

DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

BARIUM METABORATE

Chemical Code # 000973, Tolerance # 50431
SB 950 # 523

December 14, 1998

I. DATA GAP STATUS

Chronic toxicity, rat:	Data gap, no study on file
Subchronic, rat	No data gap, possible adverse effect
Chronic toxicity, dog:	Data gap, no study on file
Oncogenicity, rat:	Data gap, no study on file
Oncogenicity, mouse:	Data gap, no study on file
Reproduction, rat:	Data gap, no study on file
Teratology, rat:	Data gap, no study on file
Teratology, rabbit:	No data gap, no adverse effects
Gene mutation:	No data gap, no adverse effect
Chromosome effects:	No data gap, no adverse effect
DNA damage:	Data gap, no study on file
Neurotoxicity:	No data gap, no adverse effects (see rat subchronic)

Toxicology one-liners are attached.

All record numbers through 131023 were examined.

** indicates an acceptable study.

Bold face indicates a possible adverse effect.

File name: T981214

Prepared by Kishiyama, Green and Gee, December 14, 1998

Busan 11-M1 with which the some studies were conducted is 90+% barium metaborate

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may contain additional effects.

A Reregistration Eligibility Document (RED): Barium Metaborate, by U. S EPA is dated December, 1993. Because it is registered as an indoor, non-food use antimicrobial, EPA did not require chronic toxicity, carcinogenicity or reproductive toxicity studies as of that date.

CHRONIC TOXICITY, RAT

Subchronic:

* **004 131002** Lamb, I. C., "A Combined Oral Subchronic (13 Week) Toxicity and Neurotoxicity Study of Busan 11-M1 in Rats". WIL Research Laboratories, Inc., Lab. Study No.: WIL-94044. April 14, 1993. Busan 11-M1, purity 94.3%, was admixed with the feed at concentrations of 0, 1000, 5000 or 10000 ppm and fed to 15 Sprague-Dawley Crl:CD@BR rats/sex/group for 90-94 days. These doses were equivalent to 70, 349 and 707 mg/kg/day in males and 80, 406, and 794 mg/kg/day in females. Five of the ten rats/sex/group evaluated for subchronic toxicity were also included with 5 rats/sex in the neurotoxicity group for Functional Observation Battery (FOB) and Locomotor Activity assessment. No evidence of neurotoxicity was reported; Neurotoxicity NOEL = 10000 ppm. Body weights were reduced 9-12% for the high-dose males and females and 8% lower for mid-dose females. Food consumption was reduced 10-16% for high-dose males and females. Liver (22%) and testes (61%) weight was reduced in addition to an increase (100%) in the incidence of small and soft testes and aspermatogenesis for high-dose males (**possible adverse effect**). Reduced red cells, hemoglobin and hematocrit for the high-dose males and females and reduced globulin, cholesterol and total protein were indicated for mid and high-dose males. Systemic toxicity NOEL = 1000 ppm. **Acceptable** as a subchronic study and as a neurotoxicity study. (Kishiyama and Gee, 9/4/98).

.002 115789 Preliminary results from a 28-day dietary study, WIL-94043-28, in rats at 0, 1000, 5000, 10000 and 15000 ppm. Unaudited data suggested the testes as a possible target organ with 5/5 showing germinal epithelium degeneration.

CHRONIC TOXICITY, DOG

No study on file.

ONCOGENICITY, RAT

No study on file.

ONCOGENICITY, MOUSE

No study on file.

REPRODUCTION, RAT

No study on file.

TERATOLOGY, RAT

No study on file.

TERATOLOGY, RABBIT

** 005 131023 Lamb, I. C. "Developmental Toxicity Study of Busan 11-M1 in Rabbits". WIL Research Laboratories, Inc., Laboratory Study No.: WIL-94042. March 9, 1993. Busan 11-M1, purity 94.3%, was administered *via* gavage at concentrations of 0 (0.5% aqueous methylcellulose), 2, 10 or 20 mg/kg/day to 20 artificially inseminated New Zealand White rabbits/group during gestation days 7 through 19. The death of one high dose female was reported as treatment related. Maternal NOEL = 10 mg/kg/day. Fetal developmental variants and incidence of malformations (hydrocephaly) appeared to increase at the high dose (12.5 % of litters) but were not considered conclusively related to treatment. Developmental NOEL = 20 mg/kg/day. ACCEPTABLE. (Kishiyama and Gee, 9/2/98).

GENE MUTATION

** 001 114152, "L5178Y TK+/- Mouse Lymphoma Mutagenesis Assay with a Confirmatory Assay", (C. Anita H. Bigger and Jane J. Clarke, Microbiological Associates, Inc., Report # TA081.701020, 17 December 1991). Busan 11-M1 with 94.3% indicated purity. L5178Y mouse lymphoma cells were treated for 4 hours in the presence and absence of activation at nominal concentrations of 0 (DMSO), 1.0, 122.0, 127.0, 132.0, 137.0, 142.0, 147.0, 152.0, 157.0, 162.0, or 167.0 mg/ml. **No increased mutation frequency. Acceptable.** (Green and Gee, 9/1/98)

** 001 114154 "Salmonella/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test) with a Confirmatory Assay", (Richard H.C. San and Sheri J. Olsen, Microbiological Associates, Inc., Report # TA081.501014, 3 December 1991). Busan 11-M1 with 94.3% purity was tested. Salmonella typhimurium strains TA98, TA100, TA1535, TA1537, and TA1538 were plated in triplicate and exposed for 48 hours in the presence and absence of male rat liver microsomal activation to concentrations of 0 (DMSO), 100, 333, 1000, 3333, and 5000 ug/plate with a second trial. **No increase in the reversion rate. Acceptable** (H. Green and Gee, 9/2/98).

CHROMOSOME EFFECTS

** 001 114153 "Micronucleus Cytogenetic Assay in Mice", (Donald L. Putman. and Robert R. Young, Microbiological Associates, Inc. Report # TA081.122, 5 February 1992). 15 ICR mice per sex per group received a single intraperitoneal injection of Busan 11-M1 (94.3%) at 0 (deionized water), 11.3, 22.5, and 45.0 mg/kg. Five (5) per sex per group were sampled 24, 48, and 72 hours post-dosing. Cyclophosphamide was used as the positive control at 24 hours. 1000 polychromatic erythrocytes were scored per animal. Two males at the high dose died and were replaced with other males dosed at the high dose as

replacements. **No increased incidence of micronucleated polychromatic erythrocytes in bone marrow. Acceptable.** (H. Green and Gee, 9/2/98).

DNA DAMAGE

No study on file.

NEUROTOXICITY

See 004, 131002, above, under subchronic, rat, for 1-liner of an acceptable, subchronic neurotoxicity study in the rat.

002 115790 "A Range-Finding Acute Study of Busan 11-M1 in Rats", (Ian C. Lamb, WIL Research Laboratories, Inc., Ashland, OH. Report # WIL-94045 and WIL-94045A, the in-life portion of the study was completed 9 November 1991.) Busan 11-M1 was used as test article (technical grade, 94.3%). 1 to 4 Sprague-Dawley CrI:CD[®]BR rats per sex per group received a single dose by gavage at nominal concentrations of 12.5, 25.0, 50, 100, 150, 175, 200, 250, 400, or 600 mg/kg in 0.5% aqueous methyl cellulose. No vehicle control. The purpose was to find the peak time of any effects. Reduced male body weights were found at 400 and 600 mg/kg. Females at 400 and 600 mg/kg died. Gait abnormalities (rocking, lurching, and swaying) were noted for both sexes at dosing levels of 50 mg/kg and higher. Clinical exams were performed at pretreatment, 1, 2, 3, 4, 5, 6, 7 and 8 hours following dosing. The peak effect was 3 - 5 hours after dosing. Animals were observed for 7 days following treatment. The NOEL was reported as 25.0 mg/kg (gait abnormalities). The benchmark dose level was reported as 200.0 mg/kg. **Supplemental** information. (H. Green and Gee, 9/3/98).