

---

**DATA EVALUATION REPORT**

Reviewed by: Cindy Schaffer, Microbiologist, SACB/HED  
Secondary Reviewer: John Kough, Ph.D., Biologist, SACB/HED

---

STUDY TYPE: Intraperitoneal Safety Test-Mice  
MRID NO: 418266-09  
CASWELL NO: 066  
TEST MATERIAL: Bacillus thuringiensis  
SYNONYMS: BMP 123 - Technical Powder liquid concentrate  
PROJECT NO: S3102  
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: An 80% mortality rate was found in animals  
dosed with  $10^8$  spores of BMP 123 - Technical  
Powder liquid concentrate.  
CLASSIFICATION: ACCEPTABLE

---

**I. STUDY DESIGN**

Test Material: The microbial pest control agent (MPCA) is BMP - liquid concentrate. The concentration was determined to be  $2 \times 10^9$  spores/gram by the supplier. Each mouse received 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 20.4 and 22.6 grams and the female mice weight ranged from 18.4 to 20.2 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:**

No abnormalities in body weight or body weight gains were noted in the lower dosed ( $10^6$  and  $10^7$ ) animals. At a dose range of  $10^8$ , body weights could not be evaluated due to the high death rate.

2401

B. Clinical Observations:

$10^6$  spores: No clinical observations noted.

$10^7$  spores: No clinical observations noted.

$10^8$  spores: Following a period of decreased locomotor activity and prostration, which began at 5 hours post dosing, four female and four male mice died by day 3.

C. Necropsy Observations:

One male and one female mouse exhibited signs of autolysis upon necropsy.

III. SACB DISCUSSION:

Overall, an 80% mortality rate was found in animals treated with  $10^8$  spores of Bacillus thuringiensis.

2