

Chloramine-T Clinical Field Trials - INAD 9321

Year 2009 Annual Summary Report on the Use of Chloramine-T in Clinical Field Efficacy Trials

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Summary

Chloramine-T has been used effectively in the U. S. under compassionate INAD Exemption #9321 to control mortality in a variety of fish caused by common fish bacterial pathogens. In calendar year 2009 (CY09), the efficacy of chloramine-T (CLT) was evaluated in 220 disease trials involving approximately 28.3 million fish to control mortality in a variety of fish species caused by a variety of infectious fish pathogens. Trials were conducted at 52 fish culture facilities, including nine U.S. Fish and Wildlife Service National Fish Hatcheries (NFH), 36 state fish hatcheries, five private fish hatcheries, and two tribal hatcheries. The compassionate study protocol under which treatments were administered allowed the investigator to use chloramine-T on either three consecutive or alternate days for 1h at dosages ranging from 10 - 20 mg/L; or one day a week for 1 h at 15mg/L. Overall, results of trials conducted in CY09 indicated that treatments appeared efficacious in approximately 75% of the trials, ineffective in 6% of the trials, and were characterized as inconclusive in 5% of the trials. In the remaining 14% of the trials, the Investigators were not required to report efficacy data because the

effectiveness technical section for the specific claim has been completed and accepted by CVM.

Introduction

Bacterial gill disease (BGD) is one of the most common diseases of hatchery reared salmonids (Bullock 1990) and causes more fish losses than any other bacterial disease (Bills et al. 1988). Fish mortality is generally not a direct result of the infection, but is a consequence of the infection. Mortality is most likely the result of asphyxiation from lack of adequate oxygen exchange in severely congested gills. Stressors associated with intense fish culture may predispose fish to infection. Although *Flavobacterium branchiophilum* is the bacteria responsible for causing most outbreaks of BGD (Wakabayashi, et al., 1989; Ferguson et al., 1991), other gram-negative bacteria have also been implicated. These "other" bacteria include *F. aquatile*, *F. psychrophilus*, *F. columnaris*, as well as other flavobacters and aeromonads and pseudomonads. Clinical signs of BGD have been well documented, and it is widely known that this disease can cause the rapid proliferation of gill epithelium and the production of excess mucus as the host responds defensively to the infection. This response can "smother" gills and cause severe losses if prompt measures are not taken. If BGD, which is horizontally transmitted, is not diagnosed and treated early, an epizootic may occur within a 24-h period (Bullock et al. 1990).

Historically, several chemicals including benzalkonium chloride (available as Hyamine 1622 and 3500), diquat, and chloramine-T have been used to control mortality

caused by BGD (Bullock et al. 1990). However, none of these chemicals have been approved by the FDA to control mortality in freshwater fish caused by BGD. Because chloramine-T appears to be the most effective therapeutant when salmonids have BGD (From 1980; Bullock et al. 1990; Bowker et al, in press) it has become the prime candidate for approval with the U.S. Food and Drug Administration (FDA) as a bath treatment. Chl-T has been characterized as a non-selective sanitizing agent and has been shown to clean up gills infested with bacteria and coated with excess mucus.

Purpose of Report

The purpose of this report is to summarize the results of CY09 supplemental chloramine-T field efficacy data. Similar data have been submitted by the Service in previous years. We anticipate that CY09 data will be used to enhance the existing chloramine-T database established from previous years, and will be considered in the “body of evidence” for the purpose of developing an appropriate label claim for the use of chloramine-T in aquaculture.

Facilities, Materials, Treatment Procedures

1. Facilities

A total of 220 field efficacy trials were conducted at 52 fish culture facilities, including nine U.S. Fish and Wildlife Service NFH's, 36 state fish hatcheries, five private fish hatcheries, and two tribal hatcheries. Treatments were used to control/prevent mortality in a variety of fish species caused by various fish

pathogens. Water temperature during treatments at the various testing facilities ranged from 36.1 - 80.0 °F, with a mean treatment temperature of 55.3°F.

2. Chemical material

Chloramine-T (CAS No. 127-65-1) is a pure white crystal powder. All facilities used designated lots of chloramine-T provided by one of the following two manufactures: (1) Axcentive SARL/International Specialty Chemicals, Inc., Tarrytown, NY; or (2) B.L. Mitchell, Inc., Greenville, MS.

3. Treatment Methods

Chloramine-T treatments were administered using either a flow-through or standing bath treatment method. Both procedures called for accurately weighed amounts of dry chemical dissolved in an appropriate amount of non-chlorinated water. When using a flow-through system, dissolved chemical was metered into rearing units at a rate to achieve the desired treatment concentration during a 1 h period. When using a standing bath method, water flow to the rearing unit was turned off and dissolved chemical added to the rearing unit and mixed thoroughly to ensure uniform chloramine-T concentration throughout the tank. Thorough mixing was essential to ensure there were no chloramine-T "hot spots." After the 1 h treatment, water flow was turned on again to flush the chemical out of the rearing unit.

4. Drug dosages

During CY09, various chloramine-T doses were used. Listed below are the doses and the number of trials conducted with each dose:

1.	10 mg/L	39 trials
2.	12 mg/L	15 trials
3.	12;15;20 mg/L	1 trial
4.	15 mg/L	79 trials
5.	15 & 20 mg/L	6 trials
6.	20 mg/L	80 trials
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	Total	220 trials

5. Number of treatments per disease outbreak

According to the Study Protocol, Investigators were allowed to administer chloramine-T on three consecutive/alternate days when used to control mortality caused by BGD or once/week when used to prevent mortality. During CY09, the most common treatment regimen was to administered CLT on three consecutive days to control mortality in fish caused by BGD.

Study Protocol Deviation: Treatment regimen administered in 2 trials (approximately 1% of trials) deviated from the protocol. In these trials, fish were treated with CLT at 10 mg/L for 8 - 15 days. Fingerling muskellunge were treated

multiple times within a one month period. This facility has a history of BGD issues during the culture of northern muskellunge and CLT treatments have been beneficial in previous years.

Fish Species Treated and Fish Diseases Involved in CY09 Trials

1. Species and size of fish treated

Twenty-nine fish species, including 16 species of salmonids and 13 non-salmonids fish species, were treated during CY09. Treated fish ranged in length from 0.5 - 38.0 in. and the average length of all treated fish was 5.20 in. Species treated included:

Salmonids: (1) Atlantic salmon *Salmo salar*; (2) brown trout *S. trutta*; (3) arctic grayling *Thymallus arcticus*; (4) apache trout *Oncorhynchus apache*; (5) chinook salmon *O. tshawytscha*; (6) chum salmon *O. keta*; (7) coho salmon *O. kisutch*; (8) sockeye salmon *O. nerka*; (9) cutthroat trout *O. clarki*; (10) rainbow trout *O. mykiss*; (11) steelhead trout *O. mykiss*; (12) golden trout *O. aguabonita*; (13) lake herring *Coregonus artedii*; (14) brook trout *Salvelinus fontinalis*; (15) lake trout *Salvelinus namaycush*; and (16) splake *Salvelinus fontinalis* x *S. namaycush*.

Non-salmonids: (1) black crappie *Pomoxis nigromaculatus*; (2) blue catfish *Ictalurus furcatus*; (3) channel catfish *I. punctatus*; (4) fathead minnow *Pimephales promelas*; (5) golden shiner *Notemingonus crysoleucas*; (6) hybrid striped bass *Morone saxatilis x M. chrysops*; (7) lake sturgeon *Acipenser fulvescens*; (8) largemouth bass *Micropterus salmoides*; (9) smallmouth bass *M. dolomieu*; (10) muskellunge *Esox masquinongy*; (11) tiger Muskellunge *E. lucius x E. masquinongy*; (12) sauger *Stizostedion canadense*; and (13) walleye *Sander vitreus*.

2. Diseases treated

The disease treated most frequently was characterized as BGD (81% of the trials). Other diagnosed diseases included external columnaris, external bacterial coldwater disease, and external flavobacteriosis.

Data Collected

1. Pathologist's report

In CY09 a pathologist's report was submitted for 33% of the studies. Pathology reports are important for accurate interpretation of study results because they typically contain the following information:

1. A description of how the identity of disease agent(s) was verified,

2. Disease identification records that confirm the presence of the disease agent,
3. The name and title of the individual performing the diagnosis.

Additionally, evidence would typically be provided to document that there were no secondary infections or infestations caused by unrelated disease agents in the population of test fish.

2. Treatment response and drug accountability data

Drug receipt reports, drug use reports, diagnosis, treatment, and mortality reports (including adverse effects/toxicity observations), and fish disposition reports were prepared by study Investigators. Such reports were routed through the Study Monitor for review, and then sent to the AADAP Office for review, data analysis and report writing, entering data into a database, and archiving in permanent files.

Based on correspondence with FDA, the following efficacy and safety technical sections have been completed:

1. Effectiveness of chloramine-T at a concentration of 12 ppm administered as a 60 min bath once per day every other day for a total of three treatments to control mortality associated with bacterial gill disease in

freshwater-reared salmonids (we refer to your file number INAD 4000 H-0071 dated July 11, 2000).

2. Safety of chloramine-T at a concentration of 20 ppm administered as a 60 min bath on three consecutive or alternate days for the control of mortality associated with bacterial gill disease in freshwater-reared salmonids (we refer to your file number INAD 4000 P-0093 dated September 13, 2002).

As a result of the completed technical sections, mortality data are no longer required when Investigators administer chloramine-T at a dosage of 12 - 20 ppm on three alternate or consecutive days for 60 min to control mortality associated with bacterial gill disease in freshwater-reared salmonids. In all other cases, collection of mortality data is still required and efforts were made to collect all such data. However, for a variety of reasons, mortality data were not always collected for the entire required data collection period. Reasons for incomplete mortality data included: splitting fish into additional rearing units and stocking early life stage fish shortly after final treatment.

Discussion of Study Results

1. Relevance of study to a proposed label claim for chloramine-T

Results of CY09 trials conducted under Compassionate INAD exemption #9321 are similar to results detailed in reports previously submitted to FDA under INAD's #9321 and #4000.

2. General observations on the efficacy of CLT for the control of bacterial diseases in salmonid and non-salmonid fish (Note: Table 1 provides a list of all trials in which treatment appeared efficacious; Table 2 provides a list of all trials in which treatment appeared ineffective; Table 3 provides a list of all inconclusive trials; Table 4 provides a list of all trials where efficacy data was not required; Table 5 provides summary data for all trials; and Table 6 provides a brief description of all trials conducted during CY09 under INAD #9321).

A. Efficacy at 10 mg/L chloramine-T

Brown trout, cutthroat trout, chinook salmon, lake herring, rainbow trout, steelhead trout, and muskellunge were treated with 10 mg/L chloramine-T for 1 - 15 days in 39 trials (Tables 1 - 3). Investigators used CLT to control mortality caused by BGD, external bacterial coldwater disease, or external flavobacteriosis. CLT treatments appeared effective in 27 trials, ineffective in seven trials, and were characterized as inconclusive in five trials.

B. Efficacy at 12 mg/L chloramine-T

Rainbow trout were treated with 12 mg/L chloramine-T for 1 - 2 days in 15 trials (Tables 1 & 3). Investigators used CLT to control mortality caused by BGD. CLT treatments appeared effective in 14 trials and were characterized as inconclusive in one trial.

C. Efficacy at 12;15;20 mg/L chloramine-T

One trial was conducted using 12;15;20 mg/L chloramine-T for 4 - 5 days (Table 2) to control mortality in walleye associated with BGD. This trial was not efficacious.

D. Efficacy at 15 mg/L chloramine-T

Apache trout, arctic grayling, brook trout, brown trout, chinook salmon, chum salmon, coho salmon, cutthroat trout, golden trout, rainbow trout, sockeye salmon, steelhead trout, lake sturgeon, largemouth bass, smallmouth bass, splake, and walleye were treated with 15 mg/L chloramine-T for 1 - 17 days in 79 trials (Tables 1, 2, & 4). Investigators used CLT to control mortality caused by BGD, external flavobacteriosis, or external columnaris. CLT treatments appeared effective in 75 trials, ineffective in one trial, and were not report in three trials (due to the efficacy packet being complete).

E. Efficacy at 15 & 20 mg/L chloramine-T

Six trials were conducted using 15 & 20 mg/L chloramine-T for 3 - 14 days (Tables 1 - 3). Investigators used CLT to control mortality caused by external columnaris or BGD in blue catfish, channel catfish, lake trout, tiger musky, and walleye. CLT treatments were appeared effective in four trials, not effective in one trial, and was characterized as inconclusive in one trial.

F. Efficacy at 20 mg/L chloramine-T

Atlantic salmon, brook trout, cutthroat trout, lake trout, rainbow trout, steelhead trout, blue catfish, channel catfish, fathead minnow, golden shiner, largemouth bass, sauger, hybrid striped bass, smallmouth bass, and walleye were treated with 20 mg/L chloramine-T for 1 - 9 days in 80 trials (Tables 1 - 4). Investigators used CLT to control mortality caused by BGD, external flavobacteriosis, external columnaris, or external coldwater disease. CLT treatments appeared effective in 45 trials, not report in 27 trials (due to the efficacy packet being complete), ineffective in three trials, and were characterized as inconclusive in five trials.

3. Observed Toxicity

No toxicity or adverse effects relating to CLT treatment were reported in any of the trials.

4. Observed Withdrawal Period

No withdrawal time is needed for fish treated with CLT under the current Food-Use Authorization dated December 22, 2009.

Current Study Protocol for CLT INAD #9321

Please see the attached current study protocol for CLT INAD #9321 . Please note no changes have occurred to this study protocol.

Facility Sign-up List

Please see “Table 7. Facilities and Names of Investigators” for facilities that signed-up to participate in the CLT INAD #9321 during CY09. Facilities not listed in Appendix III-a of the current CLT INAD #9321 during CY09 study protocol have been highlighted.

Please note all of these facilities are in compliance with their reporting requirements to the NPDES authority. It should also be noted that 214 trials were either 1) in compliance with their reporting requirements to their NPDES authority for a CLT discharge higher than 0.1 ppm; or 2) met the discharge level set by CVM. In the remaining six trials the CLT discharge ranged between 0.22 - 2.39 ppm. The investigators were contacted in each of these trials and reminded of the discharge limit set by CVM. These facilities will ensure that the discharge limit is met prior to any future CLT trials.

The following facilities had chloramine-T on-hand during CY09 but never used the drug:

- | | |
|-----------------------|----------------------------|
| 1. Creston NFH | 2. Crystal Lake Hatchery |
| 3. Darrah Springs SFH | 4. Durango SFH |
| 5. Ed Weed FCS | 6. Fort Peck SFH |
| 7. Garrison Dam NFH | 8. Grover's Creek Hatchery |
| 9. Hackettstown SFH | 10. Livingston Stone NFH |
| 11. Mt. Shavano SFH | 12. Manchester SFH |
| 13. Marquette SFH | 14. Nampa SFH |
| 15. Platte River SFH | 16. Salisbury FCS |
| 17. Thompson SFH | 18. Whitman Lake Hatchery |

Correspondence sent to CLT INAD #9321 Participants

Please see the attached correspondence that was sent to all chloramine-T participants after the AADAP Office received their sign-up form for calendar year 2009.

Number of Treated Fish under Treatment Use Authorization

Total number of fish treated during CY09 was 28,367,300. The total number of treated fish to count against the treatment use authorization dated December 5, 2007 (valid through December 21, 2009) is 64,182,504. The total number of

treated fish to count against the current treatment use authorization dated is 153,326.

Summary of Study Results

Chloramine-T was used at doses ranging from 10 - 20 mg/L in 220 treatment trials in which fish were treated one, two, or three times to control mortality, or once per week when used to prevent mortality. Twenty-nine different fish species were treated and trials involved approximately 28.3 million fish. Treated fish ranged in size from 0.5 - 38.0 in. Water temperature during treatment ranged from 36.1 - 80.0°F, with a mean treatment temperature of 55.3°F. Overall, results showed that treatment appeared effective in approximately 75% of trials, ineffective in 6% of the trials, and characterized as inconclusive 5% of the trials. In the remaining 14% of the trials, mortality data collection and reporting were not required. There was no evidence of toxicity or adverse effects related to CLT treatment reported in any of the trials. Data from the CY09 trials support the results of previous Annual Report submissions under INAD #9321 and INAD #4000 that indicate that the chloramine-T treatment regimen recommended in INAD Protocol #9321 is safe and effective to control/prevent mortality in a variety of fish species caused by external bacterial infections such as BGD. As a result of the lack of quality criteria, such as dose verification, use of controls, replicates, and randomization, it is understood that these data will be considered as ancillary data, and that pivotal efficacy studies are needed to definitively demonstrate chloramine-T efficacy for the treatment of BGD. However, the ancillary data described above should provide useful, corroborative data to help support a label claim for the use of

chloramine-T to control mortality associated with BGD in a variety of fish species.

Although it is anticipated that the majority of future efficacy data collected under INAD #9321 will also be ancillary data, efforts will be directed towards the continued generation of high quality data.

References

- Bills, T.D., L.L. Marking, V.K. Dawson, and J.J. Rach. 1988. Effects of environmental factors on the toxicity of chloramine-T to fish. U.S. Fish and Wildlife Service, Investigations in Fish Control 96, Upper Mississippi Science Center, P.O. Box 818, LaCrosse, Wisconsin.
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- Bullock, G.L. 1990, Bacterial gill disease of freshwater fishes, Fish Disease Leaflet 84, U.S. Dept. of the Interior, Fish and Wildlife Service, Washington DC.
- Ferguson, H.W., V.E. Ostland, P. Byrne, and J.S. Lumsden. 1991. Experimental production of bacterial gill disease in trout by horizontal transmission and bath challenge. *Journal of Aquatic Animal Health* 3:118-123.
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Table 1. Year 2009 Chloramine-T Efficacy Results - Efficacious Studies

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Ten Sleep SFH	CUT	19.00	6,000	BGD	10	3	zero	52.0
Wigwam FRS	CUT	3.90	47,000	BGD	10	3	no withdrawal time	49.0
Wigwam FRS	CUT	14.00	4,310	BGD	10	3	0 days	49.0
Lyons Ferry SFH	FCS	3.20	312,000	BGD	10	3	not reported	53.0
Lyons Ferry SFH	FCS	3.20	519,000	BGD	10	3	not reported	53.0
Lyons Ferry SFH	FCS	3.20	190,000	BGD	10	3	not reported	53.0
Wolf Lake SFH	LAH	2.30	39,683	External Flavobacteriosis	10	3	65 days	52.2
Wolf Lake SFH	MUE	2.00	482,664	BGD	10	15	60 days	71.0
Wolf Lake SFH	MUE	2.00	606	BGD	10	3	60 days	71.0
Wolf Lake SFH	MUE	2.00	59,006	BGD	10	8 - 10	75 days	70.1
Decorah SFH	RBT	5.03	27,742	BGD	10	3	365 days	52.0
Decorah SFH	RBT	4.73	25,000	BGD	10	3	365 days	54.0
Decorah SFH	RBT	4.14	9,983	BGD	10	3	180 days	48.0
Decorah SFH	RBT	7.59	9,950	BGD	10	3	265 days	48.0
Dubois SFH	RBT	1.54	62,000	BGD	10	3	60 days	64.0
Dubois SFH	RBT	1.52	36,000	BGD	10	3	90 days	59.0
Dubois SFH	RBT	5.70	3,500	BGD	10	3	730 days	51.0
Hotchkiss NFH	RBT	1.60	69,926	BGD	10	1	43 days	56.0
Hotchkiss NFH	RBT	7.20	17,036	BGD	10	1	84 days	56.0

Table 1. Year 2009 Chloramine-T Efficacy Results - Efficacious Studies - cont.

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Hotchkiss NFH	RBT	3.00	28,378	BGD	10	1	212 days	56.0
Hotchkiss NFH	RBT	4.34	104,019	BGD	10	1	159 days	56.0
Hotchkiss NFH	RBT	4.50	394,455	BGD	10	1	125 days	56.0
Hotchkiss NFH	RBT	3.57	190,885	BGD	10	1	178 days	56.0
Hotchkiss NFH	RBT	1.60	64,502	BGD	10	1	43 days	56.0
Hotchkiss NFH	RBT	4.40	345,592	BGD	10	1 - 2	144 days	56.0
Hotchkiss NFH	RBT	4.20	239,456	BGD	10	1 - 2	166 days	56.0
Mason Valley SFH	RBT	2.10	53,499	BGD	10	3	11 months	58.0
Rifle Falls SFH	RBT	7.50	30,827	BGD	12	1	not reported	59.0
Rifle Falls SFH	RBT	9.00	54,000	BGD	12	1	>10 days	59.0
Rifle Falls SFH	RBT	7.64	36,000	BGD	12	1	>30 days	59.0
Rifle Falls SFH	RBT	6.80	18,000	BGD	12	1	>30 days	59.0
Rifle Falls SFH	RBT	7.00	54,000	BGD	12	1	>30 days	59.0
Rifle Falls SFH	RBT	7.17	36,000	BGD	12	1	not reported	59.0
Rifle Falls SFH	RBT	6.50	90,000	BGD	12	1	>30 days	59.0
Rifle Falls SFH	RBT	5.80	120,000	BGD	12	1	not reported	59.0
Rifle Falls SFH	RBT	4.30	119,400	BGD	12	1	not reported	59.0
Rifle Falls SFH	RBT	7.00	60,000	BGD	12	1	21 days	59.0
Rifle Falls SFH	RBT	8.50	90,000	BGD	12	1	not reported	59.0
Rifle Falls SFH	RBT	6.40	18,000	BGD	12	1	>30 days	59.0

Table 1. Year 2009 Chloramine-T Efficacy Results - Efficacious Studies - cont.

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Rifle Falls SFH	RBT	6.10	54,000	BGD	12	1	>30 days	59.0
Rifle Falls SFH	RBT	5.00	110,300	BGD	12	1	not reported	59.0
Alchesay-Williams Creek NFH Complex	APT	2.59	8,360	BGD	15	3	309 days	52.0
Alchesay-Williams Creek NFH Complex	APT	1.35	65,016	BGD	15	3	385 days	52.0
Alchesay-Williams Creek NFH Complex	APT	0.92	162,506	BGD	15	3	395 days	52.0
Dubois SFH	ARG	0.83	50,000	BGD	15	3	260 days	55.0
Dubois SFH	BKT	1.94	48,561	BGD	15	3	30 days	59.0
Jordan River NFH	BKT	1.40	5,956	BGD	15	8	>120 days	46.4
Paint Bank FCS	BKT	8.00	30,000	BGD	15	3	not reported	52.0
Wytheville FCS	BNT	1.00	35,000	BGD	15	3	180 days	56.0
Keta Creek Hatchery	CHS	1.00	3,868,450	BGD	15	10 - 17	1 yr	48.0
Solomon Gulch Hatchery	COS	1.50	987,898	BGD	15	1	not reported	44.0
Solomon Gulch Hatchery	COS	1.50	979,784	BGD	15	1	not reported	44.0
Eastbank SFH	CSA	38.00	1,427	External Flavobacteriosis	15	8 - 15	all fish were euthanized	54.7
Fort Richardson SFH/Ship Creek Processing Facility	CSA	1.50	524,949	External Flavobacteriosis	15	1	1 yr	36.1
Mixsawbah SFH	CSA	2.85	72,927	BGD	15	3	350 days	48.0

Table 1. Year 2009 Chloramine-T Efficacy Results - Efficacious Studies - cont.

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Mixsawbah SFH	CSA	3.21	72,927	BGD	15	3	335 days	48.0
Dubois SFH	CUT	0.92	34,000	BGD	15	3	45 days	54.0
Dubois SFH	CUT	1.17	94,800	BGD	15	3	265	52.0
Dubois SFH	CUT	1.06	2,500	BGD	15	3	300 days	51.0
Ten Sleep SFH	CUT	18.60	3,623	BGD	15	3	10 days	52.0
Ten Sleep SFH	CUT	16.00	4,039	BGD	15	3	zero	52.0
Wigwam FRS	CUT	5.10	5,200	BGD	15	3	zero	49.0
Wigwam FRS	CUT	11.70	3,918	BGD	15	3	zero	49.0
Story SFH	GOT	8.50	600	BGD	15	3	2 yrs	53.0
Story SFH	GOT	0.85	1,900	BGD	15	3	4 yrs	52.5
Story SFH	GOT	8.50	750	BGD	15	3	2 yrs	52.1
Genoa NFH	LMB	6.00	1,000	External Columnaris	15	10	>365 days	60.0
Genoa NFH	LST	1.00	81,206	External Columnaris	15	17	>365 days	66.4
Albert Powell Trout SFH	RBT	6.40	16,000	BGD	15	3	180 days	54.0
Albert Powell Trout SFH	RBT	5.90	16,000	BGD	15	3	180 days	54.0
Albert Powell Trout SFH	RBT	6.60	32,000	BGD	15	3	180 days	54.0
Albert Powell Trout SFH	RBT	4.60	32,000	BGD	15	3	180 days	54.0
Albert Powell Trout SFH	RBT	4.20	48,000	BGD	15	3	not reported	54.0
Albert Powell Trout SFH	RBT	3.00	150,000	BGD	15	3	not reported	54.0
Albert Powell Trout SFH	RBT	7.00	16,000	BGD	15	3	180 days	54.0

Table 1. Year 2009 Chloramine-T Efficacy Results - Efficacious Studies - cont.

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Boulder FRS	RBT	4.50	79,000	BGD	15	3	98 days	52.0
Boulder FRS	RBT	18.10	1,650	BGD	15	3	102 days	52.0
Boulder FRS	RBT	5.18	5,000	BGD	15	3	98 days	52.0
Boulder FRS	RBT	18.10	1,650	BGD	15	3	98 days	52.0
Dubois SFH	RBT	2.66	25,998	BGD	15	3	55 days	59.0
Dubois SFH	RBT	1.13	75,900	BGD	15	3	120 days	55.0
Dubois SFH	RBT	5.06	10,000	BGD	15	3	60 days	59.0
Dubois SFH	RBT	2.66	11,250	BGD	15	3	55 days	59.0
Dubois SFH	RBT	3.96	43,800	BGD	15	3	120 days	59.0
Dubois SFH	RBT	2.00	27,107	BGD	15	3	122 days	58.0
Dubois SFH	RBT	7.40	1,690	BGD	15	3	10 days	59.0
Ford SFH	RBT	1.50	40,000	BGD	15	3	not reported	49.0
Paint Bank FRC	RBT	9.00	7,500	BGD	15	3	not reported	52.0
Pequest SFH	RBT	6.00	25,000	BGD	15	1	9 months	53.0
Willow Beach NFH	RBT	1.14	70,708	BGD	15	3	300 days	57.8
Willow Beach NFH	RBT	1.00	62,000	BGD	15	3	300 days	60.0
Willow Beach NFH	RBT	2.00	40,000	BGD	15	3	300 days	57.0
Willow Beach NFH	RBT	2.00	104,000	BGD	15	3	240 days	57.0
Willow Beach NFH	RBT	1.70	39,689	BGD	15	3	270 days	60.0
Wolf Lake SFH	RBT	5.08	169,608	BGD	15	3	90 days	52.0

Table 1. Year 2009 Chloramine-T Efficacy Results - Efficacious Studies - cont.

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Wolf Lake SFH	RBT	5.55	61,168	BGD	15	3	70 days	52.0
Wolf Lake SFH	RBT	6.05	112,706	BGD	15	3	60 days	52.0
Wytheville FCS	RBT	7.00	8,000	BGD	15	3	120 days	56.0
Wytheville FCS	RBT	5.00	35,000	BGD	15	3	180 days	56.0
Genoa NFH	SMB	6.00	1,000	External Columnaris	15	10	>365 days	60.0
Eastbank SFH	SOS	24.00	260	External Flavobacteriosis	15	4 weekly treatments	all fish buried	54.7
Hoko Falls Hatchery - Umbrella Creek Hatchery	SOS	0.50	260,000	BGD	15	1 - 7	>2yrs	41.0
Trail Lakes/Eklutna Hatchery	SOS	1.00	210,000	External Flavobacteriosis	15	3	>10 days	40.7
Trail Lakes/Eklutna Hatchery	SOS	1.00	723,000	External Flavobacteriosis	15	3	>10 days	40.7
Trail Lakes/Eklutna Hatchery	SOS	1.00	984,000	External Flavobacteriosis	15	3	>10 days	40.7
Dubois SFH	SPL	1.99	28,000	BGD	15	3	65 days	59.0
Dubois SFH	SPL	2.46	27,000	BGD	15	3	120 days	55.0
Bodine SFH	STT	1.34	55,066	BGD	15	3	1 yr	55.0
Bodine SFH	STT	2.82	166,000	BGD	15	3	1 yr	54.0
Bodine SFH	STT	2.95	143,800	BGD	15	3	1 yr	54.0
Mixsawbah SFH	STT	3.56	76,849	BGD	15	3	485 days	51.0
Mixsawbah SFH	STT	2.67	129,400	BGD	15	3	485 days	51.0

Table 1. Year 2009 Chloramine-T Efficacy Results - Efficacious Studies - cont.

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Mixsawbah SFH	STT	2.38	238,500	BGD	15	3	450 days	50.0
Mixsawbah SFH	STT	1.97	14,543	BGD	15	3	365 days	50.0
Mixsawbah SFH	STT	3.32	125,000	BGD	15	3	455 days	51.0
Rathbun SFH/Research Facility	WAE	2.50	209,923	BGD	15	3	90 days	74.0
Genoa NFH	BCF	5.00	900	External Columnaris	15 & 20	13	>365 days	60.0
Genoa NFH	CCF	5.00	0	External Columnaris	15 & 20	13	>365 days	60.0
Jordan River NFH	LAT	1.40	3,559,315	BGD	15 & 20	3 - 6	83 days	46.4
Genoa NFH	WAE	7.00	2,500	External Columnaris	15 & 20	10	>365 days	60.0
Bald Hill FCS	ATS	4.50	40,000	External Columnaris	20	3	250 days	70.0
Bald Hill FCS	ATS	5.00	39,000	External Columnaris	20	9	210 days	70.0
Genoa NFH	BLC	3.00	2,000	External Columnaris	20	3	>365 days	53.0
Rathbun SFH/Research Facility	CCF	3.70	73,181	BGD	20	2	180 days	46.0
Dubois SFH	CUT	0.92	25,575	BGD	20	3	240 days	51.0
Dubois SFH	CUT	1.14	9,962	BGD	20	3	242 days	49.0
Leadville NFH	CUT	5.27	43,465	External CWD	20	3	270 days	45.0
Leadville NFH	CUT	5.52	25,000	External CWD	20	3	240 days	42.0
Leadville NFH	CUT	6.00	30,417	External CWD	20	3	210 days	40.0
Genoa NFH	FHM	1.00	55,000	External Columnaris	20	3	>365 days	53.0
Genoa NFH	GOS	2.00	100	External Columnaris	20	3	30 days	60.0

Table 1. Year 2009 Chloramine-T Efficacy Results - Efficacious Studies - cont.

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Bath SFH	LAT	8.25	47,000	BGD	20	1	>2 months	47.0
Bath SFH	LAT	8.25	47,000	BGD	20	1	>2 months	47.0
Bath SFH	LAT	8.25	47,000	BGD	20	3	>2 months	47.0
Genoa NFH	LMB	5.00	2,500	External Columnaris	20	3	>365 days	53.0
Texas Freshwater Fisheries Center	LMB	25.00	1	External Columnaris	20	3	63 days	68.8
Alsea Hatchery	RBT	3.50	261,308	BGD	20	1	5 months	55.0
Alsea Hatchery	RBT	4.00	254,148	BGD	20	1	5 months	61.5
Bellvue-Watson SFH	RBT	3.00	25,000	BGD	20	2	100 days	60.0
Bellvue-Watson SFH	RBT	2.40	78,000	BGD	20	3	270 days	52.0
Bennington FCS	RBT	10.20	3,000	BGD	20	3	not reported	57.0
Boulder FRS	RBT	5.00	45,000	BGD	20	3	195 days	52.0
Boulder FRS	RBT	12.00	3,280	BGD	20	3	91 days	52.0
Chalk Cliffs SFH	RBT	8.00	20,000	BGD	20	2	60 days	60.0
Chalk Cliffs SFH	RBT	9.20	21,000	BGD	20	3	120 days	57.0
Chalk Cliffs SFH	RBT	6.30	39,000	BGD	20	3	40 days	57.0
Dubois SFH	RBT	2.38	20,030	BGD	20	3	107 days	60.0
Dubois SFH	RBT	4.70	29,000	BGD	20	3	120 days	62.0
Dubois SFH	RBT	1.18	99,890	BGD	20	3	120 days	55.0
Jones Hole NFH	RBT	3.68	435,000	External CWD	20	3	1 yr	54.0
Leadville NFH	RBT	5.00	38,000	External CWD	20	3	1 yr	42.0

Table 1. Year 2009 Chloramine-T Efficacy Results - Efficacious Studies - cont.

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Marion FCS	RBT	4.11	155,000	BGD	20	3	zero	56.0
Marion FCS	RBT	1.40	397,000	BGD	20	3	>21 days	52.0
Monte Vista SFH	RBT	1.50	120,000	BGD	20	3	45 days	57.0
Monte Vista SFH	RBT	2.50	5,300	BGD	20	3	7 months	57.0
Monte Vista SFH	RBT	2.50	10,600	BGD	20	3	7 months	57.0
Monte Vista SFH	RBT	1.50	72,000	BGD	20	3	45 days	57.0
Monte Vista SFH	RBT	1.50	24,000	BGD	20	3	45 days	57.0
Monte Vista SFH	RBT	2.30	45,000	External Flavobacteriosis	20	3	7 months	68.0
Genoa NFH	SAR	6.00	1,000	External Columnaris	20	3	>365 days	53.0
Genoa NFH	SMB	5.00	2,000	External Columnaris	20	3	>365 days	53.0
Alsea SFH	STT	4.00	85,692	BGD	20	1	5 months	59.5
Alsea SFH	STT	4.00	68,937	BGD	20	1	5 months	59.5
Alsea SFH	STT	4.00	154,629	BGD	20	1	5 months	55.0
Bald Hill FCS	STT	5.50	5,500	External Columnaris	20	3	250 days	70.0

Table 2. Year 2009 Chloramine-T Efficacy Results - Ineffective Studies

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Harrietta SFH	BNT	2.36	498,841	External CWD	10	3	270 days	46.20
Oden SFH	BNT	27.20	469	External Flavobacteriosis	10	3	fish were euthanized	46.00
Oden SFH	BNT	2.55	10,820	External Flavobacteriosis	10	3	>14 days	46.00
Albert Powell Trout SFH	RBT	2.50	100,000	BGD	10	3	180 days	54.00
Albert Powell Trout SFH	RBT	2.50	50,000	BGD	10	3	180 days	54.00
Hotchkiss NFH	RBT	3.20	30,237	BGD	10	1	207 days	56.00
Hotchkiss NFH	RBT	3.00	47,895	BGD	10	1	212 days	56.00
Rathbun SFH/Research Facility	WAE	1.00	74,250	BGD	12;15;20	4 - 5	>90 days	65.00
Limestone Springs	RBT	1.00	300,000	BGD	15	3	420 days	55.00
Jordan River NFH	LAT	1.40	110,452	BGD	15 & 20	3	fish were euthanized	46.40
Chalk Cliffs SFH	RBT	2.75	275,000	External Flavobacteriosis	20	3	365 days	51.00
Jones Hole NFH	RBT	3.00	436,197	External CWD	20	3	1 yr	54.00
Susquehanna Aquaculture/ Brunner Island Fish Farm	SBH	3.00	80,000	External Flavobacteriosis	20	1	8 months	80.00

Table 3. Year 2009 Chloramine-T Efficacy Results - Inconclusive Studies

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Harrietta SFH	RBT	2.00	422,628.00	External CWD	10	3	270 days	46.20
Hotchkiss NFH	RBT	3.20	61,908.00	BGD	10	1	207 days	56.00
Hotchkiss NFH	RBT	2.77	13,546.00	BGD	10	1	219 days	56.00
Warm Springs NFH	SCS	30.00	400.00	External Flavobacteriosis	10	3	no human consumption	65.00
Dworshak NFH	STT	3.50	150,000.00	External CWD	10	1	300 days	45.90
Rifle Falls SFH	RBT	6.00	90,000.00	BGD	12	1-2	not reported	59.00
Wray SFH	MUH	2.00	8,906.00	BGD	15 - 20	14	102 days	63.00
Richloam SFH	LMB	2.30	135,000.00	External Columnaris	20	3	1 yr	75.00
Jones Hole NFH	RBT	4.00	40,000.00	External CWD	20	3	1 yr	54.00
Jones Hole NFH	RBT	2.45	39,000.00	External CWD	20	3	10 months	54.00
Rathbun SFH/Research Facility	WAE	2.00	10,500.00	BGD	20	1 - 2	>90 days	71.00
Rathbun SFH/Research Facility	WAE	4.72	88,573.00	BGD	20	1 - 5	47 days	75.00

Table 4. Year 2009 Chloramine-T Efficacy Results - Studies where efficacy data was not needed

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Dan Speas FRS	RBT	8.20	18,520.00	BGD	15	3	17 days	60.00
Dan Speas FRS	RBT	3.09	177,047.00	BGD	15	3	136 days	60.00
Dan Speas FRS	RBT	3.08	446,500.00	BGD	15	3	not reported	60.00
Roxbury FCS	BKT	1.20	78,500.00	BGD	20	3	5 months	48.00
Jones Hatchery	RBT	5.70	74,700.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	9.00	43,600.00	BGD	20	3	not reported	59.00
Jones Hatchery	RBT	8.00	42,800.00	BGD	20	3	not reported	59.00
Jones Hatchery	RBT	5.00	86,500.00	BGD	20	3	not reported	59.00
Jones Hatchery	RBT	6.60	78,700.00	BGD	20	3	not reported	59.00
Jones Hatchery	RBT	5.40	42,100.00	BGD	20	3	not reported	59.00
Jones Hatchery	RBT	7.50	39,800.00	BGD	20	3	not reported	59.00
Jones Hatchery	RBT	7.50	39,800.00	BGD	20	3	not reported	59.00
Jones Hatchery	RBT	9.40	441,300.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	6.10	74,700.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	8.50	37,600.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	9.80	3,600.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	4.60	70,700.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	10.50	80,700.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	10.00	37,000.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	6.00	70,200.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	7.40	112,600.00	BGD	20	3	not reported	57.00

Table 4. Year 2009 Chloramine-T Efficacy Results - Studies where efficacy data was not needed - cont.

Hatchery	Fish Species	Fish Size (in.)	Number of Fish	Disease	Dose (mg/L)	Number of treatment days	Observed Withdrawal Time	Temp. (°F)
Jones Hatchery	RBT	8.90	36,300.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	10.60	38,800.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	10.70	38,800.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	10.90	38,800.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	4.50	86,700.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	2.20	80,000.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	7.50	36,400.00	BGD	20	3	not reported	57.00
Jones Hatchery	RBT	8.90	41,900.00	BGD	20	3	not reported	57.00
Willamette SFH	STT	0.75	89,000.00	BGD	20	3	300 days	46.00

Table 5. Summary Data Regarding Year 2009 Chloramine-T Efficacy Studies

Total Number of Fish Treated:	28,367,300
Number of fish treated in efficacious trials	22,709,011
Number of fish treated in non-efficacious trials	2,014,161
Number of fish treated in inconclusive trials	1,060,461
Number of fish where efficacy was not needed	2,583,667

Total Number of Studies:	220
Efficacious trials	165
Non-efficacious trials	13
Inconclusive trials	12
Efficacy was not needed	30

Treatment Regimens and Frequency Used:

10 mg/L; 1 - 15 times	39 trials
12 mg/L; 1 - 2 times	15 trials
12;15; 20 mg/L; 4 - 5 times	1 trial
15 mg/L; 1 - 17 times	79 trials
15 & 20 mg/L; 3 - 14 times	6 trials
20 mg/L; 1 - 9 times	80 trials

Treatment Water Temperature (°F):

Temperature Range	36.1 - 80.0
Mean Temperature	55.3

Size of Treated Fish (in.):

Size Range	0.50 - 38.0
Mean Length	5.20

Species Treated:

Salmonids: (1) Atlantic salmon *Salmo salar* (2) brown trout *S. trutta*; (3) arctic grayling *Thymallus arcticus*; (4) apache trout *Oncorhynchus apache*; (5) chinook salmon *O. tshawytscha*; (6) chum salmon *O. keta*; (7) coho salmon *O. kisutch*; (8) sockeye salmon *O. nerka*; (9) cutthroat trout *O. clarki*; (10) rainbow trout *O. mykiss*; (11) steelhead trout *O. mykiss*; (12) golden trout *O. aguabonita*; (13) lake herring *Coregonus artedii*; (14) brook trout *Salvelinus fontinalis*; (15) lake trout *Salvelinus namaycush*; and (16) splake *Salvelinus fontinalis* x *S. namaycush*.

Non-salmonids: (1) black crappie *Pomoxis nigromaculatus*; (2) blue catfish *Ictalurus furcatus*; (3) channel catfish *I. punctatus*; (4) fathead minnow *Pimephales promelas*; (5) golden shiner *Noteminingonus crysoleucas*; (6) hybrid striped bass *Morone saxatilis* x *M. chrysops*; (7) lake sturgeon *Acipenser fulvescens*; (8) largemouth bass *Micropterus salmoides*; (9) smallmouth bass *M. dolomieu*; (10) muskellunge *Esox masquinongy*; (11) tiger Muskellunge *E. lucius* x *E. masquinongy*; (12) sauger *Stizostedion canadense*; and (13) walleye *Sander vitreus*
