------------------	---

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
2	Formaldehyde-55 Gallon Drum for Reeds Creek Hatchery	28.00000	EA	\$377.000000	\$10,556.00

Comm Code	Manufacturer	Specification	Model #
12352501			

Extended Description :	Formaldehyde-55 Gallon Drum for Reeds Creek Hatchery
------------------------	--

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
3	Formaldehyde-55 Gallon Drum for Ridge Hatchery	1.00000	EA	\$467.000000	\$467.00

Comm Code	Manufacturer	Specification	Model #
12352501			

Extended Description :	Formaldehyde-55 Gallon Drum for Ridge Hatchery
------------------------	--

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
4	Formaldehyde-55 Gallon Drum for Spring Run Hatchery	3.00000	EA	\$377.000000	\$1,131.00

Comm Code	Manufacturer	Specification	Model #
12352501			

Extended Description :	Formaldehyde-55 Gallon Drum for Spring Run Hatchery
------------------------	---

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
5	Formaldehyde-55 Gallon Drum for Tate Lohr Hatchery	1.00000	EA	\$467.000000	\$467.00

Comm Code	Manufacturer	Specification	Model #
12352501			

Extended Description : Formaldehyde-55 Gallon Drum for Tate Lohr Hatchery

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
6	Formaldehyde-55 Gallon Drum for Apple Grove Hatchery	1.00000	EA	\$467.000000	\$467.00

Comm Code	Manufacturer	Specification	Model #
12352501			

Extended Description : Formaldehyde-55 Gallon Drum for Apple Grove Hatchery

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
7	Formaldehyde-55 Gallon Drum for Palestine Hatchery	1.00000	EA	\$467.000000	\$467.00

Comm Code	Manufacturer	Specification	Model #
12352501			

Extended Description : Formaldehyde-55 Gallon Drum for Palestine Hatchery

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
8	Formaldehyde-55 Gallon Drum for Bowden Hatchery	20.00000	EA	\$377.000000	\$7,540.00

Comm Code	Manufacturer	Specification	Model #
12352501			

Extended Description : Formaldehyde-55 Gallon Drum for Bowden Hatchery

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
9	Formaldehyde-55 Gallon Drum for Edray Hatchery	1.00000	EA	\$467.000000	\$467.00

Comm Code	Manufacturer	Specification	Model #
12352501			

Extended Description :	Formaldehyde-55 Gallon Drum for Edray Hatchery
------------------------	--

STATE OF WEST VIRGINIA  
Purchasing Division

## PURCHASING AFFIDAVIT

**MANDATE:** Under W. Va. Code §5A-3-10a, no contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and: (1) the debt owed is an amount greater than one thousand dollars in the aggregate; or (2) the debtor is in employer default.

**EXCEPTION:** The prohibition listed above does not apply where a vendor has contested any tax administered pursuant to chapter eleven of the W. Va. Code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

**DEFINITIONS:**

**"Debt"** means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

**"Employer default"** means having an outstanding balance or liability to the old fund or to the uninsured employers' fund or being in policy default, as defined in W. Va. Code § 23-2c-2, failure to maintain mandatory workers' compensation coverage, or failure to fully meet its obligations as a workers' compensation self-insured employer. An employer is not in employer default if it has entered into a repayment agreement with the Insurance Commissioner and remains in compliance with the obligations under the repayment agreement.

**"Related party"** means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceeds five percent of the total contract amount.

**AFFIRMATION:** By signing this form, the vendor's authorized signer affirms and acknowledges under penalty of law for false swearing (W. Va. Code §61-5-3) that neither vendor nor any related party owe a debt as defined above and that neither vendor nor any related party are in employer default as defined above, unless the debt or employer default is permitted under the exception above.

**WITNESS THE FOLLOWING SIGNATURE:**

Vendor's Name: Western Chemical, Inc. - Jason Montgomery

Authorized Signature: [Signature] Date: 12-14-16

State of Washington

County of Whatcom, to-wit:

Taken, subscribed, and sworn to before me this 14 day of December, 2016.

My Commission expires February 10<sup>th</sup>, 2019.

AFFIX SEAL HERE



NOTARY PUBLIC [Signature]

Purchasing Affidavit (Revised 08/01/2015)

Exhibit A Pricing Page  
Hatchery Formaldehyde

Location	Address	Unit of Measure	Estimated Quantity	Unit Cost (Must Include Shipping Costs)	Extended Cost
1	Petersburg Hatchery 126 Grahams Way Petersburg, WV. 26847-8523	55 Gallon Drum	1	467.00	467.00
2	Reeds Creek Hatchery 41 Hatchery Lane Franklin, WV. 26807-5604	55 Gallon Drum	28	377.00	10,556.00
3	Ridge Hatchery 12051 Valley Road Berkley Springs, WV. 25411	55 Gallon Drum	1	467.00	467.00
4	Spring Run Hatchery 1988 Spring Run Road, Unit 1 Petersburg, WV. 26847-8877	55 Gallon Drum	3	377.00	1,131.00
5	Tate Lohr Hatchery Rt.4 Box 489 4065 Pigeon Creek Road Princeton, WV. 24740	55 Gallon Drum	1	467.00	467.00
6	Apple Grove Hatchery 743 Hatchery Lane Gallipolis Ferry, WV. 25515	55 Gallon Drum	1	467.00	467.00
7	Palestine Hatchery 27 Paddlefish Lane Elizabeth, WV. 26143	55 Gallon Drum	1	467.00	467.00
8	Bowden Hatchery Rt. 1 Box 80 Elkins, WV 26241	55 Gallon Drum	20	377.00	7,540.00
9	Edray Hatchery 753 Woodrow Road Marlinton, WV 24954	55 Gallon Drum	1	467.00	467.00

**TOTAL BID AMOUNT: 14,022.00**

Vendor: (Unit Cost) per 55 Gallon Drum including Shipping Cost) multiplied by Estimated Qty equals Extended Cost



**DESIGNATED CONTACT:** Vendor appoints the individual identified in this Section as the Contract Administrator and the initial point of contact for matters relating to this Contract.

Jason Montgomery - Sales Manager  
(Name, Title)

(Printed Name and Title)  
1269 Lattimore Rd. Ferndale WA 98248

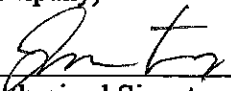
(Address)  
360 384 5898 / 360 384 0270

(Phone Number) / (Fax Number)

jasonm@wchemical.com  
(email address)

**CERTIFICATION AND SIGNATURE:** By signing below, or submitting documentation through wvOASIS, I certify that I have reviewed this Solicitation in its entirety; that I understand the requirements, terms and conditions, and other information contained herein; that this bid, offer or proposal constitutes an offer to the State that cannot be unilaterally withdrawn; that the product or service proposed meets the mandatory requirements contained in the Solicitation for that product or service, unless otherwise stated herein; that the Vendor accepts the terms and conditions contained in the Solicitation, unless otherwise stated herein; that I am submitting this bid, offer or proposal for review and consideration; that I am authorized by the vendor to execute and submit this bid, offer, or proposal, or any documents related thereto on vendor's behalf; that I am authorized to bind the vendor in a contractual relationship; and that to the best of my knowledge, the vendor has properly registered with any State agency that may require registration.

Western Chemical Inc  
(Company)

 Jason Montgomery Sales Manager  
(Authorized Signature) (Representative Name, Title)

Jason Montgomery Sales Manager  
(Printed Name and Title of Authorized Representative)

12/19/16  
(Date)

360 384 5898 / 360 384 0270  
(Phone Number) (Fax Number)

**REQUEST FOR QUOTATION**

West Virginia Division of Natural Resources-Wildlife Resources Fisheries Management  
Open-End Formaldehyde Contract

---

**8.3 Reports:** Vendor shall provide quarterly reports and annual summaries to the Agency showing the Agency's items purchased, quantities of items purchased, and total dollar value of the items purchased. Vendor shall also provide reports, upon request, showing the items purchased during the term of this Contract, the quantity purchased for each of those items, and the total value of purchases for each of those items. Failure to supply such reports may be grounds for cancellation of this Contract.

**8.4 Contract Manager:** During its performance of this Contract, Vendor must designate and maintain a primary contract manager responsible for overseeing Vendor's responsibilities under this Contract. The Contract manager must be available during normal business hours to address any customer service or other issues related to this Contract. Vendor should list its Contract manager and his or her contact information below.

**Contract Manager:** Jason Montgomery

**Telephone Number:** 360 384 5898

**Fax Number:** 360 384 0270

**Email Address:** jasonm@wchemical.com

**ADDENDUM ACKNOWLEDGEMENT FORM**  
**SOLICITATION NO.:** \_\_\_\_\_

**Instructions:** Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

**Acknowledgment:** I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

**Addendum Numbers Received:**

(Check the box next to each addendum received)

<input checked="" type="checkbox"/> Addendum No. 1	<input type="checkbox"/> Addendum No. 6
<input type="checkbox"/> Addendum No. 2	<input type="checkbox"/> Addendum No. 7
<input type="checkbox"/> Addendum No. 3	<input type="checkbox"/> Addendum No. 8
<input type="checkbox"/> Addendum No. 4	<input type="checkbox"/> Addendum No. 9
<input type="checkbox"/> Addendum No. 5	<input type="checkbox"/> Addendum No. 10

I understand that failure to confirm the receipt of addenda may be cause for rejection of this bid. I further understand that any verbal representation made or assumed to be made during any oral discussion held between Vendor's representatives and any state personnel is not binding. Only the information issued in writing and added to the specifications by an official addendum is binding.

Western Chemical, Inc  
 Company  
Jason Montgomery  
 Authorized Signature  
12-14-16  
 Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing.  
 Revised 6/8/2012

FISH HEALTH PRODUCTS  
AQUACULTURE BIOSECURITY  
SPAWNING AGENTS  
ANESTHETICS & SEDATIVES



**Western**  
Chemical, Inc.

An **AQUATIC LIFE SCIENCES** Co.  
*World Leader in Fish Health Products*

2016



## TRICAINE-S

(MS-222, TMS, tricaine methanesulfonate)

TRICAINE-S is FDA approved for the temporary immobilization of fish, amphibians, and other aquatic, cold blooded animals. It has been recognized as a valuable tool for the proper handling of these animals during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research. Pharmaceutical Drug - Guaranteed to be a minimum of 99.6% pure.

US FDA NADA # 200-226

Available in: 1 gram, 5 gram, 10 gram, 100 gram, 1 kg plastic bottle



*TRICAINE-S is packaged in quality, easy to use plastic bottles which resist slipping & breaking!*

**AQUA TIP:** MS-222 can decrease the pH of the anesthetic bath, especially in soft freshwater. Anesthetic baths can be buffered with sodium bicarbonate to maintain a steady pH. Sodium bicarbonate can be added to the anesthetic bath as a powder or as a stock solution. As a rule-of-thumb, adding twice as much sodium bicarbonate as TMS should bring most anesthetic solutions back to near normal pH. Alternatively, a saturated sodium bicarbonate solution, which usually contains about 10% sodium bicarbonate, can be added at the rate of about 5ml to each litre of MS-222 bath solution. The water in the bath should be well oxygenated, and should be changed frequently to reduce foaming and build-up and to minimize the amount of debris in the water. Under some water conditions, addition of **Vidalife** and or **Defoam** (see below) may prove beneficial.

## AQUACALM®

Aquacalm® is Indexed\* by the US FDA for the sedation and anesthesia of ornamental finfish. Sedation may be necessary in situations such as strip spawning for hatchery rearing, transporting fish from supplier to wholesaler or retailer, photographing fish as part of a strategic marketing approach, or removal of fish from exhibit tanks prior to cleaning. Anesthesia may be necessary in situations where detailed fish examination or minor surgical procedures are to be conducted. Each gram of Aquacalm powder contains 1 gm of metomidate hydrochloride. Aquacalm acts on the central nervous system to induce sedation or anesthesia in fish immersed in water containing the drug.

Available in: 1 gram, 5 gram, 10 gram & 50 gram bottles



**FDA  
INDEXED  
DRUG**

\*AQUACALM® is an FDA Indexed Drug and is for the sedation and anesthesia of ornamental finfish only. It is not for use in fish intended for human or animal consumption.

For more information from the FDA regarding Indexing, visit:

[www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm164110.htm](http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm164110.htm)

**NEW**

## HALAMID® AQUA (Chloramine-T)



In 2014, the FDA's Center for Veterinary Medicine (CVM) awarded a New Animal Drug Application (NADA) approval for the use of HALAMID® AQUA in aquaculture throughout the USA and Western is your exclusive distributor. HALAMID® AQUA is the brand name of Chloramine-T and is now approved for:

- 1) Control of mortality in all freshwater-reared salmonids due to bacterial gill disease
- 2) Control of mortality in walleye due to external columnaris disease
- 3) Control of mortality in all freshwater-reared warm water finfish due to external columnaris disease.

US FDA NADA #141-123

Available in: 5 kg buckets, 25 kg drums

## PARASITE-S (Pharmaceutical Grade 37% Formalin)

PARASITE-S is an FDA approved parasiticide for the control of external protozoa and monogenetic trematodes on all finfish, and external protozoa on penaeid shrimp. It is also approved as a fungicide for all finfish eggs. Ships from various locations to reduce our customers' shipping costs. Call for our latest bulk rates!

US FDA NADA #140-989

Available in: 1 gallon jug, 55 gallon drum, and now 1000 liter tote!


**NEW  
SIZES**


**35% PEROX-AID® is the only FDA approved hydrogen peroxide product for use on fish.**

## 35% PEROX-AID® (Pharmaceutical grade 35% hydrogen peroxide)

35% PEROX-AID® is a specially formulated hydrogen peroxide product and is the only hydrogen peroxide product with FDA approval for use in aquaculture. It is intended for use as an external microbicide for the control of mortality in freshwater-reared finfish eggs due to saprolegniasis, in freshwater-reared salmonids due to bacterial gill disease, and in freshwater-reared coolwater finfish and channel catfish due to external columnaris disease.

US FDA NADA # 141-255

Available in: 5 gallon carboy, 55 gallon drum, and now 1200 liter tote!

## OVADINE® (PVP Iodine)

OVADINE® is a PVP Iodine fish egg disinfectant and is sometimes referred to as Iodophor. It is a buffered 1% Iodine solution specifically formulated for use in disinfecting fish eggs. It contains 10% Povidone-Iodine (PVP Iodine) complex which provides 1% available iodine. Ovadine is an US FDA Low Regulatory Priority (LRP) for use as a disinfectant for fish eggs including salmon and trout eggs. It is widely used as a fish egg disinfectant in North America to reduce the transmission of diseases between generations of fish. OVADINE (PVP Iodine) fish egg disinfectant is an important part of a complete biosecurity program.

Available in: • 1 gallon jug • Case of 4 x 1 gallon jugs • 5 gallon bucket • 55 gallon drum



## AQUACULTURE BIOSECURITY PRODUCTS

### BIOSECURITY

can be defined as protection & security from the introduction or spread of disease causing agents. The products described in this brochure can be used to develop a biosecurity plan that can help to:

- Keep diseases out of your facility
- Reduce the spread of diseases that are already present
- Reduce the use of medications
- Improve the performance of your fish
- Enhance the health and quality of your fish

*Please call us to discuss your Biosecurity requirements. Our experienced staff can answer your questions and make suggestions regarding the proper use of these products.*

## VIRKON® AQUATIC (Disinfectant / Virucide)



VIRKON® AQUATIC is a powder that when mixed with water, forms a powerful cleaning and disinfecting solution that kills Viruses, Bacteria, Fungi and Molds. It is US EPA approved for cleaning and disinfecting vehicles, nets, boots, waders, dive suits, hoses, brushes, equipment and other surfaces associated with aquaculture. It is great for use in footbaths. VIRKON® AQUATIC solutions are non-staining, fast acting and stable for seven days. Proven effective against aquatic viruses including ISA, IPN, Rhabdovirus (IHN, VHS, SVC), bacteria, fungi, and molds.

US EPA Reg No. 71654-6

Available in: 10 lb. tub • Case of 4 x 10 lb. tubs



*Test strips are available to verify the solution strength in footbaths and on surfaces being disinfected.*

## AQUALIFE MULTI-PURPOSE CLEANER



Nonfood Compounds  
Program Listed

AquaLife Multi Purpose Cleaner is an economical, high quality cleaner that is designed specifically for use in fish hatcheries, aquaculture facilities, fish & food processing plants, & agricultural farms. It quickly penetrates and loosens organic soiling and is effective in removing organic matter, biofilm, grease, oils, animal & fish wastes, feed waste, proteins, etc.

**Best of all,  
AquaLife  
Multi Purpose  
Cleaner is:**

- Biodegradable
- Phosphate Free
- Contains no Volatile Organic Compounds (VOCs)
- Is NSF certified for use in food processing facilities
- Ships as a non-hazardous material

Available in: 1 gallon jug

## OVADINE®

OVADINE® (PVP Iodine) fish egg disinfectant is an important part of fish hatchery biosecurity. It is widely used as a fish egg disinfectant to reduce the transmission of diseases between generations of fish. NOTE: Some Fish and Wildlife agencies have their own guidelines for Iodophor disinfection of fish eggs with OVADINE®, which may use slightly different concentrations and/or exposure times. See our website for links for more info.



Available in: • 1 gallon jug • Case of 4 x 1 gallon jugs  
• 5 gallon bucket • 55 gallon drum



## DISINFECTING/SANITIZING FOOT MATS

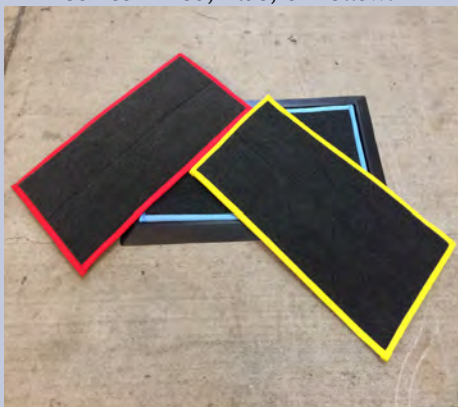
These mats are ideal for use in fish hatcheries, laboratories, farms, and etc where disinfection of foot ware is desired prior to entering a controlled area.

### SaniStride® Disinfecting Mat

The SaniStride® disinfection mat is a revolutionary footwear disinfecting system designed to lower the risk of disease spread at your facility and keep your costs down by using replaceable inserts you can rinse and reuse. See the demo on our website.

Size: 39" L x 23" W x 1 1/16" H  
 Weight: 8.6 kg (19.0 lbs)

Comes in Red, Blue, or Yellow!



### Low Wall Rubber Mat



A smaller, shallower version of the High Wall Mat and is made from the same heavy-duty, chlorine resistant black rubber.

Size: 61 cm (24") x 81 cm (32")  
 Depth: 2.2 cm (7/8")  
 Weight: 8.6 kg (19.0 lbs)

### High Wall Rubber Mat



Made of heavy-duty, chlorine resistant black rubber. This mat incorporates rubber fingers on the base to help scrub the soles of footwear while the surrounding solution sanitizes them. High walls allow for deeper immersion of footwear.

Size: 81 cm (32") x 99.0 cm (39")  
 Depth: 5.0 cm (2.0")  
 Weight: 14.5 kg (32.0 lbs)



\*Disinfectant Sold Separately\*

Call us for info on  
 great bulk prices for  
 Virkon®



### BIOSECURITY SIGNS

Signs are made of durable, waterproof, highly visible, chloroplast material for use indoors or outdoors at facilities requiring biosecurity signage. Each sign measures 11" x 17" in.





Environmental and physiological conditions will affect the response to spawning aids. Consult a professional for guidance.

## OVAPRIM®



Ovaprim is a potent ovulating/spermiating agent to promote and facilitate reproduction of many species of fish. Ovaprim is a stable solution that contains Ova-RH and a dopamine inhibitor. Time to ovulation following injection is highly predictable, with high egg fertility and viability.

**DOSE** - A general dose of Ovaprim is 0.5 ml per kilogram of body weight. This dose may vary among species and locations. Male carps may require a reduced dose. Ensure that an adequate ratio of males and females are induced at the same time.

Available in: 10 mL vial



**FDA  
INDEXED  
DRUG**

For more information from the FDA regarding Indexing, visit:  
[www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm164110.htm](http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm164110.htm)

## OVAPLANT®

Ovaplant is effective in synchronizing and advancing maturation and ovulation. Ovaplant is effective in advancing Atlantic salmon and other fish species. It is injected as a single implant dose and can be injected weeks prior to normal spawning. Spawning of groups can be advanced and synchronized. Ensure that an adequate ratio of males and females are induced at the same time. In the US, if the intended use is to treat food fish, or fish for release into the wild, it must be used according to the FDA's guidelines for Investigational New Animal Drug Application (INAD) # 11-375 - see [www.fws.gov/fisheries/aadap/sGnRHα.htm](http://www.fws.gov/fisheries/aadap/sGnRHα.htm) for more information.



Available in: 75 µg, 150 µg, or 250 µg  
(each cartridge holds 24 pellets)

**Ralgun (sold separately) for use in  
implanting Ovaplant® pellets into fish.**



## LHRHa



LHRHa is an analogue peptide spawning agent. If the intended use is to treat food fish, or fish for release, then it must be used according to the FDA's guidelines for Investigational New Animal Drug Application (INAD) #8061 (research purposes are exempt). More information including INAD application forms, study protocols, study summaries, etc can be obtained from the U.S. Fish & Wildlife Service's office of Aquatic Animal Drug Approval Partnership Program (AADAP) at:

<http://www.fws.gov/fisheries/aadap/lhrha.htm>

Available in: 1mg, 5mg, or 25mg vials



## DEFOAM FG-10

DEFOAM-FG-10 is a defoaming agent used to reduce foam in tanks containing fish and is especially helpful during transportation. It is easy to dilute and disperse and it is effective in a wide range of water temperatures. This emulsion contains 10 percent of a food grade silicone compound and it qualifies under FDA regulations for use in foods. It has also gained acceptance for use in Kosher foods.

Available in: • 1 gallon jug • Case of 4 x 1 gallon jug

## VIDALIFE

VIDALIFE is a specially formulated water conditioner for use in hatchery and transport tanks, anesthetic totes, and on handling equipment and surfaces. It works by forming a protective layer between surfaces which helps protect fish from abrasions by preserving the natural mucous layer.

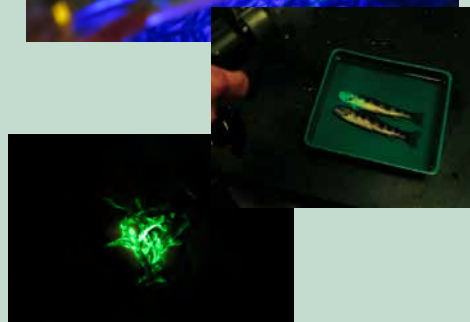
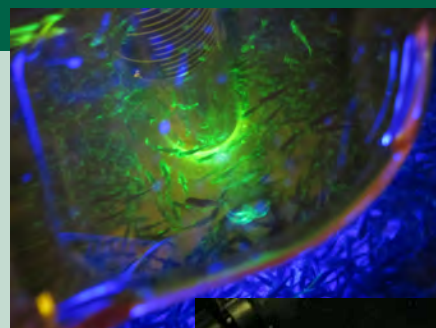
Available in: • 1 gallon jug • Case of 4 x 1 gallon jugs • 55 gallon drum



## FISH MARKING

### SE-MARK™

SE-MARK™ (calcein solution) is being developed to mark fin rays, scales, otoliths, and other calcified fish tissues through the use of immersion baths. Marks left on these tissues remain invisible to the naked eye and can only be viewed with the use of special light filters. Information on detections systems is available. SE-MARK (calcein solution) is promising in that it can be used to easily and economically mark large numbers of fish. The marks can be detected via non-lethal observations using a SE-MARK (calcein solution) detector. If the intended use is to treat food fish, or fish for release, then it must be used according to the FDA's guidelines for Investigational New Animal Drug Application (INAD) #10-987. More information including INAD application forms, study protocols, study summaries, etc. can be obtained from the U.S. Fish & Wildlife Service's office of Aquatic Animal Drug Approval Partnership Program (AADAP) at: [www.fws.gov/fisheries/aadap/calcein.htm](http://www.fws.gov/fisheries/aadap/calcein.htm)



## Other Products:

Potassium Permanganate • Calcium Chloride  
 Sodium Bicarbonate • Calcium Carbonate • Citric Acid  
 12.5% Sodium Hypochlorite • Calcium Hypochlorite

**We can source most bulk chemicals, too!**  
**Call us if you don't see what you need!**



**MADE IN**

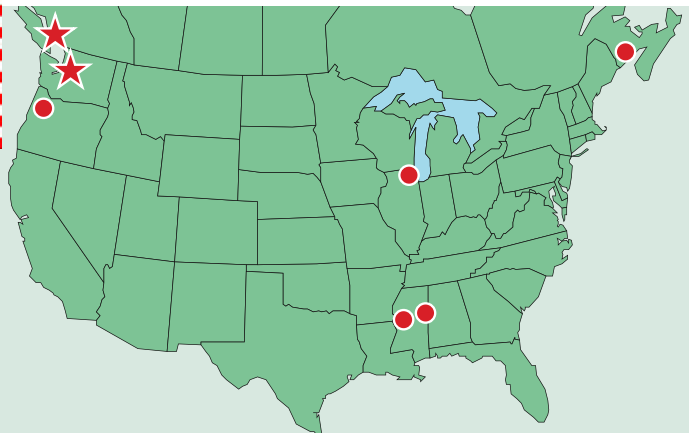
**PROUDLY MANUFACTURED IN THE USA!**

Western Chemical is a USA owned and operated company. The majority of our products are proudly made in the USA.



**WE'VE GOT YOU COVERED!**

The map at right shows the location of our offices and warehouses. These facilities (and others worldwide!) are strategically located to allow us to provide cost effective shipping throughout North America.



The **AQUATIC LIFE SCIENCES** group of companies includes:



**Western**  
Chemical, Inc.



**Syndel**  
Laboratories, Ltd.

*World Leader in Fish Health Products*

## About Western Chemical, Inc.

For over 40 years, Western has been in the forefront of developing and marketing approved aquaculture pharmaceutical products for distribution worldwide.

Western's corporate offices, quality control laboratories, and FDA inspected manufacturing plants are located near Ferndale, Washington. We operate in full compliance with all regulatory agencies including the FDA, EPA, Dept. of Ecology, etc. We take pride in our people, facilities, and products. When purchasing from Western, you can be assured that our products we produced in an environmentally responsible manner.

Western Chemical, Inc. is part of the Aquatic Life Sciences group of companies which includes Syndel Laboratories, Ltd. of Canada and Syndel Asia of Malaysia.

## About our parent company Aquatic Life Sciences

Aquatic Life Sciences, Inc. is a privately held company with corporate headquarters in Ferndale, Washington USA and offices in Nanaimo BC, Canada, and Kuala Lumpur, Malaysia. For over 40 years, Syndel Laboratories and Western Chemical have been in the forefront of developing and marketing aquaculture pharmaceutical products for distribution worldwide. Syndel is a leader in spawning agents, vaccines, biosecurity, and fish health, while Western Chemical is well known for manufacturing and distributing approved aquaculture products. Aquatic Life Sciences currently markets and distributes to more than 40 countries and aims at building strong and successful partnerships worldwide.



**Western**  
Chemical, Inc.

1269 Lattimore Road  
Ferndale, Washington 98248, USA  
Toll Free 1-800-283-5292  
Phone 360-384-5898  
Fax 360-384-0270

info@wchemical.com  
www.wchemical.com

# Drug Establishments Current Registration Site


**f** [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)


**t** [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG+ESTABLISHMENTS+CURRENT+REGISTRATION+SITE&URL=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)



**e** [EMAIL \(MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](MAILTO:?SUBJECT=DRUG+ESTABLISHMENTS+CURRENT+REGISTRATION+SITE&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

Search Results for **western chemical**

 [Download data \(downloadExcel.cfm\)](#)

Firm Name 	Facility Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Western Chemical Inc.	3020195	085803500	ANALYSIS; API MANUFACTURE; LABEL; MANUFACTURE; PACK; RELABEL; REPACK;	1269 Lattimore Road, Ferndale, Washington (WA) 98248, United States (USA)	12/31/2016
<div>« &lt; 1 &gt; »</div>					

Data Current through: Thursday, Dec 15, 2016

[Return to Drug Firm Annual Registration Status Home Page \(default.cfm\)](#)



# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)  
11/07/2016

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

**IMPORTANT:** If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

<b>PRODUCER</b> DML Insurance Services 4005 20th Ave W Ste 132 Seattle WA 98199-	<b>CONTACT NAME:</b>	
	<b>PHONE (A/C, No, Ext):</b> (206)838-9077 <b>FAX (A/C, No):</b> (206)838-9076 <b>E-MAIL ADDRESS:</b>	
<b>INSURED</b> Aquatic Life Sciences, Inc. Western Chemical, Inc. 1269 Lattimore Road Ferndale WA 98248-	<b>INSURER(S) AFFORDING COVERAGE</b>	<b>NAIC #</b>
	<b>INSURER A:</b> AIG WorldSource	
	<b>INSURER B:</b> Illinois Union Insurance	
	<b>INSURER C:</b>	
	<b>INSURER D:</b>	
	<b>INSURER E:</b>	

**COVERAGES****CERTIFICATE NUMBER:****REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
B	<input checked="" type="checkbox"/> <b>COMMERCIAL GENERAL LIABILITY</b> <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR <input checked="" type="checkbox"/> Pollution Liability <input checked="" type="checkbox"/> Vendors Liability GEN'L AGGREGATE LIMIT APPLIES PER: <input type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input checked="" type="checkbox"/> LOC OTHER:			APC G28181279 001WC	10/31/2016	10/31/2017	EACH OCCURRENCE \$ 1,000,000 DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 500,000 MED EXP (Any one person) \$ 25,000 PERSONAL & ADV INJURY \$ 1,000,000 GENERAL AGGREGATE \$ 2,000,000 PRODUCTS - COMP/OP AGG \$ 2,000,000
A	<input checked="" type="checkbox"/> <b>AUTOMOBILE LIABILITY</b> <input checked="" type="checkbox"/> ANY AUTO <input type="checkbox"/> ALL OWNED AUTOS <input type="checkbox"/> HIRED AUTOS <input type="checkbox"/> SCHEDULED AUTOS <input type="checkbox"/> NON-OWNED AUTOS			WR10007055	01/30/2016	01/30/2017	COMBINED SINGLE LIMIT (Ea accident) \$ 1,000,000 BODILY INJURY (Per person) \$ BODILY INJURY (Per accident) \$ PROPERTY DAMAGE (Per accident) \$
B	<input checked="" type="checkbox"/> <b>UMBRELLA LIAB</b> <input checked="" type="checkbox"/> OCCUR <input checked="" type="checkbox"/> EXCESS LIAB <input type="checkbox"/> CLAIMS-MADE DED <input checked="" type="checkbox"/> RETENTION \$ 10,000			XOO G28181280 001WC	10/31/2016	10/31/2017	EACH OCCURRENCE \$ 20,000,000 AGGREGATE \$ 20,000,000
B	<b>WORKERS COMPENSATION AND EMPLOYERS' LIABILITY</b> ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under: DESCRIPTION OF OPERATIONS below	Y/N N/A		APC G28181279 001WC WA Stop Gap	10/31/2016	10/31/2017	PER STATUTE <input type="checkbox"/> OTH-ER <input type="checkbox"/> E.L. EACH ACCIDENT \$ 1,000,000 E.L. DISEASE - EA EMPLOYEE \$ 1,000,000 E.L. DISEASE - POLICY LIMIT \$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)  
As respects of State of Washington Contract No. 13203, the State of Washington and all authorized users of Contract No. 13203 are added as additional insured, but only as respect the negligence of Insured and its employees.

**CERTIFICATE HOLDER****CANCELLATION**

AI 004066

State of Washington  
Attn: Office of State Procurement  
DEPT OF GENERAL ADMINISTRATION  
PO Box 41017  
Olympia WA 98504-1017

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

*Ben Mish*

# PARASITE-S

## Formalin (aqueous formaldehyde solution)

For control of External Protozoa and Monogeneic Trematodes on all Finfish and External Protozoans on Penaeid Shrimp; and for control of Fungi on all Finfish eggs.

### DESCRIPTION

PARASITE-S is the aqueous solution of formaldehyde gas (this is equivalent to formalin 37% or 37 grams of formaldehyde in 100 mL of solution). U.S.P. grade PARASITE-S contains not less than 37% (by weight) of formaldehyde gas per weight of water and 5 to 14% methanol. In solution, formaldehyde is present chiefly as  $\text{HO}(\text{CH}_2\text{O})_n\text{H}$ . Its molecular weight is 30.83. PARASITE-S is readily miscible with water, methanol, and ethanol and is slightly soluble in ether. It is a clear, colorless liquid (Hayden Newport Chemical Corporation, 1961).

### FISH AND SHRIMP TOXICITY STUDIES

The toxicity of PARASITE-S was measured by standard methods in laboratory bioassays with rainbow trout, Atlantic salmon, lake trout, black bullhead, channel catfish, green sunfish, bluegill, smallmouth bass, largemouth bass and striped bass. The 3, 6, 24 and 96-hour  $\text{LC}_{50}$  (lethal concentration for 50% of the animals) values for trout range from 1,230 to 100  $\mu\text{L/L}$  (455 to 37 ppm formaldehyde); for catfish, from 495 to 65.8  $\mu\text{L/L}$  (183 to 24 ppm formaldehyde); for bluegill, from 2,280 to 100  $\mu\text{L/L}$  (847 to 37 ppm formaldehyde); for largemouth bass, the values for 6 to 96-hour  $\text{LC}_{50}$  range from 1,030 to 143  $\mu\text{L/L}$  (381 to 53 ppm formaldehyde) (Bill et al. 1977) and for striped bass the values for 6 to 96-hour  $\text{LC}_{50}$  range from 940 to 30  $\mu\text{L/L}$  (347 to 11 ppm formaldehyde) (Bills, Marking & Howe-1993). The 24, 48, 72, and 96-hour  $\text{LC}_{50}$  values for penaeid shrimp range from 712 to 235  $\mu\text{L/L}$  (ppm) (Johnson, 1974 and Williams, 1980).

### INDICATIONS FOR USE:

1. Parasiticide for Finfish: for the control of external protozoa (*Chilodonella* spp., *Ichthyobodo* spp., *Epistylis* spp., *Ichthyophthirius* spp., *Ambloplites* spp., and *Trichodina* spp.), and the monogeneic trematode parasites (*Cleidodiscus* spp., *Dactylogyrus* spp., and *Gyrodactylus* spp.).
2. Parasiticide for Penaeid Shrimp: for the control of external protozoan parasites (*Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.).
3. Fungicide for Finfish Eggs: for the control of fungi of the family Saprolegniaceae.

### DIRECTIONS FOR USE:

1. Parasiticide for Finfish

#### Concentrations of Formalin

Aquatic species	Administer in Tanks & Raceways for up to 4 hrs ( $\mu\text{L/L}$ )*	Administer in Earthen Ponds Indefinitely ( $\mu\text{L/L}$ )*
Salmon & Trout above 50°F below 50°F	up to 170 up to 250	15-25*** 15-25***
All other finfish	up to 250	15-25***

\* Microfiter per liter ( $\mu\text{L/L}$ ) = parts per million (ppm).

\*\* Use the lower concentration when ponds, tanks or raceways are heavily loaded with phytoplankton, or fish, 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. Parasiticide for Penaeid Shrimp

#### Concentrations of Formalin

Aquatic species	Administer in Tanks & Raceways for up to 4 hours ( $\mu\text{L/L}$ )*	Administer in Earthen Ponds Indefinitely ( $\mu\text{L/L}$ )*
Shrimp	50 to 100**	25***

\* Microfiter 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 ponds, 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.

3. Fungicide for Finfish Eggs

#### Concentrations of Formalin

Aquatic species	Administer in Hatching Systems ( $\mu\text{L/L}$ )*
Eggs of all finfish except Acipenseriformes	1000-2000 for 15 minutes**
Eggs of Acipenseriformes	up to 1500 for 15 minutes**

\* Microfiter per liter ( $\mu\text{L/L}$ ) = parts per million (ppm).

\*\* Apply in constant flow water supply of incubating facilities. A preliminary bioassay should be conducted on a small subsample of fish 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.

### METHODS OF APPLICATION

**APPLICATION TO TANKS AND RACEWAYS** - Turn off water supply, provide aeration, apply appropriate amount of PARASITE-S, and thoroughly dilute and mix to assure equal distribution of PARASITE-S. Treat for up to 1 hour for fish and up to 4 hours for penaeid shrimp, then drain the solution and refill the tank with fresh, well-aerated water. While tank is under treatment, adequate oxygen must be present to maintain the fish or shrimp. If needed, aeration should be provided to prevent oxygen depletion. Treatments may be repeated daily until parasite control is achieved.

**APPLICATION TO PONDS** - Apply greatly diluted PARASITE-S to the pond evenly using a pump, sprayer, boat boiler, or other suitable device to assure even distribution. Allow PARASITE-S to dissipate naturally. Single treatments usually control most parasites, but may be repeated in 5 to 10 days if needed. Treatments for *Ichthyophthirius* should be made at 2-day intervals until control is achieved.

**APPLICATION TO EGG INCUBATORS** - Apply PARASITE-S into a constant water supply flowing around the eggs. A drip or pressure system should be used and timed. Apply PARASITE-S under the surface of the water flow.

WITHDRAWAL TIME  
Zero days.

### WARNING

Striped bass have been demonstrated to be hypersensitive to formalin; lethal toxicity has been noted to occur at levels approximately 2-3 times the recommended therapeutic concentration.

## DANGER POISON

### USER SAFETY WARNINGS

Exposure to high concentrations of formaldehyde vapor causes severe respiratory irritation which can be life-threatening. Lower vapor levels can cause irritation to the eyes, respiratory tract, and skin. Swallowing formaldehyde can be life-threatening. Formaldehyde is an irritant when splashed on skin or into the eyes. It can cause severe eye damage, even blindness.

Keep out of reach of children.

Use only with adequate ventilation.

Keep container tightly closed when not in use.

May aggravate a pre-existing asthmatic condition and allergic rhinitis.

Moderate fire and explosion hazard exists when exposed to heat or flame.

Contains methanol - cannot be made non-poisonous. Prolonged exposure to methanol has been associated with reproduction disorders.

Potential Cancer Hazard: Formaldehyde vapor may be carcinogenic if inhaled. Use applicable safety protection. (Note: This drug, used as labeled, does not cause formaldehyde tissue residues in fish).

Employers: Refer to Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.1048 for human safety guidance that may be applicable to your specific operation. OSHA's "action level" concentration for airborne formaldehyde is 0.5 part per million (ppm), calculated as an 8 hour time-weighted average (TWA). Use respiratory, skin, and eye protection when needed (refer to OSHA's regulation 29 CFR 1910.1048). OSHA's airborne exposure limits (without use of a respirator) for formaldehyde shall not exceed 1) 0.75 part per million (ppm) as an 8-hour, time-weighted average (TWA) or 2) 2 parts per million (ppm) as a 15-minute, short-term exposure limit (STEL). NOTE: The odor of formaldehyde in the air can generally be detected at about 0.5 to 0.8 ppm (range about 0.05 to 1 ppm).

### USER EXPOSURE EMERGENCY AID

**INHALATION (Breathing):** Get medical aid immediately. Remove victim from exposure wearing protective clothing and respiratory protection appropriate to the type and degree of contamination. Move victim to fresh air immediately. If breathing is difficult, give oxygen. DO NOT use mouth-to-mouth respiration. If breathing has ceased, induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

**INGESTION (Swallowing):** DO NOT induce vomiting. If the person is conscious, dilute, inactivate, or absorb the formaldehyde by giving milk, activated charcoal, or water. Get medical help immediately. If vomiting occurs, keep head lower than hips.

**EYE CONTACT:** Immediately flush eye(s) with large amounts of water for at least 15 minutes, lifting the lower and upper eyelids occasionally, until no evidence of chemical remains. Seek medical attention immediately. DO NOT allow victim to rub eyes or keep eyes closed for burns to eyes may have a delayed effect.

**SKIN CONTACT:** Remove contaminated clothing (including shoes) immediately. Wash affected area of body with soap and large amounts of water until no evidence of chemical remains (at least 15 minutes). If there are chemical burns, or appreciable eye or respiratory irritation, get medical help immediately.

### PRECAUTIONS

Store PARASITE-S indoors away from direct sunlight, heat, sparks, and open flames, and ventilate storage area. Do not subject PARASITE-S to temperatures below 40°F (4.4°C). PARASITE-S subjected to temperatures below 40°F causes the formation of paraformaldehyde, a substance which is toxic to fish. Paraformaldehyde can be recognized as a white precipitate at the bottom or on the walls of the container.

Tolerance to PARASITE-S may vary with strain and species of fish, eggs and shrimp. While the indicated concentrations are considered safe for the indicated use, a small number of each lot to be treated should be used to check for any unusual sensitivity to PARASITE-S before proceeding.

Under some conditions, fish or penaeid shrimp may be stressed by normal treatment concentrations. Heavily parasitized or diseased fish or penaeid shrimp often have a greatly reduced tolerance to PARASITE-S. Such animals do not tolerate the normal tank treatment regimen the first time they are treated. Therefore, time and dosage may need to be reduced. If they show evidence of distress (by piping at the surface), the solution should be removed and replaced with fresh, well-aerated water. Careful observations should always be made throughout the treatment period whenever tank or raceway treatments are made. Treatment should never exceed 1 hour for fish or 4 hours for penaeid shrimp (even if they show no sign of distress), nor should it exceed 15 minutes for fish eggs.

Do not apply PARASITE-S to fish ponds, tanks or raceways with water warmer than 80°F (27°C) when a heavy bloom of phytoplankton is present, or when the concentration of dissolved oxygen is less than 5 mg/L (ppm). Do not apply to penaeid shrimp ponds when the concentration of the dissolved oxygen is less than 3 to 4 mg/L (ppm). PARASITE-S may kill phytoplankton and can cause depletion of dissolved oxygen. If an oxygen depletion occurs, add fresh, well-aerated water to dilute the solution and to provide oxygen.

Because formalin may harm a biofilter, biofilters should be bypassed during treatment, and the system should be flushed and replaced with untreated water before reconnecting the biofilter.

Do not use PARASITE-S in a tank, pond or raceway in which methylene blue, or other dyes which are absorbed, have been recently used.

### ENVIRONMENTAL PRECAUTIONS

Do not discharge the contents of fish treatment tanks into natural streams or ponds without thorough dilution (greater than or equal to 10X). Do not discharge the contents of egg treatment tanks without a 100X dilution. This will avoid damage to PARASITE-S sensitive phytoplankton, zooplankton, and fish populations and avoid depletion of dissolved oxygen.

Formaldehyde is identified by the U.S. Environmental Protection Agency (EPA) as a toxic pollutant and hazardous substance and is required by regulation (40 CFR, Part 122) to be identified as a discharge for NPDES permits for aquatic animal production facilities, aquaculture projects and other facilities. Formaldehyde is subject to SARA Title III, Section 313 reporting.

Use, storage, and disposal of this product must be handled in accordance with applicable local, state and Federal laws.

### STORAGE

Recommended storage temperature 59°F (15°C). DO NOT EXPOSE TO DIRECT SUNLIGHT. Store PARASITE-S indoors away from direct sunlight, heat, spark, and open flame, and ventilate storage area. Do not subject PARASITE-S to temperatures below 40°F (4.4°C).



**Western  
Chemical, Inc.**

Manufactured for:  
Western Chemical Inc.  
1269 Latimore Road, Fendale, WA 98248  
(360) 384-5898  
ver. 020513

NADA 140-989, Approved by FDA

## 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 ( $\mu\text{L/L}$ )*
Eggs of all finfish except Acipenseriformes	1000 to 2000 for 15 minutes**
Eggs of Acipenseriformes	up to 1500 for 15 minutes**

\* Microliter per liter ( $\mu\text{L/L}$ ) = 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 ( $\mu\text{L/L}$ )*	Administer in Earthen Ponds Indefinitely ( $\mu\text{L/L}$ )*
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.

## 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 18°C, while the other was conducted at 25°C. 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 25°C**

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 18°C**

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 22°C.
  - 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<sub>50</sub> was 60.1 ppm. Refer to Table 6 below for mortality patterns.

**TABLE 6**  
**Safety of Formalin in Striped Bass at 22°C**

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<sub>50</sub>'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 12°C 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 22°C), hardness, and pH. Mean LC<sub>50</sub>'s in soft water of pH 7.5 at 12°C 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<sub>50</sub>'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  $12\pm 2^{\circ}\text{C}$  for walleye and white sucker, at  $17\pm 2^{\circ}\text{C}$  for common carp and lake sturgeon and at  $22\pm 2^{\circ}\text{C}$  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:

$$\% \text{ hatch} = (\text{number of hatched fry} \div \text{initial number of eggs}) \times 100$$

**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 14°C for Part 1 and 21 to 22°C 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:** 21°C
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:** 24°C
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 30°C
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 30°C 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., *Ichthyophthirius* 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 21 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.