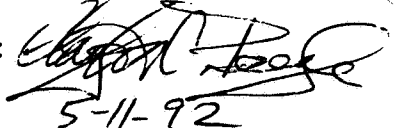


US EPA ARCHIVE DOCUMENT

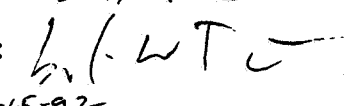
DATA EVALUATION REPORT

1. Chemical: *Bacillus thuringiensis* subsp. *aizawai* (ABG-6305)
2. Test Material: Technical, primary powder
3. Study/Action Type: 154A-19. Freshwater fish toxicity and pathogenicity testing: Tier I.
4. Study Identification: Boeri, R. L. 1991. Acute toxicity of ABG-6305 to the rainbow trout (*Oncorhynchus mykiss*). EnviroSystems Division, Resource Analysts, Inc. Laboratory Project ID # 9107-A. Submitted by Abbott Laboratories. North Chicago, IL. EPA Access.No. 419748-03.

5. Reviewed By: Clayton C. Beegle  
Entomologist  
EFED/EEB

Signature:   
Date: 5-11-92

Les W. Touart  
Head, Section 1  
EFED/EEB

Signature:   
Date: 7-15-92

6. Conclusions: This study provides scientifically valid information and demonstrates an  $LC_{50} > 100$  mg/l for the 96 hr test period. However, because ABG-6305 contains living spores, a valid 30 day toxicity and pathogenicity test is required for microbial pest control agent registration [Section (b)(6) 154A-19 Subdivision M]. This 96 hr acute toxicity test provides supplemental information.
7. Recommendations: EEB recommends that a 30 day toxicity and pathogenicity test be conducted as per Section 154A-19 of Subdivision M.
8. Background: This study was submitted to support the request for the registration of the Abbott Laboratories *B. thuringiensis* subsp. *aizawai* product Centari.
9. Materials and Methods:

A. Test organisms: Rainbow trout, *Oncorhynchus mykiss*.

Age/stage of maturity: Juvenile.

Sex: ♂ and ♀.

Source: Aquatic Research Organisms, Resource Analysts, Inc., Hampton, New Hampshire 03842.

B. Dosage Form:

Solvents/vehicles: Dilution water.

Route of administration: In suspension.

C. Referenced Protocol:

Test levels: Nominal concentrations of 0 (control) and 100 mg/l ABG-6305. Based on a technical material spore count of  $2 \times 10^{11}$  spores/g the nominal spore count was  $2 \times 10^7$  spores/ml. The measured spore count was  $6.1 \times 10^6$  spores/ml for new suspensions and  $6.6 \times 10^6$  spores/ml for old suspensions. The grand mean for all suspensions was  $6.3 \times 10^6$  spores/ml. This indicates that ABG-6305 spore-crystal complex did not settle out during the 96 hr test.

Dose spacing factor: NA.

Number per level: 10/replicate, 3 replicates/treatment.

Holding/acclimation: 16 days.

Pen/cage facilities: All glass aquaria, 20 cm wide X 40 cm long X 25 cm high (19.6 l), containing 15 l solution (depth about 18 cm).

Feeding: Commercial fish food (EnviroSystems lot # TM02), fed once or twice daily before commencement of test.

Physical condition: Apparently free of disease, injuries, and abnormalities at the beginning of the test. Not treated for disease.

Test conditions:

Temperature: Target  $12 \pm 1^\circ\text{C}$ , actual 12.2 ave. 11.4-12.7 °C range.

Dissolved oxygen: Mean 9.8 mg/l, range 9.1-11.0. Approximately 90% saturation.

pH: 6.8-7.6.

Hardness: 44-48 mg/l as  $\text{CaCO}_3$ .

Conductivity: 600 umhos/cm.

Source of dilution water: Filtered well.

Static/renewal/flow-through: Static, renewed daily during the 96 hr test.

Loading: 0.37 g/l.

Aeration: No.

Photoperiod: 16L:8D. Cool-white fluorescent with  $14 \text{ uEs}^{-1} \text{ m}^{-2}$  intensity.

Controls: Dilution water controls, three replicates of ten each.

Observation period: Initially and at 24 hr intervals to 96 hrs.

Statistical methods: No analysis needed as there were no mortality or sublethal effects observed.

10. Reported Results: There were no mortalities or sublethal effects observed at either 0 (control) or 100 mg/l ABG-6305.

11. Study Author's Conclusions/Quality Assurance Measures: "ABG-6305 was not toxic to rainbow trout at the tested concentration. The 24, 48, 72, and 96 hour LC<sub>50</sub>s are greater than 100 mg/l ABG-6305 and the 96 hour no observed effect concentration is 100 mg/l. No mortality or sublethal effects were observed in any test vessel during the 96 hour exposure."

"This study meets requirements of 40 CFR part 160. Data presented in this report were derived by methods and with materials identified in the section of the report entitled "Methods and Materials." The test was performed in accordance with EnviroSystems Protocol 9107-A and the Product Registration Aquatic Toxicology Laboratory Standard Operating Procedures Manual." Signed by Stephanie Beck, Quality Assurance Representative, on 4-4-91.

12. Reviewer's Discussion and Interpretation of:

A. Test Procedures: The procedures used do not follow fully those recommended by EPA in the 1989 Pesticide Testing Guidelines for Microbial and Biochemical Pest Control Agents, Subdivision M. The test was conducted for 96 hrs, as if it were a chemical insecticide, rather than for 30 days, which is required for microbial pest control agents.

B. Statistical Analysis: No analysis needed as there were no mortality or sublethal effects observed.

C. Discussion/Results: An LC<sub>50</sub> >100 mg/l indicates that ABG-6305 is practically nontoxic to rainbow trout over the 96 hr test period.

D. Adequacy of the Study:

1. Validation Category: Supplemental.

2. Rationale: This study does not meet EPA Guideline requirements for microbial pest control agents as it was conducted for 96 hrs instead of the required 30 days. The 96 hr test period is satisfactory when evaluating chemical insecticides as they are solely toxic in action. A 30 day fish toxicity and pathogenicity test is required for microbial pest control agents since they have the potential to infect and cause disease in nontarget organisms.