

AQUACULTURE DRUG APPROVAL DEVELOPMENT STATUS

POTASSIUM PERMANGANATE (CAIROX®): RESEARCH AND DEVELOPMENT PLAN AND LABEL CLAIM MATRICES FOR ORIGINAL AND SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA) APPROVALS

1. Potassium permanganate (CAIROX®) NADA approvals (none to date)
2. Status of technical sections that support all original and supplemental NADA approvals
3. Label Claim #1: For the control of mortality in channel catfish and hybrid striped bass due to external columnaris disease
4. Label Claim #2: For the control of mortality in freshwater-reared finfish due to external columnaris disease
5. Label Claim #3: For the control of mortality in freshwater-reared salmonids due to bacterial gill disease
6. Label Claim #4: For the control of mortality in freshwater-reared salmonids due to coldwater disease
7. Label Claim #5: For the control of external protozoa on freshwater-reared finfish

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

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POTASSIUM PERMANGANATE (CAIROX®)
(Version 2, March 2008)

ABBREVIATIONS, ACRONYMS, & CONTACT INFORMATION FOR ENTITIES IN TABLE

AOI	All Other Information Technical Section, not included in any of the other sections, that is pertinent to an evaluation of effectiveness or safety [21 CFR § 514.1(b)(8)(iv)]
CARUS	Sponsor of potassium permanganate (Cairox®): John Boll, Carus Chemical Company, 315 Fifth Street, PO Box 599, Peru, IL 61354-0599; Phone: 815-223-1500; Fax: 815-224-6697; E-mail: John.Boll@caruschem.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: 240-276-8343; E-mail: Donald.Prater@fda.hhs.gov
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
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)
SNARC	Harry K. Dupree Stuttgart National Aquaculture Research Center—Dr. David Straus, Agricultural Research Service, PO Box 860, Stuttgart, Arkansas 72160-0860; Phone: 870-673-4483; Fax: 870-673-7710; E-mail: dave.straus@ars.usda.gov
Toxicology	Part of Human Food Safety Technical Section, toxicological testing includes genetic toxicity tests and mammalian safety studies (e.g., acute, sub chronic) (Guidance Document #3)

KEY TO COLOR CODING

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

POTASSIUM PERMANGANATE (CAIROX®)

Potassium permanganate (CAIROX®) NADA approvals (none to date)

POTASSIUM PERMANGANATE (CAIROX®)

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

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Product Chemistry	CARUS (INAD #10-223)—Product Chemistry package—revision submitted 3/02; CVM requested additional information—revision in progress	None
Environmental Safety (earthen pond systems with no outflows)	SNARC (PMF #5694) & Arkansas State University—Environmental Safety/studies/earthen pond systems with no outflows—submitted 11/21/05	None—pending acceptance—outside funds
Environmental Safety (environmental assessment /earthen pond systems with no outflows)	SNARC (PMF #5694)—Environmental Safety/environmental assessment/earthen ponds with no outflows—planned in the future	None—pending acceptance—outside funds
Environmental Safety (studies/continuous-flow systems)	No entity identified—Environmental Safety/studies/continuous-flow systems—needs to be planned & funded	Needs to be planned & funded
Environmental Safety (environmental assessment/continuous-flow systems)	No entity identified—Environmental Safety/environmental assessment/continuous-flow systems—needs to be planned & funded	Needs to be planned & funded
Human Food Safety (mammalian toxicology)	CARUS (INAD #10-223)—Human Food Safety/mammalian toxicology—accepted	None
Human Food Safety (residue chemistry/all fish)	SNARC (PMF #5694)—Human Food Safety/residue chemistry/channel catfish studies—accepted for all fish 7/26/99	None
Human Food Safety (microbiological effects on bacteria of human health concern /channel catfish & hybrid striped bass)	CARUS (INAD #10-223) & SNARC—Human Food Safety/ Guidance Document #152: microbiological effects on bacteria of human health concern/channel catfish & hybrid striped bass—planned in the future	None
Human Food Safety (microbiological effects on bacteria of human health concern /all freshwater-reared finfish except channel catfish & hybrid striped bass)	CARUS (INAD #10-223) & SNARC—Human Food Safety/ Guidance Document #152: microbiological effects on bacteria of human health concern/all freshwater-reared finfish except channel catfish & hybrid striped bass—needs to be planned & funded	None
Human Food Safety (safety of residues in human food / channel	CARUS (INAD #10-223) & SNARC—Human Food safety/ Guidance Document #159: safety of residues in human food /channel catfish & hybrid striped bass—planned	None

catfish & hybrid striped bass)	in the future	
Technical Section	Entity—Data—Action	Impediments or Cost—Action
Human Food Safety (safety of residues in human food /all freshwater-reared finfish except channel catfish & hybrid striped bass)	CARUS (INAD #10-223) & SNARC—Human Food Safety/ Guidance Document #159: safety of residues in human food /all freshwater-reared finfish except channel catfish & hybrid striped bass (Guidance Document 159)—needs to be planned & funded	None
Target Animal Safety (channel catfish & hybrid striped bass)	SNARC (PMF #5694)—Target animal safety/channel catfish & hybrid striped bass—planned in the future	None—pending acceptance
Target Animal Safety (all freshwater-reared finfish except channel catfish & hybrid striped bass)	No entity identified—Target Animal Safety/all freshwater-reared finfish except channel catfish & hybrid striped bass—needs to be planned & funded	Needs to be planned & funded

POTASSIUM PERMANGANATE (CAIROX®)

LABEL CLAIM #1

SPECIES: CHANNEL CATFISH AND HYBRID STRIPED BASS

INDICATIONS: For the control of mortality in channel catfish and hybrid striped bass due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*)

DIRECTIONS FOR USE: Apply CAIROX® at a concentration range of _____ milligram potassium permanganate per liter [mg/L; equivalent to parts per million (ppm)] in earthen ponds with no outflows

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (external columnaris disease/channel catfish & hybrid striped bass)	SNARC (PMF #5694)—Pivotal & supplemental efficacy/external columnaris disease/channel catfish & hybrid striped bass—in progress	None—pending acceptance
Label	CARUS (INAD #10-223) & NADA Coordinator—Label—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
FOI	CVM—FOI—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
AOI	CARUS (INAD #10-223) & NADA Coordinator—AOI—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
NADA Package	CARUS (INAD #10-223) & NADA Coordinator—NADA package—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance

POTASSIUM PERMANGANATE (CAIROX®)

LABEL CLAIM #2

SPECIES: FRESHWATER-REARED FINFISH

INDICATIONS: [For the control of mortality in freshwater-reared finfish due to external columnaris disease associated with *Flavobacterium columnare* \(*Flexibacter columnaris*\)](#)

DIRECTIONS FOR USE: Apply CAIROX® at a concentration range of _____ milligram potassium permanganate per liter [mg/L; equivalent to parts per million (ppm)] in earthen ponds with no outflows or continuous flow-through finfish culture units at a concentration range of _____ for _____.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (external columnaris disease/channel catfish & hybrid striped bass)	SNARC (PMF #5694)—Pivotal & supplemental efficacy/external columnaris disease/channel catfish & hybrid striped bass—in progress	None—pending acceptance
Efficacy (external columnaris disease/freshwater-reared finfish except channel catfish & hybrid striped bass)	No entity identified—Pivotal & supplemental efficacy/external columnaris disease/freshwater-reared finfish except channel catfish & hybrid striped bass—needs to be planned & funded	Needs to be planned & funded
Label	CARUS (INAD #10-223) & NADA Coordinator—Label—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
FOI	CVM—FOI—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
AOI	CARUS (INAD #10-223) & NADA Coordinator—AOI—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
NADA Package	CARUS (INAD #10-223) & NADA Coordinator—NADA package—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance

POTASSIUM PERMANGANATE (CAIROX®)

LABEL CLAIM #3

SPECIES: 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 CAIROX® at a concentration range of _____ milligram potassium permanganate per liter [mg/L; equivalent to parts per million (ppm)] in continuous flow-through finfish culture units at a concentration range of _____ for _____.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (bacterial gill disease/all freshwater-reared finfish)	No entity identified—Pivotal & supplemental efficacy/bacterial gill disease/all freshwater-reared finfish—needs to be planned & funded	Needs to be planned & funded
Label	CARUS (INAD #10-223) & NADA Coordinator—Label—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
FOI	CVM—FOI—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
AOI	CARUS (INAD #10-223) & NADA Coordinator—AOI—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
NADA Package	CARUS (INAD #10-223) & NADA Coordinator—NADA package—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance

POTASSIUM PERMANGANATE (CAIROX®)

LABEL CLAIM #4

SPECIES: FRESHWATER-REARED SALMONIDS

INDICATIONS: For the control of mortality in freshwater-reared salmonids due to coldwater disease associated with *Flavobacterium psychrophilum*

DIRECTIONS FOR USE: Apply CAIROX® at a concentration range of _____ milligram potassium permanganate per liter [mg/L; equivalent to parts per million (ppm)] in continuous flow-through finfish culture units at a concentration range of _____ for _____.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (coldwater disease/all freshwater-reared salmonids)	No entity identified—Pivotal & supplemental efficacy/coldwater disease/all freshwater-reared salmonids—needs to be planned & funded	Needs to be planned & funded
Label	CARUS (INAD #10-223) & NADA Coordinator—Label—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
FOI	CVM—FOI—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
AOI	CARUS (INAD #10-223) & NADA Coordinator—AOI—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
NADA Package	CARUS (INAD #10-223) & NADA Coordinator—NADA package—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance

POTASSIUM PERMANGANATE (CAIROX®)

LABEL CLAIM #5

SPECIES: FRESHWATER-REARED FINFISH

INDICATIONS: [For the control of external protozoa on freshwater-reared finfish](#)

DIRECTIONS FOR USE: Apply CAIROX® at a concentration range of _____ milligram potassium permanganate per liter [mg/L; equivalent to parts per million (ppm)] in earthen ponds with no outflows or continuous flow-through finfish culture units at a concentration range of _____ for _____.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (external protozoa/freshwater-reared finfish)	No entity identified—Efficacy/external protozoa/freshwater-reared finfish—needs to be planned & funded	Needs to be planned & funded
Label	CARUS (INAD #10-223) & NADA Coordinator—Label—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
FOI	CVM—FOI—to be planned when product chemistry package, environmental assessment, human food safety documents, target animal safety studies,, & efficacy studies are accepted environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
AOI	CARUS (INAD #10-223) & NADA Coordinator—AOI—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance
NADA Package	CARUS (INAD #10-223) & NADA Coordinator—NADA package—to be planned when product chemistry package, environmental assessment, 2 human food safety documents, target animal safety studies, & efficacy studies are accepted	None—pending acceptance