United States
Environmental Protection
Agency

Office of Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-95-010
February 1995

Reregistration Eligibility Decision (RED)

Bromohydroxy-acetophenone (BHAP)

BHAP

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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 3032 which includes the active ingredient bromohydroxyacetophenone. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, 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 ingredients 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.

If you have questions on the generic or product specific data requirements or wish to meet with the Agency, please contact Frank Rubis in the Special Review and Reregistration Division, at (703) 308-8184.

Sincerely yours,

Peter Caulkins, Acting Director
Special Review
and Reregistration Division

Enclosures

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. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **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 to 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; telephone number 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 Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

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)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
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.

REREGISTRATION ELIGIBILITY DOCUMENT

BROMOHYDROXYACETOPHENONE

LIST C

CASE 3032

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

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
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
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized As Safe as designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
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, air or feed, e.g., mg/l, mg/kg 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
LOC	Level of Concern
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin Of Exposure
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

GLOSSARY OF TERMS AND ABBREVIATIONS

PAM	Pesticide Analytical Method
PPE	Personal Protective Equipment
ppb	Parts Per Billion
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

Bromohydroxyacetophenone is a microbicide/microbistat registered by Buckman Laboratories. Three registered products, Busan 90, Busan 93, and Busan ll30, contain this active ingredient. They are all registered to inhibit the growth of bacteria and fungi that cause the microbiological degradation of papermaking chemicals. In addition Busan 90 and 1130 are used to inhibit the growth of bacteria that cause loss of viscosity in emulsion paints, adhesives, waxes, and polishes.

The registered use sites for bromohydroxyacetophenone are Aquatic Non-food Industrial, Indoor Non-food, and Terrestrial Non-Food Crop. In l990, Busan 1130 was given approval by the FDA for its use in the manufacture of paper and paperboard materials and/or coatings for food contact use.

The Agency is requiring that certain environmental fate studies be conducted. In addition, before reregistering the products containing bromohydroxyacetophenone, 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, the Agency will reregister a product based on whether or not it meets the requirements in Section 3(c)(5) of FIFRA. 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 registered uses of bromohydroxyacetophenone. The document consists of six sections. Section I is the introduction. Section II describes bromohydroxyacetophenone, 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 bromohydroxyacetophenone. Section V discusses the reregistration requirements for bromohydroxyacetophenone. Finally, Section VI is the Appendices which support this Reregistration Eligibility Document. Additional details concerning the Agency's review of applicable data are available on request.[1]

[1]EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient(s) are covered by this Reregistration Eligibility Document:

- **Common Name:** 2-Bromo-4'-hydroxyacetophenone
- **Chemical Name:** Ethanone 2-bromo-1-(4-hydroxyphenyl)
- **CAS Registry Number:** 2491-38-5
- **OPP Chemical Code:** 008707
- **Empirical Formula:** $C_8H_7O_2Br$
- **Trade and Other Names:** Busan, BHAP
- **Basic Manufacturer:** Buckman Laboratories

B. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A usage table for **bromohydroxyactophenone** is in Appendix A.

For **bromohydroxyacetophenone**:

Type of Pesticide: Microbicide/Microbistat (slime forming bacteria and fungi)

Use Sites: AQUATIC NON-FOOD INDUSTRIAL

Commercial/Industrial Water Cooling Systems
Oil Recovery Drilling Muds/Packer Fluids
Pulp/Paper Mill Water Systems
Secondary Oil Recovery Injection Water

INDOOR NON-FOOD

Industrial Adhesives
Industrial Coatings
Latex Paints (In-can)
Specialty Industrial Products
Wet-End Additives/Industrial Processing Chemicals
Specialty Industrial Products

TERRESTRIAL NON-FOOD CROP

Oil Recovery Drilling Muds/Packer Fluids

Target Pests: Slime-forming bacteria and fungi

Formulation Types Registered: Type: End Use

Form: Soluble concentrate liquid

Method and Rates of Application:

Types of Treatment:
Pulp and paper mill systems supplemental treatment, Water treatment, Water recirculating system treatment, Industrial preservative

Equipment:
Drip-feed device, Measuring container, Metering pump, Not specified

Timing:
Initial, Subsequent/maintenance, Continuous feed (initial), Continuous feed (subsequent), Intermittent (slug) (initial), Intermittent (slug) (subsequent), Shock/slug, During manufacture, Not specified

Rate of Application:
Terrestrial Non-Food Crop:
Oil Recovery Drilling Muds/Packer Fluids
From l00 to 400 ppm active ingredient by weight

Aquatic non-food industrial:

Commercial/industrial water cooling systems:

From l up to l0 ppm of active ingredient by volume

Oil Recovery Drilling Muds/Packer Fluids:
From l00 to 400 ppm active ingredient by weight

Pulp and paper mill systems supplemental treatment:
From 20 up to 90 ppm of active ingredient by weight

Water treatment for pulp/paper mill systems:
From 30 up to 300 ppm of active ingredient by weight

Secondary oil recovery injection water:
From l up to l0 ppm of active ingredient by volume

Indoor non-food:

Industrial adhesives:
From 1.5 up to 6 parts per million active ingredient by weight

Industrial coatings:
From 1.5 up to 8 parts per million active ingredient by weight

Latex paints (in-can):
0.1 to 1.5% of product based on the weight of the emulsion

Oil Recovery Drilling Muds/Packer Fluids:
From l00 to 400 ppm active ingredient by weight

Specialty industrial products:
From 300 up to 4500 ppm of active ingredient by weight

Wet-end additives/industrial processing chemicals:
From 1 up to 6 parts per million active ingredient by weight

Use Practices Limitations: Preclean claim. Do not expose to extreme temperatures. Do not discharge effluent containing this pesticide into sewage systems without notifying

the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, ponds, estuaries, oceans, or public water (NPDES license restriction)

C. Data Requirements

Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

D. Regulatory History

Bromohydroxyacetophenone was registered in the United States in **l964** for use as a microbicide/ microbiostat. There are a total of three registered products containing the active ingredient **bromohydroxyacetophenone**. Buckman Labs, Inc. manufactures all three products and is the sole registrant. These products are Busan 90 (emulsifiable concentrate) registered in l964, Busan 93 (soluble concentrate) registered in l972, and Busan ll30 (ready-to-use solution), registered in l991. The products are registered for use in the control of slime-forming bacteria, deterioration/spoilage bacteria, fungi, slime-forming fungi (paper mills and water systems).

Busan 90, 93, and 1130 are all registered for use in pulp and paper mill systems to control bacterial and fungal slime. These products are also used to inhibit the growth of bacteria and fungi that cause the microbiological degradation of papermaking chemicals.

Busan 90 and 1130 exhibit an additional use pattern. They are used to inhibit the growth of bacteria that cause the loss of viscosity in emulsion paints, adhesives, waxes, and polishes.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Molecular weight: 215.45

Color: Reddish brown

Physical State: Viscous liquid

Odor: Odorless

Boiling Point: 139.1 +- 0.7 degrees C at 737.9 mm Hg

Density: 1.2733 at 20 degrees C

Solubility: 0.248 ± 007 g/100 water

Vapor Pressure: 1.1 x 10^{-5} Torr at 25 ± 1 degree C

Dissociation Constant (pK_a) = 7.6 ± 0,3 at 24 degrees C

$K_{o/w}$: l04 ± 5

pH: 3.25 ± 0.02 at 25 degrees C

Stability: Stable under all storage conditions

Flash Point: 48.2 ± 0.6 degrees C

Viscosity: 56.5 ± 0.1 cSt at 25 degrees C

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on bromohydroxyacetophenone is adequate and will support reregistration eligibility.

a. Acute Toxicity

The acute toxicity results for 2-bromo-4-hydroxyacetophenone [BHAP; *Busan 90*] are tabulated below:

Route	Species	Results	Toxicity Category
Oral	Rat	LD_{50} = 262 mg/kg	II
Dermal	Rabbit	LD_{50} = > 2000 mg/kg	III
Inhalation	Rat	LC_{50} = 0.19 mg/mL	II
*Eye Irritation	Rabbit	Corrosive	I
*Dermal Irritation	Rabbit	Mild Irritant	III
*Dermal Sensitization	Guinea pigs	Sensitizer	NA

*Not required in the TGAI, however, presented here for informational purposes.

In an acute oral LD50 study, oral administration of BHAP [technical, 45%] to male and female rats induced clinical signs of toxicity such as lethargy, urine stains, decreased limb tone, respiratory rales and ataxia. Gross necropsy revealed dilated meningeal blood vessels or hemorrhage of the brain, reddened intestines, dark red kidneys and reddened or dark areas of the stomach. The LD50 values were 343 mg/kg for males, < 193 mg/kg for females and 262 mg/kg for the combined sexes, results that place BHAP in Toxicity Category II [Bates and Nass, 1986].

In an acute dermal LD50 study, a single dermal application of BHAP [technical, 45%] at 2000 mg/kg to male and female rabbits resulted in moderate to severe erythema and subcutaneous hemorrhage one hour after treatment; no mortality occurred. An LD50 of > 2000 mg/kg places BHAP in Toxicity Category III [Bates and Nass, 1986].

In an acute inhalation LC50 study, both sexes of rats exposed to aerosol concentrations of BHAP [technical, 45%] for four hours

experienced ataxia, decreased activity, gasping, labored breathing, corneal opacity, nasal discharge and dark material around the eyes and nose and body weight loss. The LC50 values were 0.17 mg/mL for males, 0.21 mg/L for females, and 0.19 mg/L for the combined sexes, results that place BHAP in Toxicity Category II [Biesemeier and Voss, 1986].

In a primary eye irritation study, instillation of 0.1 mL of undiluted BHAP [technical, 45%] into the conjunctival sac induced ocular irritation of the cornea, iris and conjunctiva and vocalization. None of the rabbits were cleared of ocular irritation by Day 21, results indicating BHAP to be a corrosive material and in Toxicity Category I [Bates and Nass, 1986].

In a primary dermal irritation study, a single dermal application of 0.5 mL of undiluted BHAP [technical, 45%] resulted in moderate erythema and severe edema early in the study lasting up to 13 days with the severity decreasing during subsequent days. BHAP was classified as a mild irritant and placed in Toxicity Category III [Bates and Nass, 1986].

In a dermal sensitization study, when applied as a 50% and 10% w/v concentrations for the induction and challenge phases, respectively, BHAP [technical, 45%] was found to be a sensitizer to male and female guinea pigs [Bates and Nass, 1986].

b. Subchronic Toxicity

In a 21-day dermal toxicity study with rabbits [Koehler and Adams, 1987], repeated dermal applications of BHAP [technical, 46.03%] at 0, 20, 100, or 500 mg/kg, six hours/day, five days/week for three weeks resulted in no systemic toxicity. BHAP induced dermal irritation at all dose levels. Erythema and edema was seen after the first application while more severe lesions such as subcutaneous hemorrhages, eschar, scabbing, necrosis fissuring, exfoliation and desquamation were seen on the following days. The onset, frequency and severity of the lesions were dose-related. A dose-related increase in the number of platelets was seen in both sexes and can be attributed to the subcutaneous hemorrhage seen in all treated rabbits. Gross pathological changes observed only in the treated skin were confirmed by histopathological lesions characterized by acanthotic epidermal thickening, hyperkeratosis, parakeratosis and inflammatory changes. Based on these findings the dermal irritation NOEL was not achieved and the LOEL was 20 mg/kg/day (LDT) and the systemic toxicity NOEL was 500 mg/kg/day (HDT) and the LOEL was not established.

c. Chronic Toxicity and Carcinogenicity

The use of bromohydroxyacetophenone will not likely result in human exposure over a significant portion of human life span. Therefore, the Chronic Toxicity Study in Rodents, 83-1(a) and Non-Rodents, 83-1(b), and the Carcinogenicity Study in Mouse, 83-2(a) and Rats, 83-3(a) are not required.

d. Developmental Toxicity

In a developmental toxicity study in rats [Rodwell, 1987], oral administration of BHAP technical, 46.03%] at 0, 10, 30, or 100 mg/kg/day during days six through 15 of gestation resulted in no mortality, abortions, or premature deliveries at any dose level. Clinical signs limited to dams given 100 mg/kg/day were respiratory rales and clear and/or yellow material around the mouth. BHAP had no effect on mean body weights or body weight gains. Food consumption was significantly decreased at 100 mg/kg/day during the entire dosing period. BHAP did not cause fetal toxicity; the mean numbers of viable fetuses, early or late resorptions, implantation sites, corpora lutea, pre- and post-implantation losses, sex ratios and fetal body weights in the treated groups were comparable to that of the control group. No developmental toxicity was seen at any dose; there were no increases in the external, visceral, or skeletal malformations or variations in any of the fetuses of dams treated with BHAP. Under the conditions of this study, the NOEL for maternal toxicity was 30 mg/kg/day and the LOEL was 100 mg/kg/day. The NOEL for developmental toxicity was 100 mg/kg/day and a LOEL was not established.

e. Reproductive Toxicity

The use pattern of bromohydroxyacetophenone does not warrant a 2-Generation Reproduction Study, 83-4.

f. Mutagenicity

In a *Salmonella*/Mammalian microsome reverse mutation assay, when tested at concentrations of 0, 0.12, 0.37, 1.10, 3.30, or 10.00 µg/plate in *S.typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538, BHAP [technical, 47%] was nonmutagenic both in the presence and absence of rat liver activation [Cavagnaro and Brusick, 1985].

In a forward gene mutation assay, BHAP [technical, 47%] gave negative results following exposure of CHO cells at concentrations of 0.5, 1, 2.5, 5, 7.5, or 10 µg/mL in the absence of metabolic activation and at

2.5, 5, 7.5, 10, 25 or 50 µg/mL in the presence of activation [Cavagnaro and Sernau, 1985].

In an *in vivo* micronucleus assay, BHAP [technical, 47%] did not cause a significant increase in the frequency of micronucleated polychromatic erythrocytes [PCEs] harvested at 24, 48 and 72 hours posttreatment from mice given single oral doses of BHAP at 70, 233, or 700 mg/kg. BHAP was negative in this assay [Ivett and Myhr, 1986].

In an *in vitro* primary rat hepatocyte UDS assay, BHAP [technical, 47%] at concentrations of 0.1, 0.25, 0.5, 1.0 or 2.0 µg/mL, did not cause a significant increase in the net nuclear grain counts of treated hepatocytes [Cavagnaro and Sernau, 1985b].

g. Metabolism

A General Metabolism study, 85-1 is not required since chronic toxicity and carcinogenicity studies are not required for this use chemical.

h. Other Toxic Endpoints

Because of the use patterns of BHAP, the 90-day Oral Feeding Studies in Rodents (82-1a) and Non-Rodents (82-1b), the 90-Day Dermal Irritation Study in Rodents (82-3), and the 90-Day Inhalation Study in Rats (82-4) are not required.

Because use of BHAP is not expected to result in human exposure over a significant portion of human life span, the Chronic Toxicity Study in Rodents (83-1a) and Non-Rodents (83-1b) and the Carcinogenicity Study in Mouse (83-2a) and Rats (83-3a) are not required.

The use pattern of BHAP does not warrant a 2-Generation Reproductive Study (83-4).

A General Metabolism study (85-1) is not required since chronic toxicity and carcinogenicity studies are not required for this non-food use chemical.

A dermal penetration study (85-2) is not required since there are no toxicological endpoints to indicate that such a study is essential.

A domestic animal safety study (86-1) is not required for the use pattern of BHAP.

i. Reference Dose

Not established.

2. Exposure Assessment

a. Dietary Exposure

A food additive tolerance has been established for BHAP from food contact with food grade paper and paperboard (see 21 CFR l76.300). The use of BHAP as a slimicide in the manufacture of paper and paperboard that contact food, is regulated under the jurisdiction of the U.S. Food and Drug Administration and is not directly regulated by EPA.

b. Occupational and Residential

Occupational exposure can be expected based on the currently registered uses of this chemical. Busan is used as a water treatment in the pulp and paper industry (e.g., slush pulp storage and dry/coated broke treatment) and as a preservative in industrial adhesives, coatings, paints (added to cans during manufacture), specialty industrial processing chemicals (e.g., waxes and polishes) and wet end additives/industrial processing chemicals (e.g., alum and starch slurries for papermaking). Busan is formulated as a soluble concentrate/liquid. Treatments are made using a variety of equipment such as drip-feed devices, measuring containers and metering pumps.

Handler (Mixers, Loaders, Applicators, etc.) Exposures

There is an exposure risk for mixers, loaders, applicators, or other handlers during usual use-patterns associated with BHAP, expecially during water treatment during pulp and paper manufacturing, paint manufacturing, and industrial solution preparation.

Post-Application Exposures

There are several types of potential exposures to persons after application is complete. These include:

potential exposure, expecially inhalation exposure, to industrial/manufacturing workers immediately after BHAP use,
potential exposure, including dermal and inhalation exposure, when substances (such as paints, waxes, polishes, and adhesives) containing BHAP are used, and potential exposure, expecially

inhalation exposure, to substances containing BHAP immediately after such substances are used.

3. Risk Assessment

a. Dietary

The one potential food use for BHAP in paper and paperboard is regulated by FDA.

b. Occupational and Residential

An occupational and/or residential exposure assessment is required for an active ingredient if (l) certain toxicological criteria are triggered and (2) there is an exposure risk for handlers (mixers, loaders, applicators, etc.) during use or for persons entering treated sites after application is complete.

There is potential exposure to mixers, loaders, applicators, or other handlers during use of BHAP in industrial/manufacturing settings. However, the only toxicological endpoints of concern for such handlers (category II for inhalation toxicity and toxicity category I (corrosive for eye irritation) can be mitigated through the use of personal protective equipment. Therefore, since the eye irritation is classified as Category I, the Agency recommends the use of goggles or faceshields to prevent eye contact. In addition, the Agency recommends the use of chemical resistant gloves and a NIOSH/MSHA approved organic vapor removing cartridge respirator with prefilter (TC-23). As a result, an occupational and/or residential exposure assessment for handlers is not required for BHAP.

There is potential post-application exposure of persons to BHAP. However, an occupational and/or residential exposure assessment for post-application workers is not required since the toxicity concerns are not triggered.

BHAP has low vapor pressure. Therefore, inhalation by industrial/manufacturing workers immediately after BHAP use is likely to be negligible.

Since the amount of BHAP in substances (such as paints, waxes, polishes, and adhesives) is minimal, toxic effects from dermal and inhalation exposure when substances containing BHAP are used and

inhalation exposure to such substances after use are expected to be negligible.

Personal Protective Equipment (PPE) for Handlers (Mixer/Loader/Applicators).

For each end-use, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

l. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient. These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.

The more stringent choice for each type of PPE (i.e., hand protection, footware, eyewear, etc.) must be placed on the label of the end-use product.

There are no special toxicological concerns (i.e., certain adverse effects such as allergic effects or delayed effects as cancer, developmental toxicity, reproductive effects, etc.) about BHAP that would require setting minimum or "baseline" handler PPE.

C. Environmental Assessment

1. Environmental Fate

At this time, only data requirements for the indoor nonfood use pattern as indicated in the environmental fate guidelines (40 CFR 158) have been fulfilled for

2-bromo-4'-hydroxyacetophenone (BHAP). Data requirements have not been satisfied for BHAP's aquatic nonfood industrial use pattern (i.e., oil drilling muds and secondary oil recovery injection water). In addition, BHAP has an atypical application to paper and pulp processing water. Potentially high exposures to the environment may result from these uses; therefore, the following data are required: hydrolysis (l61-1), photodegradation in water (l61-2), anaerobic and aerobic aquatic metabolism (162-3 and l62-4), leaching and adsorption/desorption (163-1) and bioaccumulation in fish (165-4). As a result, the Agency has only sufficient data for a qualitative environmental fate assessment of BHAP.

a. Environmental Chemistry, Fate and Transport

(1) Hydrolysis

A hydrolysis study was submitted and determined to be supplemental only. However, from the information provided, it appears that BHAP has a hydrolytic half-life of 272, 250, and 173 hours at pH 5, 7, and 9, respectively. Additional data/information must be submitted to upgrade this study to meet guideline requirements. The requirement for hydrolysis data (161-1) has not been satisfied. (MRID 00158969)

(2) Photodegradation in water

A photodegradation in water study was submitted and determined to be supplemental only. However, from the information provided, it appears that BHAP photodegrades in water with a half-life of less than 2 days. Additional data must be submitted to upgrade this study to meet guideline requirements. The requirement for photodegradation in water data (161-2) has not been satisfied. (MRID 00158969)

(3) Anaerobic aquatic metabolism

Anaerobic aquatic metabolism study were submitted and determined to be supplemental and not upgradable. A new study must be conducted according to guideline requirements. The requirement for anaerobic aquatic metabolism data (162-3) has not been satisfied. (MRID 40334301 and 41586801)

(4) Aerobic aquatic metabolism

An aerobic aquatic metabolism study was submitted and determined to be supplemental only. However, from the information provided, it appears that BHAP's half-life in aerobic aquatic environments is 2.5 days. Additional data/information must be submitted to upgrade this study to meet guideline requirements. The requirement for aerobic aquatic metabolism data (162-4) has not been satisfied. (MRID 40334301)

(5) Leaching and adsorption/desorption

Leaching and adsorption/desorption studies were submitted and determined to be supplemental and not upgradable. A new study, which addresses only the adsorption/desorption component of the data requirement must be conducted according to guideline requirements. The registrant should consult with the Agency for guidance on meeting this requirement. The requirement for adsorption/desorption data (163-1) has not been satisfied. (MRID 00158970 and 00158971)

b. Environmental Fate Assessment

Based on submitted supplemental data, BHAP appears to be nonpersistent, and the data indicate that photolysis plays a major role in the degradation pathway. BHAP photodegrades in water with a half-life of less than two days. Also, BHAP's half-life in aerobic aquatic environments is 2.5 days. Its hydrolytic half-life is 272 hours, 250 hours, and 173 hours at pH 5, 7, and 9, respectively. BHAP appears to be immobile to moderately mobile, as indicated by Thin-Layer Chromatography, with Rf values of 0.25, 0.31, and 0.51 in silty clay loam, sandy loam, and silt loam soils, respectively. However, when applied to sandy soils BHAP appears to be very mobile (Rf = 0.97).

BHAP is registered with indoor nonfood and aquatic nonfood uses. BHAP's indoor nonfood use pattern has no direct exposure to the environment when used according to label directions. However, BHAP does result in environmental exposures based on its industrial uses, where indirect discharges occur. However, these discharged levels are administered under a NPDES permit granted by the Office of Water of EPA.

2. Ecological Effects

The toxicity data base is complete for the indoor nonfood use pattern. However, three estuarine studies (72-3 a,b,c) are still outstanding for the aquatic nonfood industrial use pattern (pulp and paper mills, oil drilling muds, and secondary oil recovery). With the exception of estuarine/marine data, the ecotoxicological data base is adequate to characterize the toxicity of BHAP to nontarget terrestrial and aquatic organisms when used on aquatic nonfood sites.

a. Terrestrial Data

In order to establish the toxicity of BHAP to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); one subacute dietary study (LC_{50}) on one species of waterfowl (preferably the mallard duck) or upland game bird (preferably bobwhite quail or ring-necked pheasant).

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. Because the indoor nonfood and aquatic nonfood use patterns are unlikely to expose wild mammals, these data are not required.

A honey bee acute contact LD_{50} study is required if the intended use will result in honey bee exposure. Because the proposed use patterns are not likely to expose honey bees, these data are not required.

(1) Avian Acute Toxicity

Avian Acute Oral Toxicity Findings

Species	% Test Material (TGAI)	LD_{50}	Conclusions
Bobwhite quail	47.3	313 mg/kg a.i.	moderately toxic

The avian acute oral LD_{50} of 313 mg/kg of active ingredient for bobwhite quail (Beavers and Jaber, l985) indicates that BHAP is moderately toxic to birds on an acute oral basis. The guideline requirement for the avian acute oral LD_{50} study is fulfilled. (MRID 158959)

(2) Avian Subacute Dietary Toxicity

Avian Acute Oral Toxicity Findings			
Species	**% Test Material**	**LC_{50}**	**Conclusions**
Mallard Duck	47.3	> 2658 ppm ai	slightly toxic
Bobwhite quail	47.3	> 2658 ppm ai	slightly toxic

The avian dietary LC_{50}'s of greater than 2658 ppm for bobwhite quail and mallard (Beavers and Jaber, l985) indicate that BHAP is no more than slightly toxic to birds or a dietary basis. No mortality was reported for either species at the highest level tested. The guideline requirements is satisfied. (MRID 158961 and l58960)

b. Aquatic Data

(1) Freshwater Fish Toxicity

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient is one freshwater fish toxicity study. The study should use a coldwater species (preferably the rainbow trout)or a warmwater species (preferably the bluegill sunfish).

Freshwater Fish Acute Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Rainbow trout	47.3	0.61 ppm ai	highly toxic
Bluegill sunfish	47.3	1.7 ppm ai	moderately toxic

The fish LC_{50}'s of 0.61 ppm ai for the rainbow trout (Nicholson & Surprenant, l985) and l.7 ppm ai for the bluegill sunfish (Nicholson & Surprenant, l985) indicate that BHAP is

moderately to highly toxic to freshwater fish. The guideline requirement for acute toxicity testing of the technical on freshwater fish is fulfilled. (MRID 00158963 and 00158962)

(2) Freshwater Invertebrate Toxicity

The minimum testing required to assess the hazard of a pesticide is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. A 21 day chronic life cycle study was voluntarily submitted.

Freshwater Invertebrate Toxicity Findings

Species	% Test Material	[1]EC_{50}/ [2]Chronic Effect Levels (ppm ai)	Conclusions
Daphnia magna	47.3	[1]3.2 ppm ai	moderately toxic
Daphnia magna	31.4	[2] 0.144 = LOEL 0.056 = NOEL 0.09 = MATC	reduction in offspring

The EC_{50} of 3.2 ppm for *Daphnia magna* (Nicholson & Surprenant, l985) indicate that BHAP is moderately toxic to freshwater invertebrates. The guideline requirement is fulfilled. The chronic study (Davis, J. 1994) showed a reduced number of offspring per day at 0.144 ppm, the Lowest Observed Effect Level (LOEL). The No Observed Effect Level (NOEL) was 0.056 ppm. The Maximum Allowable Toxicant Concentration (MATC), based on the most sensitive biological parameter, daphnid reproduction, was greater than 0.056 ppm and less than 0.144 ppm measured concentration (geometric mean = 0.09 ppm). (MRID 00158964 and 43124401)

(3) Estuarine/Marine Toxicity

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. The aquatic nonfood use pattern of BHAP may result in exposure to the estuarine environment.

The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters. This requirement has not been satisfied.

However, in lieu of performing and submitting these studies, the registrant has the option to request an amendment to the BHAP label to include a statement prohibiting the use or discharge of BHAP in estuarine/marine environments.

c. Non Target Plants Data

Terrestrial plant testing (seed germination, seedling emergence and vegetative vigor) and aquatic plant testing are required for herbicides which have terrestrial nonfood/feed or aquatic nonfood(except residential) use patterns and which have endangered of threatened plant species associated with the site of application.

Because BHAP is a microbiocide/microbiostat for control of fungi primarily, aquatic plant toxicity requirements are not required. However, in the event that incidents of adverse effects to plant species are reported to the Agency, these data will be required.

d. Ecological Effects Risk Assessment

Risk assessments are not conducted for nontarget organisms for indoor nonfood uses without effluents. The acute risk for the use of this pesticide is based on the residue levels in natural water receiving effluent from a facility using the pesticide. If residues should exceed one-half of the EC_{50} to aquatic invertebrates (l.6 ppm) and or freshwater fish (0.31 ppm) these organisms are acutely at risk. The risk resulting from the use of BHAP will be considered in the issuance of a NPDES permit.

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 bromohydroxyacetophenone as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing

bromohydroxyacetophenone. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of bromohydroxyacetophenone, 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 registered uses of bromohydroxyacetophenone and to determine that bromohydroxyacetophenone can be used without resulting in unreasonable adverse effects to man and the environment. The Agency therefore finds that all products containing bromohydroxyacetophenone as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, and the current guidelines for conducting acceptable studies to generate such data. Although the Agency has found that all uses of bromohydroxyacetophenone are eligible for reregistration, 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 bromohydroxyacetophenone, if new information comes to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient bromohydroxyacetophone, the Agency has sufficient information on the health effects of bromohydroxyacetophenone and on its potential for causing adverse effects in fish and wildlife and the environment. Therefore, the Agency concludes that all uses of products containing bromohydroxyacetophenone are eligible for reregistration.

The Agency has determined that bromohydroxyacetophenone products, labeled and used as specified in this Reregistration Eligibility Document, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of bromohydroxyacetophenone are eligible for reregistration.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for bromohydroxyacetophenone. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Potential Discharge to Surface Waters

The Agency has determined that discharge to surface waters of effluent containing bromohydroxyacetophenone may result from its use as a pesticide. Its use as a pesticide and its potential release to the environment subjects it to the requirements of both FIFRA and the National Pollutant Discharge Elimination System (NPDES) which is administered by the Federal Office of Water (OW) with the states.

By their nature, industrial biocides are often toxic to aquatic organisms. The environmental effects of discharges containing biocides may depend heavily upon the volume, concentration, and other constituents of a particular discharge, as well as the size, nature, and flow rate of waters receiving the discharge. FIFRA permits EPA to require the generation of data on the effects of biocides and to set general limits and conditions of use of a biocide through statements on its labeling. However, because FIFRA regulation is generally national in scope, these mechanisms are not readily adaptable to varied and changing local conditions. Generalized regulation of a pesticide under FIFRA may be insufficiently protective under some local conditions. The NPDES process is designed to take local conditions into account through the issuance of facility-specific permits for the discharge of pollutants to bodies of water. However, historically, specific information about the toxicological and environmental properties of biocides in effluent streams was not always readily available or considered in writing permits.

EPA's Office of Pesticide Programs and Office of Water intend to cooperate in the oversight of biocide uses to better take advantage of the strengths of each program while avoiding duplication of regulation. Under FIFRA, OPP will require the generation and submission to the Agency of infomation that will be used by the Agency to identify potential hazards from the discharge of biocides from pesticidal use that may require control measures under either regulatory program. This information will be shared with the Office of Water where it can be made available to NPDES permit writers to address aquatic effects of point source biocide use. In turn, Office of Water will forward to OPP any information that becomes available concerning unanticipated aquatic effects of the use of biocides for OPP's use in national registration decisions for these products. EPA believes this approach will provide adequate environmental safeguards since it allows OPP to control the general approval of the biocide as required by FIFRA, but includes a mechanism for recognizing and regulating potential local unacceptable effects through the NPDES program. Improved limitations on the use under FIFRA and more targeted NPDES permitting decisions for industrial

biocides may be developed in the future as the information gathering and exchange program between the offices progresses.

The Agency believes that the above process, absent extraordinary concerns about the adverse effects of the uses of bromohydroxyacetophenone from its potential discharge to surface waters, adequately addresses the test for (re-) registration of a pesticide under FIFRA -- "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." Therefore, the Agency concludes that the uses of bromohydroyxacetophenone will not cause unreasonable adverse effects if an effluent discharge label statement (requiring that any such discharge is subject to the NPDES process) is required for all products which have a potential for discharge to surface water.

2. Tolerance Reassessment

Non-applicable.

3. Restriction On Use

Preclean claim. Do not expose to extreme temperatures.

4. Reference Dose Exceedance

None established.

5. Endangered Species Statement

The Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

The Agency plans to publish a description of the Endangered Species Program in the Federal Register by l995 and have enforceable county-specific bulletins available. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

6. Risk Mitigation to Handlers

Personal Protective Equipment (PPE) for Handlers (Mixer/Loader/Applicators)

For each end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

(a) If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

(b) If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient.
- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.
- The more stringent choice for each type of PPE i.e., bodywear, hand protection, footwear, eyewear, respirators, etc.) must be placed on the label of the end-use product.

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 generic data base supporting the reregistration of bromohydroxyactophenone for the above eligible uses have been reviewed and it has been determined that additional studies are required. The data requirements are contained in the generic data call-in, Appendix F, Attachment 2.

2. Labeling Requirements for Manufacturing-Use Products

Personal Protective Equipment and Engineering Controls

Other Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing BHAP that are intended primarily for occupational use:

Engineering Controls:

"When handlers use closed metering systems the handler requirements may be reduced or modified to long-sleeve shirt, long pants, shoes and socks."

User Safety Requirements:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations:

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet"

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Sensitization Statement:

The following statement is required in the "Hazards to Humans (and Domestic Animals)" section of the Precautionary Statements on the labeling of all end-use products containing BHAP, because it is classified as a skin sensitizer:

"This product may cause skin sensitization reactions in some people."

Effluent Discharge Labeling Statements

All BHAP manufacturing-use or end-use pesticide products that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems must bear the following effluent discharge labeling statement.

> "This pesticide is toxic to fish. Do not use in facilities discharging directly or indirectly to the estuarine or marine environment. Do not discharge effluent containing this product into freshwater lakes, streams and ponds 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. Secondary biological treatment of BHAP effluent discharging to freshwater environments is required for all uses except for use in secondary oil recovery systems discharging to freshwater environments. 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 pesticide products distributed or sold by registrants and distributors (supplemental registrants) must bear the above labeling by October, 1995. All products distribtuted 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.

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, Attachment 3, 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 5) 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 in 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. Please follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling.

3. Protective Equipment and Engineering Controls

Refer to subsection "A" above for labeling requirements and controls.

4. Effluent Discharge Labeling Statements

Refer to subsection A. above for labeling requirements for effluent discharge.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this 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 this 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 BHAP 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. Registrants and persons other than registrants remain obligated to meet preexisting Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

Application Type, Application Timing, Application Equipment _ Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Dose	Max. Rate /crop /year	Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	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 Applicable., Not applicable for this use.	SC/L	W 1.5		W 6	*	NS	NS	NS	NS	NS	NS		C18, C24
COATINGS, INDUSTRIAL				Use Group: INDOOR NON-FOOD									
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 1.5		W 8	*	NS	NS	NS	NS	NS	NS		C18, C24
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL									
Water treatment (recirculating system)., Initial., Not on label., Not Applicable., Not applicable for this use.	SC/L	V 1		V 10	*	NS	NS	NS	NS	NS	NS		A08, C18, C24
Water treatment (recirculating system)., Subsequent/maintenance., Not on label., Not Applicable., Not applicable for this use.	SC/L	V 1		V 10	*	NS	NS	NS	NS	NS	NS		A08, C18, C24
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS				Use Group: AQUATIC NON-FOOD INDUSTRIAL									
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 100		W 400	*	NS	NS	NS	NS	NS	NS		C18, C24
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS				Use Group: INDOOR NON-FOOD									
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 100		W 400	*	NS	NS	NS	NS	NS	NS		C18, C24
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS				Use Group: TERRESTRIAL NON-FOOD CROP									
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 100		W 400	*	NS	NS	NS	NS	NS	NS		C18, C24
PAINTS, LATEX (IN-CAN)				Use Group: INDOOR NON-FOOD									
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 300		W 1500	*	NS	NS	NS	NS	NS	NS		C18, C24

Application Type, Application Timing, Application Equipment _ Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Tex. Dose	# Apps Max. @ Max. /crop cycle	Rate /year	Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes	SITE
USES ELIGIBLE FOR REREGISTRATION														
NON-FOOD/NON-FEED (con't)														
PULP/PAPER MILL WATER SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Pulp and paper mill systems supplemental treatment., Not on label., Drip-feed device., Not Applicable., Not applicable for this use.	SC/L	W 30	W 90	*	NS	NS	NS	NS	NS	NS			C18, C24	
PULP/PAPER MILL WATER SYSTEMS (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)										
Pulp and paper mill systems supplemental treatment., Not on label., Measuring container., Not Applicable., Not applicable for this use.	SC/L	W 30	W 90	*	NS	NS	NS	NS	NS	NS			C18, C24	
Pulp and paper mill systems supplemental treatment., Not on label., Metering pump., Not Applicable., Not applicable for this use.	SC/L	W 30	W 90	*	NS	NS	NS	NS	NS	NS			C18, C24	
Pulp and paper mill systems supplemental treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 20	W 60	*	NS	NS	NS	NS	NS	NS			C18, C24	
	SC/L	W 30	W 90	*	NS	NS	NS	NS	NS	NS			C18, C24	
Water treatment., Not on label., Drip-feed device., Not Applicable., Not applicable for this use.	SC/L	W 30	W 300	*	NS	NS	NS	NS	NS	NS			C18, C24	
Water treatment., Not on label., Measuring container., Not Applicable., Not applicable for this use.	SC/L	W 30	W 300	*	NS	NS	NS	NS	NS	NS			C18, C24	
Water treatment., Not on label., Metering pump., Not Applicable., Not applicable for this use.	SC/L	W 30	W 300	*	NS	NS	NS	NS	NS	NS			C18, C24	
Water treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 30	W 300	*	NS	NS	NS	NS	NS	NS			C18, C24	
SECONDARY OIL RECOVERY INJECTION WATER				Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Water treatment., Continuous feed (initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	V 1	V 5	*	NS	NS	NS	NS	NS	NS			C18, C24	

Application Type, Application Timing, Application Equipment _ Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Dose	Max. Rate /crop /year	Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
SECONDARY OIL RECOVERY INJECTION WATER (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)									
Water treatment., Continuous feed (subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	V 1	V 5	*	NS	NS	NS	NS	NS	NS			C18, C24
Water treatment., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	V 1	V 8	*	NS	NS	NS	NS	NS	NS			C18, C24
Water treatment., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	V 1	V 8	*	NS	NS	NS	NS	NS	NS			C18, C24
Water treatment., Shock/slug., Not on label., Not Applicable., Not applicable for this use.	SC/L	V 1	V 10	*	NS	NS	NS	NS	NS	NS			C18, C24
SPECIALTY INDUSTRIAL PRODUCTS				Use Group: INDOOR NON-FOOD									
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 300	W 4500	*	NS	NS	NS	NS	NS	NS			C18, C24
WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS				Use Group: INDOOR NON-FOOD									
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 1	W 6	*	NS	NS	NS	NS	NS	NS			C18, C24

LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
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

SC/L	: SOLUBLE CONCENTRATE/LIQUID

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

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.
C18 : Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority.
C24 : Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 3032 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 3032 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given 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
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Bromohydroxyacetophenone

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	**Terrestrial Non-food Crop, Aquatic Non-food Industrial, Indoor Non-food**	MRID 42231001
61-2A	**Start. Mat. & Mnfg. Process**	" "	MRID 42231001
61-2B	**Formation of Impurities**	" "	MRID 42231001
62-1	**Preliminary Analysis**	" "	MRID 42231002, 43181201
62-2	**Certification of limits**	" "	"UNFULFILLED"
62-3	**Analytical Method**	" "	MRID 42231O02
63-2	**Color**	" "	MRID 42231003
63-3	**Physical State**	" "	MRID 42231003
63-4	**Odor**	" "	MRID 42231003
63-5	**Melting Point**		"UNFULFILLED"
63-6	**Boiling Point**	" "	MRID 42231003
63-7	**Density**	" "	MRID 42288701
63-8	**Solubility**	" "	MRID 42288701
63-9	**Vapor Pressure**	" "	MRID 42288701

Data Supporting Guideline Requirements for the Reregistration of Bromohydroxyacetophenone

REQUIREMENT		USE PATTERN	CITATION(S)
63-10	**Dissociation Constant**	" "	MRID 42288701
63-11	**Octanol/Water Partition**	" "	MRID 42288701
63-12	**pH**	" "	MRID 42288701
63-13	**Stability**	" "	MRID 42288701
63-14	**Oxidizing/Reducing Action**		
63-15	**Flammability**		
63-16	**Explodability**		
63-17	**Storage stability**		
63-18	**Viscosity**		
63-19	**Miscibility**		
63-20	**Corrosion characteristics**		
63-21	**Dielectric breakdown volt**		
64-1	**Submittal of Samples**		
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	" "	158959
71-1B	**Acute Avian Oral - Quail/Duck TEP**		
71-2A	**Avian Dietary - Quail**	" "	158961
71-2B	**Avian Dietary - Duck**	" "	158960
71-3	**Wild Mammal Toxicity**		

Data Supporting Guideline Requirements for the Reregistration of Bromohydroxyacetophenone

REQUIREMENT		USE PATTERN	CITATION(S)
71-4A	**Avian Reproduction - Quail**		
71-4B	**Avian Reproduction - Duck**		
71-5A	**Simulated Field Study**		
71-5B	**Actual Field Study**		
72-1A	**Fish Toxicity Bluegill**	" "	158962
72-1B	**Fish Toxicity Bluegill - TEP**	" "	158960
72-1C	**Fish Toxicity Rainbow Trout**	" "	158963
72-1D	**Fish Toxicity Rainbow Trout- TEP**		
72-2A	**Invertebrate Toxicity**	" "	158964
72-2B	**Invertebrate Toxicity - TEP**		
72-3A	**Estuarine/Marine Toxicity - Fish**		WAIVED
72-3B	**Estuarine/Marine Toxicity - Mollusk**		WAIVED
72-3C	**Estuarine/Marine Toxicity - Shrimp**		WAIVED
72-3D	**Estuarine/Marine Toxicity Fish- TEP**		
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**		
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**		

Data Supporting Guideline Requirements for the Reregistration of Bromohydroxyacetophenone

REQUIREMENT		USE PATTERN	CITATION(S)
72-4A	Early Life Stage Fish		
72-4B	Life Cycle Invertebrate		
72-5	Life Cycle Fish		
72-6	Aquatic Organism Accumulation		
72-7A	Simulated Field - Aquatic Organisms		
72-7B	Actual Field - Aquatic Organisms		
122-1A	Seed Germination/Seedling Emergence		
122-1B	Vegetative Vigor		
122-2	Aquatic Plant Growth		
123-1A	Seed Germination/Seedling Emergence		
123-1B	Vegetative Vigor		
123-2	Aquatic Plant Growth		
124-1	Terrestrial Field		
124-2	Aquatic Field		
141-1	Honey Bee Acute Contact		
141-2	Honey Bee Residue on Foliage		
141-5	Field Test for Pollinators		

Data Supporting Guideline Requirements for the Reregistration of Bromohydroxyacetophenone

REQUIREMENT		USE PATTERN	CITATION(S)
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	" "	MRID 47019601
81-2	Acute Dermal Toxicity - Rabbit/Rat	" "	MRID 47019602
81-3	Acute Inhalation Toxicity - Rat	" "	MRID 47019603
81-4	Primary Eye Irritation - Rabbit	" "	MRID 47019604
81-5	Primary Dermal Irritation - Rabbit	" "	MRID 47019605
81-6	Dermal Sensitization - Guinea Pig	" "	MRID 47019606
81-7	Acute Delayed Neurotoxicity - Hen		
82-1A	90-Day Feeding - Rodent		
82-1B	90-Day Feeding - Non-rodent		
82-2	21-Day Dermal - Rabbit/Rat	" "	MRID 40090801
82-3	90-Day Dermal - Rodent		
82-4	90-Day Inhalation - Rat		
82-5A	90-Day Neurotoxicity - Hen		
82-5B	90-Day Neurotoxicity - Mammal		
83-1A	Chronic Feeding Toxicity - Rodent		
83-1B	Chronic Feeding Toxicity - Non-Rodent		
83-2A	Oncogenicity - Rat		

Data Supporting Guideline Requirements for the Reregistration of Bromohydroxyacetophenone

REQUIREMENT		USE PATTERN	CITATION(S)
83-2B	Oncogenicity - Mouse		
83-2B	Oncogenicity - Mouse		
83-3A	Developmental Toxicity - Rat	" "	MRID 40156901
83-3B	Developmental Toxicity - Rabbit		
83-4	2-Generation Reproduction - Rat		
84-2A	Gene Mutation (Ames Test)	" "	MRID 47019607, 47019608
84-2B	Structural Chromosomal Aberration	" "	MRID 47019609
84-4	Other Genotoxic Effects	" "	MRID 47019610
85-1	General Metabolism		
85-2	Dermal Penetration		
86-1	Domestic Animal Safety		
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	Foliar Residue Dissipation		
132-1B	Soil Residue Dissipation		
133-3	Dermal Passive Dosimetry Exposure		
133-4	Inhalation Passive Dosimetry Exposure		
231	Estimation of Dermal Exposure at Outdoor Sites		

Data Supporting Guideline Requirements for the Reregistration of Bromohydroxyacetophenone

REQUIREMENT		USE PATTERN	CITATION(S)
232	Estimation of Inhalation Exposure at Outdoor Sites		
233	Estimation of Dermal Exposure at Indoor Sites		
234	Estimation of Inhalation Exposure at Indoor Sites		
ENVIRONMENTAL FATE			
160-5	Chemical Identity		
161-1	Hydrolysis		
161-2	Photodegradation - Water	WAIVED	
161-3	Photodegradation - Soil		
161-4	Photodegradation - Air		
162-1	Aerobic Soil Metabolism		
162-2	Anaerobic Soil Metabolism		
162-3	Anaerobic Aquatic Metabolism		
162-4	Aerobic Aquatic Metabolism	WAIVED	
163-1	Leaching/Adsorption/Desorption	WAIVED	
163-2	Volatility - Lab		
163-3	Volatility - Field		
164-1	Terrestrial Field Dissipation		

Data Supporting Guideline Requirements for the Reregistration of Bromohydroxyacetophenone

REQUIREMENT		USE PATTERN	CITATION(S)
164-2	**Aquatic Field Dissipation**	WAIVED	
164-3	**Forest Field Dissipation**		
164-5	**Long Term Soil Dissipation**		
165-1	**Confined Rotational Crop**		
165-2	**Field Rotational Crop**		
165-3	**Accumulation - Irrigated Crop**	WAIVED	
165-4	**Bioaccumulation in Fish**	WAIVED	
165-5	**Bioaccumulation - Aquatic NonTarget**		
166-1	**Ground Water - Small Prospective**		
166-2	**Ground Water - Small Retrospective**		
166-3	**Ground Water - Irrigated Retrospective**		
201-1	**Droplet Size Spectrum**		
202-1	**Drift Field Evaluation**		
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**		
171-4B	**Nature of Residue - Livestock**		
171-4C	**Residue Analytical Method - Plants**		

Data Supporting Guideline Requirements for the Reregistration of Bromohydroxyacetophenone

REQUIREMENT		USE PATTERN	CITATION(S)
171-4D	Residue Analytical Method - Animal		
171-4E	Storage Stability		
171-4F	Magnitude of Residues - Potable H2O		
171-4G	Magnitude of Residues in Fish		
171-4H	Magnitude of Residues - Irrigated Crop		
171-4I	Magnitude of Residues - Food Handling		
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg		
171-4K	Crop Field Trials		
171-4L	Processed Food		
171-5	Reduction of Residues		
171-6	Proposed Tolerance		
171-7	Support for Tolerance		
171-13	Analtyical Reference Standard		

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of 3032

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the 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 the Agency, 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 identifier. These entries are listed after all MRID entries. This temporary identifying number 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 EPA, 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 an 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 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 EPA 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.

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MRID	CITATION
00043454	Powers, M.B. (1964) Acute Oral Administration--Rats: Acute Dermal Application--Rabbits. (Unpublished study received Dec 31, 1964 under 1448-23; prepared by Hazleton Laboratories, Inc., submitted by Buckman Laboratories, Inc., Memphis, Tenn.; CDL:107370-A)
00097935	Wood, J.W. (1965) Letter sent to C. George Hollis dated Jun 16, 1965: Samples of Busan 90 and Busan 881 furnished May 24, 1965. (Washington, Dept. of Fisheries, M-5 Fisheries Center; unpublished study; CDL:010022-J)
00101753	Wood, J. (1965) Letter sent to G. Hollis dated Jun 16, 1965: Samples of Busan 90 and Busan 881 furnished May 24, 1965. (State of Washington, Dept. of Fisheries; unpublished study; CDL: 024935-H)
00101855	Buckman Laboratories, S.A. (1964) Toxicity to Fish of Some Products Used in Paper Mill Slime Control. (Unpublished study received May 27, 1965 under unknown admin. no.; submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:132336-A)
00104000	WARF Institute, Inc. (1973) Report: WARF No. 3052402. (Unpublished study received Sep 19, 1973 under 1448-23; submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:131290-A)
00104001	WARF Institute, Inc. (1973) Report: WARF Institute Nos. 2122100; 3010239; 3052402. (Unpublished study received Sep 19, 1973 under 1448-23; submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:131290-B)
00107174	McCann, J. (1971) [Busan 90: Bluegill …]: Test No. 365. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:130656-A)
00119954	Watkins, J. (1966) Letter sent to K. Jackson dated Oct 26, 1966: Bio-assays: [Methyl-trithion 4E and other pesticides' toxicity to coho fry]: File No. 34-5-2-4. (Unpublished study received Dec 1, 1970 under 1F1129; prepared by Government of Canada, submitted by Stauffer Chemical Co., Richmond, CA; CDL:090905-J)

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MRID	CITATION
00122602	Kirchen, C. (1964) Letter sent to All Representatives dated Sep 28, 1964: Toxicity to fish of some products used in paper mill slime control: (Busan 90 compared with competitive products). (Unpublished study received May 27, 1965 under 1448-24; submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:005897-A)
00122603	Buckman Laboratories, Inc. (1972) [Chemical Study: Busan 93]. (Compilation; unpublished study received Mar 21, 1972 under 1448-45; CDL:009585-A)
00122604	Buckman Laboratories, Inc. (1971) [Efficacy: Busan 93]. (Compilation; unpublished study received Mar 21, 1972 under 1448-45; CDL:009585-B)
00122605	WARF Institute, Inc. (1972) Report: WARF No. 2011314. (Unpublished study received Mar 21, 1972 under 1448-45; submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:050336-A)
00122606	Booden, M. (1973) Report: WARF Institute Nos. 2122100; 3010239; 3052402. (Unpublished study received Sep 19, 1973 under unknown admin. no.; prepared by WARF Institute, Inc., submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:131334-A)
00122608	Powers, M. (1964) Acute Oral Administration--Rats; Acute Dermal Application--Rabbits: [Busan 90]. (Unpublished study received May 27, 1965 under 1448-23; prepared by Hazleton Laboratories, Inc., submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:240357-A)
00123664	Bodden, M. (1973) Report: WARF Institute Nos. 2122100, 3010239, 3042402. (Unpublished study received Sep 17, 1973 under 144847; prepared by WARF Institute, Inc., submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:008748-A)
00123871	Powers, M. (1964) Acute Oral Administration--Rats; Acute Dermal Application--Rabbits: [Busan 90]. (Unpublished study received Dec 31, 1964 under 1448-23; prepared by Hazleton Laboratories, Inc., submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:107369-B)
00134721	WARF Institute, Inc. (1972) Report: WARF No. 2011314. (Unpublished study received Mar 21, 1972 under 1448-45; submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:100598-A)

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MRID **CITATION**

00158959 Beavers, J. (1985) BHAP: An Acute Oral Toxicity Study with the Bobwhite: Final Rept.: Project No. 210-103. Unpublished study prepared by Wildlife International Ltd. 18 p.

00158960 Beavers, J. (1985) BHAP: A Dietary LC50 Study with the Mallard: Final Rept.: Project No. 210-102. Unpublished study prepared by Wildlife International Ltd. 16 p.

00158961 Beavers, J. (1985) BHAP: A Dietary LC50 Study with the Bobwhite: Final Rept.: Project No. 210-101. Unpublished study prepared by Wildlife International Ltd. 16 p.

00158962 Surprenant, D. (1985) Acute Toxicity of BHAP to Bluegill (Lepomis macrochirus): Report No. BW-85-10-1859: Study No. 995.0785.6101.100. Unpublished study prepared by Springborn Bionomics, Inc. 16 p.

00158963 Surprenant, D. (1985) Acute Toxicity of BHAP to Rainbow Trout (Salmo gairdneri): Report No. BW-85-11-1861: Study No. 995-07856101-103. Unpublished study prepared by Springborn Bionomics, Inc. 16 p.

00158964 Surprenant, D. (1985) Toxicity of BHAP to Daphnids (Daphnia magna): Report No. BW-85-11-1860: Study No. 995.0785.6101.110. Unpublished study prepared by Springborn Bionomics, Inc. 14 p.

00158969 Gohdes, M.; Blair, J.; Obrist, J.; et al. (1986) Photodegradation and Hydrolysis of BHAP in Water: Final Report: Study No. 6015231. Unpublished study prepared by Hazleton Laboratories America, Inc. 101 p.

00158970 Gohdes, M.; Blair, J.; Obrist, J. (1986) Determination of the Mobility of BHAP in Selected Soils by Soil Thin Layer Chromatography: Study No. 6015-234. Unpublished study prepared by Hazleton Laboratories America, Inc. 49 p.

00158971 Gohdes, M.; Blair, J.; Obrist, J. (1986) Determination of the Mobility of Soil-aged BHAP Residues by Soil Thin Layer Chromatography: Study No. 6015-236. Unpublished study prepared by Hazleton Laboratories America, Inc. 25 p.

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00159297	Bates, D. (1986) Acute Oral Toxicity (LD50) Study in Albino Rats with BHAP: Final Report: Project No. WIL-94003. Unpublished study prepared by WIL Research Laboratories, Inc. 36 p.
00159298	Bates, D. (1986) Acute Dermal Toxicity (LD50) Study in Albino Rabbits with BHAP: Final Report: Project No. WIL-94004. Unpublished study prepared by WIL Research Laboratories, Inc. 33 p.
00159299	Biesemeier, J. (1986) Acute Inhalation LC50 Study of BHAP in Sprague-Dawley Rats: FDRL Study No. 8840. Unpublished study prepared by Food & Drug Research Laboratories, Inc. 181 p.
00159300	Bates, D. (1986) Primary Eye Irritation Study in Albino Rabbits with BHAP: Final Report: Project No. WIL-94006. Unpublished study prepared by WIL Research Laboratories, Inc. 22 p.
00159301	Bates, D. (1985) Primary Dermal Irritation Study in Albino Rabbits with BHAP: Final Report: Project No. WIL-94005. Unpublished study prepared by WIL Research Laboratories, Inc. 22 p.
00159302	Bates, D. (1986) Skin Sensitization Study in Albino Guinea Pigs with BHAP: Final Report: Project No. WIL-94007. Unpublished study prepared by WIL Research Laboratories, Inc. 38 p.
00159303	Cavagnaro, J. (1985) Mutagenicity Evaluation of BHAP … in the Ames Salmonella/Microsome Plate Assay: Final Report: HB Project No. 20988: Genetics Assay No. 974. Unpublished study prepared by Hazleton Biotechnologies. 22 p.
00159304	Sernau, R. (1985) CHO/HGPRT Forward Mutation Assay: BHAP: Final Report: HBC Project No. 197-185. Unpublished study prepared by Hazleton Biotechnologies Corp. 17 p.
00159305	Ivett, J. (1986) Clastogenic Evaluation of BHAP … in the in vivo Mouse Micronucleus Assay: Final Report: HB Project No. 20996: Genetics Assay No. 8466. Unpublished study prepared by Hazleton Biotechnologies. 21 p.

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00159313	Buckman Laboratories, Inc. (1986) Product Chemistry: BHAP. Unpublished compilation. 39 p.
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00165309	Buckman Labs., Inc. (1972) ?Minimum Effective Concentration of Preservative: Control Sheet for Busan 93 and Busan 881 Efficacy Data. Unpublished study. 3 p.
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40090801	Adam, G. (1987) 21-Day Dermal Toxicity Study in Rabbits with BHAP: Project No. WIL-94021. Unpublished study prepared by Wil Research Laboratories, Inc. 263 p.
40099200	Buckman Laboratories, Inc. (1987) Product Chemistry Data Submitted in Response to Data Call-in. Compilation of 1 study.
40099201	Bonner, G. (1986) BHAP Storage Stability. Unpublished study prepared by Buckman Laboratories, Inc. 3 p.
40156900	Buckman Laboratories, Inc. (1987) Submission of Data in Response to Data Call-in for BHAP: Teratology Study. Transmittal of 1 study.

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40156901	Rodwell, D. (1987) A Teratology Study in Rats with BHAP: Final Report: Project No.: WIL-94018. Unpublished study prepared by WIL Research Laboratories, Inc. 240 p.
40334300	Buckman Laboratories, Inc. (1987) Submission of Environmental Data in Response to Data Call-in for BHAP. Transmittal of 1 study.
40334301	Obrist, J. (1987) Aerobic Aquatic Metabolism of BHAP: Lab. Proj. ID HLA 6015-233. Unpublished study prepared by Hazleton Laboratories, Inc. 98 p.
40334400	Buckman Laboratories, Inc. (1987) Submission of Anaerobic Aquatic Metabolism Data for the Chemical, BHAP. Submission of 1 study.
40334401	Saxena, A. (1987) Anaerobic Aquatic Metabolism of BHAP: Laboratory Project Identification HLA 6015-232. Unpublished study prepared by Buckman Laboratories, Inc. 115 p.
41087200	Buckman Laboratories, Inc. (1989) Submission of Data To Support Registration of Busan 1130: Product Chemistry Data. Transmittal of 2 studies.
41087201	Bowles, D. (1989) Product Chemistry, Series 61, Busan 1130: Project ID: Busan 1130. Unpublished study prepared by Buckamn Laboratories. 54 p.
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41417601	Terrill, J. (1990) Acute Inhalation Toxicity Study with Busan 1130 Formulation in the Rat: Final Report: Lab Study Number: HLA 197-189. Unpublished study prepared by Hazleton Laboratories America, Inc. 73 p.
41586800	Buckman Laboratories, Inc. (1990) Submission of Data To Support Registration of BHAP: Aquatic Metabolism Study. Transmittal of 1 study.

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41593200	Buckman Laboratories, Inc. (1990) Submission of Product Chemistry Data in Response to Deficiencies in Registration Application for Busan 90C. Transmittal of 1 study.
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42231000	Buckman Labs, Inc. (1992) Submission of product chemistry data to support the reregistration standard for BHAP. Transmittal of 3 studies.
42231001	Hill, C.; Conaway, L. (1992) Product Chemistry for BHAP--Series 61: Lab Project Number: 108-01. Unpublished study prepared by Buckman Labs, Inc. 60 p.
42231002	Hill, C.; Fues, R. (1992) Product Chemistry for BHAP--Series 62: Lab Project Number: 108-01. Unpublished study prepared by Buckman Labs, Inc. 95 p.
42231003	Siemann, L. (1992) Product Chemistry for BHAP--Series 63, Interim Report: Lab Project Number: 6404-F. Unpublished study prepared by MidWest Research Institute, Inc. 30 p.
42288700	Buckman Labs, Inc. (1992) Submission of product chemistry data to support the registration of BHAP. Transmittal of 1 study.
42288701	Siemann, L. (1992) Product Chemistry for BHAP: Final Report: Lab Project Number: 6404-F. Unpublished study prepared by Midwest Research Institute. 76 p.

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42393600	Buckman Laboratories International, Inc. (1992) Submission of toxicity data in support of the registration of Busan 93. Transmittal of 2 studies.
42393601	Rush, R. (1992) Acute Dermal Toxicity Study in Rats with Busan 93: Final Report: Lab Project Number: 3138.90. Unpublished study prepared by Springborn Laboratories, Inc. 26 p.
42393602	Rush, R. (1992) Primary Skin Irritation Study in Rabbits with Busan 93: Final Report: Lab Project Number: 3138.91. Unpublished study prepared by Springborn Laboratories, Inc. 22 p.
42703300	Buckman Labs International, Inc. (1993) Submission of product chemistry data in support of the BHAP reregistration. Transmittal of 1 study.
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93060001	Bowles, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 41087201. Product Chemistry, Series 61, Busan 1130 Laboratory ID: Busan 1130. Prepared by Buckman Laboratories, Inc. 19 p.
93060002	Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00158959. BHAP An Acute Oral Toxicity Study with the Bobwhite: Laboratory ID 210-103. Prepared by Wildlife International Ltd. 6 p.
93060003	Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00158960. BHAP A Dietary LC50 Study with the Mallard: Laboratory ID #210-102. Prepared by Wildlife International Ltd. 7 p.
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93060006	Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00158964. Toxicity of BHAP to Daphnids (Daphnia magna): Laboratory ID No. 995-0785-6101-110. Prepared by Springborn Bionomics, Inc. 10 p.
93060007	Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00159297. Acute Oral Toxicity (LD50) Study in Albino Rats with BHAP: Laboratory ID WIL-94003. Prepared by WIL Research Laboratories, Inc. 27 p.
93060008	Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00159298. Acute Dermal Toxicity (LD50) Study in Albino Rabbits with BHAP: Laboratory ID WIL-94004. Prepared by WIL Research Laboratories, Inc. 25 p.
93060009	Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00159299. Acute Inhalation LC50 Study of BHAP in Sprague Dawley Rats: Laboratory ID 8840. Prepared by Food and Drug Research Laboratories,Inc. 22 p.
93060010	Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00159300. Primary Eye Irritation Study in Albino Rabbits with BHAP: Laboratory ID WIL-94006. Prepared by WIL Research Laboratories, Inc. 10 p.
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93060013	Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 40090801. 21-Day Repeated Dose Dermal Toxicity Study in Rabbits with BHAP: Laboratory ID WIL-94021. Prepared by WIL Research Laboratories, Inc. 23 p.

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93060016 Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00159304. CHO/HGPRT Forward Mutation Assay: Laboratory ID 197-185. Prepared by Hazleton Laboratories America, Inc. 9 p.

93060017 Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00159305. Clastogenic Evaluation of BHAP in the in vivo Mouse Micronucleus Assay: Laboratory ID 20996. Prepared by Hazleton Laboratories America, Inc. 6 p.

93060018 Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00159306. Unscheduled DNA Synthesis Rat Hepatocyte Assay with BHAP: Laboratory ID 197-186. Prepared by Hazleton Laboratories America, Inc. 6 p.

93060019 Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00158969. Photodegradation and Hydrolysis of BHAP in Water: Laboratory ID 6015-231. Prepared by Hazleton Laboratories America, Inc. 15 p.

93060020 Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 40334401. Anaerobic Aquatic Metabolism of BHAP: Laboratory ID HLA 6015-232. Prepared by Hazleton Laboratories America, Inc. 20 p.

93060021 Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 40334301. Aerobic Aquatic Metabolism of BHAP: Laboratory ID HLA 6015-233. Prepared by Hazleton Laboratories America, Inc. 17 p.

93060022 Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00158970. Determination of the Mobility of BHAP in Selected Soils by Soil Thin Layer Chromatography: Laboratory ID 6015-234. Prepared by Hazleton Laboratories America, Inc. 9 p.

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MRID	CITATION
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93060024	Barbee, D. (1990) Buckman Labs Inc Phase 3 Summary of MRID 00158961. BHAP A Dietary LC50 Study with the Bobwhite: Laboratory ID 210-101. Prepared by Wildlife International Ltd. 5 p.
93060999	Buckman Labs Inc (1990) Reregistration Phase 3 Response: Bromo-4'-hydroxyacetophenone. Correspondence and Supporting Material.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to 3032. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for 3032 and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. 3032 RED Fact Sheet

4. PR Notice 86-5 (included in this appendix)

5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PR NOTICE 86-5

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the

entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

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A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an

application for an EUP should be subdivided into sections A, B, C,... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product

produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE**. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI

claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit

disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

[+]Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

[+]Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ _____
Name Signature

Company Name _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE REFERENCE	LINES	REASON FOR THE DELETION	FIFRA
6	14	Identity of Inert Ingredient	§10(d)(C)
28	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PAGES(S): are attached immediately behind this page

PAGES	REASON FOR THE DELETION	FIFRA REFERENCE
35-41.	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

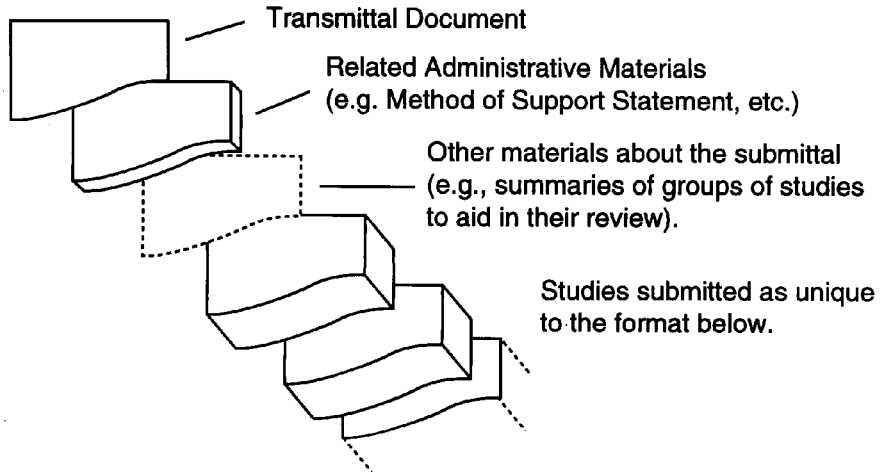
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

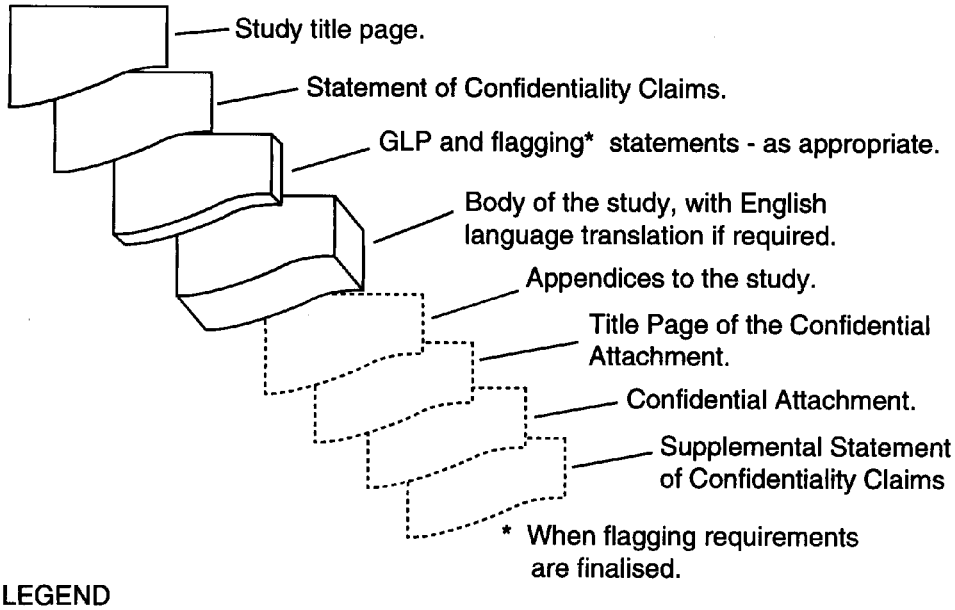
Submitter_____

ATTACHMENT 7.

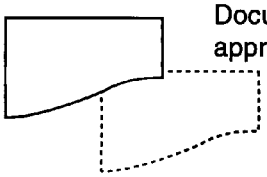
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS,
AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual

product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,"** all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

APPENDIX F. Combined Generic and Product Specific Data Call-In

GENERIC AND PRODUCT SPECIFIC
DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain 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 1 through 7; or

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

3. Why you believe EPA should not require your submission of 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. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is 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 and 2070-0057 (expiration date 3-31-96).

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 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/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 the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes 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 (Telephone number: 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, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

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].

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

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and 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

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic 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.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (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.

a. 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 completed Generic and Product Specific

Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms 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.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Reqistrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Reqistrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations

of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for 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.

2. Product Specific Data Requirements

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 choose 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.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). 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 also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. 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 Reqistrant'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.

a. 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 both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose 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.

b. 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.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Reqistrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic 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 you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (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. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

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 or protocols. 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

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

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 the 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 to 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 burden 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 normally will 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 '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, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must 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 usually are 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 EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

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 also should 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 ecological effects studies, the classification generally would be a rating of "core." 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.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 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 -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, 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.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

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, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the

pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

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 product specific 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.

SECTION 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:

   i. 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 Reqistrant's Response Form.

   ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

   iii. 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 generally would 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 also must 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 a 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 must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and 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 Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Louis P. True, Jr., Acting Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
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 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

Attachment 1. Chemical Status Sheets

BROMOHYDROXYACETOPHENONE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing bromohydroxyacetophenone.

This Generic 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 Bromohydroxyacetophenone. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Bromohydroxyacetophenone Generic Data CallIn (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Bromohydroxyacetophenone are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Bromohydroxyacetophenone are needed. These data are needed to fully complete the reregistration of all eligible Bromohydroxyacetophenone products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Frank Rubis at (703) 308-8184.

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

3032, Chemical Review Manager
PLANNING AND REREGISTRATION BRANCH
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: 3032

BROMOHYDROXYACETOPHENONE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Bromohydroxyacetophenone. 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 Bromohydroxyacetophenone 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 Bromohydroxyacetophenone are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Bromohydroxyacetophenone 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 Bromohydroxyacetophenone products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Bromohydroxyacetophenone , please contact Frank Rubis at (703) 308-8184.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Frank Rubis at (703) 308-8184.

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

FRANK RUBIS
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **3032**

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

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form**. **BOTH** "Data Call-In Response" forms must be completed.

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The 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, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1.**ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2.**ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3.**ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4.**ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5.**ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** 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."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do 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.

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.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. 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.

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

Instructions For Completing
The
"Requirements Status and Registrant's Response Forms"
For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.** Both "Requirements Status and Registrant's Response" forms must be completed.

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 30 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, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In 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. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Reqistrant's Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

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 crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the

date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. 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 and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency 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 may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. 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 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 required 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 apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, 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 the Agency 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). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. 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 required 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" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. 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

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

EPA'S DECISION NOT TO BATCH END-USE PRODUCTS CONTAINING 2-BROMO-4'-HYDROXYACETOPHENONE FOR PURPOSES OF 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 end-use products containing the active ingredient 2-bromo-4'-hydroxyacetophenone (BHAP), the Agency considered batching end-use products. This process involves grouping similar products 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.).

However, batching of end-use products containing 2-bromo-4'-hydroxyacetophenone was not possible after considering the available information described above. Table I lists all the end-use products containing 2-bromo-4'-hydroxyacetophenone. These products were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making purposes. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Registrants must generate all the required acute toxicological studies for each of their products. 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 cited, the registrant must clearly identify the material tested by its 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 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). Since the end-use products containing 2-bromo-4'-hydroxyacetophenone could not be batched, registrants cannot choose from the remaining options: Cost sharing (Option 2) or Offers to Cost Share (Option 3).

Table I. End-Use Products Containing 2-Bromo-4'-Hydroxyacetophenone

EPA Reg. No.	Percent 2-Bromo-4'-hydroxyacetophenone & other active ingredients	Formulation Type
1448-23	2-Bromo-4'-hydroxyacetophenone ……. 30.0%	liquid
1448-45	2-Bromo-4'-hydroxyacetophenone ……. 20.0% 2-(Thiocyanomethylthio)benzothiazole … 8.0%	liquid
1448-342	2-Bromo-4'-hydroxyacetophenone ……. 10.0%	liquid

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at $<$ 0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered;
  for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at > 0.1%.
2.____ Degree of accountability or closure > ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at > 0.1% and for certain toxicologically significant impurities at < 0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color
____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor
____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point
____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point
____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility
____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant
____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient
____ Measured at about 20-25° C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH
____ Measured at about 20-25° C
____ Measured following dilution or dispersion in distilled water

63-13 Stability
____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4.*___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C (±2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of <2 or >11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of < 2 or > 11.5.
3.___ One of the following methods is utilized:
_____ Freund's complete adjuvant test
_____ Guinea pig maximization test
_____ Split adjuvant technique
_____ Buehler test
_____ Open epicutaneous test
_____ Mauer optimization test
_____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice

Attachment 7. Cost Share Data Compensation Forms, Confidential Statement of Formula Form and Instructions

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

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. and 13.b. 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.

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

m. The upper and lower certified limits for ail 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.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
2070-0057
Approval Expires 3-31-96

Please fill in blanks below.

Company Name	Company Number
Product Name	**EPA Reg. No.**

I Certify that:

My company is willing to develop 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 named 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)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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-233, 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
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion 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)(F) 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)

[ ] 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)(F) 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 section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-010 January 1995

R.E.D. FACTS

Bromohydroxy-acetophenone (BHAP)

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 3032, bromohydroxyacetophenone or BHAP.

Use Profile

Bromohydroxyacetophenone, also known as BHAP, is a microbicide or microbistat used to inhibit the growth of bacteria and fungi that cause the microbiological degradation of papermaking chemicals. Two of the three registered pesticide products containing this active ingredient are also used to inhibit the growth of bacteria that cause loss of viscosity in emulsions, paints, adhesives, waxes and polishes. BHAP products, which are marketed under the trade name Busan, are formulated as a soluble concentrate/liquid. Treatments are made using a variety of types of equipment including drip-feed devices, measuring containers and metering pumps.

Use practice limitations include an equipment precleaning requirement; a warning not to expose the product to extreme temperatures; and a prohibition against discharging effluent into sewage systems without notifying the sewage treatment plant authority, or into public waters except under an NPDES permit.

Regulatory History

BHAP was first registered as a pesticide in the U.S. in 1964 for use as a microbicide/microbiostat. Currently, three Busan products are registered for various industrial water treatment uses.

Human Health Assessment

Toxicity

BHAP generally is of moderate acute toxicity but is corrosive to the eyes and has been placed in Toxicity Category I (the highest of four levels) indicating the greatest degree of primary eye irritation effects. BHAP is moderately toxic by the oral and inhalation routes (Toxicity Category II). It is slightly toxic by the dermal route and is a mild irritant to the skin (Toxicity Category III). BHAP also is a skin sensitizer.

A subacute dermal toxicity study using rabbits resulted in no systemic toxicity, but BHAP induced dermal irritation at all dose levels. Since use of BHAP will not result in human exposure over a significant portion of a human life span, chronic toxicity, carcinogenicity and reproduction studies were not required. BHAP does not cause developmental toxicity or mutagenic effects.

Dietary Exposure

A food additive tolerance, or maximum residue limit, has been established for BHAP residues remaining in food contact paper and paperboard. However, this tolerance is under FDA's regulatory purview.

Occupational and Residential Exposure

Based on current use patterns, workers may be exposed to BHAP during and immediately after water treatment in pulp and paper manufacturing, paint manufacturing and industrial solution preparation. However, the toxicological endpoints of concern for workers (eye irritation and inhalation toxicity) can be mitigated through use of personal protective equipment (PPE). The PPE recommended for handlers using BHAP in industrial/manufacturing settings is: goggles or faceshield to prevent eye contact, chemical resistant gloves, and a NIOSH/MSHA approved organic vapor removing cartridge respirator with prefilter (TC-23). Since BHAP has low vapor pressure, inhalation by workers immediately after BHAP use is likely to be negligible.

People also could be exposed to BHAP when using substances that contain BHAP residues such as paints, waxes, polishes and adhesives. However, the amount of BHAP in these substances is minimal, so both exposure and risk are expected to be negligible.

Human Risk Assessment

BHAP is corrosive to the eyes (Toxicity Category I for primary eye irritation effects) and is moderately toxic by the oral and inhalation routes (Toxicity Category II). It has no significant food uses; a single food additive tolerance for residues in food contact paper and paperboard is regulated by FDA. Although workers may be exposed to BHAP during and

immediately after water treatment, risks of severe eye irritation and inhalation exposure can be mitigated through use of the recommended PPE. Exposure and risk to the public from using paints, waxes, polishes and adhesives containing BHAP residues are believed to be negligible.

Environmental Assessment

EPA has sufficient data at this time to conduct only a qualitative environmental fate assessment of BHAP. Additional data requirements for the pulp and papermill use still must be satisfied.

Environmental Fate

BHAP appears to be nonpersistent, and photolysis plays a major role in its degradation pathway. BHAP photodegrades in water with a half-life of less than two days. It appears to be immobile to moderately mobile in clay and loam soils, but very mobile in sandy soils.

BHAP's indoor, nonfood use pattern involves no direct exposure to the environment. However, its industrial uses result in indirect environmental exposures from discharges to water. These discharges are regulated by EPA's Office of Water and the states through the National Pollutant Discharge Elimination System (NPDES) permit program.

Ecological Effects

BHAP is moderately toxic to birds on an acute oral basis, but is no more than slightly toxic to birds on a subacute dietary basis. BHAP is moderately to highly toxic to freshwater fish, and is moderately toxic to freshwater invertebrates.

Ecological Effects Risk Assessment

BHAP's acute ecological risk is based on the residue levels in natural water receiving effluent from facilities using the pesticide. If residues should exceed one-half of the established EC_{50} levels for aquatic invertebrates or freshwater fish, these organisms would be acutely at risk.

By their nature, industrial biocides are often toxic to aquatic organisms. While the use of BHAP as a pesticide is regulated by EPA's Office of Pesticide Programs (OPP) under the federal pesticide law, FIFRA, the discharge of effluent containing DCDIC to surface waters is regulated under the NPDES permit program administered by EPA's Office of Water (OW) with the states. The NPDES process takes local conditions into account in issuing permits for the discharge of pollutants to bodies of water. EPA's OPP and OW will share information and cooperate in overseeing the use of biocides such as BHAP.

Additional Data Required

EPA is requiring several additional generic environmental fate studies for BHAP to confirm its regulatory assessments and conclusions. The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs) and revised labeling for reregistration.

Product Labeling Changes Required

All BHAP end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Labeling Requirements - For end-use products intended primarily for occupational use:

User Safety Recommendations:

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

Sensitization Statement: Required in the "Hazards to Humans (and Domestic Animals)" section of Precautionary Statements on the labeling of all end-use products, because BHAP is a skin sensitizer:

"This product may cause skin sensitization reactions in some people."

Effluent Discharge Labeling Statements - All BHAP products that may be contained in an effluent discharged to the waters of the U.S. or municipal sewer systems must bear the following statement:

"This pesticide is toxic to fish. Do not use in facilities discharging directly or indirectly to the estuarine or marine environment. Do not discharge effluent containing this product into freshwater lakes, streams and ponds 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. Secondary biological treatment of BHAP effluent discharging to freshwater environments is required for all uses except for use in secondary oil recovery systems discharging to freshwater environments. 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."

Regulatory Conclusion

The use of currently registered products containing BHAP in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Discharge of effluent containing BHAP from industrial facilities using this pesticide generally will not cause unreasonable adverse effects on the environment. EPA's OPP and OW will share information to improve the regulation of BHAP's use at specific sites across the country.

Products containing BHAP will be reregistered once the required product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for BHAP during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the BHAP RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the BHAP RED, or reregistration of individual products containing BHAP, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.