Approval Date: July 17, 2007

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-414

Formacide-B
(formalin)

Aqueous Solution

Indicated for use as a parasiticide for all cultured finfish and penaeid shrimp and as a fungicide for all finfish eggs

Sponsored by:
B.L. Mitchell, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number: ANADA 200-414

b. Sponsor: B.L. Mitchell, Inc.
103 US Hwy. 82 E.
Leland, MS 38756

Drug Labeler Code: 067188

c. Established Name: Formalin

d. Proprietary Name: Formacide-B

e. Dosage Form: Aqueous solution

f. How Supplied: 1 (U.S.) Gallon [3.79 Liters]
5 (U.S.) Gallons [18.93 Liters]
55 (U.S.) Gallons [208.2 Liters]

g. How Dispensed: OTC

h. Amount of Active Ingredients: 37% (by weight) formaldehyde

i. Route of Administration: In the environmental water

j. Species/Class: All cultured finfish, penaeid shrimp, and all finfish eggs

k. Recommended Dosage: Parasiticide for Finfish
Concentration of Formalin

Aquatic species	Administer in Tanks & Raceways for up to 1 hr. (µL/L)*	Administer in Earthen Ponds Indefinitely (µL/L)*
Salmon & Trout above 50°F below 50°F	 up to 170 up to 250	 15-25** *** 15-25** ***
All other finfish	up to 250	15-25** ***

Micro liter per liter (µL/L) = parts per million (ppm)

** Use the lower concentration when ponds, tanks, or raceways are heavily loaded with phytoplankton, or fish, to avoid oxygen depletion due to the biological oxygen demand created by decay of dead phytoplankton. Alternatively, a higher concentration might be used if dissolved oxygen is strictly monitored.
*** Although the indicated concentrations are considered safe for cold and warm water finfish, a small number of each lot or pond to be treated should always be used to check for any unusual sensitivity to formalin before proceeding.

Parasiticide for Penaeid Shrimp
Concentration of Formalin

Aquatic species	Administer in Tanks and Raceways for up to 4 hours (µL/L)	Administer in Earthen Ponds indefinitely (µL/L)
Shrimp	50 to 100**	25***

Micro liter per liter (µL/L) = parts per million (ppm)
** Treat for up to 4 hours daily. Treatment may be repeated daily until parasite control is achieved. Use the lower concentration when ponds, tanks or raceways are heavily loaded with phytoplankton, or shrimp, to avoid oxygen depletion due to the biological oxygen demand created by decay of dead phytoplankton. Alternatively, a higher concentration might be used if dissolved oxygen is strictly monitored.
*** Treatment may be repeated in 5 to 10 days, if needed.

Fungicide for Finfish Eggs
Concentration of Formalin

Aquatic species	Administer in Hatchery Systems (µL/L)
Eggs of all finfish except Acipenseriformes	1000-2000 for 15 minutes**
Eggs of Acipenseriformes	Up to 1500 for 15 minutes**

Micro liter per liter (µL/L) = parts per million (ppm)

**Apply in constant flow water supply of incubating facilities. A preliminary bioassay should be conducted on a small subsample of fish eggs to determine sensitive before treating an entire group. This is necessary for all species because egg sensitivity can vary with species or strain and the unique conditions at each facility.

l. Pharmacological Category:	Parasiticide and fungicide
m. Indications:	For use on all cultured finfish, penaeid shrimp and all finfish eggs. Indications for use: 1. Parasiticide for Finfish: for the control of external protozoa (*Chilodonella* spp., *Costia* spp., *Epistylis* spp., *Ichthyophthirius* spp., *Scyphidia* spp., and *Trichodina* spp.,), and the monogenetic trematode parasites (*Cleidodiscus* spp., *Dactylogyrus* spp., and *Gyrodactylus* spp.). 2. Parasiticide for Penaeid Shrimp: for the control of external protozoan parasites (*Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.). 3. Fungicide for Finfish Eggs: for the control of fungi of the family Saprolegniaceae.
n. Pioneer Product:	Parasite-S; formalin; NADA 140-989; Western Chemical, Inc.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, B.L. Mitchell, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Formacide-B (formalin). The generic product is administered in the environmental water, contains the same active and inactive ingredients in the same concentration and dosage form as the pioneer product. The pioneer product, Parasite-S (formalin), the subject of Western Chemical, Inc., NADA 140-989, was approved on September 15, 1992.

3. HUMAN SAFETY:

Human Warnings are provided on the product label as follows:

User Safety Warning:

Exposure to high concentrations of formaldehyde vapor causes severe respiratory irritations which can be life-threatening. Lower vapor levels can cause irritation to the eyes, respiratory tract, and skin. Swallowing formaldehyde can be life-threatening. Formaldehyde is an irritant when splashed on skin or into the eyes. It can cause severe eye damage, even blindness.

May aggravate a pre-existing asthmatic condition and allergic rhinitis.

Keep out of the reach of children.

Moderate fire and explosion hazard exists when exposed to heat or flame.

Contains methanol-cannot be made non-poisonous. Prolonged exposure to methanol has been associated with reproductive disorders.

Potential Cancer Hazard: Formaldehyde vapor may be carcinogenic if inhaled. Use applicable safety protection. (Note: This drug, used as labeled, does not cause formaldehyde tissue residues in fish).

Employers: Refer to Occupational Safety and Health Administrations (OSHA) regulations 29 CFR 1910.1048 for human safety guidance that may be applicable to your specific operation. OSHA's "action level" concentration for airborne formaldehyde is 0.5 part per million (ppm), calculated as an 8-hour time-weighted average (TWA). Use respiratory, skin, and eye protection when needed (refer to OSHA's regulation 29 CFR 1910.1048) OSHA's airborne exposure limits (without use of a respirator) for formaldehyde shall not exceed 1) 0.75 part per million (ppm) as an 8-hour, the weighted average (TWA) or 2) 2 parts per million (ppm) as a 15 – minute, short term exposure limit (STEL). Note: The odor of formaldehyde in the air can generally be detected at about 0.5 to 0.8 ppm (range about 0.05 to 1 ppm).

- **Tolerance for Residues:**
  The tolerance established for the pioneer product applies to the generic product.
  A tolerance was not established for the pioneer product because the use of formalin has not been shown by studies to result in the accumulation of formaldehyde above naturally occurring levels in the edible tissue of any of these aquatic salmon, trout, catfish, largemouth bass, and shrimp. Because formalin treatment of this wide variety of aquatic species does not result in levels of formaldehyde in the edible tissue above the normal range of endogenous formaldehyde, formaldehyde is not expected to accumulate in additional finfish species which have not been specifically tested; therefore, the same applies to the generic product.

- **Withdrawal Times:**
  Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product (21 CFR 529.1030.

  A withdrawal time is not needed.

- **Regulatory Method for Residues:**
  Under NADA 140-989 a regulatory method for formalin was not required because the use did not result in the accumulation of formaldehyde above naturally occurring levels in edible tissues of any of these aquatic species; salmon, trout, catfish, largemouth bass, and shrimp. Therefore, formaldehyde is not expected to accumulate in additional finfish species which have not been tested.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that the product Formacide-B, when used under its proposed conditions of use, is safe and effective for its labeled indications.