



CVM Update

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REMINDER TO AQUACULTURE PRODUCERS ABOUT THE USE OF FORMALDEHYDE

FDA's Center for Veterinary Medicine (CVM) has received reports that some aquaculture producers are using chemical grade formaldehyde as a parasiticide drug for their fish. The use of the chemical grade product is not approved by CVM. Using a formaldehyde compound other than the approved product can be unsafe for fish and the effectiveness of an unapproved compound is questionable. CVM would like to remind aquaculture producers to read veterinary drug labels carefully and follow label directions to help avoid causing illegal residues in their products. There are three drug sponsors with approved new animal drug applications for formaldehyde including: Western Chemical, PARASITE-S (NADA 140-989), Argent Chemical Laboratories, Inc., Paracide-F (NADA 140-831), and Natchez Animal Supply Company, Formalin-F (NADA 137-687).

Parasite-S and Formalin-F are approved for the control of:

- external protozoa (*Chilodonella*, *Costia*, *Epistylis*, *Ichthyophthirius*, *Scyphidia*, and *Trichodina* spp.) and the monogenetic trematodes (*Cleidodiscus*, *Dactylogyrus*, and *Gyrodactylus* spp.) on all finfish,
- fungi of the family Saprolegniaceae on all finfish eggs, and
- protozoan parasites (*Bodo*, *Epistylis*, and *Zoothamnium* spp.) on penaeid shrimp.

Paracide-F is approved for the control of:

- external protozoa and monogenetic trematodes (as above) on salmon, trout, catfish, largemouth bass, and bluegill, and
- fungi (as above) on salmon, trout, and esocid eggs.

Paracide-F is not currently approved for use on penaeid shrimp.

The sponsors of the above drugs have approved applications filed with the Agency and have demonstrated that their products are safe and effective for the approved uses. Approved formaldehyde products are manufactured to strict good manufacturing practices (GMP) standard that ensures their quality, purity and strength. The specifications ensuring these attributes are tightly controlled. The standards by which approved formaldehyde and chemical grade formaldehyde is manufactured are different. Aquaculture producers are producing food for human consumption and should be mindful of these considerations. They should not use the chemical grade formaldehyde in place of these approved products.

Any questions about the use of formaldehyde in aquaculture may be directed to Fran Pell, Consumer Safety Officer, FDA/Center for Veterinary Medicine, Division of Compliance, 240-276-9211, e-mail frances.pell@fda.hhs.gov.

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