US EPA ARCHIVE DOCUMENT

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

JAN 25 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case barium metaborate monohydrate. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredient(s) to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED". This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from the date of this letter. The second set of required responses are due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

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If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Mr. Franklin Gee at (703) 308-8008. If you have any questions on the generic data, please contact Ms. Brigid Lowery at (703) 308-8053.

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Enclosures

REREGISTRATION ELIGIBILITY DECISION

BARIUM METABORATE

LIST A

CASE 0632

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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BARIUM METABORATE REREGISTRATION ELIGIBILITY DECISION TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOEL	Lowest Observed Effect Level
MOE	Margin of Exposure. A numerical value that characterizes the amount of safety to a toxic chemical - a ratio of exposure to a toxicological endpoint, usually a NOEL.
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts Per Million
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The dose at which a substance produces a toxic effect.
TMRC	Theoretical Maximum Residue Contribution.

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision (RED) addresses the eligibility for reregistration of products containing barium metaborate monohydrate, referred to in this document as barium metaborate, registered prior to July 1, 1993.

Barium metaborate was originally registered in the United States in November 1960. Barium metaborate is a fungicide, bacteriostat, microbiocide/microbiostat and is used as an industrial preservative in the manufacturing process of paints, paper/paper products, adhesives, and coatings to protect against slime-forming bacteria and fungi. It is used as a preservative in paper formulation to protect paper products from microbiological degradation during storage. At higher concentrations it is used to impart mold resistance in paints, coatings, latex/oil/varnish paints (applied film), and paper/paper products. Use has been permitted as a component in the manufacture of paper and paperboard under U.S. Food and Drug Administration Regulations 21 CFR 176.180, "components of paper and paperboard in contact with dry food." Since U.S. FDA regulates this use, there is no need for EPA regulation in this area. Furthermore, barium metaborate may be applied by brush or airless spray to walls, ceilings, pipes, etc. as a fungicide to protect against molds and bacteria. The product that contains this use is a mixture of barium metaborate and another active ingredient and was registered after July 1, 1993; therefore, it is not included in this RED.

A Registration Standard for barium metaborate was issued in April 1983 (NTIS #PB84-168376) which evaluated the studies available to the Agency. Product chemistry data and an acute rat inhalation study were required in the April 1983 Registration Standard. Subsequently, a Data Call-In (DCI) was issued February 1991 for this chemical. The DCI required submittal of product chemistry data, ecological effects data, and toxicology data. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and DCI. Appendix B includes all data requirements identified by the Agency to support the reregistration of all barium metaborate uses registered prior to July 1, 1993.

Sodium metaborate was included in the same case as barium metaborate when the lists of the active ingredients undergoing reregistration were published in 1989. The Agency, however, determined that sodium metaborate should be reregistered with boric acid since it is the sodium salt of boric acid. Sodium metaborate was included in the Boric Acid RED which was issued in September 1993.

The Agency has determined that the uses of barium metaborate registered prior to July 1, 1993 will not cause unreasonable risk to humans or the environment and are eligible for reregistration.

Before reregistering the products containing barium metaborate, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These

data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for registration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the uses of barium metaborate monohydrate, referred to in this document as barium metaborate, which were registered prior to July 1, 1993. The document consists of six sections. Section I is the introduction. Section II describes barium metaborate, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for barium metaborate. Section V discusses the product reregistration requirements for barium metaborate. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Document:

- **Common Name:** Barium metaborate
- **Chemical Name:** Barium metaborate monohydrate
- **CAS Registry Number:** 13701-59-2
- **OPP Chemical Code:** 011101
- **Case:** 0632
- **Empirical Molecular Formula:** $BaB_2O_4.H_2O$
- **Molecular Weight:** 241
- **TGAI:** Barium metaborate monohydrate
- **Trade and Other Names:** Busan 11-M1
- **Basic Manufacturer:** Buckman Laboratories International Inc., U.S.A

B. Use Profile

The following is information on the uses registered prior to July 1, 1993 with an overview of use sites and application methods. A detailed table of these uses is provided in Appendix A.

Barium metaborate is a fungicide, bacteriostat, microbiocide/microbiostat and is used as an industrial preservative in the manufacturing process of paints, paper/paper products, adhesives, and coatings to protect against slime-forming bacteria and fungi. It is used as a preservative in paper formulation to protect paper products from microbiological degradation during storage. At higher concentrations it is used to impart mold resistance in paints, coatings, latex/oil/varnish paints (applied film), and paper/paper products. Use has been permitted for the manufacture of paper and paperboard under U.S. Food and Drug Administration Regulations 21 CFR 176.180, "components of paper and paperboard in contact with dry food." There is

no need for EPA regulation in this area. Furthermore, barium metaborate may be applied by brush or airless spray to walls, ceilings, pipes, etc. as a fungicide to protect against molds and bacteria. The product that contains this use is a mixture of barium metaborate and another active ingredient and was registered after July 1, 1993; therefore, it is not covered in this RED.

Use group/sites:

Indoor non-food: industrial adhesives, industrial coatings, latex/oil/varnish (applied film) paints, paper/paper products, wet-end additives/industrial processing chemicals.

Target pests:

Slime-forming bacteria and fungi

Application type:

Industrial preservative treatment

Application timing:

During manufacture

Rates of Application:

Adhesives:
0.05 to 0.5 percent based on the weight of the solution
Industrial coatings:
1 to 3 percent based on total weight of coating
Latex/oil/varnish (applied film) paints
5 to 20 percent based on the total weight of the coating
Paper/paper products:
0.05 to 0.5 percent based on the weight of the solution
Wet-end additives/industrial processing chemicals:
0.05 to 0.5 percent based on the weight of the solution

C. Data Requirements and Regulatory History

Barium metaborate was originally registered in the United States in November 1960 for use as a broad spectrum bactericide and fungicide. A Registration Standard for barium metaborate was issued in April 1983 (NTIS #PB84-168376) which evaluated the studies available to the Agency. Product chemistry data and an acute rat inhalation study were required to support the uses listed in the Registration Standard. A Data Call-In Notice was issued in February 1991 which required product

chemistry data, ecological effects data, and toxicology data. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and Data Call-In. Appendix B includes all data requirements identified by the Agency to support the reregistration of all uses of barium metaborate registered prior to July 1, 1993.

Sodium metaborate was included in the same case as barium metaborate when the lists of the active ingredients undergoing reregistration were published in 1989. The Agency, however, determined that sodium metaborate should be reregistered with boric acid; therefore, it was included in the Boric Acid RED which was issued in September 1993.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

The physical and chemical characteristics of the TGAI of barium metaborate are described below (MRID numbers 00137047 and 42173701):

Color:	White
Physical state:	Powder
Odor:	None
Melting Point:	Fused between 1367.5°C to 1482.5°C
Density:	1.07 g/cm^3 at 25°C
Vapor Pressure:	8.1 x 10^{-7} Torr
Dissociation Constant:	pK_a = 8.9
Octanol/Water Partition Coefficient:	less than 2
pH:	9.76 (concentration 100 ppm in water)
Stability:	Barium metaborate is stable at ambient temperature and elevated temperature (54°C). It is also stable to galvanized steel and stainless steel and is stable in the presence of ferric oxide and zinc acetate for 14 days.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on barium metaborate is adequate; therefore, the Agency is not requiring any additional toxicological data. The uses of barium metaborate fall under the use group "indoor non-food." The Agency does not routinely require the submittal of chronic toxicity, carcinogencity, and reproductive toxicity data to support the indoor non-food use group. The results of the studies the Agency required for barium metaborate do not trigger the need for the additional toxicological testing. The results of the required studies are summarized below.

a. Acute Toxicity

The results of the acute testing are found in the table below.

ACUTE MAMMALIAN TOXICITY DATA FOR BARIUM METABORATE (90% MATERIAL)				
GDLN #	TEST	RESULT	TOXICITY CATEGORY	MRID
81-1	Acute oral LD_{50} (rat)	530 mg/kg (♀) 850 mg/kg (♂)	III	00139192
81-2	Acute dermal LD_{50} (rabbit)	> 2000 mg/kg	III	00139216
81-3	Acute inhalation LC_{50} (rat)	> 3.54 mg/L	III	00137048
81-4	Eye irritation (rabbit)	reversible irritation	III	00139192
81-5	Dermal irritation (rabbit)	no irritation	IV	00139192
81-6	Skin sensitization (guinea pig)	negative	N/A	41396401 40898401

b. Subchronic Toxicity

In a combined oral subchronic toxicity and neurotoxicity study, rats were given 0, 1000, 5000, or 10000 ppm barium metaborate in the diet for 90 days. The NOEL was 1000 ppm (70 mg/kg/day in males

and 80 mg/kg/day in females) and the LOEL was 5000 ppm (349 mg/kg/day in males and 406 mg/kg/day in females). At the high dose, there were reduced body weight gains in both sexes and decreased food consumption, red blood cells, hemoglobin, hematocrit, and liver weights. There were increased relative brain weights. High dose males also had decreased total protein, cholesterol, globulin, testes weights, and small or soft testes with aspermatogenesis. At the mid-dose (LOEL), there were reduced body weight gains and reduced relative brain weights in females, as well as decreased total protein, cholesterol and globulin in males. There was an apparent treatment-related decrease in one of the functional neurological observations, forelimb grip strength, for the high dose males and increased ambulatory activity in mid-dose females and in both sexes at the high dose. (MRID 42747801) (preliminary notification MRIDS 42310501, 42663401; range finding report MRID 42724201).

c. Developmental Toxicity

In a developmental toxicity study, rabbits were given 0, 2, 10, or 20 mg/kg/day of barium metaborate. The doses were given by gavage on gestation days 7 through 19. The NOEL for maternal toxicity was 10 mg/kg/day. The maternal LOEL was 20 mg/kg/day based on death of one animal at this dose along with impaired mobility and hypoactivity of another one. The NOEL for developmental toxicity was 20 mg/kg/day, the highest dose tested. (MRID 42720502) (preliminary information MRID 42314301; range finding report MRID 42720501).

d. Mutagenicity

The Agency reviewed three genotoxicity tests to support the reregistration of barium metaborate: i) *Salmonella* assay ("Ames" assay); ii) mammalian cells in culture forward gene mutation assay; and iii) *in vivo* cytogenetics. In an Ames assay with strains, TA98, TA100, TA1535, TA1537, and TA1538 of *Salmonella typhimurium*, barium metaborate did not cause a positive response with or without metabolic activation (MRID 42132601). An *in vivo* micronucleus assay in mice was negative for chromosomal aberrations (MRID 42207501). Furthermore, a mouse lymphoma study with barium metaborate did not show any mutagenicity. (MRIDS 42151401 and 42873201).

e. Neurotoxicity

In an acute neurotoxicity study, rats were administered a single dose of barium metaborate via gavage at levels of 0, 25, 50, 100, and 200 mg/kg. The NOEL for acute neurotoxicity was 25 mg/kg and the LOEL was 50 mg/kg based on impairment of gait in males at this and the higher doses. In females there was impairment of gait at the 200 mg/kg on day 0. There were no adverse effects on survival, body weight/gain, brain weight or dimensions, and no clinical signs, locomotor activity changes, or neuropathological lesions were observed in either sex of rat that were treatment related. No signs of toxicity were apparent on days 7 and 14 in either sex. (MRID 42734701) (range finding reports MRIDS 42343601 and 42501201) Furthermore, the Agency required a 90-day mammal neurotoxicity study. In response the registrant combined the 90-day neurotoxicty study with the 90-day oral toxicity study (see section III.B.1.b).

f. Reference Dose

A Reference Dose has not been determined for barium metaborate since there are no registered food uses.

2. Exposure Assessment

a. Dietary Exposure

Barium metaborate has no food uses; therefore, no dietary exposure is expected to occur.

b. Occupational and Residential

The barium metaborate products covered in this RED were registered prior to July 1, 1993. These products can be added into paints, paper/paper products, and coating material during the manufacturing process. During the manufacturing process, barium metaborate is used as a preservative (e.g., as a starch slurry preservative) in paper coating formulations to protect paper products from microbiological degradation during storage. At higher concentrations it is used to impart mold resistance to coated paper and paper board. Use has been permitted for the manufacture of paper and paperboard under U.S. Food and Drug Administration Regulations 21 CFR 176.180, "components of paper and paperboard in contact with dry food." It is also used in latex paints (in-can), oil/varnish (applied

film), and coatings to impart resistance to mold. From these uses, the potential for mixer/loader/applicator exposure exists during the pouring or pumping of barium metaborate into the product for preservation (i.e. paint, etc.). The Agency expects the "pour liquid" for the preservative use to provide the highest potential for exposure to barium metaborate. The exposure assessment for this use is found below (Section III.B.2.b-1).

b-1. *Mixer/Loader/Applicator Exposure from Pour Liquid Use of Barium Metaborate during Manufacturing*

Barium metaborate products can be formulated as soluble concentrates and ready to use solutions (e.g., 90%, 52%, 50%) and added into the paints, paper/paper products, and coating material during the manufacturing process. The method of open pouring into a metering pump is used as a general industrial practice and provides the highest potential for mixer/loader/applicator exposure to barium metaborate. While conducting open pouring operations of barium metaborate the potential dermal exposure could be significant, however, the potential inhalation exposure is considered minimal because of the low vapor pressure of barium metaborate. After reviewing the entire toxicological data base the Agency determined that barium metaborate should be regulated on the basis of a Margin of Exposure (MOE) instead of a RfD. The lowest NOEL is 10 mg/kg/day based on maternal toxicity in a developmental study. This compound meets the Agency's toxicity and exposure criteria for requiring exposure monitoring data. These data requirements for mixer/loader/applicator are met by the Chemical Manufacturers Association (CMA) exposure assessment database (MRID 41412201). The registrant is a participant in the CMA exposure study. This database was used to estimate mixer/loader/applicator combined inhalation and dermal exposure based on the type of application, in this case, the pour liquid for the preservative use (see table below). The estimated combined dermal and inhalation daily exposure of barium metaborate to the handler is 52.6 ug/kg/day under the use scenario as preservative.

Daily Exposure to Barium Metaborate for Mixers/Loaders/Applicator from use during manufacturing				
SCENARIO: Pour Liquid				
Setting	MCS* (ug/lb ai)	lb ai used	Body Weight (kg)	Daily Exposure (ug/kg/day)
Preservative	130	24.3	60	52.6
Assumption: Three hundred gallons of paint have been handled and treated with liquid concentrate barium metaborate (90% ai) by open pouring application method based on weight; therefore, a total of 24.3 lb ai was added per day per worker, based on maximum use rates representing the worst case situation.				

* MCS = Maximum Credible Sum was derived from the CMA study. It is a unit of exposure that is the quantitative measurement of micrograms of active ingredient exposure per pound of active ingredient handled by workers.

b-2. *Post-Application Worker Exposure*

Based on the uses in/on paper/paper board, latex paints, oil/varnishes and coatings and given the low vapor pressure of barium metaborate, the post-application exposure to workers is expected to be minimal.

3. Risk Assessment

a. Dietary

There are no registered food uses of barium metaborate; therefore, no dietary risk exists.

b. Occupational and Residential

b-1. *Risk Assessment for Mixer/Loader/Applicators*

The Margin of Exposure (MOE) for factory workers involved in mixer/loader activities may be estimated by the following equation:

$$\text{MOE} = \frac{\text{NOEL (mg/kg/day)}}{\text{Exposure (mg/kg/day)}}$$

For regulatory purposes the toxicological endpoint of concern is

maternal toxicity observed in the developmental study on rabbits at 20 mg/kg/day in the form of mortality, impaired mobility and hypoactivity. The NOEL for the study is 10 mg/kg/day. The potential exposure based on the worst-case scenario is 0.0526 mg/kg/day. Therefore, the MOE for factory workers involved in mixer/loader/applicator activities is 190. An MOE of 100 or greater is considered acceptable. The risk to mixers/loaders/applicators is considered to be minimal.

b-2. Post-application workers

The risk associated with post application exposure to workers is considered minimal since exposure is limited by the low vapor pressure of barium metaborate.

C. Environmental Assessment

1. Environmental Fate

a. Environmental Chemistry, Fate and Transport

In nature, boron does not occur in its elemental (uncombined) form. However, boron compounds are widely found in soil and water. Much of the naturally occurring boron is present in inorganic species where the boron is bound to oxygen. These form a variety of "borate" compounds, which have similar properties, and include barium metaborate, $BaB_2O_4.H_2O$, the subject of this document. These borate ions are combined with various metallic ions also occurring naturally, and dissociate into the respective borate and metallic ions when dissolved in water. A common form of borate is the negatively charged ion BO_3^{3-} which occurs in association with positively charged metal ions such as sodium and barium. An additional example is the compound known as borax, which has the formula $Na_2B_4O_7$ and in the solid state is associated with ten molecules of water of crystallization. In these forms, boron serves as an essential micronutrient for microorganisms, thereby becoming bound to an organic component in plants or microorganisms.

In soil the concentration of boron (expressed as elemental boron) can range from 5-150 ppm. A typical surface soil might contain 50 ppm boron. Boron salts (combinations of borates with metal ions) also occur naturally in low concentrations in lakes, ponds, rivers, and oceans. In some geographical areas such as the American Southwest, boron occurs in concentrations in surface waters that have been shown

to be toxic to plants of commercial importance. Seawater boron concentrations average 4.5 mg/liter. The average concentration for boron in surface waters has been reported to range from 0.001 mg/liter to 0.1 mg/liter.

b. Environmental Fate Assessment

The Agency is not requiring any environmental fate data at this time. No studies have been submitted regarding the environmental fate of boron salts, and none have been reviewed. It is doubtful that the information which would be developed by performing standard environmental fate studies would justify the effort. Since soils are naturally rich in these boron compounds, high background levels would make analyses unusually difficult. Analytical procedures could not distinguish between native and added boron compounds without the use of isotopic labeling. Moreover, the normal degradative processes would only produce compounds which are already present in the environment, such as the metaborate salts with different hydration states.

2. Ecological Effects

a. Ecological Effects Data

The ecological effects data base on barium metaborate is adequate; therefore, the Agency is not requiring any additional ecological effects data. The results of the ecological toxicity testing are summarized in this section.

(1) Terrestrial Data

In September 1991, the Agency received notification of potential adverse effects from preliminary results of the acute avian oral study being conducted on the bobwhite quail (MRID 42033601). The information was submitted because of possible neurotoxicity in quail treated with barium metaborate at doses ranging from 486 to 2250 mg/kg. This study was not designed to address the neurotoxic potential of barium metaborate. The Agency has reviewed data from an acute neurotoxicity study in rats and combined rat subchronic oral toxicity and neurotoxicity study (see section III.B.1.e).

The terrestrial data indicate that barium metaborate is slightly toxic to bobwhite quail on an acute oral toxicity basis.

A single dose oral toxicity study administered to bobwhite quail resulted in an LD_{50} value of 1254 mg/kg [MRID 42339501 and MRID 42546001 (final amended report)]. However, barium metaborate is practically non-toxic to birds, both an upland species (bobwhite quail) and a waterfowl species (mallard duck) on a subacute dietary toxicity basis. Avian subacute dietary toxicity studies demonstrate LC_{50}'s > 5620 ppm for both bobwhite quail [MRID 42338701 and MRID 42546701 (amended final report)] and mallard duck [MRID 42338702 and MRID 42546702 (amended final report)].

(2) Aquatic Data

Three studies were conducted on the 90% material for aquatic toxicity, two on fish and one on an aquatic invertebrate. Data on end-use products are not required for the registered uses of barium metaborate. The available acute toxicity data indicate that barium metaborate is practically non-toxic to bluegill sunfish with a LC_{50}=151 ppm (MRID 42338601) but slightly toxic to rainbow trout with a LC50=62 ppm (MRID 42338602). It is also slightly toxic to *Daphnia magna* with a EC_{50}=19 ppm based on a 48 hour acute toxicity test (MRID 42338603).

SUMMARY OF ECOLOGICAL EFFECTS TOXICITY TESTS (TERRESTRIAL AND AQUATIC DATA)						
GUIDELINE #	**SPECIES**	**% A.I.**	**LC_{50} or LD_{50} (mg/kg)/ NOEL (mg/kg)**	**AUTHOR**	**DATE**	**MRID**
Avian Single-Dose Oral Toxicity Test						
71-1a	bobwhite quail	90%	LD_{50} = 1254 NOEL = 292	Campbell & Lynn	1992	42546001
Avian Subacute Dietary Toxicity Tests						
71-2a	bobwhite quail	90%	LC_{50} > 5620 NOEL = 1780	Campbell et al.	1992	42546701
71-2b	mallard duck	90%	LC_{50} > 5620 NOEL = 5620	Campbell et al.	1992	42546702
Acute Freshwater Fish Toxicity Tests						
72-1a	bluegill sunfish	90%	LC_{50} = 151 ppm NOEL = 42.8	Linott	1992	42338601
72-1c	rainbow trout	90%	LC_{50} = 62 ppm NOEL = 14.9	Linott	1992	42338602
Non-target Aquatic Invertebrate Toxicity Test						
72-2a	*Daphnia magna*	90%	19 ppm	Linott	1992	42338603

b. Ecological Effects Risk Assessment

Barium metaborate is registered as a microbiocide for indoor non-food end-use. Because of the indoor, in-product nature of the use of this chemical, it is not expected that barium metaborate will be released to the environment in significant amounts through the effluent from a manufacturing plant. Furthermore, any minor amount of the chemical that would be released in this manner would be expected to dissociate rapidly to its naturally occurring ionic components. Little direct exposure to fish, wildlife, and endangered species is expected from the use of this chemical and any potential exposure would be regulated under permit by the National Pollutant Discharge Systems; therefore, risk to fish, wildlife, and endangered species will be minimal from the microbiocidal use of this chemical.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing barium metaborate active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing barium metaborate registered prior to July 1, 1993. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of barium metaborate, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the uses of barium metaborate registered prior to July 1, 1993 and to determine that these uses will not result in unreasonable adverse effects to humans and the environment. The Agency finds that all products registered prior to July 1, 1993 which contain barium metaborate as the sole active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document. Those products that contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and the data identified in Appendix B. It should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing barium metaborate, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient barium metaborate, the Agency has sufficient information on the health effects of barium metaborate products subject to this RED and on its potential for causing adverse effects in fish and wildlife and the environment. Therefore, the Agency concludes that products containing barium metaborate registered prior to July 1, 1993 are eligible for reregistration. Those products that contain other active ingredients will be eligible for reregistration only when the

other active ingredients are determined to be eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of barium metaborate products registered prior to July 1, 1993 are eligible for reregistration.

B. Regulatory Position

The Agency has determined that the uses of barium metaborate registered prior to July 1, 1993 will not cause unreasonable risk to humans or the environment and are eligible for reregistration. The following is a summary of the regulatory positions and rationales for barium metaborate. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

There are no registered food or feed uses for barium metaborate; therefore, no tolerances or exemptions from the requirement of a tolerance are established for this chemical.

2. Restricted Use Classification

Barium metaborate does not meet the criteria for a Restricted Use Pesticide.

3. Labeling Rationale

a. Since the mixers/loaders/applicators exposure for barium metaborate by using open pouring methods could be significant the Agency is now requiring PPE (Personal Protective Equipment) (i.e. long-sleeved shirt, long pants, socks, shoes, chemical-resistant gloves) for mixers/loaders/applicators of end-use products.

b. Although the Agency does not expect effluent from the microbiocidal use of these products to contain more than minimal amounts of barium metaborate, the Agency requires an environmental hazard statement on end-use products registered for industrial preservative uses. The environmental hazard statement currently on product labels must be revised according to PR Notice 93-10, issued July 29, 1993. The specific language is set forth in section V.

c. Due to the indoor and in-product nature of its use, minimal direct exposure to endangered species is expected from the use of this chemical; therefore, the effect on endangered species from the reregistered uses of this chemical is considered minimal. Accordingly, the Agency is not requiring any endangered species labeling at this time.

At the present time, EPA is working with the U.S. Fish and Wildlife Service and other federal and state agencies to develop a program to avoid jeopardizing the continued existence of listed species by the use of pesticides. When the Endangered Species Protection Program is implemented and subsequent guidance is given, endangered species labeling amendments may be required on affected end-use products. Labeling statements for end-use products will likely refer users to county specific bulletins specifying detailed limitations on use to protect endangered species.

V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The Agency is not requiring additional data to support the reregistration of the active ingredient barium metaborate.

2. Labeling Requirements for Manufacturing-Use Products

There are no registered technical or manufacturing-use products for barium metaborate. In the future, if any are registered, they will be required to meet the requirements of 40 CFR 156.10, this RED, and other current policies.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix F, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they

meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions for the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10.

a. Personal Protective Equipment

Since the mixer/loader/applicator exposure for barium metaborate by using open pouring methods could be significant, the Agency is now requiring the following PPE (Personal Protective Equipment) for mixers/loaders/applicators of end-use products:

- long-sleeved shirt and long pants;
- socks and shoes; and
- chemical-resistant gloves.

b. Environmental Hazard Statement

The following revised effluent discharge labeling statement must appear on all manufacturing and end-use products subject to this RED:

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

All affected products distributed or sold by registrants and distributors (supplemental registrants) must bear the above labeling by October 1, 1995. All products distributed or sold by persons other than registrants or supplemental registrants after October 1, 1997 must bear the correct labeling. Refer to PR Notice 93-10 or 40 CFR 152.46(a)(1) for additional information.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of a Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of a RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell barium metaborate products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED.

APPENDIX A

USE PATTERNS SUBJECT TO REREGISTRATION

SITE Application Type, Application Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED											
ADHESIVES, INDUSTRIAL			Use Group: INDOOR NON-FOOD								
Industrial preservative treatment., During manufacture., Not on label., Not on the Label., Not applicable for this use.	FM?	No Calc	NA	*	NS		NS	NS	NS		C23
COATINGS, INDUSTRIAL			Use Group: INDOOR NON-FOOD								
Industrial preservative treatment., During manufacture., Not on label., Not on the Label., Not applicable for this use.	FM?	No Calc	NA	*	NS		NS	NS	NS		C23
PAINTS, LATEX/OIL/VARNISH (APPLIED FILM)			Use Group: INDOOR NON-FOOD								
Industrial preservative treatment., During manufacture., Not on label., Not on the Label., Not applicable for this use.	FM?	No Calc	NA	*	NS		NS	NS	NS		C23
PAPER/PAPER PRODUCTS			Use Group: INDOOR NON-FOOD								
Industrial preservative treatment., During manufacture., Not on label., Not on the Label., Not applicable for this use.	FM?	No Calc	NA	*	NS		NS	NS	NS		C23
WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS			Use Group: INDOOR NON-FOOD								
Industrial preservative treatment., During manufacture., Not on label., Not on the Label., Not applicable for this use.	FM?	No Calc	NA	*	NS		NS	NS	NS		C23

LEGEND

HEADER ABBREVIATIONS
Max. Apps @ Max Rate : Maximum number of Applications at Maximum Dosage Rate
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)

SOIL TEXTURE FOR MAX APP. RATE
* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES
FM? : FORM NOT IDENTIFIED
RTU : LIQUID-READY TO USE

ABBREVIATIONS
AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label)

APPLICATION RATE
DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES
A08 : Preclean claim.
C04 : Proper ventilation required.
C23 : NPDES license restriction.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Barium Metaborate

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Barium Metaborate

REQUIREMENT		USE PATTERN[1]	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	all	00137047
61-2A	Start. Mat. & Mnfg. Process	all	00137047
61-2B	Formation of Impurities	all	00137047
62-1	Preliminary Analysis	all	00137047
62-2	Certification of limits	all	CSF
62-3	Analytical Method	all	00137047
63-2	Color	all	42173701
63-3	Physical State	all	42173701
63-4	Odor	all	42173701
63-5	Melting Point	all	42173701
63-7	Density	all	42173701
63-8	Solubility	all	42173701
63-9	Vapor Pressure	all	42173701
63-10	Dissociation Constant	all	42173701
63-11	Octanol/Water Partition	all	42173701
63-12	pH	all	facsimile dated 4/29/93
63-13	Stability	all	42173701

Data Supporting Guideline Requirements for the Reregistration of Barium Metaborate

REQUIREMENT		USE PATTERN[1]	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	M	42546001, 42339501, 42033601
71-2A	Avian Dietary - Quail	M	42338701, 42546701
71-2B	Avian Dietary - Duck	M	42338702, 42546702
72-1A	Fish Toxicity Bluegill	M	42338601
72-1C	Fish Toxicity Rainbow Trout	M	42338602
72-2A	Invertebrate Toxicity	M	42338603
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	M	00139192
81-2	Acute Dermal Toxicity - Rabbit/Rat	M	00139216
81-3	Acute Inhalation Toxicity - Rat	M	00137048
81-4	Primary Eye Irritation - Rabbit	M	00139192
81-5	Primary Dermal Irritation - Rabbit	M	00139192
81-6	Dermal Sensitization - Guinea Pig	M	41396401, 40898401
81-8-ss	Acute Neurotoxicity - rat	M	42734701, 42343601, 42501201
82-1A	90-Day Feeding - Rodent	M	42747801, 42310501, 42663401, 42724201
82-5B	90-Day Neurotoxicity - Mammal	M	42747801, 42310501, 42663401, 42724201
83-3B	Developmental Toxicity - Rabbit	M	42720502, 42314301, 42720501
84-2A	Gene Mutation (Ames Test)	M	42132601

Data Supporting Guideline Requirements for the Reregistration of Barium Metaborate

REQUIREMENT		USE PATTERN[1]	CITATION(S)
84-2B	Structural Chromosomal Aberration	M	42207501
84-4	Other Genotoxic Effects	M	42151401, 42873201
OCCUPATIONAL AND RESIDENTIAL EXPOSURE			
233	Estimation of Dermal Exposure and Indoor Sites	M	41412201
234	Estimation of Inhalation Exposure at Indoor Sites	M	41412201

1 Use Patterns: a= terrestrial food; b = terrestrial feed; c = terrestrial non-food; d = aquatic food; e = aquatic non-food outdoor; f = aquatic non-food industrial; g = aquatic non-food residential; h = greenhouse food; i = greenhouse non-food; j = forestry; k = residential outdoor; l = indoor food; m = indoor non-food; n = indoor medical; o = indoor residential

APPENDIX C

BIBLIOGRAPHY

Citations considered to be Part of the Data Base Supporting Reregistration of Barium Metaborate

GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by the Agency in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Decision. Primary sources for studies in this bibliography have been the body of data submitted to the Agency and its predecessor agencies in support of past regulatory decisions. Selections from other sources including published literature, in those instances where they have been considered, are included.

2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to EPA, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID Number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifying number which is also to be used whenever specific reference is needed.

4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to the Agency, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown a identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. **Document Date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

c. **Title.** In some cases, it has been necessary for the Agency's bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. **Trailing Parentheses.** For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received".

(2) Administrative Number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the Agency accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL", which stands for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

00137047 Buckman Laboratories, Inc. (1983) ¢Chemistry: Barium Metaborate Monohydrate & Others | . (Compilation; unpublished study received Dec 27, 1983 under 1448-17; CDL:252065-A)

00137048 Coate, W.; Zoetis, T.; Hardy, R. (1983) Acute Inhalation Toxicity Study in Rats--Busan 11-M1--Project No. 197-178. Final rept. (Unpublished study received Dec 27, 1983 under 1448-17; prepared by Hazleton Laboratories America, Inc., submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:252065-B)

00139192 Raltech Scientific Services, Inc. (1979) Busan 11-M1, Lot No. 47601, Nov. 17, 1978: ¢Acute Oral LD50/Prim Skin Irritation on Rats & Rabbits | : Lab. No. 709240.

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40898401 Kreuzmann, J. (1988) Delayed Contact Hypersensitivity Study in Guinea Pigs: Busan 11 M1: Study No. 88-3288-21. Unpublished study prepared by Hill Top Biolabs, Inc. 28 p.

42033601 Campbell, S.; Lynn, S. (1991) Busan 11-M1: An Acute Oral Toxicity Study with the Northern Bobwhite: Lab Project Number: 210/117. Unpublished study prepared by Wildlife International Ltd. 21 p.

42132601 San, R.; Olson, S. (1991) Salmonella/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test) with a Confirmatory Assay: Busan 11-M1: Lab Project Number: TA081.501014. Unpublished study prepared by Microbiological Associates, Inc. 52 p.

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42207501 Putman, D.; Young, R. (1992) Micronucleus Cytogenetic Assay in Mice: Lab Project Number: TA081.122. Unpublished study prepared by Microbiological Associates, Inc. 28 p.

42310501 Lamb, I. (1992) 28-Day Dietary Range-finding Study of Busan 11-M1 in Rats: Lab Project Number: WIL-94043. Unpublished study prepared by WIL Research Labs. Inc. 6 p.

42314301 Drake, K. (1992) Developmental Toxicity Study of Busan 11-M1 in Rabbits: Lab Project Number: WIL/94042. Unpublished study prepared by Buckman Laboratories International, Inc. 31 p.

42338601 Lintott, D. (1992) Busan 11-M1: Acute Toxicity to Bluegill, Lepomis macrochirus, under Static Test Conditions: Lab Project Number: J9107001C. Unpublished study prepared by Toxikon Environmental Sciences. 47 p.

42338602 Lintott, D. (1992) Busan 11-M1: Acute Toxicity to Rainbow Trout, Oncorhynchus mykiss, under Static Test Conditions: Lab Project Number: J9107001D. Unpublished study prepared by Toxikon Environmental Sciences. 47 p.

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APPENDIX D

LIST OF AVAILABLE DOCUMENTS

APPENDIX D

The following is a list of available documents related to barium metaborate. Its purpose is to provide a path to more detailed information if it is requried. These accompanying documents are part of the Administrative Record for Barium Metaborate and are included in the Agency's Office of Pesticide Programs Public Docket.

1. Health and Environmental Science Chapters

2. Detailed Label Usage Information System (LUIS) Reports

3. Barium Metaborate Fact Sheet (included in this RED)

4. PR Notice 91-2 pertains to the Label Ingredient Statement

Federal publications on barium metaborate are available and may be purchased from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

1. Guidance for the Reregistration of Pesticide Products Containing Barium Metaborate as the Active Ingredient: NTIS # PB84-168376

APPENDIX E

Instructions for Responding to the RED and

Instructions for the Confidential Statement of Formula

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. DATA CALL-IN (DCI) OR "90-DAY RESPONSE"--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. Complete the two response forms provided with each DCI letter by following the instructions contained in each DCI. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); otherwise, your product may be suspended.**

2. TIME EXTENSIONS AND DATA WAIVER REQUESTS--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. Application for Reregistration (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. Five copies of draft labeling which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; 703-487-4650).

c. Generic or Product Specific Data. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. Two copies of the Confidential Statement of Formula (CSF) for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal**

concentration. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Citation of Data**. Complete and sign this form (EPA form 8570-29) for each product. **Cite-all is not a valid option for reregistration.**

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB-XXXX)***
(XXXX = the case code for the RED)
Office of Pesticide Programs (H7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB-XXXX)***
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

INSTRUCTIONS FOR THE CONFIDENTIAL STATEMENT OF FORMULA

Two copies of the Confidential Statement of Formula (CSF) (EPA Form 8570-4) are required to be signed and completed for each basic and each alternate formulation. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product-specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The lower certified limits in pure active forms must not fall below the efficacious level per P.R. Notice 91-2.

n. The upper and lower certified limits for all active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

APPENDIX F
Product Specific Data Call-In

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

DATA CALL-IN NOTICE

JAN 25 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments A through G; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 3-31-96).

Recycled/Recyclable
Printed with Soy/Canola Ink on paper that contains at least 50% recycled fiber

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III- Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule

including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to

develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the

requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5. Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

   b. fulfill the commitment to develop and submit the data as required by this Notice; or

   c. otherwise take appropriate steps to meet the requirements stated in this

Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the

quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

Attachment 1. Chemical Status Sheet

BARIUM METABORATE: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing barium metaborate.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of barium metaborate. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for barium metaborate are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on barium metaborate are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible barium metaborate products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Mr. Franklin Gee at (703) 308-8008.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Mr. C. P. Moran
Special Review and Reregistration Division (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Barium Metaborate

Attachment 2. Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

INSTRUCTIONS FOR COMPLETING THE "DATA CALL-IN RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-4. Already completed by EPA.

Item 5. If you wish to voluntarily cancel your product, answer "yes". If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is identical to another product and you qualify for a data exemption, you must respond with "yes" to Item 7a (MUP) or 7B (EUP) on this form, provide the EPA reregistration numbers of your source (s); you would not complete the requirements status and registrant's response" form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

Item 7a. For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes." if you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver. See item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

SAMPLE

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
BUCKMAN LABS INC 1256 MCLEAN BLVD MEMPHIS TN 38108	0632 Barium metaborate	PRODUCT SPECIFIC JAN 25 1994

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
1448-105		N.A.	N.A.		

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

9. Date

10. Name of Company Contact

11. Phone Number

Attachment 3. Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-3. Completed by EPA. Note the unique identifier number assigned by EPA in item 3. This number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. The guidelines reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use patters (s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/ or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on 8 months after issuance of the Reregistration Eligibility Documents unless EPA determines that a longer time period is necessary.

Item 9. Enter Only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table. Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available on for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this notice that my product is similar. Enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product my be subject to suspension.

3. I have made offers to share in the cost to develop data (Offers to Cost Share).

I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed " Certification of offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the require data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgrade (upgrading a study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this Option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s) number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registratrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver

request, I will not be require to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status chosen. I also understand that the deadline for submission of data as specified by the original data cal-in notice will not change.

Items 10-13. Self-explanatory.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
BUCKMAN LABS INC
1256 MCLEAN BLVD
MEMPHIS TN 38108

2. Case # and Name
0632 Barium metaborate

EPA Reg. No. 1448-105

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 1448-RD-3390
JAN 25 1994

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descriptn starting materials, (1,2) productn & formulatn process					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of (1,3) impurities					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-11	Octanol/water partition (8) coefficient					ABCDEFGHIJKLMNO	PAI	8 mos.	

10. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
BUCKMAN LABS INC
1256 MCLEAN BLVD
MEMPHIS TN 38108

2. Case # and Name
0632 Barium metaborate

EPA Reg. No. 1448-105

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 1448-RD-3300
JAN 25 1994

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-13	Stability					ABCDEFGHIJKLMNO	MP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility (14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
	Acute Toxic - Regular Chemical								
81-1	Acute oral toxicity-rat (1,36,37)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat (1,2,37)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-3	Acute inhalation toxicity-rat (3)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-4	Primary eye irritation-rabbit (2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization (4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0632 Barium metaborate

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product.[NOTE: If a product is a 100 percent repackage of another registered product that is purchased, and any use for the product does not differ from those of the purchased and registered source, users are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
8 Required if technical chemical is organic and non-polar.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0632 Barium metaborate

Footnotes (cont.):

36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

EPA'S BATCHING OF BARIUM METABORATE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient barium metaborate, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to

participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

The table below shows the three products which were batched together.

BATCH NO.	EPA REG. NO.	% of Barium Metaborate	Formulation Type
1	1448-105	52.00% - Barium Metaborate	Ready-to-Use Solution
	1448-106	50.00% - Barium Metaborate	Ready-to-Use Solution
	1448-17	90.00% - Barium Metaborate	Soluble Concentrate

United States Environmental Protection Agency
Washington, D. C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0632 Barium metaborate

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
001448	BUCKMAN LABS INC		1256 MCLEAN BLVD	MEMPHIS TN	38108

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Chemical Name	EPA Chemical Number

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

   [ ] All companies on the data submitters' list for the active ingredient listed on this form (Cite-All Method or Cite-All Option under the Selective Method). (Also sign the General Offer to Pay below.)

   [ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form."

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number

Chemical Name	EPA Chemical Number

I Certify that:

My company is willing to develp and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company name above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date

Name and Title (Please Type or Print)