

# **MATRICES FOR TRACKING MAJOR AQUACULTURE DRUG APPROVAL DEVELOPMENT**

## **HYDROGEN PEROXIDE (PEROX-AID®) MATRIX 1 OF 4: MATRIX RESEARCH AND DEVELOPMENT PLAN AND DRAFT LABEL CLAIM FOR ORIGINAL NEW ANIMAL DRUG APPLICATION (NADA) APPROVAL FOR THE CONTROL OF MORTALITY IN**

- 1. Freshwater-reared finfish eggs due to saprolegniasis**
- 2. Freshwater-reared salmonids due to bacterial gill disease**
- 3. Freshwater-reared coolwater finfish and channel catfish due to external columnaris disease**

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

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**HYDROGEN PEROXIDE MATRIX 1 OF 4, VERSION 3  
(May 20, 2007)**

## 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: 301-827-7567; Fax: 301-827-4317; E-mail: <a href="mailto:DPrater@CVM.FDA.GOV">DPrater@CVM.FDA.GOV</a> ; Dr. Susan Storey; Phone: 301-827-7581
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)]
EKA	Sponsor of hydrogen peroxide (PEROX-AID®): Dr. David Lovetro, Eka Chemicals Inc., 1519 Johnson Ferry Road, Marietta, Georgia 30062; Phone: 770-321-4198; Fax: 770-578-1359; E-mail: <a href="mailto:DLovetro@EkaChem.com">DLovetro@EkaChem.com</a>
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)
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, U.S. Geological Survey—Dr. William Gingerich, 2630 Fanta Reed Road, La Crosse, Wisconsin 54603; Phone: 608-783-6451; Fax: 608-783-6066; E-mail: <a href="mailto:bill_gingerich@usgs.gov">bill_gingerich@usgs.gov</a>

### KEY TO COLOR CODING

COLOR	STATUS
Red	No current plans and/or funds
Yellow	In progress or planned; funded
Blue	Submitted to CVM
Green	Accepted as complete by CVM

**ORIGINAL NADA—HYDROGEN PEROXIDE (PEROX-AID®) = For the control of mortality in**

1. Freshwater-reared finfish eggs due to saprolegniasis
2. Freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*
3. Freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*)

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Product Chemistry	EKA (INAD #9671)—Product chemistry package for PEROX-AID®—accepted 2/11/04	None
Environmental Safety (flow-through)	UMESC (INAD #10-023)—Environmental assessment final revision incorporating 21-day chronic <i>Daphnia</i> study—accepted 6/22/06	None
Human Food Safety—Toxicology	EKA (INAD #9671)—Toxicology request—accepted 3/22/00	None
Human Food Safety—Residue Chemistry (all finfish)	EKA (INAD #9671)—Residue chemistry request—accepted 3/22/00 (no tolerances, withdrawal times, Acceptable Daily Intake limits, or regulatory methods required)	None
Human Food Safety—Microbiological toxicology of residues (all finfish)	EKA (INAD #9671) & NADA Coordinator—Microbiological toxicology of residues/all finfish (Guidance Document #52, now #159)—accepted 6/6/05	None
Human Food Safety—Microbial food safety (all finfish)	EKA (INAD #9671) & NADA Coordinator—Microbial food safety/all finfish (Guidance Document #152)—accepted 9/16/05	None
Target Animal Safety (all finfish)	UMESC (INAD #10-023 & PMF #5639)—Target animal safety/all finfish—accepted 10/4/01	None
Target Animal Safety (all finfish eggs)	UMESC (INAD #10-023 & PMF #5639)—Target animal safety/all finfish eggs—accepted 11/26/03	None
Efficacy (Saprolegniasis/all finfish eggs)	UMESC (INAD #10-023 & PMF #5639)—Pivotal efficacy studies/Saprolegniasis/coldwater and coolwater fish eggs—accepted 8/16/02 & 11/26/03; Saprolegniasis/catfish & all warmwater fish eggs—accepted 2/10/04	None
Efficacy (bacterial gill disease/all freshwater-reared salmonids)	UMESC (INAD #10-023 & PMF #5639)—Pivotal efficacy studies/bacterial gill disease/all freshwater-reared salmonids—accepted 10/12/00	None
Efficacy (columnaris disease/all coolwater finfish & channel catfish)	UMESC (INAD #10-023 & PMF #5639)—Pivotal efficacy studies/external columnaris disease/ all coolwater finfish & channel catfish—accepted 11/21/03	None
Label	EKA (INAD #9671) & NADA Coordinator—Label/three label claims—accepted 11/9/06	None
FOI	CVM—FOI/three label claims—UMESC submitted to CVM 5/05 & accepted	None
AOI	EKA (INAD #9671) & NADA Coordinator—AOI/three label claims—accepted 9/6/06	None
NADA Package	<b>EKA (INAD #9671) &amp; NADA Coordinator—PEROX-AID® NADA package—accepted 1/11/07</b>	<b>APPROVED</b>

## LABEL CLAIM FOR 35% PEROX-AID® FOR THREE DISEASE INDICATIONS

### LABEL CLAIM #1: FOR FRESHWATER-REARED FINFISH EGGS

**INDICATIONS:** For the control of mortality in freshwater-reared finfish eggs due to saprolegniasis (fungi of the family Saprolegniaceae)

**DIRECTIONS FOR USE:** Apply 35% PEROX-AID® at a rate of 500 to 1,000 milligrams hydrogen peroxide per liter of culture water [mg/L; equivalent to parts per million (ppm)] for cold or coolwater finfish freshwater-reared finfish eggs and 750 to 1,000 mg/L for warmwater finfish eggs in continuous flow water supply of finfish egg incubation units for 15 minutes. Treat finfish egg incubation units once per day on consecutive or alternate days until hatch to control mortalities associated with external saprolegniasis in a tiered dosing system as follows:

SPECIES	DOSE (as H <sub>2</sub> O <sub>2</sub> )	DURATION
All cold and coolwater freshwater-reared finfish eggs <sup>1</sup>	500-1,000 mg/l	15 MINUTES
All freshwater-reared warmwater finfish eggs <sup>2</sup>	750-1,000 mg/L	15 MINUTES

<sup>1</sup>An initial bioassay on a small number is recommended before treating the entire group.

The amount of 35% PEROX-AID® required for treatment is dependent on the volume of water treated (which equals the water flow rates times 15 min; 10 L/min x 15 min = 150 L)

### LABEL CLAIM #2: FOR FRESHWATER-REARED SALMONIDS

**INDICATIONS:** For the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*

**DIRECTIONS FOR USE:** Apply 35% PEROX-AID® at a concentration of 100 milligrams hydrogen peroxide per liter of culture water [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply or as a static bath in salmonid culture units for 30 minutes or 50 to 100 mg hydrogen peroxide/L for 60 minutes once per day on alternate days for three treatments in salmonid culture units.

### LABEL CLAIM #3: FOR FRESHWATER-REARED COOLWATER FINFISH AND CHANNEL CATFISH

**INDICATIONS:** For the control of mortality in freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*)

**DIRECTIONS FOR USE:** Apply 35% PEROX-AID® at a concentration of 50 to 75 milligrams hydrogen peroxide per liter of culture water [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply or as a static bath in coolwater finfish or channel catfish culture units for 60 minutes once per day on alternate days for three treatments in a tiered dosing system as follows:

Species	DOSE (as H <sub>2</sub> O <sub>2</sub> )	Duration
Channel catfish and freshwater-reared coolwater finfish fingerlings and adults <sup>1,3</sup>	50-75 mg/L	60 minutes
Channel catfish and freshwater-reared coolwater finfish fry <sup>2,3</sup>	50 mg/L	60 minutes

<sup>1</sup>. Except northern pike

<sup>2</sup>. Except northern pike or pallid sturgeon

<sup>3</sup>. An initial bioassay on a small number is recommended before treating the entire group.

Use caution on walleye *Sander vitreus*