Finding of No Significant Impact (FONSI)
in support of an approval of an original new animal drug application (NADA)
for
AQUI-S® E10%
(eugenol immersion solution)
in
freshwater finfish
for
sedation to a handleable condition (field-use only)

AQUI-S New Zealand Ltd.

The Center for Veterinary Medicine (CVM) 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, therefore, an environmental impact statement will not be prepared.

AQUI-S New Zealand Ltd (AQUI-S NZ) is requesting the approval of an original new animal drug application (NADA) for the use of AQUI-S® E10% (eugenol immersion solution) for use in freshwater finfish for sedation to a handleable condition (field-use only). AQUI-S® E10% is administered via static immersion bath at a dose of 25 – 40 mg L^{-1} eugenol (salmonids) and 40 – 100 mg L^{-1} eugenol (non-salmonids) for a duration necessary to achieve sedation to a handleable condition.[1] The product will be dispensed over the counter. Field-use is the use of AQUI-S® E10% to sedate wild populations of freshwater finfish for resource management for spawning, tagging, weighing and measuring, and other activities.

In support of the application, AQUI-S NZ has provided an environmental assessment (EA) titled, "Environmental Assessment of AQUI-S® E10% (eugenol immersion solution) for Field-Use in Freshwater and Saltwater Finfish." The EA evaluates the currently proposed action – the original NADA in freshwater finfish. The EA also evaluates use in saltwater finfish, which is not part of the original NADA but may be pursued under future approval action. A copy of the EA can be found on the Food and Drug Administration's (FDA's) CVM website Animal Drugs at FDA under the Environmental Documents tab.[2] CVM provided guidance to and assisted AQUI-S NZ by outlining the types of environmental information required for inclusion in the EA. CVM independently evaluated the EA to ensure the scope and content were adequate and to ensure that the information presented in the EA was accurate. CVM determined that the EA provides sufficient evidence to support a finding of no significant impact (FONSI).

The EA evaluates the exposure and potential for environmental impacts arising from the use of AQUI-S® E10%. This evaluation consists of an exposure assessment, effects assessment, and risk characterization for the original NADA approval.

For the exposure assessment, predicted environmental concentrations of eugenol in surface water (PEC_{SW}) were conservatively estimated for multiple freshwater exposure scenarios, including use at streamside and lakeside sites, and use in electroshocking boats. The PEC_{SW} values were calculated using the maximum labeled dosage and waterbody-specific estimation methods. Dilution, dispersion, and sorption to organic solids were incorporated into the estimates, as appropriate.

[1] Under tested conditions, finfish were sedated to a handleable condition within minutes (mean approximately 1 – 3 minutes) when exposed to the low end of the dose range.
[2] https://animaldrugsatfda.fda.gov/adafda/views/#/environmentalAssessments

For streamside use, PEC_{SW} values were determined for a 2-hour period assuming dilution in a flowing water body based on a conservative (10^{th} percentile) streamflow value. In addition, dissipation via sorption to organic matter was incorporated based on eugenol's organic carbon normalized soil-water partition coefficient (K_{OC}). Streamside PEC_{SW} values ranged from 0.082 to 6.30 µg L^{-1} (median 1.80 µg L^{-1}). For lakeside and electroshocking boat exposure scenarios, PEC_{SW} values were determined for 24- and 48-hour periods, and dilution was estimated using a shear diffusion model incorporating horizontal and vertical dispersion in the waterbody. In addition, dissipation via sorption to organic matter was incorporated into the PEC_{SW} estimates for the lakeside exposure scenario (but not for the electroshocking boat exposure scenario). For the 24-hour exposure period, lakeside PEC_{SW} values ranged from 0.0006 to 5.11 µg L^{-1} (median 0.22 µg L^{-1}), and electroshocking boat PEC_{SW} values ranged from 0.0 to 10.5 µg L^{-1} (median 0.86 µg L^{-1}). All the estimated PEC_{SW} values are considered conservative estimates of exposure, as additional environmental processes that would serve to further dilute or disperse eugenol residues in surface waters (e.g., wave action, wind mixing) were not considered.

Based on the conditions of use for AQUI-S® E10%, the exposure pathways evaluated are expected to result in short duration (i.e., acute) exposure events for non-target aquatic organisms due to rapid dissipation in the water column after disposal of the sedative solution via mixing, dilution, dispersion, degradation, sorption, and transport of drug residues in surface waters. Therefore, the effects assessment evaluated the potential for acute effects of eugenol on non-target aquatic organisms including algae, invertebrates, and fish. The species resulting in the most sensitive acute effect was *Daphnia magna*, an aquatic invertebrate. The 24- and 48-hour median effect concentrations (EC_{50}) for immobilization in *D. magna* were identified as > 1.7 mg L^{-1} and 0.74 mg L^{-1}, respectively. Acute predicted no effect concentration (PNEC) values for *D. magna* were derived by dividing the EC_{50} values by an assessment factor (AF) of 100. According to CVM Guidance for Industry (GFI) # 166, the typical AF for an acute aquatic invertebrate study is 1,000. However, the AF was reduced by a factor of 10 because it was not necessary to account for extrapolation of acute to chronic effects, because chronic exposures are not expected to occur.

To characterize risk, the maximum PEC_{SW} values for each exposure scenario were compared with the acute PNEC value derived for *D. magna*. In this approach, risk quotients (RQs) for each exposure scenario were calculated as the ratio of the PEC_{SW} to the PNEC ($RQ = PEC_{SW} \div PNEC$). For all exposure scenarios, the RQ values were < 1, indicating that there is no expectation of significant environmental effects from the use of AQUI-S® E10%.

In addition, potential impacts to scavenger or predator species (i.e., carnivorous birds, fish, or mammals) that may consume wild fish or fish carcasses containing eugenol residues were assessed. This pathway is considered incidental and is expected to be infrequent and sporadic. To determine exposure concentrations in fish tissues, residue depletion studies in rainbow trout (*Oncorhynchus mykiss*) were used to characterize the maximum potential fish tissue concentration of eugenol, which was determined to be 77.3 mg kg^{-1}. To determine the potential effects in non-target scavenger or predator species, acute oral toxicity studies were consulted from the published literature, and the lowest no observed effect level (NOEL) of 200 mg kg^{-1} for dogs was selected for use in the risk analysis. The maximum eugenol concentration found in fish tissues (i.e., 77.3 mg kg^{-1}) was 2.5-times below the NOEL of 200 mg kg^{-1} for dogs. Thus, effects in non-target scavenger or predator species from consumption of fish containing eugenol residues are not expected.

Based on information in the EA, no significant environmental effects are expected from the use of AQUI-S® E10% (eugenol immersion solution) in freshwater finfish for sedation to a handleable condition (field-use only).

{see appended electronic signature page}

Matthew Lucia, DVM
Director
Office of New Animal Product Evaluation
Center for Veterinary Medicine
U.S. Food and Drug Administration

Electronic Signature
Addendum for Submission ID

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