

Form CLT-W: Worksheet for Designing Individual Field Trials under Chloramine-T INAD 9321

INSTRUCTIONS

1. Investigator must fill out Form CLT-W for each trial conducted under this INAD **before** actual use of Chloramine-T. The Investigator is responsible that Form CLT-W is completed accurately.
2. Investigator should keep the original on file, and Fax a copy to the Study Monitor for review.
3. After review, the Study Monitor will fax a copy to the Bozeman NIO for assignment of the Study Number.
4. The Bozeman NIO will review the worksheet, and then fax the assigned trial Study Number to both the Investigator and Study Monitor, at which time the trial may be initiated.
5. **Note:** Both Investigator and Study Monitor should sign and date Form CLT-W.

SITE INFORMATION

Facility			
Address			
Investigator			
Reporting Individual (if not Investigator)			
Phone		Fax	

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species to be treated		Disease to be treated	
Average fish weight (gm)		Average fish length (in)	
No. of fish per unit (e.g. 10,000 fish/raceway)			
Number of treated units		Number of treated fish	
Number of untreated control units		Number of control fish	
Anticipated date treatment will be initiated			
Check type of treatment method used		___ Flow through ___ Standing bath	
Check treatment objective		___ A	___ B ___ C ___ D
Intended drug target dosage (mg/L)	10 mg/L	Estimated total amount of drug needed for proposed treatment (Kg)	
	15 mg/L		
	20 mg/L		
Drug manufacturer		Drug lot number	

STUDY DESIGN: Describe in detail the purpose of the clinical trial. For example you might compare dosage, treatment frequency, or treatment method (Flow-Through vs. Standing Bath). Study design must be carefully focused and lend itself to rigorous evaluation. If more space is required to describe study details, title additional page(s) "Study Design" and attach them to this Worksheet.

Study designed by _____

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

- Investigator should initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in Section VI, B, page 3 of the Study Protocol.

WORKER SAFETY CONSIDERATIONS:

- Investigator should initial here to indicate that all personnel handling drug have read Material Safety Data Sheet for Chloramine-T and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: _____ Investigator: _____

Date Reviewed: _____ Study Monitor: _____

FORM CLT-1. Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

INSTRUCTIONS

1. Investigator must fill out Form CLT-1 **immediately** upon receipt of chloramine-T.
2. Investigator should keep the original on file, and send one copy to the Study Monitor for review.
3. Within 10 days of receipt, the Study Monitor should send a copy to the Bozeman NIO.
4. **Note:** Both Investigator and Study Monitor should sign and date Form CLT-1.

The sponsor, U.S. Fish and Wildlife Service, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetics Act.

Name of Drug	Chloramine-T	INAD Number	9321
Product Name (check one)	<input type="checkbox"/> Halamid [®] <input type="checkbox"/> Actamide		
Proposed Use of Drug	Treatment or control of bacterial gill disease or certain flavobacteriosis that occur in a variety of fish species		
Date of CVM Authorization Letter	December 5, 2007		
Date of Drug Receipt		Amount of Drug Received	
Drug Lot Number		Study Worksheet Number	
Name of Investigator			
Address of Investigator			
Location of Trial			
Pivotal Study (yes/no)		Non-pivotal Study (yes/no)	
Approximate Number of Treated Animals		Approximate Number of Control Animals	
Number of Animals Used Previously ¹			
Study Protocol Number	9321		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum daily dose and duration	20 mg/L for 1 hour		
Methods(s) of Administration	Immersion (static bath or flow-through treatment)		
Withdrawal Period	Zero		

¹ To be filled out by the NIO

Date Prepared: _____

Investigator: _____

Date Reviewed: _____

Study Monitor: _____

Date Reviewed: _____

Sponsor: _____

**Form CLT-3b: Results Report Form for use of Chloramine-T under
INAD 9321 - All use excluding salmonids treated for BGD at 12 -
20 mg/L; treatment on 3 consecutive or 3 alternate days**

INSTRUCTIONS

1. Investigator must fill out Form CLT-3B no later than 10 days after completion of the 14-day post-treatment observation period. Study Number must be recorded on all pages of Form CLT-3B. Attach lab reports and other information.
2. If Chloramine-T was not used under the assigned Study Number, fill out only the Site Information portion on this page, and skip to the end of page 3 and fill out only the "Negative Report" section.
3. Investigator should keep the original on file, and send a copy to the Study Monitor. Within 10 days of receipt, the Study Monitor should send a copy to the Bozeman NIO for inclusion in the permanent file.
4. **Note:** Both Investigator and Study Monitor should sign and date Form CLT-3B.

SITE INFORMATION

Facility	
Reporting Individual	

TREATMENT INFORMATION AND SCHEDULE

Drug lot number		Total amount drug used (kg)	
Fish species treated		CLT dosage used (mg/L)	
Disease treated		Disease diagnosed by	
Average fish weight (gm)		Average fish length (in)	
Number of fish per unit (e.g. 10,000 fish/raceway)			
Number of treated units		Total number of treated fish	
Number of control units		Total number of control fish	
Check type of treatment	___ Flow through ___ Standing bath		
Check treatment objective	___ A ___ B ___ C ___ D		
Dates of treatment (disease control)	1st	2nd	3rd
Date treatment started (disease prevention)	Date treatment ended (disease prevention)		

WATER QUALITY PARAMETERS

Ave pre-treatment temp (°F)		Dissolved Oxygen (mg/L)	
Ave treatment temp (°F)		pH	
Ave post-treatment temp (°F)		Hardness - CaCO ₃ (mg/L)	

Daily Mortality Record

INSTRUCTIONS

1. Investigator should fill out the Daily Mortality Record as completely as possible.
2. Prior to initiation of the trial, fill out Rearing Unit ID, whether a rearing unit is Treated or Control, and the number of fish in each rearing unit.
3. Water temperature and individual tank mortality should be recorded on a daily basis.
4. If treatment is on 3 consecutive days, fill in only days 1-3 of the "treatment period" and proceed directly to day 1 of the "post-treatment period". If treatment is on 3 alternate days, fill in days 1-5 of the "treatment period" and proceed to day 1 of the "post-treatment period". If less than 3 treatments are used, proceed directly to day 1 of the "post-treatment period" after the final treatment. Please mark all treatment days with an asterisk.
5. Use additional copies of this form if more than 6 rearing units are involved in the trial.

FACILITY										
	Rearing Unit ID									
	<u>T</u> reated or <u>C</u> ontrol									
	Number of Fish									
	Day	Date	Water Temp (F°)	Mortality						
Pre-treatment period	1									
	2									
	3									
	4									
	5									
Treatment period	1									
	2									
	3									
	4									
	5									
Post-treatment period	1									
	2									
	3									
	4									
	5									
	6									
	7									
	8									
	9									
	10									

RESULTS: Describe in detail treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Were there any mitigating environmental conditions that may have impacted treatment results? Were there any deviations from the Study Protocol?

Pathology Report: Attach pathology report to this form. Report should include: 1) a description of how the pathogen(s) was identified; 2) disease identification records that confirm the presence of the pathogen; and 3) the name and title of the individual performing the diagnosis.

Pathology Report included: pre-treatment post-treatment

Toxicity observations: Report any apparent drug toxicity including a description of unusual fish behavior.

DRUG DISCHARGE RESULTING FROM THIS TREATMENT: Use Addendum 2: Discharge Worksheet for calculations and attach completed Discharge Worksheet to this form. Enter the value from Addendum 2 step 3 in this space.

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Investigator should initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in Section VI, B, page 3 of the Study Protocol.

Estimated number of days between last treatment and first availability of fish for human consumption (ensure this time period meets the withdrawal period). _____

NEGATIVE REPORT Chloramine-T was not used at this facility under this Study Number during the reporting period. (Investigator should initial for negative reports as soon as the Study Number is known to be no longer needed or valid.)

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Discharge Worksheet - Chloramine-T

Instructions: Use this Worksheet to calculate estimates of 1) the *maximum* amount of Chloramine-T to be used for a single treatment of fish at your facility, and 2) the resulting concentration of Chloramine-T in your total hatchery wastewater discharge.

Handy conversion factors: 1 part per million (ppm) = 0.0283 grams/cuft; or, 0.0038 grams/gallon.

Calculations:

Step 1 - Calculate the total flow of treated and untreated water during treatment period:

1a Number of rearing units to be treated: _____

1b Total water volume (at treatment flow rates) to these units during treatment period: _____ (gal.) or (cuft.) of treated flow

1c Total water volume to all other untreated units during treatment period: _____ (gal.) or (cuft.) of untreated flow

1d Grand total hatchery discharge (Treated + Untreated):

_____ (gal.) or (cuft.) of flow during treatment period.

Step 2 - Calculate the amount of Chloramine-T needed:

2a _____ gms = _____ * _____ * _____ ppm
 Amount Vol. from line 1b Conv. factor* Desired dosage

Step 3 - Calculate Chloramine-T level in hatchery discharge during treatment period:

3a _____ ppm = _____ / (_____ * _____)
 Disch. level Amt. from line 2a Total vol. (line 1d) Conver. factor*
 *If in gallons use 0.0038
 If in cubic ft use 0.0283