

Form CALC-3: Results Report Form for Use of SE-MARK[®] Under INAD 10-987

INSTRUCTIONS

1. Investigator must fill out Form CALC-3 no later than 30 days after completion of treatment. Study Number must be recorded on all pages of Form CALC-3. Attach lab reports and other information.
2. If SE-MARK[®] 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 AADAP Office for inclusion in the permanent file.
4. **Note:** Both Investigator and Study Monitor should sign and date Form CALC-3.

SITE INFORMATION

Facility	
Reporting Individual	

FISH CULTURE AND DRUG TREATMENT INFORMATION

SE-MARK [®] lot number		Amount SE-MARK [®] used (ml)	
Treatment option used (see study circle one)		Option A	Option B
Treatment dosage		Treatment duration	
Pre-treatment with salt solution (circle one)	Yes or No	If yes, salt solution conc. (%) and treatment duration (min)	
Fish species treated		Total number of fish treated	
Ave fish weight (gm or number/pound); circle one used and enter data		Average fish length (in)	
Treatment bath vol (gal)		Number fish per treatment	
Number of rearing units treated		Treatment date	

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)	

Marking Record - Version 1

INSTRUCTIONS

1. Investigator should fill out the Marking Record as completely as possible.
2. Enter the **"Marking Grade"** for each unit in the proper column to indicate the quality of the mark:
3 = readily visible bright green mark; **2** = clearly visible green mark; **1** = dimly visible dull green mark;
and **0** = no mark.
3. Use additional copies of this form if more than 1 rearing unit/lot is involved in the trial.
4. If more that 15 fish are evaluated, append another copy of this form labeled "continuation sheet"

		Facility:								
		Rearing Unit ID								
		Number of Fish								
Fish Number	Date	Days Post Treatment	Pectoral Fin Ray Mark	Pelvic Fin Ray Mark	Opercle Mark	Jaw Mark	Scale Mark	Other Mark (identify)	Observer Initials	
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										

**STUDY
NUMBER** _____

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?

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

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Observed withdrawal period: _____ **21 days**

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

DISPOSITION OF MARKING SOLUTION

SE-MARK[®] solution has been stored on-site in a secure, leak-proof container that clearly identifies container contents (Investigator should initial)

SE-MARK[®] solution disposed of by shipment to Emerald Services, Inc., 1825 Alexander Avenue, Tacoma, WA 98451 according to procedures detailed in general Waste-stream Profile #216200B (Investigator should initial)

NEGATIVE REPORT SE-MARK[®] immersion marking 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: _____