US ERA ARCHIVE DOCUMENT

FEE - 5 2004

Mr. Eliot Harrison Consultant for Lonza, Inc. 122 C Street, NW Ste. 740 Washington, DC 20001

Subject:

Bardac 22C50

EPA Registration No. 6838-236

Dear Mr. Harrison,

The Agency has completed a review of the seven ecological effects protocols that were submitted as a condition of registration for Bardac 22C50 and Carboquat. We have also completed a review of your request to reconsider the need for a soil column leaching study, and we also reviewed the additional information submitted to upgrade the aquatic invertebrate life cycle study.

General Comments

The use of 10% HCl instead of the test solution to precondition the test apparatuses due to the tendency of the test solution to bind to the apparatus is acceptable. However, all negative and control apparatus must be treated in the same manner as the test apparatus. We request additional information regarding the binding tendency of Carboquat to the apparatus along with any comparative analytical data verifying the effectiveness of the HCl preconditioning in preventing subsequent binding of Carboquat to the apparatus.

Guideline OPPTS 850.5400: 96-Hour Toxicity Test with Freshwater Alga, Anabbaena flosaquae, freshwater diatom, Navicula pelliculosa, and marine diatom, Sleletonema costatum

The Agency concurs with the 96-hour toxicity test protocol with freshwater alga, Anabbaena flos-aquae, the freshwater diatom, Navicula pelliculosa, and the marine diatom, Sleletonema costatum. In regard to the routine studies with ZnCl being conducted to ensure algal cell fitness, you should note that a solvent control must be used in addition to the negative control in any study in which a solvent is used.

Guideline 850.4400: 7-Day Toxicity Test with Duckweed, Lemna gibba

The Agency concurs with the proposed protocol for the 7-day toxicity test with

Duckweed (Lemna gibba). As stated above, you must use a solvent control in addition to the

negative control in any study with a solvent:

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Guideline OPPTS 850.4225 and 850.4250 (OECD 208/227): Toxicity Test to determine the effects on seedling emergency, growth, and vegetative vigor on rice, *Oryza sativa*

The Agency accepts the protocol for the Seedling Emergency, Growth, and Vegetative Vigor in Rice, *Oryza sativa*.

Guideline OPPTS 850.1735 and ASTM E 1706-00: Survival and Growth Acute Toxicity Test with *Chironomus tentans* using spiked sediment

In regard to the Freshwater Sediment Toxicity with *Chironomus tentans*, the Agency concurs with the protocol. In regard to the aging of organisms at test initiation (3rd instar) to be determined based on the time from hatching (10 days), you must note that OPPTS Guidelines require measurement of the head capsule width in midges to confirm the instar stage. If this cannot be performed, you must submit a justification.

Guideline OPPTS 850.1735 and ASTM E 1367-99: 10-Day Sediment Toxicity with Leptocheirus plumulos using sediment spiked with Bardac 22C50

The Marine-Estuarine Sediment Toxicity with *Leptocheirus plumulos* protocol is acceptable provided that salinity of the pore water is measured prior to test initiation, and it must be between 2 and 34 parts per thousand. The ammonium and pH content of the pore water does not have to be measured; however, these and other water quality parameters should be measured in overlying water at test initiation and termination.

Guideline OPPTS 850.1400; OECD 210: Early Life Stage Toxicity with Fathead minnow, *Pimephales promelas*

The Agency accepts the Fish Early Life-Stage toxicity with Pathead minnow, Pimephales . promelas.

'Guideline OPPTS 850.3020; OECD 214: Acute Contact Toxicity Study with Honeybee

In regard to the Honeybee acute contact protocol, the Agency is concerned with corrosive nature of the test chemical that would preclude any meaningful results. Therefore, you will not have to address this data requirement as a condition of registration. However, additional testing to address these concerns may be required in the future.

Guideline OPPTS 835.1240: Soil Column Leaching

In addition to the protocols being reviewed, the requirement of a soil column leaching study was reconsidered based on the acceptable adsorption/desorption study, MRID Nos. 413853-01 and 930040-14, that showed that the compound binds extremely tightly to soil and would not leach into groundwater or runoff into surface water. The justification is acceptable

And the soil column leaching requirement is WEDNEURRENCES

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Guideline OPPTS 850.1300: Daphnid Reproduction Test

The addendum to MRID No. 458217-02 confirmed that observations for ephippia were made, and no epphippia were observed, yet the conducted study did not include observations for growth. While growth is not a required endpoint in the OECD Guideline for a daphnid reproduction study, it is required in OPPTS Guideline 850.1300 and is an important endpoint in Agency risk assessments. Growth is often the more sensitive endpoint than the reproduction and survival parameters evaluated in the study. Therefore, a new aquatic invertebrate life-cycle study which evaluates the growth as well as survival and reproduction is required to support the proposed uses of this chemical. The submitted study is upgraded to "supplemental."

A copy of our review is enclosed. Please refer to it for additional details regarding our review of your proposals. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

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