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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: SACB review of acute toxicity/pathogenicity studies submitted by Ecogen, Inc. to upgrade earlier acute studies, and to provide additional data to support the registration of Foil OF Insecticide (EPA ID No. 55638-RN; Record No. 256,400; MRID Nos. 413086-1, -2, -3, -4, -5, -6, -7; HED Project No. 0-0344; Tox. Chem No. 66).

TO: Mike Mendelsohn/Phil Hutton (PM-17)
Insecticide/Rodenticide Branch
Registration Division (H7505C)

FROM: Roy D. Sjoblad, Ph.D., Microbiologist
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THROUGH: Reto Engler, Ph.D., Chief
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Background: On July 27, 1989 (Memorandum from W. Hazel and R. Sjoblad to P. Hutton/M. Mendelsohn) SACB reviewed Product identity/Residue chemistry data and Mammalian toxicity/pathogenicity studies submitted by Ecogen, Inc. to support the registration of Foil OF (active ingredient: Bacillus thuringiensis transconjugant strain EG2424). Ecogen has now submitted studies to either upgrade deficiencies in the prior mammalian studies, or to provide additional data to support registration of the end-use formulation. The following studies have been amended and resubmitted: acute oral and acute intravenous toxicity/pathogenicity studies in the rat. The following new studies have been submitted: acute pulmonary toxicity/pathogenicity study in mice; acute intraperitoneal study in mice with technical grade powder; acute oral and acute dermal toxicity studies with the formulated product; and, an acute pulmonary toxicity study with the oil flowable vehicle.

SACB Conclusions: All submitted studies either were Acceptable or were adequate to upgrade earlier studies. An Acceptable and complete Mammalian Toxicology data base exists for the TGAI and for the Foil OF end-use product.

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