US EPA ARCHIVE DOCUMENT

DATA EVALUATION REPORT

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STUDY TYPE:	Intraperitoneal Safety Test-Mice
MRID NO:	418266-08
CASWELL NO:	066
TEST MATERIAL:	Bacillus thuringiensis
SYNONYMS:	BMP 123 - Technical Powder
PROJECT NO:	S3101
SPONSOR:	Becker Microbial Products, Inc.
TESTING FACILITY:	Cosmopolitan Safety Evaluation, Inc., Branchville, N.J.
TITLE OF REPORT:	Intraperitoneal Safety Test in Mice.
AUTHOR(S):	Geoffrey Robbins, M.R.C.V.S., Dip. ABT
STUDY COMPLETED:	20 January 1991
CONCLUSION:	A 10% mortality rate was found in animals dosed with 10^8 spores of BMP 123- Technical Powder.
CLASSIFICATION:	ACCEPTABLE

I. STUDY DESIGN

Test Material: The microbial pest control agent (MPCA) is BMP - Technical Powder. The concentration was determined to be 25 x 10^9 spores/gram by the supplier. Each mouse recieved a dose of either 10^6, 10^7 or 10^8 spores in a 1 ml intraperitoneal dose.

Test Animals: Fifteen male and fifteen female young adult Swiss-Webster albino mice were obtained from Camm Research Lab Animals, Wayne, New Jersey. The male mice weighed between 18.5 and 22.2 grams and the female mice weight ranged from 18.5 to 19.4 grams at the beginning of the study.

Methods: Five animals of each sex were dosed with either 10^6, 10^7, or 10^8 Bacillus thuringiensis spores by intraperitoneal injection. The animals were weighed prior to treatment and on day 7. Clinical signs were noted at 1, 3 and 5 hours post dosing and daily thereafter. A gross necropsy was conducted on the animals that died during the study.

II. RESULTS

A. Body Weights:

As the B. thuringiensis dosage increased, the mouse body weight gains decreased.

B. Clinical Observations:

10^6 spores:	No clinical observations noted.
10^7 spores:	No clinical observations noted.
10^8 spores:	One male and one female displayed signs of decreased locomotor activity 5 hours post dosing. Four males and one female exhibited decreased locomotor activity on day 2. One male was found dead day 3.

C. Necropsy Observations:

One male mouse exhibited signs of autolysis upon necropsy.

III. SACB DISCUSSION:

A distinct correlation in body weight gains and doseage was established. Overall, a 10% mortality rate was found in animals treated with 10^8 spores of *Bacillus thuringiensis.*