

HALAMID- chloramine-t trihydrate powder
Western Chemical Inc.

HALAMID.
AQUACHLORAMINE-T POWDER FOR IMMERSION

FOR FRESHWATER-REARED SAMONIDS

INDICATIONS: For the control of mortality in freshwater-reared salmonoids due to bacterial gill disease associated with *Flavobacterium spp.*

DIRECTIONS FOR USE: Apply HALAMID AQUA at concentrations of 12 to 20 milligrams per liter water [mg/L; equivalent to parts per million (ppm)] in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments in fish culture units.

FOR WALLEYE

INDICATIONS: For the control of mortality in walleye due to external columnaris disease associated with *Flavobacterium columnare*

DIRECTIONS FOR USE: Apply HALAMID AQUA at concentrations of 10 to 20 milligrams per liter water [mg/L; equivalent to parts per million (ppm)] in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments in fish culture units.

FOR FRESHWATER-REARED WARMWATER FINFISH

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

DIRECTIONS FOR USE: Apply HALAMID AQUA at a concentration of 20 milligrams per liter water [mg/L; equivalent to parts per million (ppm)] in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments in fish culture units.

USE CALCULATIONS

For Static Bath Treatment:

HALAMID AQUA needed (grams)	Volume of water = to be treated (gallons)	Treatment X Concentration (ppm or mg/L)	0.0038 X (correction factor)*
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For Constant Flow (flow-through) Treatment:

HALAMID AQUA needed (grams)	Water Flow = (Gallons per minute)	Treatment X Duration (minutes)	Treatment X Concentration (ppm or mg/L)	0.0038 X (correction factor)
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* Correction (or conversion) factor is equal to: 3.785 L/gal/1000 mg/g

DIRECTIONS FOR STATIC AND CONTINUOUS FLOW (FLOW THROUGH) TREATMENTS

1. **STATIC TREATMENT:** Shut off water flow to culture unit before adding drug. Completely dissolve HALAMID AQUA in a separate container of culture water and thoroughly mix into the

culture unit. The drug solution should be used immediately and not stored. End treatment by flushing system with fresh water. Resume normal flow.

2. **CONTINUOUS FLOW TREATMENT:** Determine flow rate for culture unit. Pre-charge culture unit by administering the amount of drug needed for a static treatment. Meter additional drug solution into culture unit at a concentration and rate necessary to maintain the target dose in the culture unit for the duration of the treatment period (see table above for calculations).

LIMITATIONS AND CAUTIONS FOR FINFISH USE

1. Before using this drug for the first time, you must inform the appropriate National Pollutant Discharge Elimination System (NPDES) permitting authority of your intentions and of the following information. A water quality benchmark for the protection of freshwater aquatic life has been derived by FDA. The acute benchmark is 0.13 mg/L, which is equivalent to the Secondary Maximum Concentration (one-half of the Secondary Acute Value). The NPDES authority may require an NPDES permit before you can discharge chloramine-T. The water quality benchmark concentration is not a discharge limit, but it may be used by the NPDES authority to derive one for the permit. The acute benchmark should be protective of aquatic life when the receiving water pH is at or above pH 6.5. Additional environmental information on chloramine-T and the benchmark value are available in an environmental assessment posted at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentAssessments/ucm300656.htm>.
2. Before conducting treatments with HALAMID AQUA, user should test the sensitivity of the finfish species and the life stage to the treatment concentration in a small number before treating the entire group.
3. Walleye fingerlings may be more sensitive than walleye fry to HALAMID AQUA.
4. Avoid feeding finfish immediately before or during exposure
5. Additional aeration may be necessary to maintain adequate oxygenation levels during static treatments
6. Do not use in earthen ponds or systems that cannot be flushed after treatment.
7. If used in recirculating systems, bypass biofilter during treatment and flushing. Effects on biofilter and water quality have not been evaluated. Ensure that drug is flushed from the system after treatment.

WITHDRAWAL PERIOD: ZERO DAYS

HUMAN WARNING

EMERGENCY FIRST AID:

- In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. Remove contact lenses before flushing eyes and hold the eyelids apart during the flushing. Do not rub eyes. Call a physician. Remove and wash contaminated clothing and shoes promptly and thoroughly. Do not attempt to neutralize with chemical agents.
- If inhaled, move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
- If swallowed, do not induce vomiting. Give large quantities of water. Never give anything by mouth to an unconscious person. Call a physician.

INHALATION (Breathing):

- Avoid breathing dust; causes irritation to mucous membranes and may cause asthma-like symptoms.

INGESTION (Swallowing):

- Do not swallow. Swallowing may cause irritation or burns of the mouth, throat, esophagus and stomach that may cause nausea and vomiting.

EYE CONTACT:

- Do not get in eyes; considered corrosive to the eyes.

SKIN CONTACT:

- Avoid contact with skin; considered corrosive to skin and may cause allergic reaction in sensitive individuals.

HUMAN PRECAUTIONS:

- Keep out of reach of children
- Wear suitable personal protective equipment including gloves, protective clothing and footwear, goggles, and respirator. See product Material Safety Data Sheet (MSDS) for additional information.
- Use only with adequate ventilation
- May aggravate pre-existing skin and/or respiratory disease

ENVIRONMENTAL WARNING:

- Chloramine-T may be hazardous to aquatic life, including invertebrates and algae. Do not release the undiluted product directly into natural waterways.

PHYSICAL AND CHEMICAL HAZARDS:

- Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source (heat, sparks, or flame) is a potential explosion hazard.
- Sweep up spilled solid material, being careful not to create dust.
- May decompose violently if heated above 266°F (130° C).
- Contact with acids liberates toxic gas.
- In the case of fire, use water fog or spray, dry chemical, foam or carbon dioxide extinguishing agents.

STORAGE:

- Store at temperatures below 86° F (30° C).
- Store away from foodstuff or animal feed
- Containers should be kept tightly capped and stored in a cool, dry, well-ventilated area protected from direct sunlight and away from flammable, reducing or oxidizing materials and sources of heat or flame.
- Store in a manner designed to prevent spills that may result in discharge to surface waters.
- Exercise due caution to prevent damage or leakage from the container.

DISPOSAL:

- Implement procedures for properly containing, cleaning, and disposing of any spilled material.
- Contact your State Environmental Control Agency, or Hazardous Waste Representative at the nearest EPA Regional Office for guidance on disposal of unused product, empty containers, and spilled materials.
- Do not allow undiluted product to escape into sewage or surface water.
- Empty containers should be cleaned of residual drug before disposal or return. Follow label warnings even after container is emptied because empty containers can still contain drug residues.

PACKAGE LABEL

HALAMID

AQUA

CHLORAMINE-T POWDER FOR IMMERSION

For control of mortality in freshwater-reared salmonids due to bacterial gill disease, in walleye due to external columnaris disease, in freshwater-reared warmwater finfish due to external columnaris disease

ACTIVE DRUG INGREDIENT

Chloramine-T trihydrate

GUARANTEED ANALYSIS

Chloramine-T (C₇H₇ClNNaO₂S · 3H₂O).....98% w/w (minimum)

NET CONTENT:

55 pounds
(25 kilograms)

NADA 141-423,
approved by FDA

Keep out of reach of children

To report suspected adverse events, for technical assistance or to obtain a copy of the MSDS, contact **Western Chemical** at 1-800-283-5292 or 1-360-384-5898 or info@wchemical.com.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

MANUFACTURED FOR : Axcentive SARL. For information in the USA contact: Western Chemical, 1269 Lattimore Road, Ferndale, WA 98248 USA Phone: 1-800-283-5292 or 1-360-384-5898

axcentive

HUMAN WARNING

EMERGENCY FIRST AID:

- In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. Remove contact lenses before flushing eyes and hold the eyelids apart during the flushing. Do not rub eyes. Call a physician. Remove and wash contaminated clothing and shoes promptly and thoroughly. Do not attempt to reinsert contact lenses.
- If inhaled, move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
- If swallowed, do not induce vomiting. Use large quantities of water. Never give anything by mouth to an unconscious person. Call a physician.

INHALATION (Warning):

- Avoid breathing dust. Causes irritation to mucous membranes and may cause asthma-like symptoms.

INGESTION (Warning):

- Do not swallow. Swallowing may cause irritation or burns of the mouth, throat, esophagus and stomach that may cause nausea and vomiting.

EYE CONTACT:

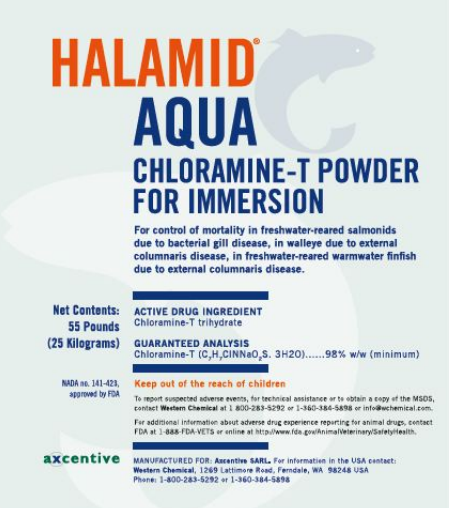
- Do not get in eyes; considered corrosive to the eyes.

SKIN CONTACT:

- Avoid contact with skin; considered corrosive to the skin and may cause allergic reaction in sensitive individuals.

HUMAN PRECAUTIONS:

- Keep out of reach of children.
- Wear suitable personal protective equipment including gloves, protective clothing and footwear, goggles, and respirator. See product Material Safety Data Sheet (MSDS) for additional information.
- Use only with adequate ventilation.
- May aggravate pre-existing skin and/or respiratory disease.



HALAMID[®] AQUA
CHLORAMINE-T POWDER FOR IMMERSION

For control of mortality in freshwater-reared salmonids due to bacterial gill disease, in walleye due to external columnaris disease, in freshwater-reared warmwater finfish due to external columnaris disease.

Net Contents:
55 Pounds
(25 Kilograms)

ACTIVE DRUG INGREDIENT
Chloramine-T trihydrate

GUARANTEED ANALYSIS
Chloramine-T (C₂H₃ClN₃O₃ · 3H₂O).....98% w/w (minimum)

Keep out of the reach of children

NADA no. 141-423,
approved by FDA

axcentive

MANUFACTURED FOR: Axcentive SARL. For information in the USA contact: Western Chemical, 1269 Lattimore Road, Ferndale, WA 98248 USA Phone: 1-800-283-5292 or 1-360-384-5898

FOR FRESHWATER-REARED SALMONIDS

INDICATIONS: For the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium columnare*.

DIRECTIONS FOR USE: Apply HALAMID[®] AQUA at concentrations of 12 to 20 milligrams per liter water (mg/L, equivalent to parts per million (ppm)) in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments in fish culture units.

FOR WALLEYE

INDICATIONS: For the control of mortality in walleye due to external columnaris disease associated with *Flavobacterium columnare*.

DIRECTIONS FOR USE: Apply HALAMID[®] AQUA at concentrations of 12 to 20 milligrams per liter water (mg/L, equivalent to parts per million (ppm)) in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments in fish culture units.

FOR FRESHWATER-REARED WARMWATER FINFISH

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

DIRECTIONS FOR USE: Apply HALAMID[®] AQUA at a concentration of 20 milligrams per liter water (mg/L, equivalent to parts per million (ppm)) in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments in fish culture units.

USE CALCULATIONS

For Static Bath Treatment:

HALAMID [®] AQUA =	Volume of water to be treated (gallons)	X	Treatment Concentration (ppm or mg/L)	X	0.0038 (correction factor)
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For Constant Flow (Flow-through) Treatment:

HALAMID [®] AQUA =	Water Flow (Gallons per minute)	X	Treatment Duration (minutes)	X	Treatment Concentration (ppm or mg/L)	X	0.0038 (correction factor)
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*Correction (or conversion) factor is equal to: $\frac{3.785 \text{ L/gal}}{1000 \text{ mg/L}}$

DIRECTIONS FOR STATIC AND CONTINUOUS FLOW (FLOW THROUGH) TREATMENTS

- STATIC TREATMENT:** Shut off water flow to culture unit before adding drug. Completely dissolve HALAMID[®] AQUA in a separate container of culture water and thoroughly mix into the culture unit. The drug solution should be used immediately and not stored. End treatment by flushing system with fresh water. Resume normal flow.
- CONTINUOUS FLOW TREATMENT:** Determine flow rate for culture unit. Pre-charge culture unit by administering the amount of drug needed for a static treatment. Meter additional drug solution into culture unit at a concentration and rate necessary to maintain the target dose in the culture unit for the duration of the treatment period (see table above for calculations).

LIMITATIONS AND CAUTIONS FOR FINFISH USE

- Before using this drug for the first time, you must obtain the appropriate National Pollutant Discharge Elimination System (NPDES) permitting authority or your jurisdiction and of the following information: A water quality benchmark for the protection of freshwater aquatic life has been approved by EPA. The acute benchmark is 11.5 mg/L, which is equivalent to the Secondary Maximum Concentration (one-half of the Secondary Acute Value). The NPDES authority may require an NPDES permit before you can discharge chloramine-T. The water quality benchmarks comparison is not a discharge limit, and it may be used by the NPDES authority to derive one for the permit. The acute benchmark should be protective of aquatic life when the receiving water pH is 6.5 or above pH 6.5. Additional environmental information on chloramine-T and the benchmark value are available in an environmental assessment posted at <http://www.fda.gov/AnimalVeterinary/Development/ApprovalProcess/EnvironmentalAssessments/030836.htm>.
- Before conducting treatments with HALAMID[®] AQUA, user should test the sensitivity of the fish species and the live stage to the treatment concentration in a small number of fish treating the entire group.
- Walleye fingerlings may be more sensitive than walleye fry to HALAMID[®] AQUA.
- Avoid feeding finfish immediately before or during exposure.
- Additional aeration may be necessary to maintain adequate oxygenation levels during static treatments.
- Do not use in earthen ponds or systems that cannot be flushed after treatment.
- If used in recirculating systems, bypass biofilter during treatment and flushing. Effects on biofilter and water quality have not been evaluated. Ensure that drug is flushed from the system after treatment.

WITHDRAWAL PERIOD: ZERO DAYS

HALAMID

chloramine-t trihydrate powder

Product Information			
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:50378-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CHLORAMINE-T TRIHYDRATE (UNII: 4IU6VS00E1) (CHLORAMINE-T ANHYDROUS - UNII:328AS34YM6)	CHLORAMINE-T ANHYDROUS	980 g in 1 kg	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50378-015-05	5 kg in 1 PAIL		
2	NDC:50378-015-25	25 kg in 1 DRUM		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141423	10/24/2014	

Labeler - Western Chemical Inc. (085803500)

Establishment

Name	Address	ID/FEI	Business Operations
Axcentive SARL		275016769	label, pack

Establishment

Name	Address	ID/FEI	Business Operations
Tianjin Tiancheng Pharmaceutical Co., Ltd.		547987057	api manufacture, manufacture

Revised: 11/2014

Western Chemical Inc.