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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAR 27 2003

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT:	DDAC/BARDAC® 22C50 Review of Ecological Effects a	nd Environmental Fate
	Data Submitted in Support of Registration (D288345)	069149/069208

- TO: Dennis Edwards, Branch Chief Marshall Swindell, PM-33 Portia Jenkins, PMT-33 Regulatory Management Branch I Antimicrobials Division (7510C)
- FROM: Kathryn V. Montague, Biologist Risk Assessment and Science Support Branch Antimicrobials Division (7510C)

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THRU: Nader Elkassabany, Acting Team Leader $N \in 3/24/03$ Risk Assessment and Science Support Branch Antimicrobials Division (7510C)

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Norm Cook, Branch Chief *Wmwr* Risk Assessment and Science Support Branch Antimicrobials Division (7510C)

Lonza, Inc., has submitted several ecological effects and environmental fate studies in support of the registration of BARDAC® 22C50 (formulated product containing didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate) for wood preservation. These studies were conducted using standard or radiolabeled technical grade didecyl dimethyl ammonium chloride (DDAC), which is acceptable as a surrogate chemical for BARDAC® 22C50. The results of the submitted studies are summarized below:

Chronic Toxicity of Sediment-Incorporated Didecyldimethylammonium Chloride (DDAC) to *Chironomas tentans*. (Submitted to fulfill Guideline 850.1735, Acute Sediment Toxicity to



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Freshwater Invertebrates) (MRID #458217-01): This study was a 28-day chronic toxicity study, submitted to fulfill acute sediment toxicity Guideline requirements. An acute sediment toxicity study would provide endpoints for 10 days of exposure; the submitted study provides endpoints for days 14 and 28 of exposure. The study does not meet Guideline requirements and is classified as "supplemental," since it does not address the 10-day acute toxicity of the treated sediment, and also because water quality parameters were extremely variable throughout the testing period. This variability is likely due to the study being conducted as a static test, and not flow-through or renewal as recommended in the Guidelines. Additionally, second-instar larvae were used in the test, instead of the recommended newly-hatched (first instar) larvae, which could have affected the emergence time. The Day 14 endpoints provided in the study (LC50 > 1000 mg ai/kg dry sediment and NOEC of 530 mg ai/kg dry sediment) can be used in a preliminary risk assessment, but an acute freshwater sediment toxicity study must be submitted in order to fulfill Guideline requirements for registration.

Intermittent Flow-Through Reproduction Test with Didecyldimethylammonium chloride and Daphnia magna. (Guideline 850.1300/old 72-4b) (MRID #458217-02): The study is invalid because there is no mention of whether observations for ephippia were made. The presence of ephippia invalidates the study due to the ability of the ephippia to withstand adverse conditions, such as exposure to toxic chemicals. If sufficient information can be provided as to whether observations for ephippia were made and none were found, the study can be upgraded, but would only be "supplemental" because no observations of growth were made. The study needs to be repeated to fulfill Guideline requirements.

Bioconcentration and Elimination of ¹⁴C-Residues by Bluegill (*Lepomis macrochirus*) Exposed to Didecyldimethylammonium Chloride (DDAC). (Guideline 850.1730/old 165-4) (MRID #458341-01): The study fulfills Guideline requirements. The BCF was 52X in edible tissues, and 160X in non-edible tissues, indicating that DDAC does not significantly bioaccumulate in fish tissue.

Aerobic Aquatic Metabolism of ¹⁴C-Didecyl dimethyl ammonium chloride (¹⁴C-DDAC). (Guideline 835.4300/old 162-4). (MRID #422538-03): The study fulfills Guideline requirements, provided the registrant submits data demonstrating that aerobic conditions were achieved and maintained. The aerobic half-lives determined were 180 days in water, 22,706 days (62.2 years) in sediment, and 8,366 days (22.9 years) in the entire system. No major transformation products were formed.

Anaerobic Aquatic Metabolism of ¹⁴C-Didecyl dimethyl ammonium chloride (¹⁴C-DDAC). (Guideline 835.4400/old 162-3). (MRID #422538-02): The study fulfills Guideline requirements, provided the registrant submits information describing how the anaerobic conditions were assured and maintained. The anaerobic half-lives determined were 261 days in water, 4,594 days (12.5 years) in sediment, and 6217 days (17 years) for the entire system. No major transformation products were formed.

Aerobic Soil Metabolism of ¹⁴C-Didecyl dimethyl ammonium chloride (¹⁴C-DDAC). (Guideline 835.4100/old 162-1) (MRID # 422538-01): The study fulfills Guideline requirements, provided the registrant submits additional data demonstrating that aerobic conditions were maintained throughout the experiment. Under the conditions tested, the half-life of the compound in sandy loam soil was determined to be 1048 days (about 3 years). No major transformation products were formed.

The following ecological effects and environmental fate data requirements are still **outstanding** for the wood preservative use of BARDAC® 22C50:

850.1300 (old 72-4a) Fish Early Life-stage with a Freshwater species
850.1400 (old 72-4b) Aquatic Invertebrate Life-cycle with Freshwater species
850.1735 Whole Sediment Acute Toxicity to Freshwater Invertebrates
850.3020 (old 141-1): Honeybee Acute Contact LD50
850.4225 (old 123-1) Seedling Emergence Dose-Response in Rice (*Oryza sativa*)
850.4250 (old 123-1) Vegetative Vigor Dose-Response in Rice (*Oryza sativa*)
850.4400 (old 123-2) Vascular aquatic plant toxicity dose-response
850.5400 (old 123-2) Algal toxicity dose-response using 4 species
(no Guideline #) Acute Pore Water Toxicity to Invertebrates
835.4200 (old 162-2) Anaerobic Soil Metabolism
835.1240 (old 162-3) Soil Column leaching

The following ecological effects and environmental fate data requirements are **reserved** for the wood preservative use of BARDAC® 22C50, and may be required, pending evaluation of lowertier ecological effects or environmental fate information: 850.1500 (old 72-5) Fish Life-cycle testing 850.1950 (old 72-7) Field Testing for Aquatic Organisms 850.2300 (old 71-4) Avian Reproduction Testing 840.1100 Aquatic field study 850.1710 (old 72-6) Oyster bioaccumulation factor test 850.1850 (old 72-6) Aquatic food chain transfer test

If you have any questions on the above, please contact Kathryn Montague (703-305-1243).