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

55638-10

JAN 17 1991

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: SACB Review of Data submitted by Ecogen Inc. on Viable Spore Count and Total Count of Five Production Batches of Condor®, Cutlass®, and Foil® (ID No. 055638-00008; Submission S386459; Tox Chem. No. 66G; MRID No. 416371-01; HED Project No. 1-0199).

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

FROM: Roy D. Sjoblad, Ph.D., Microbiologist
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

THROUGH: Reto Engler, Ph.D., Chief
SACB, HED (H7509C)

Study and Data/Information Submitted: "Condor®, Cutlass®, and Foil®: Viable Spore Count and Total Count of Five Production Batches." by H.J. Dicker of Ecogen, Inc., September 18, 1990; Report No. 90-03.

Total viable cell counts were determined by dilution of five different production batches of technical grade material in phosphate buffer and subsequent plating of diluted materials by mixing with molten agar (47-52°C) in Petri dishes. For the total spore count, dilutions of the test substances were heated to 65°C for 30 minutes prior to pour plating. Duplicate dilution series were prepared for each sample. The results were as follows:

Sample	CFU/g technical powder for:	
	Total Count	Spore Count
Condor	4.2x10 ¹⁰	2.0x10 ¹⁰
	3.2x10 ¹⁰	1.0x10 ¹⁰
	3.8x10 ¹⁰	1.5x10 ¹⁰
	1.3x10 ¹¹	9.4x10 ¹⁰
	1.2x10 ¹¹	8.3x10 ¹⁰
Cutlass	8.2x10 ¹⁰	6.6x10 ¹⁰
	2.9x10 ¹⁰	2.3x10 ¹⁰
	1.4x10 ¹¹	1.3x10 ¹¹
	1.5x10 ¹¹	2.6x10 ¹¹
	3.6x10 ¹⁰	4.2x10 ¹⁰
Foil	1.5x10 ¹¹	1.8x10 ¹¹
	1.4x10 ¹¹	1.3x10 ¹¹
	1.5x10 ¹¹	1.3x10 ¹¹
	1.3x10 ¹¹	7.6x10 ¹⁰
	1.3x10 ¹¹	9.4x10 ¹⁰



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MEMORANDUM

SUBJECT: SACB Review of One-year Storage Stability Study for Condor®, Cutlass®, and Foil® Technical Powders and Formulated Products (ID No. 055638-00008; Submission S386451; MRID No. 416372-01; Tox Chem No. 66G; HED Project No. 1-0200).

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

FROM: Roy D. Sjoblad, Ph.D., Microbiologist
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

THROUGH: Reto Engler, Ph.D., Chief
SACB, HED (H7509C)

Study and Data/Information Submitted: "One Year Storage Stability of Condor®, Cutlass®, and Foil® Technical Powders and Formulated Products"; by G.L. Cuffari, T.B. Johnson, R.G. Groat of Ecogen, Inc., September 17, 1990, Study No. 90-02.

Samples of Condor (EG 2348; Oil Flowable Bioinsecticide, Lot # 179-34; and, Technical Powder, Lot # PP0003) and Cutlass (EG 2371; Oil Flowable Insecticide, Lot # 179-66; and, Wettable Powder Bioinsecticide, Lot # 159-49; and, Technical Powder, Lot # PP0010), and Foil (EG 2424; Oil Flowable Bioinsecticide, Lot # 179-40; and, Technical Powder, Lot # PP0009) were analyzed after one year storage for 1) Percent toxin protein (via discontinuous SDS-PAGE and densitometric scanning), 2) Insecticidal activity (against Lymantria dispar for Condor, Spodoptera exigua for Cutlass, and Leptinotarsa decemlineata for Foil), and 3) Presence of Beta-exotoxin (HPLC). Samples had been stored at room temperature (approx. 25°C) and formulated products were also stored in original containers.

Beta-exotoxin was not detectable (i.e., was below the limit of detection) in any of the samples after at least one year storage.

The limits of detection were 50 ppm for Cutlass Technical; 100 ppm for Condor technical and Foil Technical; 200 ppm for Cutlass Wettable Powder and Condor Oil Flowable; and, 300 ppm for Foil Oil Flowable, and Cutlass Oil Flowable.

The results for the percent active protein were as follows. The data are summarized from the report and give the average % value for six replicates, and also the range of % values for the six replicates. The P2 toxin % is applicable to the Condor and Cutlass

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test materials, and the CryC % was measured in the Foil products.

Test material	Time of Storage (Mos.)	Mean (%) and range (%) of protein toxin:		Stability*
		P1	P2/CryC	
Condor Tech.	0	23.5 (17.9-26.6)	2.9 (2.5-3.4)	
	16	22.7 (19.2-26.7)	3.0 (2.3-3.5)	NC
Condor OF	0	6.1 (4.3-7.9) ^a	0.6 (0.6-0.6)	
	15.5	5.0 (4.3-5.5)	0.7 (0.5-0.8)	NC
Cutlass Tech.	0	17.1 (15.8-19.1)	2.6 (2.4-2.8)	
	16.5	20.9 (16.4-25.4) ^b	3.1 (2.8-3.3) ^b	>
Cutlass OF	0	4.9 (4.0-6.1) ^b	0.8 (0.6-1.1) ^b	
	11	8.3 (7.6-9.2)	1.2 (1.0-1.4)	>
Cutlass WP	0	10.1 (9.0-11.3)	1.8 (1.6-2.3)	
	12	11.8 (7.1-14.0) ^b	2.1 (1.9-2.5) ^b	NC
Foil Tech.	0	17.2 (16.5-17.9)	7.4 (7.1-8.5)	
	15	11.3 (9.8-13.4)	6.2 (5.3-7.0)	<
Foil OF	0	3.2 (3.1, 3.3) ^c	1.5 (1.4, 1.5) ^c	
	14	3.2 (2.8-3.6)	1.7 (1.5-2.0)	NC

^a Data from 3 replicate samples.

^b Data from 4 replicate samples.

^c Data from 2 replicate samples.

* < = Decrease, > = Increase, and NC = No apparent change in activity.

The bioassay results were summarized as follows:

Test material	Time of storage (Mos.)	LC50 values (and 95% C.I.); ug sample/ml diet	Stability*
Condor Tech.	0	0.51 (0.44-0.58)	
	16.5	0.37 (0.32-0.43)	>
Condor OF	0	2.52 (2.2-2.9)	
	16.5	1.38 (1.0-1.9)	>
Cutlass Tech.	0	48 (33-68)	
	8	44 (38-51)	NC
Cutlass WP	0	86 (73-101)	
	8	108 (73-157)	<
Cutlass OF	0	164 (115-235)	
	7	304 (217-405)	<
Foil Tech.	0	240 (182-309)	
	7	397 (301-510)	<
Foil OF	0	4104 (3207-5107)	
	8	3162 (2350-4169)	>

* < = Decrease, > = Increase, and NC = No apparent change in activity.

SACB Discussion: Except for the Foil Technical material, there was no readily apparent loss of activity after the indicated storage times when stability was based on a percent active toxin measurement. The Foil Technical material also showed a decrease in activity in the bioassay analysis. In addition, the insect bioassay data showed an apparent decrease in biological activity of the Cutlass OF and WP products. No beta-exotoxin was detected in any of the test material samples.