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

Microfiche

Oct 30 1992

009857

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Barium Metaborate - Subchronic Neurotoxicity Protocol; Request for Waiver of Study to be Presented to Gray Beard Committee on 10/30/92.

TO: Barry O'Keefe
PM Team Reviewer (72)
Reregistration Branch, SRRD (H7508C)

FROM: Linda L. Taylor, Ph.D. Linda Lee Taylor 10/22/92
Toxicology Branch II, Section II,
Health Effects Division (H7509C)

THRU: K. Clark Swentzel K. Clark Swentzel 10/22/92
Section II Head, Toxicology Branch II
Health Effects Division (H7509C)

and

Marcia van Gemert, Ph.D Marcia van Gemert 10/26/92
Chief, Toxicology Branch II/HFAS/HED (H7509C)

Registrant: Buckman Laboratories International, Inc.
Chemical: Barium metaborate
Synonym: Busan 11-M1
Case No.: 818581
Caswell No.: 071
Submission No.: S424863
Identifying No.: 011101
DP Barcode: D182271
MRID No.:

Action Requested: Please review this Subchronic Neurotoxicity Protocol (Guideline 82-5(b)). Note: The Registrant requested a waiver on this requirement. The waiver was received on 6/11/91; however, it is just now being given to the Gray Beard Committee for expeditious review.

Comment: The Registrant has submitted a protocol (dated June 8, 1991) for a combined oral subchronic (13 week) toxicity and neurotoxicity study of Busan 11-M1 in rats. The cover memo indicated that the study was to be initiated during the first week of August, 1992.

With respect to the waiver request for the 90-day neurotoxicity

study in mammals [85-5(b)], the Registrant stated that in accordance with CFR 158.340, the requirements for this study are not met, in that no effects indicative of neuropathy or neurotoxicity were observed in the acute studies. TB II disagrees with this statement and points out that a draft report of a range-finding acute neurotoxicity study in rats was submitted by the Registrant under FIFRA 6(a)(2) "for the following possible adverse effect: Gait abnormalities (rocking, lurching and swaying) and reduced or absent forelimb/hindlimb grasp were consistently the major clinical findings in males and females at dose levels of 50.0, 100.0, 200.0, 400.0 and 600 mg/kg."

The protocol has been reviewed, and it appears to be adequate, although no dose levels are identified. Additionally, there is no mention of whether a positive control will be run simultaneously or whether positive control data are available from the performing laboratory that demonstrate the sensitivity of the procedures to be used.

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