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**FINDING OF NO SIGNIFICANT IMPACT
and
Environmental Assessments**

PARASITE-S for Use in Finfish, Finfish Eggs and Shrimp

NADA 140-989 C0018

**Western Chemical Inc.
Ferndale, WA**

FOR PUBLIC DISPLAY

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The Center for Veterinary Medicine has considered the potential environmental impact of this action and has concluded that this action will not have a significant impact on the quality of the human environment and that, therefore, an environmental impact statement will not be prepared.

Western Chemical Inc. has submitted a supplement to the approved new animal drug application for PARASITE-S (formalin, an aqueous formaldehyde solution). The supplement provides for the use of the product in all species of finfish and finfish eggs to treat protozoan, parasites and fungi. The product is currently approved in the treatment of specified species of finfish, finfish eggs and penaeid shrimp. The drug is administered as a bath at dosages up to 250 ppm for finfish, 100 ppm for penaeid shrimp and 2000 ppm for finfish eggs. In support of the application, Western Chemical Inc. has referenced an Environmental Assessment (EA) dated January 1995, that was prepared by the National Research Support Project No. 7.

The January 1995 EA provides information on the potential environmental effects from the use of the product in all species of finfish. An amendment to the EA, dated September 6, 1995, was prepared by the Environmental Staff of the Center for Veterinary Medicine to analyze the potential for environmental impacts from the use of formalin to treat fungus on the eggs of all species of finfish. The amendment also refers to the original July 29, 1981, EA for the use of formalin in specified finfish species. Copies of these three documents are attached.

The January 1995 EA requires additional clarification not provided in the September 6, 1995, amendment to the EA, as follows:

(1) The EAs and the amendment refer to the use of formalin on fish and fish eggs. The terms "fish" and "finfish" are normally considered synonymous but the labeling of the product and other components of the NADA contain the term "finfish," which is considered the more specific term.

(2) The January 1995 EA stipulates that the treatment water should be discharged in such a manner that the concentration in the mixing zone of the receiving water is no greater than 1.00 ppm to avoid damage to sensitive aquatic species. This stipulation is too restrictive because 1.00 ppm and greater levels of formalin can occur in the mixing zone of a stream for a short period without causing significant damage to sensitive aquatic species. Data in the EAs indicate that the most sensitive organisms tested were ostracods. The LC50 for these organisms is 1.15 ppm. However, this resulted from exposure to formalin for 24 hours. Exposure in a receiving stream are expected to be much more transient than 24 hours and are expected to be for no more than minutes (e.g., see Case Situation 1 in the January 1995 EA). Exposure to 1 ppm of formalin for several minutes is not expected to cause significant adverse effects.

Instead of stipulating a limitation on the concentration of formalin in the receiving water, the Center is requiring a 10-fold dilution of the finfish and penaeid shrimp treatment water, and 100-fold dilution of finfish egg treatment water. Dilution of the treatment water will result in a concentration of formalin at the point of introduction into the aquatic environment of no greater than 25 ppm. This concentration will further dilute in the receiving stream. These dilutions, the periodic use of the product and the rapid environmental degradation of formalin are expected to reduce the environmental concentration below a level that causes significant effects on aquatic organisms.

The January 1995 EA, the September 6, 1995, amendment to the EA and the July 29, 1981, EA provide adequate information to determine that the use of PARASITE-S, following the approved labeling, is not expected to cause a significant impact on the environment.

3/19/98
Date

Maureen Ann Nulle
for Director, Office of New Animal Drug Evaluation, HFV-100

Attachments: January 1995 EA, September 6, 1995 EA amendment and PARASITE-S labeling