

AQUACULTURE DRUG APPROVAL DEVELOPMENT STATUS

CHLORAMINE-T (HALAMID® PHARMA GRADE): RESEARCH AND DEVELOPMENT PLAN AND LABEL CLAIM MATRICES FOR ORIGINAL AND SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA) APPROVALS

1. [Chloramine-T \(HALAMID® PHARMA GRADE\) NADA approvals \(none to date\)](#)
2. [Status of technical sections that support all original and supplemental NADA approvals](#)
3. [Label Claim #1: Control of mortality in freshwater-reared salmonids due to bacterial gill disease](#)
4. [Label Claim #2: Control of mortality in freshwater-reared walleye and largemouth bass due to external columnaris disease](#)
5. [Label Claim #3: Control of mortality in freshwater-reared finfish due to external columnaris disease](#)
6. [Label Claim #4: Control of mortality in freshwater-reared finfish due to bacterial gill disease](#)

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

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CHLORAMINE-T (HALAMID® PHARMA GRADE)
(Version 1, November 2007)

ABBREVIATIONS, ACRONYMS, & CONTACT INFORMATION FOR ENTITIES IN TABLE

AADAP	Aquatic Animal Drug Approval Partnership Program—Dr. David Erdahl, U.S. Fish and Wildlife Service, 4050 Bridger Canyon Road, Bozeman, Montana 59715; Phone: 406-994-9904; Fax: 406-582-0242; E-mail: Dave_Erdahl@fws.gov
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)]
AXC	Paul J. Raadsen, Director of Axcentive SARL, Axcentive SARL, Chemin de Champouse, Quartier Violesi, 13320 Bouc Bel Air, France; Phone: 33 442 694 090; Fax: 33 442 694 099; E-mail: p.raadsen@axcentive.com ; Technical consultant in the United States: Dr. Edwin Bisinger, Akzo Nobel Chemicals, Inc., 300 South Riverside Plaza, Chicago, Illinois 60606; Phone: 312-906-7637; Fax: 312-906-7532; E-mail: Edwin.c.Bisinger@akzo-nobel.com
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; E-mail: DPrater@CVM.FDA.GOV
CVM-OR	Analytical Methods Team (HFV-511), Division of Residue Chemistry, Office of Research, Center for Veterinary Medicine, Food and Drug Administration, U.S. Department of Health and Human Services, Dr. Philip Kijak, Analytical Methods Team Leader (HFV-511), Phone: 301-827-8166; Fax: 301-827-8170
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: RozSchnick@centurytel.net
p-TSA	para-toluenesulfonamide, marker residue of chloramine-T
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—Dr. William Gingerich, 2630 Fanta Reed Road, La Crosse, Wisconsin 54603; Phone: 608-783-6451; Fax: 608-783-6066; E-mail: bill_gingerich@usgs.gov

KEY TO COLOR CODING

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

CHLORAMINE-T (HALAMID® PHARMA GRADE)

Chloramine-T (HALAMID® PHARMA GRADE) NADA approvals (none to date)

CHLORAMINE-T (HALAMID® PHARMA GRADE)

Status of Technical Sections that support all original and supplemental NADA approvals

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Product Chemistry	AXC (INAD #8086)—Product Chemistry—preliminary package submitted to CVM 5/22/06; more information needed	None—pending acceptance
Environmental Safety (flow-through)	UMESC (PMF #5637)—Validation of dilution model—accepted 5/7/03	None—model accepted
Environmental Safety (flow-through/all freshwater-reared finfish)	UMESC (INAD #10-974)—Environmental assessment/flow-through systems/all freshwater-reared finfish—accepted 10/12/07	None
Environmental Safety (flow-through/all freshwater-reared finfish)	AXC (INAD #8086) & NADA Coordinator—Environmental Safety Technical Section/Complete Letter—in progress	None—pending acceptance
Human Food Safety/Toxicology	AXC (INAD #8086)—Toxicology/genotoxicity studies—accepted 7/19/02	None
Human Food Safety/Toxicology	AXC (INAD #8086)—Toxicology/all mammalian safety—accepted 4/9/03	None—This portion of the Technical Section is complete
Human Food Safety—Residue Chemistry/analytical method in water (all finfish)	UMESC (PMF #5637)—Residue Chemistry/analytical method in water for monitoring—accepted 1/15/03	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/hybrid striped bass—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/yellow perch—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/rainbow trout—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Residue Chemistry (regulatory method developed)	UMESC (PMF #5637)—Residue chemistry/regulatory method developed/p-TSA/rainbow trout, channel catfish, & walleye—accepted 4/24/03	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Residue Chemistry (regulatory method validated)	UMESC (PMF #5637)—Residue chemistry/regulatory method validated/p-TSA/all freshwater-reared finfish—accepted 4/15/04	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Residue Chemistry (confirmatory method)	CVM-OR—Residue Chemistry/confirmatory method/all freshwater-reared finfish (funded by UMESC)—accepted 3/4/05	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Microbial Food Safety (all freshwater-reared finfish)	AXC (INAD #8086) & NADA Coordinator—Microbial food safety (Guidance Document #152/all freshwater-reared finfish)—accepted 5/07	None
Human Food Safety—Microbial Food Safety (all	AXC (INAD #8086) & NADA Coordinator—Microbial food safety (Guidance Document 159/all	None—pending acceptance

freshwater-reared finfish)	freshwater-reared finfish)—revision submitted 7/23/07	
Technical Section	Entity—Data—Action	Impediments or Cost—Action
Human Food Safety— Technical Section Complete Letter	AXC (INAD #8086) & NADA Coordinator— Human Food Safety/Technical Section Complete Letter—planned which all parts are accepted	None—pending acceptance
Target Animal Safety (all coolwater & warmwater finfish)	UMESC (PMF #5637 & INAD #10-974)—Target Animal Safety/all coolwater & warmwater fish—accepted 3/11/04 & 3/11/05	None—This Technical Section is complete for all freshwater-reared finfish
Target Animal Safety (all freshwater-reared salmonids)	AADAP (INAD #4000 & #9321)—Target animal safety/all salmonids—accepted 9/13/02	None—This Technical Section is complete for all freshwater-reared finfish

CHLORAMINE-T (HALAMID® PHARMA GRADE)

LABEL CLAIM #1

SPECIES: FRESHWATER-REARED SALMONIDS

INDICATIONS: [For the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium* spp.](#)

DIRECTIONS FOR USE: Apply HALAMID® PHARMA GRADE at concentrations of 12 to 20 milligrams chloramine-T 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 60 minutes once daily on alternate days for a total of three treatments.

LABEL CLAIM #2

SPECIES: FRESHWATER-REARED WALLEYE & LARGEMOUTH BASS

INDICATIONS: [For the control of mortality in walleye and largemouth bass due to external columnaris disease associated with *Flavobacterium columnare*](#)

DIRECTIONS FOR USE: Apply HALAMID® PHARMA GRADE at concentrations of 10 to 20 milligrams chloramine-T per liter of culture water [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply or as a static bath in walleye and largemouth bass culture units for 60 minutes once daily on alternate days for a total of three treatments.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (bacterial gill disease/all freshwater-reared salmonids)	AADAP (INAD #4000 & #9321)—Efficacy/bacterial gill disease/all freshwater-reared salmonids—accepted 7/12/00; dose confirmation for flow-through—accepted 6/10/02	None—This Technical Section is complete for all freshwater-reared salmonids
Efficacy (external columnaris disease/walleye)	UMESC (PMF #5637 & INAD #10-974)—Efficacy/external columnaris disease/walleye—accepted 1/30/04	None—This Technical Section is complete for walleye
Efficacy (external columnaris disease/largemouth bass)	AADAP (INAD #4000 & #9321)—Efficacy/external columnaris disease/largemouth bass—submitted 9/25/07	None—pending acceptance
Label	AXC (INAD #8086) & NADA Coordinator—Label/bacterial gill disease/all freshwater-reared salmonids & external columnaris disease/walleye & largemouth bass—CVM provided comments for revision of the label 12/12/06; revision in progress	None—pending acceptance
FOI	CVM—FOI/bacterial gill disease/all freshwater-reared salmonids & external columnaris disease/walleye & largemouth bass—in progress	None—pending acceptance
AOI	AXC (INAD #8086) & NADA Coordinator—AOI/bacterial gill disease/all freshwater-reared salmonids & external columnaris disease/walleye & largemouth bass—planned before Administrative NADA submission	None—pending acceptance
NADA Package	AXC (INAD #8086) & NADA Coordinator—NADA package/bacterial gill disease/all freshwater-reared salmonids & external columnaris disease/walleye & largemouth bass—in progress	None—pending acceptance

CHLORAMINE-T (HALAMID® PHARMA GRADE)

LABEL CLAIM #3:

SPECIES: FRESHWATER-REARED FINFISH

INDICATIONS: For the control of mortality in freshwater-reared finfish due to external columnaris disease associated with *Flavobacterium columnare*

DIRECTIONS FOR USE: Apply HALAMID® PHARMA GRADE at concentrations of 10 to 20 milligrams chloramine-T per liter of culture water [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply or as a static bath in finfish culture units for 60 minutes once daily on alternate days for a total of three treatments.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (external columnaris disease/walleye)	UMESC (PMF #5637 & INAD #10-974)—Efficacy/external columnaris disease/walleye—accepted 1/30/04	None—This Technical Section is complete for walleye
Efficacy (external columnaris disease/largemouth bass)	AADAP (INAD #4000 & #9321)—Efficacy/external columnaris disease/largemouth bass—submitted 9/25/07	None—pending acceptance
Efficacy (pivotal/external columnaris disease/all freshwater-reared finfish except walleye & largemouth bass)	AADAP (INAD #4000 & #9321)—Pivotal efficacy/external columnaris disease/all freshwater-reared finfish except walleye & largemouth bass—being planned	None—pending acceptance
Efficacy (supplemental/external columnaris disease/all freshwater-reared finfish except walleye & largemouth bass)	AADAP (INAD #4000 & #9321)—Supplemental efficacy/external columnaris disease/all freshwater-reared finfish except walleye & largemouth bass—being planned	None—pending acceptance
Label	AXC (INAD #8086) & NADA Coordinator—Label/external columnaris disease/all freshwater-reared finfish—planned if efficacy accepted	None—pending acceptance
FOI	CVM—FOI/external columnaris disease/all freshwater-reared finfish except walleye & largemouth bass—planned if efficacy accepted	None—pending acceptance
AOI	AXC (INAD #8086) & NADA Coordinator—AOI/external columnaris disease/all freshwater-reared finfish except walleye & largemouth bass—planned if efficacy accepted	None—pending acceptance
NADA Package	AXC (INAD #8086) & NADA Coordinator—NADA package/external columnaris disease/all freshwater-reared finfish except walleye & largemouth bass—planned if efficacy accepted	None—pending acceptance

CHLORAMINE-T (HALAMID® PHARMA GRADE)

LABEL CLAIM #4:

SPECIES: FRESHWATER-REARED FINFISH

INDICATIONS: [For the control of mortality in freshwater-reared finfish due to bacterial gill disease associated with *Flavobacterium* spp.](#)

DIRECTIONS FOR USE: Apply HALAMID® PHARMA GRADE at concentrations of 10 to 20 milligrams chloramine-T per liter of culture water [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply or as a static bath in finfish culture units for 60 minutes once daily on alternate days for a total of three treatments.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (bacterial gill disease/all freshwater-reared salmonids)	AADAP (INAD #4000 & #9321)—Efficacy/bacterial gill disease/all freshwater-reared salmonids—accepted 7/12/00; dose confirmation for flow-through—accepted 6/10/02	None—This Technical Section is complete for all freshwater-reared salmonids
Efficacy (pivotal/bacterial gill disease/all freshwater-reared finfish except salmonids)	AADAP (INAD #4000 & #9321)—Pivotal efficacy/bacterial gill disease/all freshwater-reared finfish except salmonids—being planned	None—pending acceptance
Efficacy (supportive/bacterial gill disease/all freshwater-reared finfish except salmonids)	AADAP (INAD #4000 & #9321)—Supportive efficacy/bacterial gill disease/freshwater-reared finfish except salmonids—being planned	None—pending acceptance
Label (bacterial gill disease/all freshwater-reared finfish)	AXC (INAD #8086) & NADA Coordinator—Label/all freshwater-reared finfish—planned when efficacy accepted	None—pending acceptance
FOI (bacterial gill disease/all freshwater-reared finfish except salmonids)	CVM—FOI/all freshwater-reared finfish except salmonids—planned when efficacy accepted	None—pending acceptance
AOI (bacterial gill disease/all freshwater-reared finfish)	AXC (INAD #8086) & NADA Coordinator—AOI/all freshwater-reared finfish—planned when efficacy accepted	None—pending acceptance
NADA Package (bacterial gill disease/all freshwater-reared finfish except salmonids)	AXC (INAD #8086) & NADA Coordinator—NADA package/all freshwater-reared finfish except salmonids—planned when efficacy accepted	None—pending acceptance