



Chemical name: Hydrogen peroxide - containing 35% hydrogen peroxide by weight (approximately 396100 mg H<sub>2</sub>O<sub>2</sub>/L). All concentrations are based on active ingredient.

Original NADA Claim supported by accepted pivotal efficacy data

Potential NADA Claim pending development of additional efficacy data

Species: Salmonids

Indication: For the control of mortalities associated with external fungus on fish eaas.1

**Dosage Regimen:** Apply 500 milligrams H<sub>2</sub>O<sub>2</sub> per liter [mg/L; equivalent to parts per million (ppm)] in constant flow water supply of fish egg incubation units.

### Limitations/comments:

- Treat fish egg incubation units once per day on consecutive or alternate days through hatch to control mortalities associated with external fungus on fish eggs.
- Some strains of rainbow trout eggs are sensitive to hydrogen peroxide treatment at a time during incubation concurrent with blastopore formation through closure, about 70 to 140 Daily Temperature Units, °C. Consider withholding treatment or an alternate therapeutant during that sensitive time period to reduce egg mortality due to hydrogen peroxide toxicity. Although it is unknown if species other than rainbow trout also have a similar sensitive period, hatchery personnel unfamiliar with the effects of hydrogen peroxide treatments on the species they are culturing should carefully monitor eggs treated with hydrogen peroxide.
- <sup>1</sup> Note: Original NADA is contingent on acceptance by CVM of technical guidelines for product chemistry and environmental safety.

Species: All freshwater fish<sup>1</sup>

Indication: For the control of mortalities associated with external fungus on fish eggs. **Dosage Regimen:** Apply 500 to 1000<sup>2</sup> milligrams H<sub>2</sub>O<sub>2</sub> per liter [mg/L; equivalent to parts per million (ppm)] in constant flow water supply of fish egg incubation units.

#### Limitations/comments:

- Treat fish egg incubation units once per day on consecutive or alternate days through hatch to control mortalities associated with external fungus on fish eggs.
- Some strains of rainbow trout eggs are sensitive to hydrogen peroxide treatment at a time during incubation concurrent with blastopore formation through closure, about 70 to 140 Daily Temperature Units, °C. Consider treating at the lower end of the dose range, withholding treatment, or an alternate therapeutant during that sensitive time period to reduce egg mortality due to hydrogen peroxide toxicity. Although it is unknown if species other than rainbow trout also have a similar sensitive period, hatchery personnel unfamiliar with the effects of hydrogen peroxide treatments on the species they are culturing should carefully monitor eggs treated with hydrogen peroxide.
- <sup>1</sup> Note: Assumes that pivotal INAD efficacy data for a major cool- and warmwater aquaculture species are developed and accepted and supporting INAD efficacy data are developed for additional cool- and warmwater species. The number of species included in the potential NADA claim is directly related to the number of species included in the supporting INAD efficacy trials.
- <sup>2</sup> Note: Based on submitted target animal safety studies, UMESC anticipates that the upper dose range will be 1000 mg/L, however, requirements for additional target animal safety data will be determined by CVM reviewers. UMESC also assumes that CVM will not require additional environmental safety data with the addition of this disease indication.









Original NADA Claim supported by accepted pivotal efficacy data	Potential NADA Claim pending development of additional efficacy data
Species: None Indication: For the control of mortalities associated with external fungus on fish. Dosage Regimen:  None currently supportable.	Species: All freshwater fish¹ Indication: For the control of mortalities associated with external fungus on fish.  Dosage Regimen: Apply 100 to 250² milligrams H <sub>2</sub> O₂ per liter [mg/L; equivalent to parts per million (ppm)] in constant flow water supply³ of fish culture units or as a static bath in fish culture units for 30 minutes or 50 to 100 mg H <sub>2</sub> O₂/L for 60 min.  Limitations/comments:  • Treat fish culture units once per day on consecutive⁴ or alternate days three times per epizootic to control mortalities associated with external fungus on fish.  • The following fish species have been shown to be especially sensitive to hydrogen peroxide in laboratory studies: Fathead minnow (Pimephales promelas), northern pike (Esox luscius), paddlefish (Polyodon spathula), pallid sturgeon (Ascipenser fulvescens), walleye (Stizostedion vitreum), white sucker (Catostomus commersoni), and yellow perch (Perca flavescens).  • Application of hydrogen peroxide should be preceded by a bioassay with a representative sample of the target population to assess the sensitivity of the target population, especially with these sensitive species.  ¹ Note: The number of species included in the potential NADA claim is directly related to the number of species included in the supporting INAD efficacy trials. Assumes that pivotal INAD efficacy data for a major cold-, cool- and warmwater aquaculture species are developed and accepted and supporting INAD efficacy data are developed for additional cold-, cool- and warmwater species.  ² Note: Based on submitted efficacy studies, UMESC anticipates that the upper dose range will be 250 mg/L, however, requirements for additional target animal safety data will be determined by CVM reviewers. UMESC also assumes that CVM will not require additional environmental safety data with the addition of this disease indication. ³ Note: Use in continuous flow water supply of fish culture units would require the development of data that show the ability to maintain the minimum nominal treatment concentrations a









Original NADA Claim supported by accepted pivotal efficacy data

Potential NADA Claim pending development of additional efficacy data

Species: Salmonids

Indication: <u>For the control of mortalities</u> <u>associated with external flavobacterial</u> infections of gills.<sup>1</sup>

**Dosage Regimen:** Apply 100 milligrams H<sub>2</sub>O<sub>2</sub> per liter [mg/L; equivalent to parts per million (ppm)] as a static bath in fish culture units for 30 minutes or 50 mg H<sub>2</sub>O<sub>2</sub>/L for 60 min. **Limitations/comments:** 

- Treat fish culture units once per day on alternate days three times per epizootic to control mortalities associated with external fungus.
- Application of hydrogen peroxide should be preceded by a bioassay with a representative sample of the target population to assess the sensitivity of the target population, especially with these sensitive species.
- <sup>1</sup> Note: Original NADA is contingent on acceptance by CVM of technical guidelines for product chemistry, target animal safety, and environmental safety.

Species: All freshwater fish<sup>1</sup>

Indication: For the control of mortalities associated with external flavobacterial infections of gills. Dosage Regimen: Apply  $100 \text{ to } 250^2 \text{ milligrams } H_2O_2 \text{ per liter}$  [mg/L; equivalent to parts per million (ppm)] in constant flow water supply<sup>3</sup> of fish culture units or 30 minutes or 50 to 100 mg  $H_2O_2L$  for 60 min.

#### Limitations/comments:

- Treat fish culture units once per day on consecutive<sup>4</sup> or alternate days three times per epizootic to control mortalities associated with external flavobacterial infections of gills.
- The following fish species have been shown to be especially sensitive to hydrogen peroxide in laboratory studies: Fathead minnow (*Pimephales promelas*), northern pike (*Esox luscius*), paddlefish (*Polyodon spathula*), pallid sturgeon (*Ascipenser fulvescens*), walleye (*Stizostedion vitreum*), white sucker (*Catostomus commersoni*), and yellow perch (*Perca flavescens*).
- Application of hydrogen peroxide should be preceded by a bioassay with a representative sample of the target population to assess the sensitivity of the target population, especially with these sensitive species.
- <sup>1</sup> Note: The number of species included in the potential NADA claim is directly related to the number of species included in the supporting INAD efficacy trials. Assumes that pivotal INAD efficacy data for a major cool- and warmwater aquaculture species are developed and accepted and supporting INAD efficacy data are developed for additional cool- and warmwater species.
- <sup>2</sup> Note: Based on submitted efficacy studies, UMESC anticipates that the upper dose range will be 250 mg/L, however, requirements for additional target animal safety data will be determined by CVM reviewers. UMESC also assumes that CVM will not require additional environmental safety data with the addition of this disease indication.
- <sup>3</sup> Note: Use in continuous flow water supply of fish culture units would require the development of data that show the ability to maintain the minimum nominal treatment concentrations and that there is an acceptable environmental assessment for this use.
- <sup>4</sup> Note: Use to treat on consecutive days would require the development of additional target animal safety data.









Original NADA Claim supported by accepted pivotal efficacy data

Potential NADA Claim pending development of additional efficacy data

Species: None

Indication: For the control of external trematode and protozoan parasites on fish.

Dosage Regimen:

None currently supportable.

Species: All freshwater fish 1

Indication: For the control of external trematode and protozoan parasites on fish.

**Dosage Regimen:** Apply 100 to  $250^2$  milligrams  $H_2O_2$  per liter [mg/L; equivalent to parts per million (ppm)] in constant flow water supply<sup>3</sup> of fish culture units or as a static bath in fish culture units for 30 minutes or 50 to 100 mg  $H_2O_2/L$  for 60 min.

#### Limitations/comments:

- Treat fish culture units once per day on consecutive<sup>4</sup> or alternate days three times per epizootic to control external trematode and protozoan parasites on fish.
- The following fish species have been shown to be especially sensitive to hydrogen peroxide in laboratory studies: Fathead minnow (*Pimephales promelas*), northern pike (*Esox luscius*), paddlefish (*Polyodon spathula*), pallid sturgeon (*Ascipenser fulvescens*), walleye (*Stizostedion vitreum*), white sucker (*Catostomus commersoni*), and yellow perch (*Perca flavescens*).
- Application of hydrogen peroxide should be preceded by a bioassay with a representative sample of the target population to assess the sensitivity of the target population, especially with these sensitive species.

<sup>1</sup> Note: The number of species included in the potential NADA claim is directly related to the number of species included in the supporting INAD efficacy trials. Assumes that pivotal INAD efficacy data for a major cold-, cool-, and warmwater aquaculture species are developed and accepted and supporting INAD efficacy data are developed for additional cold-, cool-, and warmwater species.

<sup>2</sup> Note: Based on submitted efficacy studies, UMESC anticipates that the upper dose range will be 250 mg/L, however, requirements for additional target animal safety data will be determined by CVM reviewers. UMESC also assumes that CVM will not require additional environmental safety data with the addition of this disease indication.

<sup>3</sup> Note: Use in continuous flow water supply of fish culture units would require the development of data that show the ability to maintain the minimum nominal treatment concentrations and that there is an acceptable environmental assessment for this use

<sup>4</sup> Note: Use to treat on consecutive days would require the development of additional target animal safety data.

Limitations and Cautions that apply to all uses:

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- Follow NPDES or state discharge regulations for discharge of Hydrogen peroxide treatment water.
- Flow to the culture unit must be sufficient to rapidly flush hydrogen peroxide from the culture unit after treatment.
- Avoid feeding fish before or during exposure. Before treatment, remove dead fish and clean rearing units to be treated.
- Consider using aeration to help disperse the chemical and to ensure adequate oxygen levels.

Withdrawal time in days:

For Ingredient: Hydrogen peroxide

There is a zero-withdrawal time for this ingredient.

Tolerance in food animals:

For Ingredient: Hydrogen peroxide CFR Tolerance Paragraph Number: N/A

There is no requirement to establish a tolerance for this ingredient.



