UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 3 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Pseudomonas fluorescens (EG-1053). Ecogen, Inc. Product Chemistry Data Clarification for Dagger™ G Biofungicide (I.D. No. 55638-5; MRID No. 40510701; Record Nos. 217875 and 218198; RCB Nos. 3554 and 3612)

FROM: William J. Hazel, Ph.D., Chemist
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TO: Lois Rossi (PM-21)
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THRU: Charles L. Trichilo, Ph.D., Chief
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Introduction

Ecogen, Inc., in a 3/15/88 letter to Lois Rossi, has submitted information clarifying product chemistry data submitted under PP#8F3579 on Pseudomonas fluorescens EG-1053 (Dagger™ G Biofungicide) reviewed by W.J. Hazel in a memorandum from C.L. Trichilo to A. Rispin and L. Rossi dated 2/19/88. This clarifying information (not critical for registration) was requested by W. Hazel via telephone on 2/12/88 due to the expedited nature of the subject registration. Also, dated 12/10/87 and received by the Agency 2/10/88, is supplemental product chemistry information (MRID 40510701); this package duplicates data received 12/15/87 but not entered into PDMS. An exemption from the requirement of a tolerance was established (40 CFR 180.1088) for Pseudomonas fluorescens EG-1053 in or on cottonseed and cotton forage [FR 53(47):7739]. Conditional registration was granted for Ecogen's granular product (EPA Reg. No. 55638-5) contingent upon submission of data further characterizing the organism down to the biovar level and a growth curve to establish an upper temperature limit for growth. Also, as required in the 2/19/88 RCB review, five commercial batches of the end-use product (EP) must be analyzed for the ai, P. fluorescens EG-1053, and an upper temperature limit for storage, if applicable, should be specified on product labels. The subject Ecogen submissions are not intended to fulfill the deficiencies associated with either the conditional registration or the 2/19/88 RCB review.

Discussion of the Data

151-20. Product Identity.

In their original submission (MRID 40384801; 2/19/88 RCB review), Ecogen stated that their strain of P. fluorescens, EG-1053, had been designated as NRRL B-15965 in the

Northern Regional Research Laboratories culture collection. In their 3/15/88 letter, Ecogen stated that NRRL B-15965 was weakly hemolytic whereas EG-1053, recently assigned entry number NRRL B-18338, was not hemolytic. Also, colonies of NRRL B-18338 are slightly less mucoid than those of NRRL B-15965. Ecogen stated that all field trials and registration studies had been conducted using EG-1053 (NRRL B-18338). In a telephone conversation with W.J. Hazel on 4/22/88, Robert R. Stewart of Ecogen, Inc. stated that Allied Chemical Co. had submitted NRRL B-15965 to the culture collection. Dr. Stewart assured the reviewer that any changes in hemolytic activity or colony morphology had occurred prior to the conduct of testing and that Ecogen would certify this in writing. Joe Lepo (Ecogen microbiologist), in a 4/25/88 telephone conversation with W. Hazel, verified Dr. Stewart's statements and, further, said that, in his hands, EG-1053 had never been hemolytic.

RCB accepts the explanation of the seemingly conflicting culture collection codes provided that written certification is forthcoming.

151-26. Physical and Chemical Properties.

In their 3/15/88 letter, Ecogen stated that the pH of the manufacturing-use product (MP) is 6.5-7.1 and the pH of the EP is 7.2-7.8. The bulk density of the EP is stated as being 30 lb/ft^3. An additional storage stability data point, 5.2×10^6 CFU/g EP at 3 months (sample 2), was provided; this represents a loss of 60% viability compared to the 0-day value.

The submitted data regarding pH and bulk density are adequate to clarify conflicting data originally submitted. Note, however, that density/bulk density data are not currently required for EPs and that pH is not a current requirement in Subdivision M (although the revised guidelines, in press, do require pH and density/bulk density for all registered products). The additional storage stability data point indicates a somewhat higher degree of stability (or evidence of some bacterial growth) than previously indicated.

Conclusions

The submitted data adequately clarify those questions asked of Ecogen during the 2/12/88 telephone conversation. We await the data required in the 2/19/88 RCB review and those data required as a condition of registration [FR 53(47):7739]. In accordance with a recent Agency policy [PR Notice 87-7 (6/3/87)] which requires the registration of all pesticide products transferred between the EP registrant and/or its contractors, we now assess one additional requirement. This requirement applies to Ecogen's currently unregistered MP because it is manufactured by one contractor and formulated into an EP by another contractor. As stated in the 2/12/88 RCB review of PP#8F3579, we will entertain a request for waiver of product chemistry data requirements for the MP due to the manufacturing process and the indigenous, non-engineered nature of the pesticide. Such waiver requests should accompany the MP registration application. Now that the MP must be registered, however, the following necessary exceptions to the waiver exist: (i) an MP label ingredient statement in terms of CFU/ml and on a wt/wt basis and (ii) a Confidential Statement of Formula on EPA Form 8570-4 providing the ai (CFU/ml and wt/wt) and each intentionally-added inert, their sources, their purposes, and their upper and lower limits.

cc: Roy Sjoblad (TOX), EEB, EAB, PMSD/ISB, SF (Pseudomonas spp.), RF, PP#8F3579, W. Hazel, circulate (7)

TS-769C:CM#2:RCB:Rm.810:557-7484:W.Hazel:4/27/88:W.Boodee:4/27/88:R.Schmitt:6/3/88