United States
Environmental Protection
Agency

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

EPA 738-R-94-029
September 1994

Reregistration Eligibility Decision (RED)

Bentazon

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

January 27, 1995

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 Bentazon. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes 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 your reciept 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 product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Eric Feris at (703) 308-8048 via 1-800-828-1140.

Sincerely yours,

Louis P. True, Jr., 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"**--A Product Specific Data Call- In is enclosed with this RED and must be completed and submitted within 90 days of receipt of this package. The response consists of a "Data Call-In Response" form and a "Requirements Status and Registrant's Response" form. Additional generic may also be required to confirm or support the assessment of the active ingredient. If generic data are required, Generic Data Call-Ins are being sent only to certain manufacturing use registrants. Generic Data Call-Ins are not being sent to end use product registrants. However, please note that instructions for completing the Data Call-Ins, which are incorporated as an Appendix to the RED, may address both generic and product specific data. If you are an end use registrant, be sure to follow the instructions for product specific data.

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 DECISION

BENTAZON

LIST A

CASE 0182

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

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BENTAZON REREGISTRATION ELIGIBILITY DECISION TEAM

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Policy and Special Projects Staff

Jean Frane	Food Safety and Regulation Tracking Section

GLOSSARY OF TERMS AND ABBREVIATIONS

ae	acid equivalent
a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
DWEL	Drinking Water Equivalent Level
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
GRAS	Generally Recognized As Safe as designated by FDA
HA	Health Advisories
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

GLOSSARY OF TERMS AND ABBREVIATIONS

LEL	Lowest Effect Level
LOC	Level of Concern
LOEL	Lowest Observed Effect Level
µg/g	Micrograms Per Gram
MCLG	Maximum contaminant Level Goal
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
ppb	Parts Per Billion
ppm	Parts Per Million
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
RfD	Reference Dose

GLOSSARY OF TERMS AND ABBREVIATIONS

RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The dose at which a substance produces a toxic effect.
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TRR	Total Radioactive Residue

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide bentazon, 3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide. The active ingredient in all end-use products is sodium bentazon and in this document, the term "bentazon" includes the sodium salt.

Bentazon is a selective, contact, early postemergent herbicide that is manufactured by BASF Corporation and marketed under the trade name Basagran. The products are applied aerially and on the ground for control of many broadleaf weeds and yellow nut sedge. Bentazon is registered for use on such terrestrial food and feed crops as alfalfa, beans, corn, peanuts, peas, pepper, peppermint, rice, sorghum, soybeans and spearmint. In addition, bentazon is registered for use on two terrestrial nonfood crops: ornamental lawns and turf. Registered formulations of bentazon have active ingredient concentrations ranging from 6.6 to 53 percent.

A Registration Standard was issued in September, 1985. The Registration Standard summarized available data supporting the registration of products containing bentazon and required additional product chemistry, residue chemistry, toxicology, environmental fate, and fish and wildlife data.

The Agency has now completed its review of the bentazon target data base including data submitted in response to the Registration Standard and has determined that the uses of bentazon as currently registered will not cause unreasonable risk to humans or the environment. All currently registered uses of bentazon are eligible for reregistration. The Agency is requiring additional product chemistry, residue chemistry, toxicology, and environmental fate studies on a confirmatory basis.

Bentazon has been classified as a "Group E" carcinogen (evidence of non-carcinogenicity to humans) by the Office of Pesticide Programs (OPP) Peer Review Committee on 6/26/91. The Agency determined that the RfD for bentazon should be established at 0.03 mg/kg/bwt/day, based on a No-Observed-Effect-Level (NOEL) of 3.2 mg/kg bwt/day in a one-year dog feeding study and an uncertainty factor of 100. The theoretical maximum residue concentration (TMRC) for the overall U.S. population represents 2.2% of the RfD. Based on these risk estimates, chronic dietary risk from registered uses is not of concern. Tolerances for all uses have been reassessed with changes noted in Part IV. There are no concerns that warrant the establishment of personal protective equipment requirements beyond what is required by the Worker Protection Standard (WPS) or is on current labels for uses not covered by the WPS.

All ecological effect data requirements necessary to complete a risk assessment for the reregistration of bentazon are fulfilled. However, additional studies (avian reproduction, freshwater fish toxicity, mollusk toxicity, and aquatic plant growth) are being required on a confirmatory basis. New avian reproduction studies may help determine risk reduction measures.

Based on the existing data base, the Agency concludes that the use of bentazon as an herbicide will not pose a serious acute or chronic human toxicity or environmental threat. However, the Agency does have ground and surface water concerns as well as concerns about chronic effects to birds. Ground water monitoring data show bentazon detections in ground water in four of eight states sampled, at concentrations ranging from 0.07 to 120 ppb. The greatest number of detections have been in California, where 64 wells out of 200 have reported concentrations of bentazon. Since bentazon is an herbicide, it is anticipated that the risk to non-target terrestrial and semi-aquatic plants will be high. To address these concerns, the Agency is requiring a ground water label advisory.

Bentazon is not currently regulated under the Safe Drinking Water Act (SDWA). Therefore no MCL has been established and water supply systems are not required to sample and analyze for it. Bentazon currently has a lifetime drinking water health advisory of 20 µg/L. However, the HA level will likely be increased to 200 µg/L (200 ppb) because the Office of Pesticide Programs now has a complete data base which has reduced the uncertainty factor in the reference dose calculation from 1,000 to 100. Based on the levels in surface waters of other pesticides with characteristics comparable to bentazon, it is unlikely for the time weighted annual average concentrations of bentazon to exceed the lifetime HA at one or more surface water source supply systems.

Use limitations to protect endangered plant species may be required but have not yet been defined. These will be based on recommendations from the Endangered Species Protection Program which is expected to be completed in 1995.

Before reregistering the products containing bentazon, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of bentazon. The document consists of six sections. Section I is the introduction. Section II describes bentazon, 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 bentazon. Section V discusses the reregistration requirements for bentazon. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredients are covered by this Reregistration Eligibility Document:

- **Common Name:** bentazon
- **Chemical Name:** 3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide
- **Chemical Family:** Based on chemical affinities, bentazon is considered a member of the thiadiazine group, containing nitrogen and sulphur hetero atoms.
- **CAS Registry Number:** 50723-80-3 sodium bentazon
  (25057-89-0 bentazon technical)
- **OPP Chemical Code:** 103901 sodium bentazon
  (275200 bentazon technical)
- **Empirical Formula:** $C_{10}H_{12}N_2O_3S$
- **Trade and Other Names:** Basagran, Twister
- **Basic Manufacturer:** BASF Corporation
  P.O. Box 13528
  Research Triangle Park, NC 27709-3528

B. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of these use of bentazon is in Appendix A.

Type of Chemical: herbicide

Mode of Action: benzothiadiazinone contact herbicide, photosynthetic electron transport inhibitor

Use Groups and Sites:

AQUATIC FOOD CROP
Rice

TERRESTRIAL FOOD CROP
Pepper (chili type)

TERRESTRIAL FOOD + FEED CROP
Beans, beans (dried-type), beans (succulent, lima), beans (succulent, snap), corn, corn (unspecified), corn (field), corn (pop), corn (sweet), peanuts (unspecified), peas (dried-type), peas (southern), peas (succulent), peppermint, rice, sorghum, soybeans (unspecified), spearmint

TERRESTRIAL FEED CROP
Alfalfa, corn, sorghum

TERRESTRIAL NONFOOD + OUTDOOR RESIDENTIAL
Ornamental lawns and turf

Pests: arrowhead, balloonvine, beggarticks, bristly starbur, bulrush, Canada thistle, cocklebur, coffee senna, common groundsel, common purslane, common waterplantain, dayflower, devilsclaw, ducksalad, galinsoga, gooseweed, hairy nightshade, jimsonweed, kochia, ladysthumb, lambsquarters, morningglory, marshelder, prickly sida, ragweed, redstem, redweed, sandbur, sesbania, shepherdspurse, smallflower umbrella sedge, smartweed, spikerush, spurred anoda, sunflower, tropic croton, velvetleaf, Venice mallow, wild buckwheat, wild mustard, wild poinsettia, yellow nutsedge

Formulation Types:
Flowable concentrate--19 to 27.6% + 1 other active ingredient (AI)
Soluble concentrate/liquid--29 to 53% + 1 other AI

Methods and Rates of Application:

Flowable concentrate
At postemergence, spray by aircraft or ground equipment at 0.726 to 1.0 lb acid equivalent (AE)/acre/yr.

Soluble concentrate/liquid
At postemergence or ratoon, spray by aircraft or ground equipment at 0.5 to 4 lb AE/acre/yr.

Use Limitations: Do not apply through any type of irrigation system. Do not discharge effluent containing product into sewage systems or bodies of water. Do not use treated plants for feed or forage. Do not treat within 30 to 75 days of harvest or 12 to 50 days of grazing.

C. Data Requirements

Data requested in the September 1985 Registration Standard for bentazon included studies on product chemistry, ecological effects, environmental fate, toxicology, and residue chemistry. These data were required to support the uses listed in the Registration Standard. Appendix B

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

D. Regulatory History

In September 1985, EPA issued a Registration Standard on bentazon. In the Registration Standard, EPA identified data required to support existing uses of the pesticide and determined whether existing data were acceptable and sufficient to satisfy the requirement. Under the 1985 Registration Standard, registrants were required to generate data, to supply missing data, and to replace unacceptable studies.

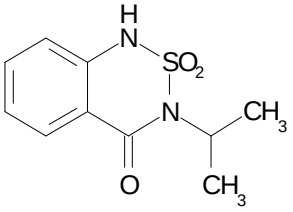
By 1990, the Agency had reviewed data submitted in response to the 1985 Registration Standard and reevaluated its position on data needed to support the continued registration of bentazon products. A Data Call-In notice was issued on August 20, 1990 requiring additional data on bentazon to address terrestrial and aquatic animal effects, environmental fate, toxicology, residue chemistry, and plant protection.

This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and the Data Call-In.

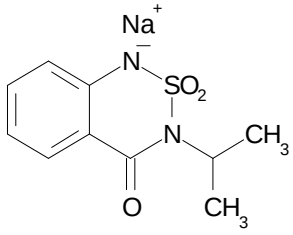
III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Bentazon (3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide) is a selective herbicide used post-emergence on broadleaf weeds and sedges. Bentazon is formulated and used as the sodium salt alone or in combination with atrazine.



Bentazon



Bentazon, sodium salt

Empirical Formula:	$C_{10}H_{12}N_2O_3S$
Molecular Weight:	240.3
CAS Registry No.:	50723-80-3
Shaughnessy No.:	103901 bentazon sodium salt (275200 bentazon)

Identification of Active Ingredient

Technical grade bentazon is a colorless to white solid with a melting point of 137-139° C and a vapor pressure of $<1 \times 10^{-7}$ mm Hg at 20° C. The solubility (g/100 g solvent, 20° C) of bentazon is 0.05 in water, 150.7 in acetone, 3.3 in benzene, 18.0 in chloroform, 86.1 in ethanol, 61.6 in ethyl acetate, 0.02 in cyclohexane, and 2.7 in olive oil. The bentazon sodium salt is more soluble in water (230 g/100 g).

Manufacturing-Use Products

There are two registered bentazon sodium salt manufacturing-use products (MPs), BASF Basagran Manufacturers Concentrate (EPA Reg. No. 7969-42) and BASF Basagran Manufacturers Concentrate - 600 g/L (EPA Reg. No. 7969-84). Both products are sodium salt formulation intermediates (FIs) registered to BASF Corporation. The sodium salt FIs are manufactured by an integrated system. Based on information in Agency records and the Bentazon Reregistration Standard dated 7/26/84, this product is a 46% formulation. Throughout this document the product will be identified as the 46% FI. The two currently registered BASF MPs are subject to a reregistration eligibility decision.

B. Human Health Assessment

1. Toxicology Assessment

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

a. Acute Toxicity

Bentazon has been evaluated for a variety of acute toxicity effects. The results obtained are summarized in the table below.

Acute Toxicity		
Test	**Result**	**Category**
Oral LD_{50} - rat	1100 mg/kg; M&F	III
Dermal LD_{50} - rat	>2500 mg/kg	III
Eye Irritation - rabbit	Slight irritation	III
Acute Inhalation	Data gap	-

Dermal Irritation - rabbit	Minimal	III
Dermal Sensitization - guinea pig	Sensitizer	n/a

* Note: Data pertaining to acute eye irritation, dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

The acute oral LD_{50} for technical bentazon from rat studies was 1100 mg/kg (category III toxicity; Coberly, 1972; Coberly, 1974). The acute oral LD_{50} in the guinea pig was similar at 1100 mg/kg, category III toxicity, MRID No. 00064316, whereas the acute oral LD_{50}s in rabbits (750 mg/kg; category III toxicity), MRID No. 00135397, and cats (500 mg/kg; category III toxicity), MRID No. 00135396, were comparable.

The LD_{50} for technical bentazon in acute dermal studies was over 2500 mg/kg in rats (category III toxicity; MRID No. 00072789).

The acute inhalation studies available do not meet the present standards; thus, an adequate acute inhalation study is required.

Bentazon produced mild irritation in the rabbit eye which lasted for about a week (category III toxicity; MRID No. 00072791). Minimal skin irritation (i.e. reddening) lasting about 72 hours was produced by bentazon in a primary dermal irritation study in rabbits (category III toxicity; MRID No. 00072790). Bentazon was reported to produce sensitization of the skin in guinea pigs (BASF, 1986).

b. Subchronic Toxicity

In a 13-week dietary feeding study in Wistar rats, the doses were 0, 400, 1200, or 3600 ppm in the diet. The systemic toxicity NOEL was 1200 ppm (equivalent to 60 mg/kg/day). The LOEL was 3600 ppm (180 mg/kg/day; highest dose tested) based on reductions in body weight gain, increased thromboplastin and prothrombin times, diuresis, clinical chemistry changes (e.g. increases in albumin, A/G ratios, and sodium), and increased kidney and liver weights. In addition, females in the 3600 ppm group showed suggestive evidence for the presence of lung thrombi and dilated uterine horns (MRID No. 40222201). The available 21-day dermal toxicity study with bentazon does not meet the present standards; thus, an adequate 21-day dermal toxicity study is required. The study is considered confirmatory because there does not appear to be a concern for worker risk based on available information.

c. Chronic Toxicity and Carcinogenicity

Administration of bentazon in the feed of beagle dogs for one year at levels of 0, 100, 400, or 1600 ppm resulted in a systemic toxicity NOEL of 100 ppm (approximately 3.2 mg/kg/day) and a LOEL of 400 ppm (approximately 13.1 mg/kg/day). Adverse toxicological effects at the two higher dose levels consisted of clinical signs of toxicity (emaciation, dehydration, loose and/or bloody stools, pale mucous membranes, and reduced activity), hematological changes suggestive

of anemia (decreased red cells, hemoglobin and hematocrit, abnormal red cell morphology, and increased reticulocytes, platelets, leukocytes, and partial thromboplastin time), depressed body weight gains, intestinal inflammation, and congestion of the small intestine and spleen. The anemia appeared to be due to blood loss from the gastrointestinal tract (MRID No. 41054901).

Fischer 344 rats were given 0, 200, 800, or 4000 ppm bentazon in the diet in a two-year combined chronic toxicity-carcinogenicity study. The systemic toxicity NOEL was 200 ppm, equivalent to 10 mg/kg/day (lowest dose tested). Adverse effects were observed at levels of 800 ppm (40 mg/kg/day; LOEL) and 4000 ppm (200 mg/kg/day) and consisted of increases in prothrombin time and partial thromboplastin time, increases in urine volume, blood urea nitrogen, and kidney weight along with reduced urinary specific gravity, a reduction in body weight gain, and a decrease in thyroid gland weight. No compound-related increase in tumors was observed (MRID No's 00142832, 40871702). B6C3F1 mice were fed 0, 100, 400, or 2000 ppm bentazon in a two-year combined chronic toxicity-carcinogenicity study. The systemic toxicity NOEL was 100 ppm, equivalent to 15 mg/kg/day (lowest dose tested). Adverse effects were observed at levels of 400 ppm (60 mg/kg/day; LOEL) and 2000 ppm (300 mg/kg/day). There were an increased prothrombin time, calcification of the tunica albuginea of the testes, hyperplasia of pancreatic islet cells and liver, slight increase in mortality, reduced weight gain, areas of hemorrhage in the liver and heart, and increased weights of the kidney, thyroid gland, and pituitary gland. No compound- related increase in tumors was observed. (MRIDs 00142832, 40871701)

Bentazon was classified as a "Group E" carcinogen, which denotes evidence of non-carcinogenicity for humans, by the Agency's Health Effects Division Carcinogenicity Peer Review Committee, 6/26/91.

d. Developmental Toxicity

In pregnant Wistar rats gavaged with 0, 40, 100, or 250 mg/kg/day of bentazon on gestation days 6-15, the maternal toxicity NOEL was over 250 mg/kg/day. The developmental toxicity NOEL was 100 mg/kg/day. The LOEL was 250 mg/kg/day based upon an increase in postimplantation loss that was characterized by fetal resorptions accompanied by a reduction of body weights of fetuses surviving to day 21. In addition, there was a reduced rate of ossification in phalangeal nuclei of fore- and hind-limb digits, sternebrae, and cervical vertebrae (MRID 40114201).

When pregnant Chinchilla rabbits were gavaged with 75, 150, or 375 mg/kg/day, on gestation days 6-18, the maternal toxicity NOEL was 150 mg/kg/day. The maternal LOEL was 375 mg/kg/day due to the occurrence in a single doe of a partial abortion, embryonic resorptions, and the absence of living fetuses. The developmental toxicity NOEL was over 375 mg/kg/day (MRID 40114202).

e. Reproductive Toxicity

A reproductive NOEL at 200 ppm (approximately 15 mg/kg/day; lowest dose tested) was

found in a two-generation study in Wistar rats. Doses were 0, 200, 800, or 3200 ppm bentazon in the diet. Higher levels of 800 ppm (reproductive LOEL) and 3200 ppm (approximately 62 and 249 mg/kg/day, respectively) were associated with a decrease in the body weights of the pups during lactation. For parental toxicity, the NOEL was 800 ppm, and the LOEL was 3200 ppm based on reductions in food consumption and weight gain, and increased incidence of renal mineralization and liver microgranuloma (MRID 41054902).

f. Mutagenicity

Bentazon was not mutagenic in the tests for gene mutations, which were reverse mutation assays in S. typhimurium and in E. coli WP2 uvrA (MRID 00158382) as well as forward mutation assays with in vitro Chinese hamster ovary cell (HGPRT) cultures (MRID 42129610). Bentazon was also negative in the mouse micronucleus test for assessing structural chromosomal aberrations (MRID 00158388) and the unscheduled DNA synthesis assay with primary mouse hepatocyte for detecting DNA damage (MRID 00158386).

g. Metabolism

The metabolism of [phenyl-U-14C]-bentazon was studied in male and female CD rats. The labeled compound was administered (a) as a single intravenous dose of 4.1 mg/kg, (b) as a single oral dose of 3.8 or 205 mg/kg, (c) or as a single oral dose of 3.6 mg/kg following a 14-day pretreatment with unlabeled bentazon at approximately 4 mg/kg/day. About 88.1-95.9% of the dose was absorbed from the gastrointestinal tract. Among the orally dosed groups, approximately 88.1-95.9% of the dose was eliminated in the urine and 0.8-2.3% of the dose was eliminated in the feces over a period of 168 hours. At sacrifice, total radioactive residue was less than 0.69% of the dose in all groups. Parent bentazon was the major metabolite found in the urine, amounting to 77.37 - 91.02% of the dose among the orally dosed animals of the main experiment. In addition, 6-OH-bentazon was present in amounts up to 6.34% of the dose. The isomeric 8-OH-bentazon was present in trace amounts, up to 0.23% of the dose (MRID 40481801).

h. Dermal Penetration

Single topical applications of radioactive sodium bentazon at doses of 0.12, 1.2, 12.0, or 120.0 mg/kg did not appear to significantly penetrate the skin of rats. Only 1-2% of the radioactivity was recovered, primarily in the urine. Negligible amounts of applied radioactivity were retained in the body (MRID 00796942).

i. Reference Dose

The reference dose for bentazon was determined to be 0.03 mg/kg/day based on results of a one-year feeding study in beagle dogs. The NOEL was 100 ppm (approximately 3.2 mg/kg/day from measurement of dietary intake). The LOEL (400 ppm or approximately 13.1 mg/kg/day) was based on hematological changes and bloody stool. An uncertainty factor of 100 was employed. A value of 0.1 mg/kg/day was established for this chemical by the World Health Organization (WHO)

Panel of the Joint Meeting on Pesticide Residues in 1991.

2. Exposure Assessment

a. Dietary Exposure

(1) Plant Metabolism

The qualitative nature of the residue in plants is understood adequately. Studies with a variety of plants including beans (dry and succulent), corn, soybeans (seeds, forage, and hay), rice (grain and straw), and wheat indicate that bentazon is absorbed readily from foliage, roots, and seeds. Translocation throughout rice and wheat plants is extensive; limited translocation in navy beans and soybeans occurs. Bentazon is metabolized rapidly, conjugated, and incorporated into natural plant constituents. Metabolism involves the hydroxylation of bentazon at the 6- and 8-position and subsequent conjugation with carbohydrates or fragmentation and incorporation into natural constituents such as lignin, proteins, and polysaccharide fractions (starch, pectin, hemicellulose, and cellulose). The terminal residues of concern are bentazon, 6-hydroxy bentazon, and 8-hydroxy bentazon.

(2) Animal Metabolism

The qualitative nature of the residue in animals is understood adequately. Studies involving dairy cows dosed with [U-^{14}C]bentazon, [^{14}C]8-hydroxy bentazon, and [^{14}C]6-hydroxy bentazon at 1 ppm (0.5x), 5 ppm (2.5x), and 20 ppm (10x) in the diet for a maximum of 28 days demonstrated that bentazon is absorbed and eliminated rapidly in the urine after oral dosing. Bentazon and 2-amino-N-isopropyl benzamide (AIBA) accounted for the majority of the terminal residues in tissues and milk. Studies involving laying hens dosed with [U-^{14}C]bentazon at 100 ppm (2000x) in the diet for 5 days demonstrated that limited accumulation and metabolism occurs; $\geq$80% of the TRR in tissues and eggs was identified as unchanged bentazon; 16% of the TRR in liver consisted of N-glucuronide conjugate of bentazon. Dosing at this highly exaggerated rate yielded the highest total radioactivity (1.632 ppm) in liver. The presence of detectable residues of bentazon in poultry tissues and eggs from a 1x feeding level is unlikely. The terminal residues to be regulated in animal tissues, eggs, and milk consist of bentazon and its metabolite AIBA. The current tolerances and tolerance expression adequately cover these residues in animal commodities.

(3) Residue Analytical Methods - Plants and Animals

Adequate enforcement methods are available for the determination of residues of bentazon and its 6- and 8-hydroxy metabolites in/on plant commodities and for the determination of bentazon and AIBA in animal commodities. The Pesticide Analytical Manual (PAM) Vol. II lists Method II, a GLC method with flame photometric detection for the determination of bentazon and its hydroxy metabolites in/on corn, rice, and soybeans; the limit of detection for each compound is 0.05 ppm. Method I, a GLC method with nitrogen-specific Coulson conductivity detection, is available for the determination of residues of bentazon and AIBA in animal tissues, eggs, and milk; the limit

of detection for each compound is 0.05 ppm in tissues and eggs and 0.02 ppm in milk. Method III, modified from Method II, is available for the determination of bentazon and its hydroxy metabolites in/on peanuts and seed and pod vegetables with a limit of detection of 0.05 ppm for each compound.

Radiolabeled validation of the current tolerance enforcement method (PAM Vol. II, Section 180.355, Method II) by analysis of methanol soluble fractions of soybean forage samples from the soybean metabolism study indicates that methanol-soluble residues of bentazon and its hydroxy metabolites are recovered adequately by this method.

Residue data submitted in response to the Guidance Document and in support of petitions for the establishment of new tolerances were collected using modifications of the available PAM Vol. II methods. These modified methods, along with the methods listed in PAM Vol. II, are adequate for bentazon data collection and tolerance enforcement.

The FDA PESTDATA database January 1994 (PAM Vol. I, Appendix II) does not contain data concerning the applicability of FDA multiresidue methods for recovery of bentazon, and its hydroxy-metabolites. Data depicting the recovery of bentazon, 6-hydroxy bentazon, and 8-hydroxy bentazon, through the multiresidue methods remain outstanding.

(4) Storage Stability

Storage stability studies have been conducted using samples of rice grain, rice straw, snapbean vines, snapbean cannery waste, soybeans, soybean forage, corn forage, peanut forage, flax seed, flax straw and flax meal. These data indicate that residues of bentazon, 8-OH-bentazon, and 6-OH-bentazon are relatively stable in these matrices for up to two years of frozen storage (-5 to -27 $\pm^0$C). Thus, by translation, representative storage stability data are available for samples of oil seeds, non-oily grains, legume vegetables (dried and succulent), and low moisture content forages/hays stored under conditions and intervals of those samples from residue field trials used to reassess existing tolerances. Additional storage stability data are needed to validate processing studies (corn, peanuts, rice, and soybeans) for which data are either lacking or incomplete. Storage stability data for processed items reflecting up to 14 months of frozen storage are needed to support these processing studies. These data are considered confirmatory to the existing evidence that residues of bentazon, 6-OH-bentazon, and 8-OH-bentazon are relatively stable in unprocessed frozen plant matrices.

No storage stability data for animal commodities are available; these data are outstanding and are considered confirmatory. Data are required reflecting the storage stability of bentazon and AIBA in cattle and poultry tissues, milk, and eggs. Storage intervals and conditions must reflect the existing cattle metabolism/feeding study (MRID 00039849), the existing poultry metabolism/feeding study (MRID 00039856), and the existing poultry metabolism study (MRID 41089101). Because available storage stability data for plant commodities indicate that residues are generally stable, CBRS considers the available information sufficient to support the cattle and poultry metabolism/feeding studies. The additional data are required to confirm the conclusions that the existing animal commodity tolerances are adequate.

(5) Magnitude of the Residue in Plants

All data submitted in response to reregistration requirements pertaining to the magnitude of the residue in plants have been evaluated and deemed adequate. Field trials typically were conducted according to the parameters of registered use patterns. The geographical representation for each commodity is generally adequate and a sufficient number of trials reflecting representative formulation classes were conducted. The existing 3 ppm tolerances for residues of bentazon in/on bean forage, pea vine hay, soybean forage, and soybean hay are inadequate to cover the currently registered use; tolerances of 10 ppm for "beans, vines", 8 ppm for pea vine hay, 8 ppm for soybean forage, and 8 ppm for soybean hay would be adequate to cover the expected residues resulting from the currently registered use pattern. The existing 0.05 ppm tolerance for dried peas is inadequate to cover the currently registered use; a tolerance of 1 ppm would be adequate to cover the expected residues resulting from the currently registered use pattern.

(6) Magnitude of the Residue in Processed Food/Feed

Processing studies have been conducted on the following RACs: field corn, peanuts, rice grain, mint, soybeans, and snapbeans (forage/cannery waste). Data on the potential for residue concentration in grain sorghum processed products have not been required. All data submitted in response to reregistration requirements for magnitude of the residue in processed food/feed have been evaluated and deemed adequate, pending submission of acceptable storage stability data on processed food/feed items. Residue concentration was observed in snapbean cannery waste, spent mint hay, and rice hulls. A 4 ppm feed additive tolerance for residues in spent mint hay has been established; a feed additive tolerance of 0.25 ppm must be proposed for residues of bentazon in rice hulls.

(7) Magnitude of the Residue in Meat, Milk, Poultry and Eggs

The ruminant metabolism studies in which lactating dairy cows received [U-^{14}C]bentazon at 1 ppm (0.25x), 5 ppm (2.5x), and 20 ppm (10x) in the diet for a maximum of 28 days provide data to reassess the adequacy of the existing 0.02 ppm tolerance for the combined residues of bentazon and AIBA in milk and the 0.05 ppm tolerances for the combined residues of bentazon and AIBA in fat, meat byproducts and meat of cattle, goats, hogs, and sheep. The poultry metabolism studies in which laying hens received [U-^{14}C]bentazon at 100 ppm (2000x) in the diet for 5 days provide data to reassess the adequacy of the existing 0.05 ppm tolerances for the combined residues of bentazon and AIBA in eggs and the fat, meat byproducts and meat of poultry. The storage stability data to support these studies are outstanding. Because existing data provide evidence indicative of stability of the residues, the available information is considered adequate to conclude that the established tolerances on livestock commodities are appropriate.

(8) Confined/Field Rotational Crops

Data pertaining to rotational crop studies are currently under review. A preliminary review of the data indicates that residues of regulated metabolites in rotated crops are greater than 0.01 ppm

at the 40-day plantback interval; thus, limited rotational crop data must be provided. These conclusions may change upon full review of the data by the Agency.

b. Occupational and Residential Exposure

Mixer/Loader/Applicator (Handler) Exposure: Sodium bentazon is a post-emergent herbicide that is applied to the foliage of terrestrial food, feed and food, feed, and non-food/outdoor residential crops/targets. Crops/targets that bentazon may be applied to include: alfalfa, beans (dried, succulent/lima, and snap), corn (field, pop, sweet), ornamental lawns and turf, peanuts, peas (dried, southern, and succulent), chili type peppers, peppermint, rice (post emergent and ratoon), sorghum, soybeans, and spearmint. Applications can be made to all targets, except for ornamental lawn/turf, using aircraft or typical ground equipment. Applications to ornamental lawn/turf are limited to ground equipment.

Mixer/loader/applicator (i.e., handler) exposure issues are addressed by Subdivision U of the Pesticide Assessment Guidelines. Mixer/loader/applicator exposure monitoring data were not required in the 1985 Registration Standard. The bentazon toxicity data did not meet the triggers which were in place at the time the registration standard was issued (i.e., September 1985). Although chemical-specific mixer/loader/applicator data have not been submitted to EPA, a limited exposure/risk assessment was conducted for this RED using the Pesticide Handlers Exposure Database (PHED).

Based on the use patterns described above, two major exposure scenarios were identified, groundboom and aerial applications. The exposure scenarios are presented in the first table below. The second table summarizes the caveats and parameters specific to each exposure scenario.

Summary Exposure Values

Exposure Scenario (Scen. #)	Dermal Exposure[a] (mg/lb ai)	Inhalation Exposure[b] (Fg/lb ai)	Maximum Label Application Rate[c] (lb ai/acre)	Daily Maximum[d] Treated	Daily Dermal Exposure[e] (mg/kg/day)	Daily Inhalation Exposure[e] (Fg/kg/day)
Mixer/Loader Exposure						
Open Mixing Liquids, Groundboom Application (I-a)	0.15	0.4	2 lb ai/A	80 acres	0.4 (0.008)*	1.1
Open Mixing Liquids, Fixed-Wing Aerial (I-b)	0.15	0.4	2 lb ai/A	350 acres	1.7 (0.035)*	4.6
Applicator Exposure						
Groundboom Application (II)	0.02	1.3	2 lb ai/A	80 acres	0.05 (.001)*	3.5
Fixed-Wing Aerial (III)	0.005	0.2	2 lb ai/A	350 acres	0.06 (.001)*	2.3

[a] Dermal unit exposures are reported as the best fit mean, unless noted. The best fit mean is the composite total dermal

exposure based on using the geometric mean for lognormal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types.

[b] Inhalation exposure values are reported as geometric means (lognormal distributions).

[c] LUIS Report dated 2/3/93, Bentazon.

[d] Values represent the maximum area or the maximum volume of spray solution which can be used in a single day to complete treatments for each exposure scenario of concern.

[e] Daily Exposure (mg/kg/day) (adjusted for chemical resistant gloves)

$$= \frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/acre)} * \text{Max. Treated}}{60\text{kg}}$$

Mixer/Loader Exposure Scenario Descriptions

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario[a]	Equipment	Standard Assumptions[b] (8 hr work day)	Comments[c]
Mixer/Loader Exposure					
Open Mixing (I)	PHED	Long Pants, Long-Sleeved Shirt, No gloves	Open Mixing	25 gal/acre x 80 acres (Groundboom)	Acceptable grades; Dermal = 14 + replicates; Inhalation = 40 replicates
Applicator Exposure					
Groundboom Application (II)	PHED	Long Pants, Long-Sleeved Shirt, No gloves	Open Cab Tractor	80 acres/day	Grades A, B, C; Dermal = 6 + replicates; Inhalation = 56 replicates.
Aerial (III)	PHED	Long Pants, Long-Sleeved Shirt, No Gloves	All Cab Types	350 acres/day	Inhalation grades A, B, C; Dermal all grades; Dermal = 4 to 41 replicates; Inhalation = 25 replicates.

[a] Clothing scenario represents actual monitored exposure data. The dermal exposure values on Table 1 have been adjusted using protection factors to simulate chemical resistant gloves.

[b] Standard Assumptions based on an 8 hour work day.

[c] If dermal and inhalation grades are not listed separately, then the listed grades pertain to both dermal and inhalation. "Acceptable grades" for meeting Subdivision U Guidelines are grades A and B for dermal and inhalation, and grade C for hand rinse method.

The Worker Protection Standard (WPS) requires workers handling bentazon to wear long pants, long sleeved shirts, and chemical resistant gloves. Mixer/loader/applicator exposure estimates from PHED were used to calculate daily dermal and inhalation exposure for workers handling end-use products. Exposure scenarios were developed based on the equipment types and practices specified in the available equipment for a labelled use/instruction (e.g. open cab groundboom tractor applications on various crops).

3. Risk Assessment

a. Dietary

Toxicological Endpoint: The DRES chronic analysis used a Reference Dose (RFD) of 0.03 mg/kg bwt/day, based on a No-Observed-Effect-Level (NOEL) of 3.2 mg/kg bwt/day and an uncertainty factor of 100. The NOEL was derived from a 1 year feeding study in dogs which demonstrated hematological changes and bloody stools.

The DRES acute analysis used a NOEL of 100 mg/kg/day which was derived from a developmental toxicity study in rats, with increased postimplantation loss and reduced body weights of pups being the effects observed.

Results: Exposure calculated in the DRES chronic analysis was compared to a Reference Dose (RFD) of 0.03 mg/kg bwt/day. The DRES chronic exposure analysis used tolerance level residues and a 100 percent crop treated assumption to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. These exposure estimates then were compared to the RfD to estimate chronic dietary risk. The TMRC for the overall U.S. population from uses supported through reregistration is 0.000651 mg/kg bwt/day, which represents 2.2% of the RfD. The subgroup most highly exposed, non-nursing infants less than one year old, has a TMRC from supported uses of 0.002444 mg/kg bwt/day, or 8.1% of the RfD. Based on the risk estimates calculated in this analysis, it appears that chronic dietary risk from the uses supported through reregistration is not of concern.

The DRES detailed acute exposure analysis evaluates individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and estimates the distribution of single day exposures through the diet for the U.S. population and certain subgroups. The analysis reflects consumers only and assumes a uniform distribution of bentazon in the commodity supply. Since the toxicological effect to which high end exposure is being compared in this analysis is developmental toxicity, the DRES population group of interest is "females aged 13 years and above," the DRES subgroup which most closely approximates females of child bearing age. The Margin of Exposure (MOE) is a measure of how closely the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/ Exposure = MOE).

In this analysis, the calculated exposure for the highly exposed individuals in the distribution (0.2 mg/kg bwt/day) was compared to the NOEL of 100 mg/kg bwt/day from the rat developmental toxicity study to get an MOE of 500. This means that those persons most highly exposed to bentazon in their diet would receive 1/500 the dose that represents the NOEL in animals for developmental toxicity. Acute risk probably is overestimated by this analysis, since it is very unlikely that tolerance level residues would exist on all of the food items considered in this analysis and eaten in one day by an individual.

b. Occupational and Residential

The Agency has a concern for developmental toxicity based on a toxicity study in the rat where the NOEL equals 100 mg/kg/day. Because workers may be at risk for toxic effects from exposure to bentazon, margins of exposure (MOE) are calculated by this equation:

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

MOE = NOEL/Dermal Exposure with a 2% absorption factor.

Private applicator is defined as a "short term" exposed individual (i.e., one day). A developmental toxicity NOEL of 100 mg/kg/day is used in the MOE calculation.

Commercial applicator is defined as a "short term" and an "intermediate" exposed individual (i.e., 10 days). A systemic toxicity NOEL of 60 mg/kg/day is used in the MOE calculation.

Exposure scenarios were developed based on the equipment types and practices specified in the available labels for each of the various bentazon formulations. All exposure estimates were completed by considering the most typical equipment for a labelled use/instruction (e.g., open cab groundboom tractor applications on various crops).

The table below gives the MOEs for the workers exposed for short term and intermediate term. Based on available information, the MOEs are greater than 100 for exposure scenarios.

Summary Risk Values

Exposure Scenario (Scen. #)	Daily Dermal Exposure[e] (mg/kg/day)	Daily Inhalation Exposure[e] (Fg/kg/day)	Margin of Exposure[f]		
			Private Applicator	Commercial Applicator (short term)	Commercial Applicator
Mixer/Loader Exposure					
Open Mixing Liquids, Groundboom Application (I-a)	0.4 (0.008)*	1.1	12500	12500	7500
Open Mixing Liquids, Fixed-Wing Aerial (I-b)	1.7 (0.035)*	4.6	2857	2857	1714
Applicator Exposure					
Groundboom Application (II)	0.05 (.001)*	3.5	100,000	100,000	60,000

Fixed-Wing Aerial (III)	0.06 (.001)*	2.3	None		60,000

[e] Daily Exposure (mg/kg/day) (adjusted for chemical resistant gloves)
= Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/acre) * Max. Treated
60 kg

[f] MOE = NOEL/Dermal Exposure with a 2% absorption factor

[*] Values in parentheses are dermal exposure values in conjunction with a 2% absorption value

The risk to homeowners who handle bentazon is expected to be lower than the risk to persons who handle bentazon in their occupation.

C. Environmental Assessment

1. Environmental Fate

At this time, five data requirements in the environmental fate guidelines are not fulfilled for sodium bentazon salt: aquatic field dissipation (164-2), confined rotational crops (165-1), small-scale prospective groundwater studies (166-1), droplet size spectrum (201-1), and drift field studies (202-1). Although these five guidelines are not fulfilled, the Agency has sufficient data for comprehensive qualitative and quantitative environmental fate, ground- and surface-water assessments for sodium bentazon salt.

a. Environmental Chemistry, Fate and Transport

(1) Hydrolysis

Parent bentazon was stable to hydrolysis in pH 5, 7, and 9 buffer solutions. The requirement for hydrolysis data (161-1) has been satisfied. (TRID 4470236029)

(2) Photodegradation in Water

Phenyl-ring labeled bentazon photodegraded ($t_{1/2}$ = 63 hours) in pH 7 buffer solution. The photodegradates were tentatively identified as 3-isopropyl-2,2-dioxo-5-oxo-cyclopentena acid (21% after 142 hours of irradiation) and 1-[N-(1-methyl- ethyl)]-1-sulfoamino-benzamide (6.46% after 142 hours irradiation), unidentified polar degradates (total of 11.27%), and polar degradates (total of 8.34%). Photodegradation in water (161-2) is partially satisfied; additional data are required on identification and quantification of degradates. (MRIDs 41448001, 41432401)

(3) Photodegradation on Soil

Phenyl-ring labeled bentazon was photolytically stable ($t_{1/2}$ > 941 hours) on loam soil. The data requirement (161-3) has been satisfied. (TRID 470236031)

(4) Aerobic and Anaerobic Soil Metabolism

Phenyl-ring labeled bentazon, applied at a rate of 20 lb/A (or 3X application rate), degraded in mineral soils with a half-life of 24 days in clay loam soil, 31 days in loamy sand soil, and 65 days in sandy loam soil. Methanol extractable residues in soil were bentazon, n-methyl-bentazon, and 8-chloro-bentazon. Nonlabile residues were extracted from humic, fulvic, and humin fractions of soil organic matter. Ring-labeled bentazon, applied at a rate of 3 ppm (6 lbs a.i./A), had a half-life of 6 weeks in Sandhofen (German) loamy sand soil. Ring-labeled bentazon, applied at rates of 2 to 10 ppm (4 to 20 lbs a.i./A), had half-lives ranging from < 2 weeks to 14 weeks in Limburgerhoff (German) loamy sand soil, Bruchfeld (German) sandy clay loam soil, Niedereschbach (German) loam soil, and Sandhofen (German) loamy sand soil. Most of the methanol extractable bentazon residues (95%) were found in nonextractable soil fractions (or unavailable) over a 350 day incubation period. The degradate AIBA was detected at low concentrations (<0.1 ppm). The degradate AIBA (unknown test substance), applied at a cumulative rate of 1340 ppm (2680 lbs a.i./A), had a half-life of 1 to 10 days.

Aerobically aged ring-labeled bentazon residues, applied at rate of 1.7 ppm (3.4 lbs bentazon/A), did not rapidly degrade (estimated first-order degradation half-life of 89 days) in anaerobic, Sandhofen (German) loamy sand soil. The only identifiable degradate was AIBA. This degradate did not appear to degrade during an 8 week anaerobic incubation period. Soil metabolism data indicate that bentazon degradation is dependent on oxidative mineralization to CO_2 with subsequent residue incorporation into nonlabile soil organic matter. The aerobic and anaerobic soil metabolism requirements (162-1 and -2) have been satisfied. (MRIDs 40470502, 00040204, 000400208, 00051659, 00040204, 00040208)

(5) Anaerobic and Aerobic Aquatic Metabolism

Phenyl-labeled bentazon in flooded sandy loam soil and rice clay soil did not degrade under anaerobic or aerobic conditions. The major route of bentazon dissipation was through incorporation into nonlabile soil organic matter (20% of applied bentazon after 374 days). Both anaerobic and aerobic metabolism data requirements (162-3 and -4) have been satisfied. (MRIDs 40470503, 40470504)

(6) Leaching and Adsorption/Desorption

Phenyl-labeled bentazon had low binding affinities in clay sediment (K_d=0.176), clay soils (K_d=0.422 to 0.384), heavy clay soils (K_d=3.056), and loamy sand (K_d=0.450). However, Freundlich exponents or soil organic carbon contents were not reported in bentazon equilibrium studies.

Radiolabeled bentazon, applied at a rate of 1.8 lbs a.i./A, was quantitatively leached through 30 cm columns of Limburgerhof (German) loamy sand soil and Bruchfeld (German) sandy clay loam soil. Aged phenyl labeled bentazon soil residues (including N-methyl-bentazon) were retained at the point of application (66.5% TRR) in loamy sand soil columns. However, parent bentazon was

quantitatively eluted (26% TRR) through the soil column. The degradate AIBA was quantitatively leached through 30 cm column of Limburgerhof (German) loamy sand soil. The mobility data indicate bentazon and AIBA are very mobile in soil. However, most soil degradates (except AIBA) of bentazon appear to be relatively immobile in soil. The data requirement (163-1) has been satisfied. (MRIDs 40470501, 40470505, 00041081)

(7) Terrestrial Field Dissipation

Terrestrial field dissipation studies were considered acceptable from Data Evaluation Records used to fulfill the 164-1 data requirement in the 1985 Bentazon Registration Standard. These studies were not rereviewed for the Reregistration Eligibility Decision.

Field dissipation studies were conducted in Texas on sandy soil (0.5% OM) planted with peanuts, Mississippi on a Commerce silt loam soil planted with soybeans and peanuts, Mississippi on a Sharkey silty clay loam soil planted with soybeans, North Carolina on acidic, sandy loam soil (2.8% OM) planted to peanuts, Minnesota on clay soil planted to soybeans, and Idaho on a sandy loam soil. Bentazon, applied as a wettable powder or soluble concentrate at cumulative rates of 1.0 to 10 lbs a.i./A, had field dissipation half-lives of 7 to 33 days. The degradate AIBA was detected (< 0.05 ppm) in the North Carolina, Mississippi, Alabama, and Idaho field dissipation studies. Bentazon and AIBA were not detected in deep soil samples (> 12 inches of soil) in field studies. The data requirement (164-4) has been satisfied. (MRIDs 00108287, 00108288, 00044400, 00044439, 00106226, 00044404, 00044401, 00044402, 00108296)

(8) Aquatic Field Dissipation

Aquatic field dissipation studies are required to confirm the qualitative aquatic fate and transport assessments. In addition, this study can be used to determine the need for chronic testing of aquatic animals. This data requirement (164-2) has not been satisfied.

(9) Confined Crop Accumulation

The submitted confined rotational crop study (MRID 42963701) is adequate to satisfy the 165-1 guideline requirements provided acceptable raw data showing dpm levels in extracts and analytes are submitted.

Radioactive residues accumulated at levels **$**0.01 ppm in/on all commodities of chard, radish, sorghum, turnip, and wheat that were planted 39, 102, 145, 316, and 369 days after [phenyl-^{14}C]bentazon was applied to sandy soil at 0.5x the maximum seasonal rate under field conditions. Although the study was conducted at <1x, the Agency concludes that residues were sufficiently characterized to allow determination of the nature of bentazon residues in rotational crops. Accumulation of radioactive residues was lowest in radish roots (0.04 ppm) and radish tops (0.08 ppm) and highest in chard (1.76 ppm) and sorghum fodder (1.09 ppm). Accumulation of ^{14}C-residues peaked in crops from the 39-day rotation and declined in subsequent rotations.

Combined residues of bentazon and its 6- and 8-hydroxy metabolites were identified at levels **$**0.01 ppm in chard (0.02 and 0.04 ppm, 4.8% and 2.5% TRR, respectively) from the 39- and 102-day rotation, in turnip tops (0.02 ppm, 2.8% TRR) from the 39-day rotation, and in sorghum fodder (0.01 ppm, 1.2% TRR) from the 39-day rotation; combined residues of concern were <0.01 ppm in all other commodities at all other rotations.

The data suggest that the rapid uptake and metabolism of bentazon in rotational crops involves hydroxylation to 6- and 8-hydroxy bentazon, fragmentation, and possibly incorporation into natural constituents such as polysaccharides, hemicellulose, and cellulose. Metabolism proceeds similarly in primary crops.

Limited and/or extensive field rotational crop studies are required because the residues of concern (bentazon, 6-hydroxy bentazon, and 8-hydroxy bentazon) were identified in various rotational crops at various intervals and were quantified at levels greater than 0.01 ppm in crops from the 39- and 102-day rotations. Rotational crop restrictions are required on bentazon end-use product labels. The appropriate plantback intervals will be determined upon submission and review of the required field rotational crop studies.

(10) Field Crop Rotation

Field rotational crop studies provide supplemental data on accumulation of bentazon residues in field crops. Bentazon and its major degradate 6 N-methoxy-N-bentazon and 8-methoxy-bentazon do not appear to accumulate in mature leafy, root, and grain crops planted at emergency, full, and annual rotation intervals in soils amended with 1 lb a.i./A with parent bentazon. (MRIDs 41146601, 41146602, 41146603, 41146604, 41146605, 41146606, 41146607, 41146608)

(11) Bioaccumulation in Fish

This study is required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and/or may accumulate in aquatic organisms.

Bentazon accumulated in the tissues of bluegill sunfish, channel catfish, and crayfish. The bioconcentration factor (BCF) for ^{14}C-bentazon residues in bluegill sunfish was 0.4 in edible fish tissue, 2.3 in non-edible fish tissues, and 1.4 in the whole body. Low BCF for bentazon were also observed in channel catfish. The maximum concentration of ^{14}C-bentazon residues was 11.39 µg/g in non-edible tissues, 8.84 µg/g in whole tissues, and 2.47 µg/g in edible tissues. First-order depuration rates of bioaccumulated ^{14}C-bentazon residues were 0.03 d^{-1} ($t_{1/2}$=23.1 days; R^2=0.49) in edible fish tissues, 0.05 d^{-1} ($t_{1/2}$=13.9 days; R^2=0.86) in non-edible fish tissues, and 0.05 d^{-1} ($t_{1/2}$=13.9 days; R^2=0.87) in whole body fish tissues. Nondepurated radiolabeled bentazon residue concentrations were 5.29 µg/g in non-edible fish tissues, 3.39 µg/g in whole fish, and 1.09 µg/g in edible fish tissues. Accumulated residues were identified as N-methyl bentazon and methyl esters of fatty acids. Radiolabeled bentazon was accumulated in tail meat (<1-10X) and viscera (<1-4X) in crayfish (Procambrus Clark). This data requirement (165-4) has been satisfied. (MRIDs

42236501, 00108300, 40954801, Accession Number 00026408)

(12) Ground and Surface Water Monitoring

Bentazon residues have been detected in the well water in four states: California, Florida, Missouri, and Virginia. Wells were sampled without detections in Louisiana, Mississippi, Oregon, and Washington. Bentazon degradates were not considered in any of the well-water monitoring studies. In the studies, 11% (83 out of 750) of the wells sampled had detections of bentazon residues, at concentrations ranging from 0.01 to 120 parts per billion (ppb).

The greatest number of detections have been in California, where 64 wells out of 200 have reported concentrations of bentazon. In California, Bentazon has been reported in 11 counties in the Pesticides in Ground Water Data Base (PGWDB) (Hoheisel et al., 1992); California Environmental Protection Agency, Department of Pesticide Regulation (Maes et al., 1992) indicates that bentazon in well water has been detected in four additional counties. The detections ranged from 0.01 to 20.0 µg/L. Califomia reports that the source of bentazon in ground water is the result of non-point source legal, agricultural use (Maes et al., 1992). Thus in California bentazon residues have been detected in ground water at the EPA lifetime HA of 20 µg/L, or less. However, the HA level will likely be increased to 200 µg/L (200 ppb) because the Office of Pesticide Programs now has a complete data base which has reduced the uncertainty factor in the reference dose calculation from 1,000 to 100.

The United States Geological Survey (USGS) and the Florida Department of Environmental Protection (FDEP) have recently initiated a study (not included in the PGWDB) to evaluate the influence of municipal reclaimed water on the leaching of pesticides from golf courses in Florida (USGS, 1994). One of the objectives of the project is to determine if selected pesticides applied to golf courses in Florida are leached into the shallow ground water. Four shallow wells were sampled at each of six golf courses studied. The wells were located near greens and tees. Bentazon residues were detected in 3 of 24 wells. The reported bentazon detections ranged from 3.3 to 120 µg/L, with the low value, 3.3 µg/L, being between the method detection limit and the practical quantification limit.[1]

Bentazon residues were detected in 5 of 12 wells (4 household wells and 8 monitoring wells) located in the 3700 acre Nomini Creek Watershed, Westmoreland County, VA (Hoheisel et al., 1992). The site was selected as representative watershed in the Virginia coastal plain for monitoring to document changes in ground-water quality resulting from the implementation of Best Management Practices. Bentazon concentrations ranged from 0.07 to 0.547 µg/L. Sources of the bentazon contamination were not stated.

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[1] 1994 United States Geological Survey Preliminary Data Release: "The Influence of Municipal Reclaimed Water on the Leaching of Pesticides from Golf Courses in Florida." Swancar, A., USGS Geological Survey, Tampa, FL. and R. DeHan and D. Vogel, FL Dept. of Environmental Protection, Tallahassee, FL.

For the monitoring studies conducted in Missouri, which are summarized in the Pesticides in Ground Water Data Base (Hoheisel et al., 1992), bentazon was found in five private rural wells out of 266 (1.9%) located in three agricultural counties. Measured bentazon concentrations ranged from 0.6 to 1.0 µg/L. The detection limits of several studies for bentazon ranged from 0.6 to 5.0 µg/L. With detection limits as high as 5 µg/L, the potential for bentazon to be present (at levels less than the detection limit) in water samples, but at levels up to 5 µg/L, is feasible. Bentazon was not detected in ground water samples collected in limited studies conducted in four states: Louisiana (3 wells sampled), Mississippi (120 wells), Oregon (44 wells), and Washington (81 wells).

The data requirement (166-1) is not satisfied; small-scale prospective ground-water monitoring studies are needed to establish the conditions under which bentazon is prone to leach into ground water under normal agricultural use conditions.

(13) Droplet Size Spectrum and Drift Field

Droplet size spectrum (201-1) and field drift studies (202-1) are needed to support ground spray, aerial spray, and air-blast application methods for bentazon. These spray drift studies are required for aerially applied herbicides. EPA recognizes the registrant, BASF, is a member of the Spray Drift Task Force (SDTF) and, therefore, may satisfy the spray data requirements using SDTF data.

b. Environmental Fate Assessment

Bentazon dissipation is dependent on microbial-mediated degradation, leaching, and surface water runoff. Bentazon is moderately resistant to degradation ($t_{1/2}$ = 2 to 14 weeks) in aerobic mineral soils. Bentazon degradation in aquatic environments appears to be dependent on photolysis. Bentazon degradation in soil appears to be controlled by oxidative microbial-mediated processes with subsequent residue incorporation into nonlabile soil organic matter. Bentazon has a low binding affinity to soil (K_d 0.176 to 3.056) and hence may be expected to leach into ground and to undergo dissolved runoff to surface waters. Bentazon degradates are N-methyl-bentazon, 8-chloro-bentazon, and 2-amino-N-isopropylbenazamide (AIBA). The degradate N-methyl-bentazon and 8-chloro-bentazon are relatively immobile in soil. The degradate AIBA is mobile and nonpersistent in soil. Terrestrial field studies indicate bentazon dissipates rapidly ($t_{1/2}$ < 33 days) under typical use conditions. Leaching did not appear to be a major route of dissipation in field studies.

In the 1985 Registration Standard, it was recognized that bentazon may contaminate surface waters in use areas through runoff waters; however, bentazon leaching through soil was not considered a major route of dissipation at that time. The parameters developed in laboratory studies (such as, soil metabolism and adsorption/desorption studies) are used as predictors of persistent and mobility. The ranges demonstrated by bentazon for the K_ds and soil metabolism half-lives are similar to those parameters associated with known ground-water contaminants. Also, the EPA Pesticides in Ground Water Data Base (PGWDB) indicates bentazon was detected in ground water in Virginia, Missouri, and California. A recent study, not included in the PGWDB, also reported bentazon in ground water in Florida. Based on available information, EPA concludes that leaching

of bentazon through the soil profile is also a major route of dissipation in the environment.

Bentazon exceeds levels of concern (LOC) for ground-water quality. In addition, bentazon has a high dissolved runoff potential; as a result bentazon may also impact the quality of surface water. Possible chronic effects of long-term drinking water exposure resulted in the establishment of a lifetime Health Advisory (HA) of 20 parts per billion (ppb). Concentrations of bentazon at the HA have been detected in some ground-water wells in California and above the HA in some ground-water wells in Florida. However, as noted earlier, the HA will likely be increased to 200 ppb. Small-scale runoff studies indicate that bentazon was found in surface waters. Based on evaluation of available information, however, bentazon is not expected to exceed the HA in drinking water as a result of surface water contamination.

Bentazon Degradates. The soil degradates of bentazon were identified as 2-amino-N-isopropyl benzamide (AIBA) and N-methylbentazon. In laboratory studies, the degradate AIBA demonstrated high mobility and vulnerability to microbial mediated degradation in soil. Hence it is considered very mobile but not persistent. The degradate N-methylbentazon demonstrated a lack of mobility in the column leaching study. There are no data available relating to persistence in the environment. Based on the available information, it is concluded that these compounds should not pose a threat to ground-water. AIBA is also considered to have an insignificant impact on surface water due to its short half-life. Whereas information is not available to conclude that N-methylbentazon will not have an impact on surface water; however any of the compound getting to surface water should be adsorbed to sediments.

2. Ecological Effects

a. Ecological Effects Data

The ecotoxicological data base is adequate to characterize the toxicity of sodium bentazon salt to nontarget terrestrial and aquatic organisms when used on terrestrial food, feed and nonfood sites.

(1) Terrestrial Data

(a) Avian Acute Toxicity

In order to establish the acute toxicity of sodium bentazon salt to birds, one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail) is required using the technical grade material.

Avian Acute Oral Toxicity Findings			
Species	**% Test Material (TGAI)**	**LD_{50}**	**Conclusions**

Bobwhite quail	94	1171 mg/kg	slightly toxic
Mallard duck	50	7241 mg/kg	practically nontoxic

These results show that sodium bentazon is slightly toxic to birds. The guideline requirement for the avian acute oral LD_{50} study is fulfilled. (MRIDs 00161296, 00041804)

(b) Avian Subacute Dietary Toxicity

To determine the dietary toxicity to birds exposed to sodium bentazon salt through the diet, a minimum of two subacute dietary studies (LC_{50}) are required using the technical grade material and the following test species: one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail or ring-necked pheasant).

Avian Subacute Dietary Toxicity Findings

Species	% Test Material	LC_{50}	Conclusions
Bobwhite Quail	94	>5000 ppm	practically nontoxic
Mallard Duck	42	4830 ppm	slightly toxic

On a subacute dietary basis, sodium bentazon salt is slightly toxic to birds. Two studies, one on the mallard duck and one on the bobwhite quail produced LC_{50}s >4800 ppm. The above studies indicate a potential "may affect" for endangered avian species. The guideline requirement is fulfilled. (MRIDs 00161297, 00108850)

(c) Avian Reproduction

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Present product labeling of sodium bentazon salt allows several applications of the end-use product per growing season.

Avian Reproduction Findings

Species	% A.I.	Reproductive Impairment	Conclusions
Bobwhite Quail	97.6	Lowest observed effects = 100 ppm	may affect avian reproduction at dietary residues as low as 100 ppm

Mallard Duck	97.6	NOEL = 50 ppm LOEL = 200 ppm	

Two avian reproductive studies, one on the bobwhite quail and one on the mallard duck were deemed supplemental data. With the bobwhite quail, an unacceptably high control mortality occurred, and a "no observed effect level" (NOEL) was not obtained. With the mallard duck, the results indicated that inadequate mixing and uneven distribution of bentazon occurred within the test diet. Analysis of duplicate samples taken during the study revealed that concentrations varied by as much as 40 percent. In addition, the stability of bentazon in the diet was not determined. (MRIDs 42617501, 42651201)

The above avian reproduction tests, however, did provide sufficient information to complete a preliminary risk assessment. The effects on the avian reproductive cycle, as inferred by the two supplementary studies, suggest that sodium bentazon salt may affect avian reproduction at dietary residue levels as low as 100 ppm. Therefore, sodium bentazon salt exceeds the level of concern for avian chronic effects.

(d) Toxicity to Nontarget Mammals

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.

Mammalian Acute Oral Toxicity Findings		
Species	**LD_{50}(mg/kg)**	**Conclusion**
Rat (small mammal surrogate, 2 studies)	1480	slightly toxic

The available mammalian data indicate that sodium bentazon salt is slightly toxic to small mammals on an acute basis. (MRIDs 00092065, 00064314)

(e) Nontarget Insect Toxicity

A honey bee acute contact LD_{50} study is required if the proposed use is likely to expose honey bees.

Nontarget Insect Acute Contact Toxicity Findings			
Species	**% Test Material**	**LD_{50}**	**Conclusion**
Apis mellifera	94	>100 µg/bee	practically nontoxic

There is sufficient information to characterize sodium bentazon salt as practically nontoxic to bees. The guideline requirement is fulfilled. (MRID 00161305)

(2) Aquatic Data

(a) 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 are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish).

Freshwater Fish Acute Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Rainbow trout (3 studies)	97, 48.9, & 48.9	>100 ppm	practically nontoxic
Bluegill sunfish (2 studies)	94, 48.9	>100 ppm	practically nontoxic

The results of the six 96-hour acute toxicity studies indicate that sodium bentazon salt is practically nontoxic to both cold and warm water fish. The guideline requirement for acute toxicity testing of the technical on freshwater fish is fulfilled. (MRIDs 00161299, 00161300, 41922801, 41922802, 00161302, and 42129601)

(b) 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.

Freshwater Invertebrate Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Daphnia magna (2 studies)	94, 48.9	>100 ppm	practically nontoxic

There is sufficient information to characterize sodium bentazon salt as practically nontoxic to aquatic invertebrates. The guideline requirement is fulfilled. (MRIDs 00161303, 00161304)

(c) 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 terrestrial nonfood use of sodium bentazon salt on ornamental lawns and turf 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.

Estuarine/Marine Acute Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Eastern oyster embryo larvae	53	>109 ppm	practically nontoxic
Sheepshead minnow	94	136 ppm	practically nontoxic
Pink Shrimp	53	>132.5 ppm	practically nontoxic
Quahog (clam embryo larvae)	94	NOEL = 20 ppm, EC_{50} not available	supplemental

There is sufficient information to characterize sodium bentazon salt as practically nontoxic to oyster embryos and to pink shrimp. The Quahog or clam embryo larvae, *Mercenaria*, study (MRID 47029702) was rated supplemental because it failed to determine an EC_{50} and did not

address the mortality effects of the 94 percent active ingredient test material; however, this study is not essential to meet guideline requirements. (MRIDs 4229935, 42129602)

(3) Non-Target Plants Data

Terrestrial plant testing (seed germination, seedling emergence and vegetative vigor) is required for herbicides which have terrestrial nonfood/feed or aquatic nonfood (except residential) use patterns and which have endangered or threatened plant species associated with the site of application. The above conditions apply for sodium bentazon salt (refer to Section IV.B.4, Endangered Species).

Aquatic plant testing is required for any herbicide applied to terrestrial nonfood or aquatic nonfood (except residential) as in the case of sodium bentazon salt. The following species should be tested: *Selenastrum capricornutum, Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

Tier 1 toxicity data on the technical material for the most sensitive species are listed below:

Nontarget Terrestrial Plant Toxicity Findings		
Species	**% A.I.**	**EC_{25}**
Seed Germination (10 species)	53	>0.67 lb a.i./Acre for cabbage

The Tier II toxicity data on the technical material are listed below for the most sensitive test species:

Nontarget Terrestrial and Aquatic Plant Toxicity Findings		
Species	**% A.I.**	**EC_{50}**
Navicula pelliculosa	53	Invalid
Lemna gibba	53	5.35 ppm
Selenastrum capricornutum	98	4.5 ppm
Seedling emergence & Vegetative Vigor (10 species)	53	EC_{25} = 0.11 lb a.i./A for emergence of lettuce EC_{25} = 0.04 lb a.i./A for vegetative vigor (plant dry weight) of cabbage

The *Navicula pelliculosa* test (MRID 42129608) was found to be invalid because the variability in the cell counts precluded determination of valid endpoints. However, a similar aquatic plant species, *Lemna gibba*, had a LC_{50} of 5.35 ppm, and *Selenastrum capricornutum* had the lowest LC_{50} at 4.5 ppm of all the aquatic plant species tested. These data suggests a low risk to aquatic plants. (MRIDs 42129603, 42129604, 42129605, 42129609)

When considering the environmental fate, ecotoxicological data (Tier I and II effects) in combination with the proposed application methods and rates, The Agency concludes that sodium bentazon may represent a hazard to true terrestrial and semi-aquatic terrestrial plants (1.3 **#** RQ **#** 16). Both Tier I and II data requirements have been satisfied. (MRIDs 42129606, 42129607)

b. Ecological Effects Risk Assessment

(1) Risk to Terrestrial Animals

Nontarget insects will be exposed to sodium bentazon based on the end-use product's terrestrial food and nonfood use patterns. For nontarget insects, the honeybee or *Apis mellifera* is the representative test species; with an acute contact LD_{50} value of greater than 100 µg/bee, sodium bentazon salt is practically nontoxic to honeybees. Hence, a low risk to nontarget insects is anticipated as a result of exposure to sodium bentazon salt.

Avian and mammalian species will be exposed to sodium bentazon through the consumption of insect and plant food material containing bentazon residues. The criterion for the presumption of high risk from exposure for acute avian and mammalian species is a value greater than or equal to 0.5 for the quotient of the estimated environmental concentration (EEC) divided by the lowest LD_{50} value for birds and mammals -- this is known as the risk quotient (RQ).

$$\text{Acute RQ} = EEC/LC_{50} \geq 0.5 \text{ for birds and mammals}$$

(a) Avian Acute Oral/Subacute Dietary Effects

Sodium bentazon is expected to be slightly toxic to birds (LD_{50} of 1171 mg/kg), based on the acute oral toxicity tests using the bobwhite quail as the representative test species. Moreover, bentazon is expected to be slightly toxic to birds (LC_{50} of 4830 ppm), based on the subacute dietary toxicity tests using the mallard duck as the representative test species. However, minimal risk to nonendangered and endangered nontarget birds are expected to result from present label uses of sodium bentazon salt.

Bentazon's maximum single application rate is 2 lbs a.i./acre. Present product labeling allows several applications per season. The highest of these multiple rates involves an initial application of 2 lbs a.i./acre, followed by another 2 lbs a.i./acre application, approximately 7 to 10 days later.

Thus, the maximum cumulative application rate for bentazon is 3.6 lbs a.i./acre (1.6 lbs

a.i./acre + 2 lbs a.i./acre). Taking into account the degradation/dissipation of residues from the first treatment, the remaining bentazon is estimated to be 1.6 lbs a.i./acre when the second application occurs.

Regarding dietary exposure, terrestrial estimated environmental concentrations (EECs) can be derived from the use of the Kenega nomograph, an exposure scenario which estimates residues on a variety of crops and food sources. The maximum concentration of residues of bentazon salt which may be expected to occur on selected avian or mammalian dietary food items following foliar application(s) at different application rates is provided in the table below:

Residues on Avian and Mammalian Dietary Food Items in PPM

Use Sites	Application rates (lb a.i./A) 0.75	1.0	1.5	1.75	2.0	[3.6]*
Range Grasses (short)	180	240	360	420	480	820
Leaves and Leafy Crops	95	125	185	215	250	450
Forage and Insects	44	58	87	100	127	210
Seeds	9	12	18	21	25	44
Fruits	6	7	11	12	14	26

*** Note:** The result after two applications, each at a rate of 2 lbs a.i./acre (assuming a half-life of 24 days and a 7-day interval between applications).

The highest expected environmental concentration is 820 ppm on short range grasses for the maximum estimated application rate of 3.6 lbs of active ingredient per acre (using a T1/2 value for 24 days). Residues found on dietary food items following bentazon application may be compared to LC_{50} values to predict hazard.

The acute avian dietary residue for the mallard duck corrected for 42 percent active ingredient concentration is the following (concentration of test material referenced in the Dietary Toxicity Table):

4830 X 0.42 = 2029 ppm

The risk quotient value would be 820 ppm divided by 2029 ppm (EEC/LC_{50}) or 0.4 indicating high risk to nonendangered birds has not been exceeded, but the risk exceeds the LOC for endangered birds. The table above indicates that endangered grazing birds, like geese and ducks may be affected, with risk quotients greater than 0.1.

There are three "goose/duck" endangered species which inhabit the United States along part

or all of their ancestral travel routes or "flyways." The Aleutian Canada goose grazes, but it only winters in areas where sodium bentazon may be used. During that time, it feeds on grain left from the previous year. Thus, the potential for exposure to sodium bentazon is negligible. The Hawaiian goose and the Hawaiian duck do not inhabit areas near any of the use sites for which sodium bentazon is registered.

However, omnivorous birds, and birds that eat seeds, insects and fruits are unlikely to be affected with risk quotients less than 0.1. As indicated in the table above the estimated environmental concentration on seeds, forage and insects ranges from 44 to 210 ppm. Thus the risk quotient would be the EEC, 210 ppm, divided by the LC_{50}, 5,000 ppm:

RQ = 210 ppm/5,000 ppm = 0.04

Therefore, endangered birds are unlikely to be acutely affected by present label rates and uses of sodium bentazon.

(b) Avian Chronic Effects

Chronic effects to birds are anticipated based on supplementary avian reproduction studies and estimated residues on avian food items. Even at the lowest rate of 0.75 lb of active ingredient per acre, maximum residues on short grass exceed the LOEL (100 ppm) at which biologically significant reproductive effects occur. Because a NOEL was not determined, but must be below 100 ppm, there is a risk of chronic effects to birds.

(c) Mammalian Acute Oral and Subacute Dietary Effects

Sodium bentazon is expected to be slightly toxic to small mammalian species based on the acute oral toxicity tests using the rat (LD_{50} of 1480 mg/kg), as a small mammal surrogate. However, acute oral and subacute dietary risks to nonendangered and endangered nontarget mammals are not expected to result from present label uses of sodium bentazon salt.

Regarding mammalian dietary toxicity, one day LC_{50} values were calculated using the formula below for three representative species: the meadow vole, a herbivore; the adult field mouse, a granivore; and the least shrew, an insectivore. The formula estimates the dietary LC_{50} for these species using a rat acute oral LD_{50} value of 1480 mg/kg.

$$LC_{50} = \frac{LD_{50}\ mg/kg \times Body\ Weight\ in\ grams}{Weight\ Consumed\ in\ grams}$$

Small Mammal One Day LC_{50} in PPM (Based on an LD_{50} = 1480 mg/kg)				
Small Mammal	Body Weight in Grams	% of Weight Eaten Per Day	Food Consumed Per Day in Grams	Estimated LC_{50} Per Day in PPM
Meadow vole	46 g	61 %	28.1 g	2423 ppm
Old field mouse	13 g	16 %	2.1 g	9161 ppm
Least shrew	5 g	110 %	5.5 g	1345 ppm
This table is based on information contained in Principles of Mammology by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.				

Regarding mammalian dietary risks, the table below indicates the risk quotients for each of the following application rates:

Mammalian Dietary Risk Quotients (based on Dietary RQ = EEC/Lowest LC_{50})				
Small Mammal LC_{50}	**Application Rates in lbs. A.I./A**			
	1.5	**1.75**	**2.0**	**[3.6]***
Meadow vole consuming range grasses estimated LC_{50}s (2,423 ppm)	0.15	0.18	0.20	0.34
Adult field mouse consuming seeds (9161 ppm)	0.002	0.0025	0.0027	0.0048
Least shrew consuming forage and insects (1345 ppm)	0.065	0.075	0.095	0.155

*** Note:** The result after two applications, each at a rate of 2 lbs a.i./acre (assuming a half-life of 24 days and a 7-day interval between applications).

The last column of this table indicates that no hazard would be expected even for small nonendangered mammals where the EEC on short grass equals 820 ppm, and the risk quotient is 0.34.

However, under certain conditions, the risk quotient for acute effects exceeds the LOC for endangered mammal species (0.1). But the Agency maintains the conclusion that it is unlikely that endangered mammals would be adversely affected by the use of sodium bentazon.

The risk quotients for shrews and voles were calculated to be greater than 0.1. However, further refinement of the risks for these representative species supports the Agency's conclusion that small endangered insectivores and herbivores are unlikely to be adversely effected by sodium bentazon salt.

Refined Risk Assessment for Shrews. The typical food item that comprises a shrew's diet is insects. While in some environmental compartments, it may be appropriate to combine sequential applications of sodium bentazon, it is probably not appropriate for insects. Because of the following reasons, only a 2 lbs a.i./acre application should be used to estimate residues on insects:

- Insects are mobile, such that a second treatment on the same individual insects is unlikely; and

- sodium bentazon is soluble, and does not bind tightly, therefore, it would likely wash/rub off any treated insects before the second application occurred.

Residues on **insects** treated with 2 lbs a.i./acre would be 127 ppm (see Residue Table). The LC_{50}/Day for a shrew weighing 5 grams would be 1345 ppm.

$$\frac{1480 \text{ mg/kg} \times 5 \text{ g}}{5.5 \text{ g}} = 1345 \text{ mg/kg} = 1345 \text{ ppm}$$

The risk quotient, using the estimated LC_{50} per day for a shrew, is 0.09. This is less than the endangered mammal LOC of 0.1.

$$RQ = 127 \text{ ppm} / 1345 \text{ ppm} = 0.09$$

Refined Risk Assessment for Voles. The available information suggests that the endangered **Amargosa vole** feeds primarily on *underground* herbaceous items. The **Florida Salt Marsh vole** feeds on seeds and succulent plant parts. The original exposure residues were calculated assuming short grass exposed to direct treatment. Therefore the derived risk quotients were very conservative and probably are not representative of the actual exposure and potential risk

to voles.

It is anticipated that residues on underground herbaceous food items would be very low, and would not affect endangered voles. If 3.6 lbs a.i./acre were applied to a 3" layer of soil, the concentration would be approximately 2.6 ppm. The LC_{50}/Day for a vole weighing 46 grams would be 2423 ppm.

$$\frac{1480 \text{ mg/kg} \times 46 \text{ g}}{28.1 \text{ g}} = 2423 \text{ mg/kg} = 2423 \text{ ppm}$$

A case in point, if an **Amargosa vole** fed all day on underground herbaceous material contaminated with 2.6 ppm of sodium bentazon, then the risk quotient would be 0.001.

$$RQ = 2.6 \text{ ppm} / 2423 \text{ ppm} = 0.001$$

Residues from a maximum label rate of 3.6 lbs a.i./acre application on seeds and forage would range from 44 ppm to 210 ppm. If the **Florida Salt Marsh vole** fed all day on forage containing residues of 210 ppm, then the risk quotient would be 0.09.

$$RQ = 210 \text{ ppm} / 2423 \text{ ppm} = 0.09$$

The risk quotients from these exposures are less than 0.1, the LOC for endangered mammals.

(2) Risk to Aquatic Animals

Minimal acute risk to aquatic animals is expected. Moreover, chronic risk to aquatic animals is not anticipated because of the relatively low exposure values when compared to the acute toxicity test results.

The following table shows the preliminary estimates of bentazon residues that could occur in aquatic habitats with different rates of application. The 3.6 lbs of active ingredient per acre is considered the highest possible exposure resulting from the two applications, applied approximately seven day apart, each at rates of 2 lbs of active ingredient per acre. Five percent of the applied sodium bentazon is assumed to be transported with surface runoff from a 10 acre field into a 1 acre shallow water body. Exposure in 6 feet deep water is estimated on the table below.

Estimated Environmental Concentrations for Broadcast Ground Application in PPM	
Application Rate (lbs of a.i./acre)	**6 Foot-Deep Water Body**
0.25	0.077 ppm
0.50	0.015 ppm

0.75	0.023 ppm
1.00	0.031 ppm
3.60	0.220 ppm

An aerial or mist blower application of 2 lbs of active ingredient would contribute a total pesticide loading of 0.7 lbs to a one-acre, 6 foot-deep water body (0.6 lb from runoff and 0.1 lb from drift). This total loading of 0.7 lbs of active ingredient produces a preliminary estimated environmental concentration of 0.0427 ppm.

Given the same aerial application scenario as stated for 2 lbs of active ingredient, an application rate of 3.6 lbs a.i./acre would result in a preliminary estimated environmental concentration of 0.077 ppm. This preliminary EEC has been compared to the aquatic animal endpoints (LC_{50}) obtained experimentally by the registrant to attempt to establish risk levels for the various groups of aquatic animals.

The table above indicates that at the highest recommended label rate of 3.6 lbs active ingredient per acre, the preliminary maximum estimated residue would be about 2.65 ppm which is far below any of the aquatic animal LC_{50} s of greater than 100 ppm. Therefore, no hazard to aquatic animals is anticipated.

(3) Risk to Terrestrial, Semi-Aquatic & Aquatic Plants

The level of concern for terrestrial plants is exceeded by all registered uses of sodium bentazon salt. The highest risk to terrestrial plants results from runoff to areas containing semi-aquatic plants after two ground applications, each at 2 lbs of active ingredient per acre. The next highest risk is to semi-aquatic plants, resulting from multiple (2) aerial applications.

The following table summarizes the highest risk quotients from various methods of application and routes of uptake. It assumes two applications of 2 lbs of active ingredient per acre, 7 days apart.

Risk Quotients for True Terrestrial and Semi-Aquatic Plants
(Two, 2 lbs of active ingredient/acre Applications)

Method of Application	Terrestrial Plant Route of Exposure		Semi-Aquatic Plant Route of Exposure	
	Emerging Seedlings	Foliage/Leaves	Emerging Seedlings	Foliage/Leaves
Ground	1.7	Minimal Exposure	16	Minimal Exposure
Aerial	2.6	4.5	11.5	4.5

The highest risk quotient of 16 results from runoff to wetlands containing semi-aquatic terrestrial plants after two ground applications, each at 2 lbs of active ingredient per acre. The next highest risk quotient, 11.5, is for semi-aquatic terrestrial plants from two aerial applications.

The LOC for terrestrial and semi-aquatic terrestrial plants is exceeded when the risk quotient is greater than or equal to 1. All use patterns having two applications each at a rate of 2 lbs of active ingredient per acre exceed a level of concern for both true terrestrial and semi-aquatic terrestrial plants. However, a single ground application does not exceed the level of concern for true terrestrial plants immediately adjacent to treated sites.

Ground application of 1.5 lbs of active ingredient per acre on soybeans, however, is not significantly different than the 2 lbs of active ingredient per acre application and also exceeds the level of concern for terrestrial plants.

Two applications at 7-day intervals of 1 lb of active ingredient per acre would result in the following risk quotients:

Risk Quotients for True Terrestrial and Semi-Aquatic Terrestrial Plants
(Two Applications of One lb of active ingredient/Acre)

Method of Application	Terrestrial Plant Route of Exposure		Semi-Aquatic Plant Route of Exposure	
	Emerging Seedlings	Foliage/Leaves	Emerging Seedlings	Foliage/Leaves
Ground	0.9	Minimal Exposure	8	Minimal Exposure
Aerial	1.3	2.25	5.75	2.25

Any use rate greater than 0.125 lb a.i./acre would exceed at least one level of concern for terrestrial plants. The risk quotient for semi-aquatic terrestrial plants receiving runoff from ground applied sodium bentazon salt at 0.125 a.i./acre would be 1.

Because all uses of sodium bentazon salt at use rates from 1 to 2 lbs of active ingredient per acre exceed the level of concern for terrestrial plants, it is expected that the use of sodium bentazon salt will have significant adverse effects to terrestrial and semi-aquatic plants near treated sites. This could alter the vegetative community structure or reduce or eliminate populations of ecologically significant plant species.

(a) Nontarget Terrestrial Plant Effects

Exposure to terrestrial plants may occur through drift and runoff via aerial and ground application. Two types of habitat containing terrestrial plants are subject to exposure: terrestrial sites immediately adjacent to treated areas, and semi-aquatic terrestrial sites covered with shallow

water or wetlands receiving runoff from treated areas.

Terrestrial plants adjacent to treated areas may take up sodium bentazon salt both through the soil and through foliage. Soil may be contaminated both from runoff and drift; however, terrestrial plant foliage would only be exposed from drift. The type of runoff considered to be the route of exposure for this group of plants is *sheet runoff*, where the runoff water moves over a relatively flat ground surface that is not channelized. As it moves over the treated area, it is assumed to pick up some of the applied sodium bentazon. Then as it moves over adjacent untreated area, it is assumed, for modeling purposes, to deposit this load of pesticide, thus contaminating the soil. Only that amount applied to one acre is assumed to be available for transport by this means to an adjacent 1-acre off-site area containing nontarget terrestrial plants.

Exposure Resulting from a Single Broadcast Ground Application. Based on preliminary estimates of exposure in *off-site soil* from a single application, the seedling emergence level of concern for nontarget terrestrial plants immediately adjacent to treated areas is approached, but not exceeded, with a risk quotient of 0.9. Runoff is expected to result in exposure to the roots of nontarget plants adjacent to treated areas. The terrestrial plant seedling emergence EC_{25} of 0.11 lb of active ingredient per acre for lettuce is not exceeded by the estimated exposure of 0.1 lb of active ingredient per acre from runoff alone. The risk quotient is calculated below.

RQ = 0.1 lb a.i./acre / 0.11 lb a.i./acre = 0.9

Exposure Resulting from Two Broadcast Ground Applications. Due to multiple applications and the relative persistence of sodium bentazon, exposure in off-site soil from runoff may be higher, resulting in a greater risk quotient. Assuming two applications 7 days apart, the terrestrial plant seedling emergence level of concern is exceeded with a risk quotient of 1.7. By assuming a half-life of 20-to-24 days, then the residual from the first application after 7 days will have declined to about 82 percent of the initial application or 1.7 lbs of active ingredient per acre. Adding this to the second application results in an combined application rate of 3.7 lbs of active ingredient per acre.

Total Combined Application = 2 lbs a.i. + 1.7 lbs a.i. = 3.7 lbs a.i./acre

The preliminary estimate of exposure from runoff to nontarget terrestrial plant roots from this combined application is 0.185 lb of the active ingredient per acre. From this, the risk quotient is calculated.

RQ = 0.185 / 0.11 = 1.7

Exposure Resulting from a Single Aerial Application. Based on preliminary estimates of exposure in off-site soil, the seedling emergence level of concern for nontarget terrestrial plants immediately adjacent to treated areas is exceeded with a risk quotient of 1.45. A combination of drift and runoff from aerial applications is expected to result in exposure to the roots of nontarget plants adjacent to treated areas. The seedling emergence EC_{25} of 0.11 lb of active ingredient per acre for lettuce is exceeded by the estimated exposure of 0.16 lb of active ingredient per acre from

runoff and drift combined. The risk quotient is calculated below.

RQ = 0.16 / 0.11 = 1.45

Exposure Resulting from Two Aerial Applications. Due to multiple applications and the relative persistence of sodium bentazon, exposure in off-site soil from runoff may be higher, resulting in a greater risk quotient. By assuming two applications, 7 days apart, the terrestrial plant seedling emergence level of concern will be exceeded with a risk quotient of 2.6.

In addition, by assuming a half-life of 20-to-24 days, then after 7 days, the residual from the first aerial application will have declined from 1.2 lbs of active ingredient per acre[2] to about 82 percent of the initial application or 0.984 lb of active ingredient per acre. Adding this to a second aerial application of 1.2 lbs of active ingredient per acre[1] results in a combined application rate of 2.184 lbs of active ingredient per acre available to transport via runoff.

Total combined loading = 1.2 lbs a.i./acre + 0.984 lb a.i./acre = 2.184 lbs a.i./acre

By assuming 5 percent of the combined loading or 2.184 lbs of active ingredient per acre transports via runoff to off-site soil, then resultant exposure will be 0.1092 lb of active ingredient per acre.

2.184 X 0.05 = 0.1092 lb a.i./acre

Exposure in wetland soil from drift following two aerial applications of bentazon is estimated to be 0.182 lb of active ingredient per acre.

0.1 (exposure from 1st drift) X 0.82[3] = 0.082 lb a.i./acre

The drift exposure remaining from the first spraying is added to the drift exposure from the second drift episode.

0.1 (exposure from second drift) + 0.082 = 0.182 lb a.i./acre

Combine the exposure from runoff (based on two applications 7 days apart) with the exposure from drift to obtain the total exposure in off-site soil; the total exposure is 0.29 lb of active ingredient per acre.

0.1092 lb a.i./acre + 0.182 lb a.i./acre (drift) = 0.29 lb a.i./acre

From this, the risk quotient is calculated.

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[2] With aerial application, it is commonly assumed that only 60% of what is sprayed actually reaches the target site (60% of 2 lb a.i./acre is 1.2 lb a.i./acre).

[3] Assumes degradation (half-life 20-24 days) during the 7 days between drift episodes such that only 82% of the exposure from the first drift episode remains when the second drift reaches the nontarget plants.

RQ = 0.29 / 0.11 = 2.6

Exposure to Nontarget Plant Foliage from a Single Aerial Application. Based on preliminary estimates of exposure to nontarget plant foliage, the vegetative vigor (cabbage) level of concern for nontarget terrestrial plants immediately adjacent to treated areas is exceeded with a risk quotient of 2.5. Assuming 5 percent of the aerially applied sodium bentazon drifts to adjacent habitat, then the expected exposure will be 0.1 lb of active ingredient per acre. The vegetative vigor EC_{25} of 0.04 lb of active ingredient per acre is exceeded by this exposure. The risk quotient is calculated below.

RQ = 0.1 / 0.04 lb a.i./acre = 2.5

Exposure to Nontarget Plant Foliage Resulting from Two Aerial Applications. Exposure to nontarget plant foliage from drift from a second application is likely to have a greater adverse effect than from a single application only. Because of the physiology of plants and the fate of the chemical in the plants, it is not possible to calculate a risk quotient with great confidence, however. If it is assumed that the exposure from the first drift episode declines to about 82 percent of the original by the time the second drift episode occurs, then the combined exposure would result in a risk quotient of 4.5.

The first episode of drift results in exposure of 0.1 lb of active ingredient per acre as explained in the discussion of a single application. This would decline to 0.082 lb of active ingredient per acre in 7 days assuming a 20-to-24 day half-life. This figure, 0.082 lb of active ingredient per acre, is added to 0.1 lb of active ingredient per acre, which is the estimated exposure from the second drift episode, to obtain the total combined exposure resulting from two drift episodes.

0.1 + 0.082 = 0.182 lb a.i./acre from two drift episodes

From this, the risk quotient for effects to plants from foliar exposure is calculated:

RQ = 0.182 / 0.04 lb a.i./acre = 4.55

(b) Nontarget Semi-Aquatic Plant Effects

Semi-aquatic nontarget terrestrial plants may be exposed to sodium bentazon both from channelized runoff and drift. Channelized runoff may carry bentazon from treated sites, through channels and ditches, to shallow water and wetlands, and thus contaminating the soil where semi-aquatic plants occur. Drift from aerial application would contaminate the foliage of these semi-aquatic nontarget species.

Exposure Resulting from a Single Broadcast Ground Application. Based on preliminary estimates of exposure in wetland soil where semi-aquatic plants grow, the seedling emergence level of concern is exceeded through runoff from the treated field based on a risk quotient of 9. Assuming a drainage basin of 10 acres is treated at 2 lbs of active ingredient per acre, no soil incorporation, and relatively high solubility (i.e., 5 percent of applied transports with runoff), the

following preliminary exposure concentration is estimated:

2 lb X 10 acres X 0.05 = 1 lb a.i./acre

This represents exposure to the roots of semi-aquatic plants. From this, the risk quotient is calculated.

$$RQ = \frac{\text{1 lb a.i./acre}}{\text{0.11 lb a.i./acre}} = 9$$

Exposure Resulting from Two Broadcast Ground Applications. Based on preliminary estimates of exposure in wetland soil where semi-aquatic plants grow, the seedling emergence level of concern is exceeded through runoff from a field treated twice with sodium bentazon salt; the risk quotient is 16.

Assuming a drainage basin of 10 acres is treated twice, with a 7-day interval between treatments, of 2 lbs of active ingredient per acre, no soil incorporation, and relatively high solubility (i.e., 5 percent of applied transports with runoff), the following preliminary exposure concentration is estimated:

3.6[4] lb X 10 acres X 0.05 = 1.8 lb a.i./acre

This represents exposure to the roots of semi-aquatic plants. From this, the risk quotient is calculated.

RQ = 1.8 lbs a.i./acre / 0.11 lb a.i./acre = 16

Exposure Resulting from a Single Aerial Application. Based on preliminary estimates of exposure in wetland soil where semi-aquatic plants grow, the seedling emergence level of concern is exceeded through drift and runoff from a field treated once with sodium bentazon salt; the risk quotient is 6.4.

If a drainage basin of 10 acres is sprayed by air at 2 lbs of active ingredient per acre, then only a portion, approximately 60 percent of the spray will hit the ground.

60% of 2 lbs a.i. = 1.6 lbs a.i./acre

The amount available for transport by runoff is 1.6 lbs of active ingredient per acre. Assuming high solubility and no soil incorporation, then 5 percent of the active ingredient reaching the ground could runoff.

1.6 lbs X 10 acres treated X 0.05 = 0.8 lb a.i./acre in the

[4] This assumes the active ingredient from the first treatment has degraded on site with a half-life of 20 to 24 days. Approximately 1.6 lbs of active ingredient or 82% would remain after 7 days. This is added to the second application and the combined amount is assumed to be available for transport via runoff.

wetland

This loading from drift is 5 percent of the 2 lbs of active ingredient per acre originally sprayed.

2 lbs a.i./acre X 0.05 = 0.1 lb a.i./acre reaching wetlands

The exposure from runoff is added to the exposure from drift because both would be affecting the plant during the same timeframe. This does not assume both runoff and drift reach the nontarget plant simultaneously. The physiological response of plants is such that effects from drift would still be occurring when the exposure to the runoff occurred, that is, they are considered to be additive even if the exposures were separated by a few days.

0.1 lb from drift + 0.6 lb from runoff = 0.7 lb total exposure or loading

From this, a risk quotient is calculated:

RQ = 0.7 / 0.11 = 6.4

Exposure Resulting from Two Aerial Applications. Based on preliminary estimates of exposure in wetland soil where semi-aquatic plants grow, the seedling emergence level of concern is exceeded through drift and runoff from a field treated twice aerially with sodium bentazon salt; the risk quotient is 11.5.

Assuming a drainage basin of 10 acres is aerially treated twice, with a 7-day interval between treatments, of 2 lbs active ingredient per acre, no soil incorporation, and relatively high solubility (i.e., 5 percent of applied transports with runoff), then the following preliminary exposure concentration from runoff is estimated:

3.6[5] lbs X 0.6 X 10 acres X 0.05 = 1.08 lbs a.i./acre*

** Assumes that only 60% of aerial spray reaches the ground*

Exposure in wetland soil from drift following two aerial applications of sodium bentazon salt is estimated to be 0.182 lb of active ingredient per acre.

0.1 (exposure from 1st drift or 5% of 2 lbs a.i.) X 0.82[6] = 0.082 lbs a.i./acre

[5] This assumes the active ingredient from the first treatment has degraded on site with a half-life of 20 to 24 days. Approximately 1.6 lbs of active ingredient or 82% would remain after 7 days. This is added to the second application and the combined amount is assumed to be available for transport via runoff.

[6] Assumes degradation (half-life 20-24 days) during the 7 days between drift episodes such that only 82% of the exposure from the first drift episode remains when the second drift reaches the nontarget plants.

The drift exposure remaining from the first spraying is added to the drift exposure from the second drift episode.

0.1 (exposure from second drift or 5% of 2 lbs a.i.) + 0.082 = 0.182 lbs a.i./acre

The exposure from runoff is added to the drift exposure from both first and second applications.

0.182 lb + 1.08 lbs = 1.262 lbs a.i./acre is the total loading

This represents total exposure to the roots of semi-aquatic plants from both runoff and drift resulting after two aerial applications, 7 days apart. From this, the risk quotient is calculated.

RQ = 1.262 lbs a.i./acre / 0.11 lbs a.i./acre = 11.5

Exposure to Semi-Aquatic Plant Foliage Resulting from Two Aerial Applications. The exposure to foliage of semi-aquatic plants from drift is expected to be essentially the same as to true terrestrial plant foliage. The vegetative vigor level of concern is exceeded with a risk quotient of 2.5.

(c) Nontarget Aquatic Plant Effects

A preliminary estimated environmental concentration of 0.734 ppm has been calculated for direct application of 1.0 lb active ingredient per acre, in a 0.5 feet deep water body which is considerably lower than the 4.5 ppm LC_{50} for *S. capricornutum*. At a maximum application rate of 2.0 lbs of active ingredient per acre the estimated environmental concentration under similar conditions would be 1.471 ppm of active ingredient or 0.33 of the *S. capricornutum*'s LC_{50}. No hazard to aquatic plants is expected at the rate of 2.0 lb active ingredient per acre. Even with two, two-pound applications seven days apart and assuming no degradation, a 2.9 ppm concentration (1.471 X 2 = 2.9 ppm) would still not result in risk that exceeds the level of concern. Therefore, minimal hazard is expected for aquatic plants.

(4) Risk to Endangered Species

Below are the LOCs for endangered plants and animals.

$RQ = EEC/LC_{50}$ > or = 0.1 for endangered birds and mammals

$RQ = EEC/LC_{50}$ > or = 0.05 for endangered aquatic animals

$RQ = EEC/EC_{25}$ and the EEC/EC_{50} > or = 1 for terrestrial, semi-aquatic and aquatic plants

Acute LOCs were exceeded for endangered birds and mammals based on preliminary EEC values. By refining the assessment, however, the Agency has concluded that endangered birds and

mammals are no longer at risk from present bentazon label rates and usage. But endangered true terrestrial and semi-aquatic terrestrial plants occurring adjacent to, or receiving runoff from, areas treated with sodium bentazon may be affected.

The Endangered Species Protection Program is expected to become final in 1994. Limitations in the use of sodium bentazon salt will be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county bulletins.

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 bentazon as the 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 bentazon. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of bentazon, 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 bentazon and to determine that bentazon can be used without resulting in unreasonable adverse effects to humans and the environment provided that the changes specified in this document are incorporated into product labels. The Agency therefore finds that all products containing bentazon as the active ingredients 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, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found that all uses of bentazon 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 bentazon, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient bentazon, the Agency has

sufficient information on the health effects of bentazon and on its potential for causing adverse effects in fish and wildlife and the environment. Therefore, the Agency concludes that products containing bentazon for all uses are eligible for reregistration.

The Agency has determined that bentazon products, labeled and used as specified in this Reregistration Eligibility Decision, 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 bentazon are eligible for reregistration.

B. Regulatory Position

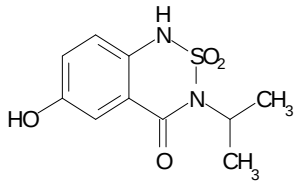
The following is a summary of the regulatory positions and rationales for bentazon. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

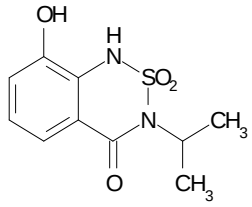
Tolerances Listed Under 40 CFR §180.355(a):

The tolerances listed in 40 CFR §180.355(a) are for the combined residues of bentazon and its 6- and 8-hydroxy metabolites, as shown in Figure A.

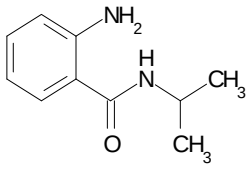
Figure A. Chemical structures of bentazon metabolites presently included in the tolerance expressions.



6-hydroxy bentazon: 6-hydroxy-3-isopropyl-1*H*-2,1,3-benzothiadizin-4-(3*H*-)one-2,2-dioxide



8-hydroxy bentazon: 8-hydroxy-3-isopropyl-1*H*-2,1,3-benzothiadizin-4-(3*H*-)one-2,2-dioxide



AIBA: 2-amino-*N*-isopropyl benzamide

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.355(a) for the following commodities: beans, dried; beans, succulent; beans, hay; corn, field and pop, grain; corn, field, pop, and sweet, forage; corn, field and pop, fodder; corn, sweet (K+CWHR); mint; peanuts; peanuts, hay; peanuts, hulls; peanuts, vines; peas, succulent; peas, vines; peppers, chili, Bohemian; rice, grain; rice, straw; sorghum, fodder; sorghum, forage; and sorghum, grain; see Table C for modifications in commodity definitions.

The available residue data indicate that the established tolerances for bean vines, dried peas, pea hay, soybean forage, and soybean hay are too low. Tolerance revisions must be proposed as follows: (i) from 3 ppm to 10 ppm for bean vines; (ii) from 0.05 ppm to 1 ppm for dried peas; (iii) from 3 ppm to 8 ppm for pea hay and soybean forage; and (iv) from 0.3 ppm to 8 ppm for soybean hay. Tolerance revisions have been proposed (PP#9F3782) for dry beans and dried peas (from 0.05 ppm to 1 ppm), bean hay, bean vines, pea hay, pea vines, soybean forage (from 3 ppm to 8 ppm), and soybean hay (from 0.3 ppm to 8 ppm).

The established tolerance for succulent lima beans should be revoked since residues in/on lima beans are covered under the tolerance for succulent beans.

The tolerance for Bohemian chili peppers is listed incorrectly as 0.5 ppm in 40 CFR §180.355(a). The entry should be revised to reflect the correct tolerance of 0.05 ppm.

Bentazon is registered for alfalfa grown for seed. No tolerances are required for alfalfa grown for seed since label restrictions prohibit the use of the treated plant for sprouting and the use of any portion of the treated field including forage, hay, seed, or seed screenings for human or animal feed.

Tolerances Listed Under 40 CFR §180.355(b):

The tolerances listed in 40 CFR §180.355(b) are for food items derived from animals and are expressed in terms of the combined residues of bentazon and AIBA.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.355(b) for milk and eggs and the fat, meat byproducts, and meat of cattle, goat, hogs, poultry, and sheep.

Tolerances Listed Under 40 CFR §186.375:

The tolerance listed in 40 CFR §186.375 is for the combined residues of bentazon and its 6- and 8-hydroxy metabolites. Sufficient data are available to ascertain the adequacy of the established feed additive tolerance listed in 40 CFR §186.375 for mint, hay, spent; see the table below for the modification in the commodity definition.

A feed additive tolerance must be proposed for the combined residues of bentazon and its 6- and 8-hydroxy metabolites in rice hulls.

Tolerance Reassessment Summary

Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment/*Correct Commodity Definition***
Tolerances listed under 40 CFR §180.355(a)			
Beans (except soybeans), dried	0.05	0.05	*Beans, dry*

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Beans (except. soybeans), dried, vine hays	3	3	*Beans, hay*
Beans (except. soybeans), forage	3	10	Established tolerance is too low/*Beans, vines*
Beans, lima (succulent)	0.05	Revoke	Covered under tolerance for beans, succulent
Beans, succulent	0.5	0.5	
Bohemian chili peppers	0.5	0.05	Tolerance is listed incorrectly in 40 CFR/ *Peppers, chili, Bohemian*
Corn, fodder	3	3	*Corn, field, fodder* and *Corn, pop, fodder*
Corn, forage	3	3	*Corn, field, forage*; *Corn, pop, forage*; and *Corn, sweet, forage*
Corn, grain	0.05	0.05	*Corn, field, grain*; and *Corn, pop, grain*
Corn, fresh (inc. sweet K+CWHR)	0.05	0.05	*Corn, sweet (K + CWHR)*
Mint	1	1	
Peanuts	0.05	0.05	
Peanuts, hay	3	3	
Peanuts, hulls	0.3	0.3	
Peanuts, forage	3	3	*Peanuts, vines*
Peas (dried)	0.05	1	Established tolerance is too low/*Peas, dried*
Peas (dried), vine hays	3	8	Established tolerance is too low/*Peas, hay*
Peas, forage	3	3	*Peas, vines*
Peas, succulent	0.5	0.5	
Rice	0.05	0.05	*Rice, grain*
Rice, straw	3	3	
Sorghum, fodder	0.05	0.05	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Sorghum, forage	0.20	0.20	
Sorghum, grain	0.05	0.05	
Soybeans	0.05	0.05	
Soybeans, forage	3	8	
Soybeans, hay	0.3	8	
Tolerances listed under 40 CFR §180.355(b)			
Cattle, fat	0.05	0.05	
Cattle, mbyp	0.05	0.05	
Cattle, meat	0.05	0.05	
Eggs	0.05	0.05	
Goats, fat	0.05	0.05	
Goats, mbyp	0.05	0.05	
Goats, meat	0.05	0.05	
Hogs, fat	0.05	0.05	
Hogs, mbyp	0.05	0.05	
Hogs, meat	0.05	0.05	
Milk	0.02	0.02	
Poultry, fat	0.05	0.05	
Poultry, mbyp	0.05	0.05	
Poultry, meat	0.05	0.05	
Sheep, fat	0.05	0.05	
Sheep, mbyp	0.05	0.05	
Sheep, meat	0.05	0.05	
Tolerances listed under 40 CFR §186.375			
Spent mint hay	4	4	*Mint, hay, spent*
Tolerances to be proposed			
Rice, hulls	N/A	0.25	

CODEX HARMONIZATION

No Codex MRLs for bentazon have been established. However, there are bentazon Codex proposals for several crops at Step 3 of the Codex procedure. The Codex definitions of the residue for plants and animals are the same as current U.S. definitions. For most of the proposed limits, there is compatibility with current U.S. tolerances. However, the proposed Codex MRL and U.S tolerance levels are incompatible for succulent beans and garden peas (Codex, 0.2 ppm; U.S., 0.5 ppm), milk (Codex, 0.05 ppm, the limit of detection; U.S., 0.02 ppm), and rice (Codex, 0.1 ppm; U.S., 0.05 ppm). If these proposed Codex levels reach the CXL step, compatibility with U.S. tolerances may be achieved by increasing the U.S tolerances for milk and rice grain to 0.05 and 0.1 ppm, respectively, toxicological considerations permitting, and by reducing the established U.S. tolerances for succulent beans and peas from 0.5 ppm to 0.2 ppm; the available residue data would support these tolerance reductions.

2. Restricted Use Classification

Bentazon is not currently classified for restricted use and no change is being required in this document. However, bentazon may be considered for restricted use for ground water concerns once the Restricted Use Rule is finalized.

3. Reference Dose

The reference dose for bentazon was determined to be 0.03 mg/kg/day based on results of a one-year feeding study in beagle dogs. The NOEL was 100 ppm (approximately 3.2 mg/kg/day from measurement of dietary intake). An uncertainty factor of 100 was employed. Although bentazon currently has a lifetime drinking water health advisory of 20 µg/L, the HA level will likely be increased to 200 µg/L (200 ppb) because the Office of Pesticide Programs now has a complete data base which has reduced the uncertainty factor in the reference dose calculation from 1,000 to 100.

4. Cancer Risk Assessment

Bentazon was classified as a "Group E" carcinogen, which denotes evidence of non-carcinogenicity for humans, by the Agency's Health Effects Division Carcinogenicity Peer Review Committee, 6/26/91.

5. Ground Water

Ground water monitoring data currently available to the EPA show bentazon has been detected in ground water in four of eight states sampled, at concentrations ranging from 0.07 to 120 ppb. These detections were the result of normal agricultural practices which may include application to the fields, mixing, loading, and disposal of the pesticide. A small-scale prospective ground water study must be conducted with bentazon used on soybeans or on turf. A final decision on the site must be made in consultation with the Agency. Because ground water monitoring studies have demonstrated that bentazon can leach to ground water in certain vulnerable environments, the

Agency requires a ground water label advisory to minimize the effects of bentazon contamination on ground water quality. See Section V for language. The registrant has also agreed to prepare educational materials for distributors, dealers, and end users regarding ground and surface water protection. These materials must be submitted to the Agency for review within one year after the issuance of this document.

6. Surface Water

No advisory for surface water is being required at this time.

7. Spray Drift Advisory

In order to inform the user of best management practices that would minimize spray drift from the target site, the Agency is currently preparing spray drift labeling statements. This future labeling may be required for all bentazon products that may be applied aerially to agricultural crops.

8. Chronic Avian Risk

Chronic effects to birds are anticipated based on supplementary avian reproduction studies and estimated residues on avian food items. Even at the lowest application rate, maximum residues on short grass exceed the LOEL (100 ppm) at which biologically significant reproductive effects occur. Because a NOEL was not determined, but must be below 100 ppm, risk to birds feeding on food items other than short grass are likely to be impaired. Decreasing the current maximum application rate to limit the maximum seasonal use rate to 2 lbs a.i./acre may reduce the potential for chronic risk to birds, but it would not eliminate this risk. Further, new avian reproduction studies will be useful to increase certainty of chronic risk to birds and to evaluate risk reduction measures. The registrant has agreed to lower the maximum seasonal application rate from four to two pounds per acre.

9. Rotational Crop Restrictions

Rotational crop restrictions are also required on bentazon end-use product labels. The appropriate plantback intervals will be determined upon submission and review of the required field rotational crop studies.

10. Worker Protection Requirements

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 9311, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA' s labeling regulations for worker protection statements (4 0 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all

statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

a. Mixer/Loader/Applicator PPE Requirements

For each end-use product, Personal Protective Equipment (PPE) requirements for pesticide handlers will be set during reregistration in one of the two ways below.

i) If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be established 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.

ii) 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, cancer, developmental toxicity, or reproductive effects:

- 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, etc.) must be placed on the label of the end-use product.

There are no special toxicological concerns about bentazon that warrant the establishment of active-ingredient-based PPE requirements for handlers.

b. Early Entry PPE Requirements

The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and a requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who enter areas that remain under a restricted-entry interval and who contact treated surfaces are

based on the toxicity concerns about the active ingredient. The requirements are set in one of the two ways below.

i) If EPA has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.

ii) 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, cancer, developmental toxicity, or reproductive effects, it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since bentazon is classified as category III for acute dermal toxicity, skin irritation potential and eye irritation potential and EPA has no special concerns about other adverse effects, the PPE required for early entry is the minimum early entry PPE permitted under the WPS: coveralls, chemical-resistant gloves, shoes, and socks.

c. Postapplication Entry Restrictions

Restricted Entry Interval: Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: product-specific REI's established on the basis of adequate data and interim REI's that are longer than those that would be established under the WPS.

WPS Uses: For occupational end-use products containing bentazon as an active ingredient, the Agency is establishing a 12-hour restricted-entry interval established for uses within the scope of the WPS.

Non-WPS Uses: Label statements prohibiting use until sprays have dried are required for occupational uses outside the scope of the WPS and for homeowner uses. See part V.

d. Precautionary Labeling

Because bentazon is a skin sensitizer, the Agency is requiring a precautionary statement on all end-use products. See part V.

11. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered plant and animal species to bentazon. Endangered terrestrial plants occurring adjacent to, or receiving runoff from, areas treated with bentazon may be affected.

Currently, 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 and by 1995 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. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

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 bentazon for all uses has been reviewed and determined to be substantially complete. However, confirmatory data in the areas of environmental fate, ecological effects, toxicology, product chemistry, and residue chemistry are required, as discussed previously in this document and as specified in the Data Call-In Notice appended to this document.

The available 21-day dermal toxicity study with bentazon does not meet the present standards; thus, an adequate 21-day dermal toxicity study is required. The study is considered confirmatory because there does not appear to be a concern for worker risk based on available information.

Aquatic field dissipation studies (guideline 164-2) are required to confirm the qualitative aquatic fate and transport assessments under typical use conditions. In addition, this study can be used to determine the need for chronic testing of aquatic animals. If this study indicates extremely long persistence in aquatic habitats, then requesting the submission of chronic studies would have

added value.

Field rotational crop studies (guideline 165-2) are required because the residues of concern (bentazon, 6-hydroxy bentazon, and 8-hydroxy bentazon) were identified in various rotational crops at various intervals and were quantified at levels greater than 0.01 ppm in crops from the 39- and 102-day rotations. Rotational crop restrictions are required on bentazon end-use product labels. The appropriate plantback intervals will be determined upon submission and review of the required field rotational crop studies.

A small-scale prospective ground water study (guideline 166-1) is needed to establish the conditions under which bentazon is prone to leach into groundwater. Ground water monitoring data currently available to EPA show that bentazon has been detected in ground water in four of eight states sampled, at concentrations ranging from 0.07 to 120 ppb. A small-scale prospective ground water study must be conducted with bentazon covering its use in soybeans or turf following consultation with the Agency.

Because bentazon is a herbicide and could be phytotoxic to nontarget plants, spray drift studies (Droplet Size Spectrum, guideline 201-1, and Drift Field Evaluation, guideline 202-1) are needed to assess off-target aerial movement of bentazon. The Agency recognizes the registrant, BASF, is a member of the Spray Drift Task Force (SDTF) and may, therefore, choose to satisfy the spray drift data requirements using SDTF data.

All ecological effect data requirements necessary to complete a risk assessment for the reregistration of bentazon are fulfilled. However, fish toxicity, mollusk toxicity, and avian reproduction studies would provide added value in increasing the certainty of the risk assessment.

2. Labeling Requirements for Manufacturing-Use Products

No additional requirements are being imposed by this RED for Manufacturing-Use products.

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 G, the Product Specific Data Call-In Notice.

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

2. Labeling Requirements for End-Use Products

The following statements, some of which may currently be on some product labels, are now required on all labels as specified below.

a. Environmental Hazard Statement

Environmental Hazard Statements for crayfish and catfish commercial farms are required for non-residential end-use product labeling. Environmental hazard requires the following labeling statement:

"For terrestrial uses only, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do contaminate water when disposing of equipment washwater or rinsate."

b. Ground Water Label Advisory

The Agency is requiring a ground-water label advisory to minimize the effects of bentazon contamination on ground-water quality. The label advisory must state:

"This chemical is known to leach through soil into groundwater under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination."

c. Worker Protection Requirements

i) The Agency is establishing the following entry restriction for all non-WPS occupational uses of bentazon products:

"Do not enter or allow others to enter the treated area until sprays have dried."

ii) The Agency is establishing the following entry restrictions for all homeowner-use products:

"Do not allow persons or pets to enter the treated area until sprays have dried."

iii) The Agency is requiring the following label statements for all bentazon products intended primarily for occupational uses. This includes uses both within the scope and not in the scope of the WPS.

Application Restrictions:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Engineering Controls:

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If there are no such instructions for washables, 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."

iv) In addition, because bentazon is classified as a skin sensitizer, the Agency requires the following statement to be placed in the "Hazards to Humans (and Domestic Animals)" section of the Precautionary Statements on the labeling of all end-use products containing bentazon:

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

d. Reduction in Application Rate

All bentazon labels must be amended to reflect a maximum seasonal application rate of 2 lbs ai/a.

e. Labeling for Products Registered for Residential Use Only

The Agency is requiring the following label statement for all bentazon products intended for use on lawns and turf:

"Do not apply directly to water. Do not contaminate water when disposing of equipment washwater or rinsate."

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 products bearing old labels/labeling, i.e., labels absent the modifications specified in this RED document, except as noted below, 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 pre-existing 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

SITE 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. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES												
ALFALFA					Use Group: TERRESTRIAL FEED CROP							
Spray., Postemergence., Aircraft.	SC/L	NA	1 lb (AE) A	*	NS NS	2 lb (AE)	NS	NS	2	WA		C14, C46, G99
Spray., Postemergence., Ground.	SC/L	NA	1 lb (AE) A	*	NS NS	2 lb (AE)	NS	NS	2	WA		C14, C46, G99
BEANS					Use Group: TERRESTRIAL FOOD+FEED CROP							
Spray., Postemergence., Aircraft.	SC/L	NA	1 lb (AE) A	*	NS NS	NS	2 lb (AE)	NS	2	, , , ,		C20, C46, H01(30)
Spray., Postemergence., Ground.	SC/L	NA	1 lb (AE) A	*	NS NS	NS	2 lb (AE)	NS	2	, , , ,		C20, C46, H01(30)
BEANS, DRIED-TYPE					Use Group: TERRESTRIAL FOOD+FEED CROP							
Spray., Postemergence., Aircraft.	SC/L	NA	1 lb (AE) A	*	NS NS	2 lb (AE)	NS	NS	2	, , , ,		C20, C46, H01(30)
	SC/L	NA	UC	*	NS NS	UC	NS	NS	NS			C46, H01(30)
Spray., Postemergence., Ground.	SC/L	NA	1 lb (AE) A	*	NS NS	2 lb (AE)	NS	NS	2	, , , ,		C20, C46, H01(30)
	SC/L	NA	UC	*	NS NS	UC	NS	NS	NS			C46, H01(30)
BEANS, SUCCULENT (LIMA)					Use Group: TERRESTRIAL FOOD+FEED CROP							
Spray., Postemergence., Aircraft.	SC/L	NA	1 lb (AE) A	*	NS NS	2 lb (AE)	NS	NS	2	, , , ,		C20, C46, H01(30)
	SC/L	NA	UC	*	NS NS	UC	NS	NS	NS			C46, H01(30)
Spray., Postemergence., Ground.	SC/L	NA	1 lb (AE) A	*	NS NS	2 lb (AE)	NS	NS	2	, , , ,		C20, C46, H01(30)
	SC/L	NA	UC	*	NS NS	UC	NS	NS	NS			C46, H01(30)
BEANS, SUCCULENT (SNAP)					Use Group: TERRESTRIAL FOOD+FEED CROP							
Spray., Postemergence., Aircraft.	SC/L	NA	1 lb (AE) A	*	NS NS	2 lb (AE)	NS	NS	2			C20, C46, H01(30)
	SC/L	NA	UC	*	NS NS	UC	NS	NS	NS			C46, H01(30)
Spray., Postemergence., Ground.	SC/L	NA	1 lb (AE) A	*	NS NS	2 lb (AE)	NS	NS	2			C20, C46, H01(30)

SITE 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. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
BEANS, SUCCULENT (SNAP) (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
	SC/L	NA		UC	* NS	NS / UC	NS	NS	NS		C46, H01(30)
CORN				Use Group: TERRESTRIAL FEED CROP							
Spray., Postemergence., Aircraft.	FlC	NA	.726 lb (AE) A	*	1	NS / NS	NS	NS	2	CA	C46, G01(21), G83(21)
	SC/L	NA	1 lb (AE) A	*	NS	NS / 2 lb (AE)	NS	NS	2		C20, C46, G01(12)
Spray., Postemergence., Ground.	FlC	NA	.726 lb (AE) A	*	1	NS / NS	NS	NS	2	CA	C46, G01(21), G83(21)
	SC/L	NA	1 lb (AE) A	*	NS	NS / 2 lb (AE)	NS	NS	2		C20, C46, G01(12)
				Use Group: TERRESTRIAL FOOD+FEED CROP							
Spray., Postemergence., Aircraft.	FlC	NA		UC	* NS	1/1 yr / NS	NS	NS	NS	CA	C46, G01(21)
Spray., Postemergence., Ground.	FlC	NA		UC	* NS	1/1 yr / NS	NS	NS	NS	CA	C46, G01(21)
CORN (UNSPECIFIED)				Use Group: TERRESTRIAL FOOD+FEED CROP							
Spray., Postemergence., Aircraft.	FlC	NA	.726 lb (AE) A	*	1	NS / NS	NS	NS	2	CA	C14, C46, G01(21), G83(21)
	FlC	NA		UC	* NS	1/1 yr / NS	NS	NS	NS	CA	C46, G01(21)
	SC/L	NA	1 lb (AE) A	*	NS	NS / 2 lb (AE)	NS	NS	2		C14, C20, C46, G01(12)
	SC/L	NA		UC	* NS	NS / UC	NS	10	NS		C14, C46, G01(12)
Spray., Postemergence., Ground.	FlC	NA	.726 lb (AE) A	*	1	NS / NS	NS	NS	2	CA	C14, C46, G01(21), G83(21)
	FlC	NA		UC	* NS	1/1 yr / NS	NS	NS	NS	CA	C46, G01(21)
	SC/L	NA	1 lb (AE) A	*	NS	NS / 2 lb (AE)	NS	NS	2		C14, C20, C46, G01(12)
	SC/L	NA		UC	* NS	NS / UC	NS	10	NS		C14, C46, G01(12)
CORN, FIELD				Use Group: TERRESTRIAL FOOD+FEED CROP							

SITE 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. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
CORN, FIELD (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
Spray., Postemergence., Aircraft.	FlC	NA	.726 lb (AE) A	*	1 NS	NS	NS	NS	2	CA		C46, G01(21), G83(21)
	FlC	NA	UC	*	NS 1/1 yr	NS	NS	NS	NS	CA		C46, G01(21)
	SC/L	NA	1 lb (AE) A	*	NS NS	2 lb (AE)	NS	NS	2			C20, C46, G01(12)
	SC/L	NA	UC	*	NS NS	UC	NS	10	NS			C46, G01(12)
Spray., Postemergence., Ground.	FlC	NA	.726 lb (AE) A	*	1 NS	NS	NS	NS	2	CA		C46, G01(21), G83(21)
	FlC	NA	UC	*	NS 1/1 yr	NS	NS	NS	NS	CA		C46, G01(21)
	SC/L	NA	1 lb (AE) A	*	NS NS	2 lb (AE)	NS	NS	2			C20, C46, G01(12)
	SC/L	NA	UC	*	NS NS	UC	NS	10	NS			C46, G01(12)
CORN, POP				Use Group: TERRESTRIAL FOOD+FEED CROP								
Spray., Postemergence., Aircraft.	FlC	NA	.726 lb (AE) A	*	1 NS	NS	NS	NS	2	CA		C46, G01(21), G83(21)
	FlC	NA	UC	*	NS 1/1 yr	NS	NS	NS	NS	CA		C46, G01(21)
	SC/L	NA	1 lb (AE) A	*	NS NS	2 lb (AE)	NS	NS	2			C20, C46, G01(12)
	SC/L	NA	UC	*	NS NS	UC	NS	10	NS			C46, G01(12)
Spray., Postemergence., Ground.	FlC	NA	.726 lb (AE) A	*	1 NS	NS	NS	NS	2	CA		C46, G01(21), G83(21)
	FlC	NA	UC	*	NS 1/1 yr	NS	NS	NS	NS	CA		C46, G01(21)
	SC/L	NA	1 lb (AE) A	*	NS NS	2 lb (AE)	NS	NS	2			C20, C46, G01(12)
	SC/L	NA	UC	*	NS NS	UC	NS	10	NS			C46, G01(12)
CORN, SWEET				Use Group: TERRESTRIAL FOOD+FEED CROP								
Spray., Postemergence., Aircraft.	FlC	NA	.726 lb (AE) A	*	1 NS	NS	NS	NS	2	CA		C46, G01(21), G83(21)

SITE 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. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
CORN, SWEET (con't)	Use Group: TERRESTRIAL FOOD+FEED CROP (con't)											
	FlC	NA	UC	*	NS	1/1 yr	NS	NS	NS	NS	CA	C46, G01(21)
	SC/L	NA	1 lb (AE) A	*	NS	NS	1 lb (AE)	NS	NS	2		C20, C46, G01(12)
	SC/L	NA	UC	*	NS	NS	UC	NS	10	NS		C46, G01(12)
Spray., Postemergence., Ground.	FlC	NA	.726 lb (AE) A	*	1	NS	NS	NS	NS	2	CA	C46, G01(21), G83(21)
	FlC	NA	UC	*	NS	1/1 yr	NS	NS	NS	NS	CA	C46, G01(21)
	SC/L	NA	1 lb (AE) A	*	NS	NS	1 lb (AE)	NS	NS	2		C20, C46, G01(12)
	SC/L	NA	UC	*	NS	NS	UC	NS	10	NS		C46, G01(12)
PEANUTS	Use Group: TERRESTRIAL FEED CROP											
Spray., Postemergence., Aircraft.	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46, G01(50)
Spray., Postemergence., Ground.	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46, G01(50)
PEANUTS (UNSPECIFIED)	Use Group: TERRESTRIAL FOOD+FEED CROP											
Spray., Postemergence., Aircraft.	SC/L	NA	.501 lb (AE) A	*	NS	NS	1.001 lb (AE)	NS	15	2		C46, GD7, H01(75)
	SC/L	NA	1 lb (AE) A	*	NS	NS	2 lb (AE)	NS	NS	2		C20, C46, G01(50), G10, GI5
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46, G01(50)
Spray., Postemergence., Ground.	SC/L	NA	.501 lb (AE) A	*	NS	NS	1.001 lb (AE)	NS	15	2		C46, GD7, H01(75)
	SC/L	NA	1 lb (AE) A	*	NS	NS	2 lb (AE)	NS	NS	2		C20, C46, G01(50), G10, GI5
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46, G01(50)
PEAS, DRIED-TYPE	Use Group: TERRESTRIAL FOOD+FEED CROP											
Spray., Postemergence., Aircraft.	SC/L	NA	1 lb (AE) A	*	NS	NS	2 lb (AE)	NS	NS	2		C20, C46, H01(30)
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46, H01(30)

SITE 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. Rate Max. /crop /year	Max. 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												
FOOD/FEED USES (con't)												
PEAS, DRIED-TYPE (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
Spray., Postemergence., Ground.	SC/L	NA	1 lb (AE) A	*	NS	NS	2 lb (AE)	NS	NS	2		C20, C46, H01(30)
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46, H01(30)
PEAS, SOUTHERN				Use Group: TERRESTRIAL FOOD+FEED CROP								
Spray., Postemergence., Aircraft.	SC/L	NA	1 lb (AE) A	*	NS	NS	2 lb (AE)	NS	NS	2		C20, C46, H01(30)
Spray., Postemergence., Ground.	SC/L	NA	1 lb (AE) A	*	NS	NS	2 lb (AE)	NS	NS	2		C20, C46, H01(30)
PEAS, SUCCULENT				Use Group: TERRESTRIAL FOOD+FEED CROP								
Spray., Postemergence., Aircraft.	SC/L	NA	1 lb (AE) A	*	NS	NS	2 lb (AE)	NS	NS	2		C20, C46, H01(30)
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46, H01(30)
Spray., Postemergence., Ground.	SC/L	NA	1 lb (AE) A	*	NS	NS	2 lb (AE)	NS	NS	2		C20, C46, H01(30)
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46, H01(30)
PEPPER (CHILI TYPE)				Use Group: TERRESTRIAL FOOD CROP								
Spray., Postemergence., Ground.	SC/L	NA	1 lb (AE) A	*	NS	NS	2 lb (AE)	NS	NS	NS NC		C46
PEPPERMINT				Use Group: TERRESTRIAL FOOD+FEED CROP								
Spray., Postemergence., Aircraft.	SC/L	NA	2 lb (AE) A	*	NS	NS	4 lb (AE)	NS	7	2		C20, C46
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46
Spray., Postemergence., Ground.	SC/L	NA	2 lb (AE) A	*	NS	NS	4 lb (AE)	NS	7	2		C20, C46
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46
RICE				Use Group: AQUATIC FOOD CROP								
Spray., Postemergence., Aircraft.	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS	CA	C46
Spray., Postemergence., Ground.	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS	CA	C46

SITE 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. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
RICE (con't)					Use Group: TERRESTRIAL FEED CROP							
Spray., Postemergence., Aircraft.	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS	CA	C46
Spray., Postemergence., Ground.	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS	CA	C46
					Use Group: TERRESTRIAL FOOD+FEED CROP							
Spray., Postemergence., Aircraft.	SC/L	NA	1.98 lb (AE) A	*	NS	NS	2.97 lb (AE)	NS	NS	NS		G59, G60
	SC/L	NA	1 lb (AE) A	*	NS	NS	3 lb (AE)	NS	NS	2	CA	C20, C46, G59, G60, GM5
Spray., Postemergence., Ground.	SC/L	NA	1.98 lb (AE) A	*	NS	NS	2.97 lb (AE)	NS	NS	NS		G59, G60
	SC/L	NA	1 lb (AE) A	*	NS	NS	3 lb (AE)	NS	NS	2	CA	C20, C46, G59, G60, GM5
Spray., Ratoon., Aircraft.	SC/L	NA	.99 lb (AE) A	*	NS	NS	2.97 lb (AE)	NS	NS	NS		G59, G60
	SC/L	NA	1 lb (AE) A	*	NS	NS	3 lb (AE)	NS	NS	2	CA	C20, C46, G59, G60, GM5
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS	CA	C46
Spray., Ratoon., Ground.	SC/L	NA	.99 lb (AE) A	*	NS	NS	2.97 lb (AE)	NS	NS	NS		G59, G60
	SC/L	NA	1 lb (AE) A	*	NS	NS	3 lb (AE)	NS	NS	2	CA	C20, C46, G59, G60, GM5
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS	CA	C46
SORGHUM					Use Group: TERRESTRIAL FEED CROP							
Spray., Postemergence., Aircraft.	FlC	NA	.726 lb (AE) A	*	1	NS	NS	NS	NS	2	CA	C46, G01(21), G83(21)
	SC/L	NA	1 lb (AE) A	*	NS	NS	1 lb (AE)	NS	NS	2		C20, C46, G01(12)
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46, G01(12)
Spray., Postemergence., Ground.	FlC	NA	.726 lb (AE) A	*	1	NS	NS	NS	NS	2	CA	C46, G01(21), G83(21)

SITE 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. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
SORGHUM (con't)				Use Group: TERRESTRIAL FEED CROP (con't)								
	SC/L	NA	1 lb (AE) A	* NS	NS	1 lb (AE)		NS	NS	2		C20, C46, G01(12)
	SC/L	NA	UC	* NS	NS	UC		NS	NS	NS		C46, G01(12)
				Use Group: TERRESTRIAL FOOD+FEED CROP								
Spray., Postemergence., Aircraft.	FlC	NA	.726 lb (AE) A	* 1	NS	NS		NS	NS	2	CA	C46, G01(21), G83(21)
	FlC	NA	UC	* NS	1/1 yr	NS		NS	NS	NS	CA	C46, G01(21)
	SC/L	NA	1 lb (AE) A	* NS	NS	1 lb (AE)		NS	NS	2		C20, C46, G01(12)
	SC/L	NA	UC	* NS	NS	UC		NS	NS	NS		C46, G01(12)
Spray., Postemergence., Ground.	FlC	NA	.726 lb (AE) A	* 1	NS	NS		NS	NS	2	CA	C46, G01(21), G83(21)
	FlC	NA	UC	* NS	1/1 yr	NS		NS	NS	NS	CA	C46, G01(21)
	SC/L	NA	1 lb (AE) A	* NS	NS	1 lb (AE)		NS	NS	2		C20, C46, G01(12)
	SC/L	NA	UC	* NS	NS	UC		NS	NS	NS		C46, G01(12)
SOYBEANS (UNSPECIFIED)				Use Group: TERRESTRIAL FOOD+FEED CROP								
Spray., Postemergence., Aircraft.	SC/L	NA	.499 lb (AE) A	* NS	1/1 yr	NS		NS	NS	NS	AL, AR, DE, GA, KY, LA, MD, MS, NC, NJ, PA, SC, TN, VA, MO, IN, IL, ME, MA, NH, NY, OH, RI, VT, WV, IA	C46, GA6
	SC/L	NA	.748 lb (AE) A	* NS	1/2 yr	.748 lb (AE)		NS	NS	NS	DE, NY, OH, WV, IL, IN, KY, MD, MA, ME, NH, RI, MO, NJ, PA, VA	C13, C46, GA6
	SC/L	NA	.501 lb (AE) A	* NS	NS	1.001 lb (AE)		NS	15	2		C46, GD7, H01(50)
	SC/L	NA	.75 lb (AE) A	* NS	NS	1.125 lb (AE)		NS	NS	2		C46, GD7, H01(50)

SITE 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. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
SOYBEANS (UNSPECIFIED) (con't)	Use Group: TERRESTRIAL FOOD+FEED CROP (con't)											
	SC/L	NA	1 lb (AE) A	*	NS	NS	2 lb (AE)	NS	NS	2		C20, C46, G01(30), H01(30)
	SC/L	NA	UC	*	NS	NS	UC	NS	14	NS		C46, GN6
Spray., Postemergence., Ground.	SC/L	NA	.499 lb (AE) A	*	NS	1/1 yr	NS	NS	NS	NS	AL, AR, DE, GA, KY, LA, MD, MS, NC, NJ, PA, SC, TN, VA, MO, IN, IL, ME, MA, NH, NY, OH, RI, VT, WV, IA	C46, GA6
	SC/L	NA	.748 lb (AE) A	*	NS	1/2 yr	.748 lb (AE)	NS	NS	NS	DE, NY, OH, WV, IL, IN, KY, MD, MA, ME, NH, RI, MO, NJ, PA, VA	C13, C46, GA6
	SC/L	NA	.501 lb (AE) A	*	NS	NS	1.001 lb (AE)	NS	15	2		C46, GD7, H01(50)
	SC/L	NA	.75 lb (AE) A	*	NS	NS	1.125 lb (AE)	NS	NS	2		C46, GD7, H01(50)
	SC/L	NA	1 lb (AE) A	*	NS	NS	2 lb (AE)	NS	NS	2		C20, C46, G01(30), H01(30)
	SC/L	NA	UC	*	NS	NS	UC	NS	14	NS		C46, GN6
SPEARMINT	Use Group: TERRESTRIAL FOOD+FEED CROP											
Spray., Postemergence., Aircraft.	SC/L	NA	2 lb (AE) A	*	NS	NS	4 lb (AE)	NS	7	2		C20, C46
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46
Spray., Postemergence., Ground.	SC/L	NA	2 lb (AE) A	*	NS	NS	4 lb (AE)	NS	7	2		C20, C46
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	NS		C46
NON-FOOD/NON-FEED												
ORNAMENTAL LAWNS AND TURF	Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL											
Spray., Postemergence., Ground.	FlC	NA	.726 lb (AE) A	*	NS	NS	NS	NS	7	NS		C13, C46, GA4, GC1

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

FlC	: FLOWABLE CONCENTRATE
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

C13 : Groundwater restriction.
C14 : Grown for seed only.
C20 : Endangered species restriction.
C46 : Do not apply through any type of irrigation system.
G01 : __ day(s) pregrazing interval.
G59 : Do not apply where catfish are considered commercial resources.
G60 : Do not apply where crayfish are considered commercial resources.
G99 : Do not feed or graze animals on treated areas.
GA4 : Do not feed treated forage to livestock.
GA6 : Do not graze treated areas or harvest for forage or hay.
GC1 : Do not graze treated areas.
GD7 : Do not use treated plants for feed or forage.
GM5 : Straw from harvested fields may be used for feed.
GN6 : Do not cut crop for feed or graze within 30 days after application.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

:	
AL	: Alabama
AR	: Arkansas
CA	: California
DE	: Delaware
GA	: Georgia
IA	: Iowa
IL	: Illinois

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IN  : Indiana
KY  : Kentucky
LA  : Louisiana
MA  : Massachussets
MD  : Maryland
ME  : Maine
MO  : Missouri
MS  : Mississippi
NC  : North Carolina
NH  : New Hampshire
NJ  : New Jersey
NY  : New York
OH  : Ohio
PA  : Pennsylvania
RI  : Rhode Island
SC  : South Carolina
TN  : Tennessee
VA  : Virginia
VT  : Vermont
WA  : Washington
WV  : West Virginia
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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 BENTAZON covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to BENTAZON 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 Bentazon

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-2A	**Start. Mat. & Mnfg. Process**	All	**00157712, 00165273**
61-2B	**Formation of Impurities**	All	**00165273, 00148848**
62-1	**Preliminary Analysis**		**40549003, 00165274**
63-7	**Density**	All	**00157712, 00155470**
63-10	**Dissociation Constant**	All	**00157712, 00155470**
63-11	**Octanol/Water Partition**		**00155470, 00157712**
63-12	**pH**		**00157712, 00155470**
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	ABC	**00161296, 00041804, 00041077**
71-2A	**Avian Dietary - Quail**	ABC	**00161297**
71-2B	**Avian Dietary - Duck**	ABC	**00164084**
71-4A	**Avian Reproduction - Quail**	ABC	**42617501**
71-4B	**Avian Reproduction - Duck**	ABC	**42651201**
72-1A	**Fish Toxicity Bluegill**	ABC	**00161299, 00161300**
72-1B	**Fish Toxicity Bluegill - TEP**	C	**00161300**
72-1C	**Fish Toxicity Rainbow Trout**	ABC	**41922801**
72-1D	**Fish Toxicity Rainbow Trout- TEP**	C	**41922802, 41922801**
72-2A	**Invertebrate Toxicity**	ABC	**00161303**
72-2B	**Invertebrate Toxicity - TEP**	C	**00161304**

Data Supporting Guideline Requirements for the Reregistration of Bentazon

REQUIREMENT		USE PATTERN	CITATION(S)
72-3A	**Estuarine/Marine Toxicity - Fish**	ABC	**42129601**
72-3B	**Estuarine/Marine Toxicity - Mollusk**	ABC	**42293501**
72-3C	**Estuarine/Marine Toxicity - Shrimp**	ABC	**42129602**
123-1A	**Seed Germination/Seedling Emergence**	ABC	**42129607**
123-1B	**Vegetative Vigor**	ABC	**42129606**
123-2	**Aquatic Plant Growth**	ABC	**42129603, 42129604, 42129605, 42129608, 42129609**
141-1	**Honey Bee Acute Contact**	ABC	**00161305**
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	ABC	**00064314**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	ABC	**00041088**
81-3	**Acute Inhalation Toxicity - Rat**	ABC	**40549008, 40232304, 00164089**
81-4	**Primary Eye Irritation - Rabbit**	ABC	**00072791**
82-1A	**90-Day Feeding - Rodent**	ABC	**40222201**
82-1B	**90-Day Feeding - Non-rodent**	ABC	**40222201**
82-2	**21-Day Dermal - Rabbit/Rat**	ABC	**42885302**
83-1A	**Chronic Feeding Toxicity - Rodent**	ABC	**40871701, 40871702**
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	ABC	**41054901**

Data Supporting Guideline Requirements for the Reregistration of Bentazon

REQUIREMENT		USE PATTERN	CITATION(S)
83-2A	**Oncogenicity - Rat**	ABC	**40871701**
83-2B	**Oncogenicity - Mouse**	ABC	**40871701, 40871702**
83-3A	**Developmental Toxicity - Rat**	ABC	**40114201**
83-3B	**Developmental Toxicity - Rabbit**	ABC	**40114202**
83-4	**2-Generation Reproduction - Rat**	ABC	**41054902**
84-2A	**Gene Mutation (Ames Test)**	ABC	**42129610, 00158382**
84-2B	**Structural Chromosomal Aberration**	ABC	**00158387, 00158388**
84-4	**Other Genotoxic Effects**	ABC	**4212960**
85-1	**General Metabolism**	ABC	**40481801, 00158379**
85-2	**Dermal Penetration**	ABC	**00158380**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	ABC	**00161293**
161-2	**Photodegradation - Water**	ABC	**41447702, 41432401, 41448001**
161-3	**Photodegradation - Soil**	A	**41447703, 00161295**
162-1	**Aerobic Soil Metabolism**	AB	**40470502**
162-2	**Anaerobic Soil Metabolism**	A	**00040204, 00040208**
162-3	**Anaerobic Aquatic Metabolism**	C	**40470503**
162-4	**Aerobic Aquatic Metabolism**	C	**40470504**
163-1	**Leaching/Adsorption/Desorption**	ABC	**40470501, 40470502, 40470503, 40470504, 40470505**
164-1	**Terrestrial Field Dissipation**	ABC	**TRID 470119-015**

REQUIREMENT		USE PATTERN	CITATION(S)
165-1	**Confined Rotational Crop**	A	**42361901**
165-2	**Field Rotational Crop**	A	**41146601, 41146602, 41146603, 41146604, 41146605, 41146606, 41146607, 41146608**
165-4	**Bioaccumulation in Fish**	ABC	**42236501, 00108300, 40954801**
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	ABC	**41779501, 41779503**
171-4B	**Nature of Residue - Livestock**	ABC	**41779502**
171-4D	**Residue Analytical Method - Animal**	ABC	**41730101**
171-4E	**Storage Stability**	ABC	**42587004, 42587005, 42587006, 42587007, 42587008, 42587009**
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	ABC	**41730101**
171-4K	**Crop Field Trials**	ABC	**41101701, 41101702**
171-4L	**Processed Food**	ABC	**41123101, 42587001, 42587003, 42587002**

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

The bibliography for bentazon is over 100 pages and is therefore not being included with the RED. It is, however, available upon request.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to BENTAZON. Its purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for BENTAZON 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. BENTAZON RED Fact Sheet
   Note that the fact sheet is included with this document, but is also available separately.

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

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 pet-

itions 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	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
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_____

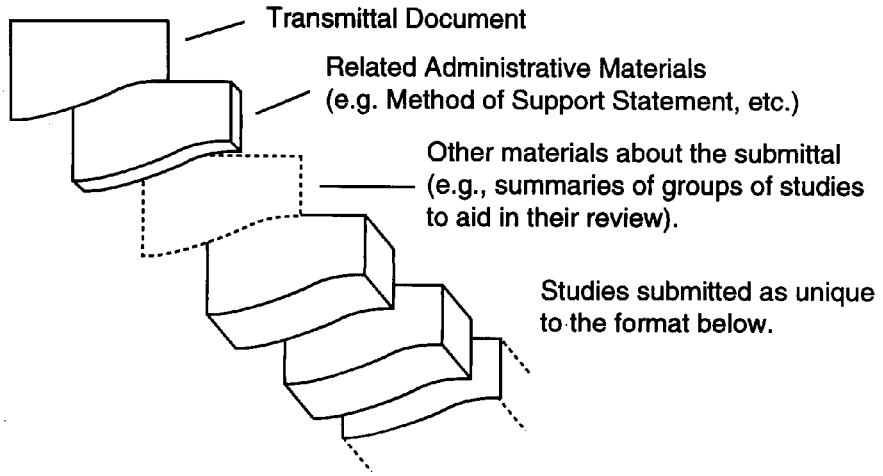
Example 3.

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.

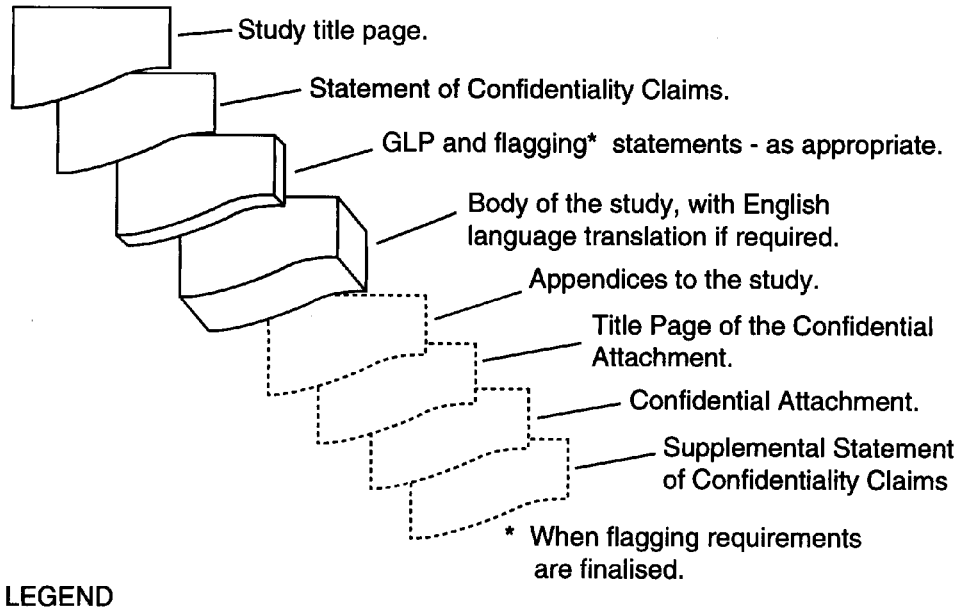
Submitter_____

ATTACHMENT 7.

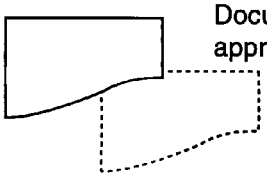
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



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

Documents submitted at submitter's option.

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

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

January 27, 1995

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 Registrant'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 Registrant'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 Registrant'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 Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have

questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

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 Registrant'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 Sheet

BENTAZON DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Data Call-In Notice because you have products containing BENTAZON.

This 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 BENTAZON. This attachment is to be used in conjunction with (1) the Combined Generic and Product Specific Data Call-In Notice, (2) the Data Call-In Response Forms (Attachment 2), (3) the Requirements Status and Registrant's Forms (Attachment 3), (4) EPA's Batching of End-Use Products for Meeting Acute Toxicology Data Requirements (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) the list of registrants receiving this DCI (Attachment 6), and (7) the Cost Share and Data Compensation Forms in replying to this BENTAZON 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 BENTAZON are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional generic product chemistry, ecological effects, toxicology, environmental fate, and residue chemistry data on BENTAZON are needed. The Agency has also concluded that additional data on BENTAZON are needed for specific products. These data are required to be submitted to the Agency within the time frames listed. These data are needed to fully complete the reregistration of all eligible BENTAZON products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements, please contact Eric Feris at (703) 308-8048 via relay (800-828-1140) or by electronic mail at FERIS.ERIC@EPAMAIL.EPA.GOV. All responses to this Notice for the generic data requirements should be submitted to:

Eric Feris, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: BENTAZON

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

Attachment 2. Combined Generic and Product Specific Data Call-In Response Forms 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.

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

Attachment 3. Generic and Product Specific Requirement Status and Registrant's Response Forms and 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

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

EPA'S BATCHING OF PRODUCTS CONTAINING BENTAZON AS THE ACTIVE INGREDIENT FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient bentazon (3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one-2,2-dioxide, sodium salt) the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

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

preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the products containing the active ingredient bentazon.

Table 1

Batch	Registration Number	% Active Ingredient	Form
1	7969-45	bentazon ... 42.0%	liquid
	NC81002300	bentazon ... 42.0%	liquid
	WA90001200	bentazon ... 42.0%	liquid
2	7969-84	bentazon ... 53.0%	liquid
	7969-112	bentazon ... 53.0%	liquid
3	7969-54	bentazon ... 19.0% atrazine ... 17.5%	liquid
	7969-103	bentazon ... 19.0% atrazine ... 17.5%	liquid
4	7969-82	bentazon ... 29.0% fomesafen ... 12.9%	liquid
	7969-83	bentazon ... 29.8% fomesafen ... 7.2%	liquid

Table 2 lists those products the Agency was unable to batch. These products were considered not to be similar to other products for purposes of acute toxicity. Registrants of

these products are responsible for meeting the acute toxicity data requirements for each product.

Table 2

Unbatched Products		
Reg. No.	% Active Ingredient	Form
7969-42	bentazon ... 46%	liquid
7969-76	bentazon ... 29.2% acifluorfen, sodium salt ... 13.4%	liquid
7969-77	bentazon ... 33.4% acifluorfen, sodium salt ... 6.8%	liquid
7969-78	bentazon ... 37.0% MCPA ... 6.2%	liquid
7969-100	bentazon ... 27.6% atrazine ... 25.0%	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.

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 ($\pm 2^{o}$), 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.

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).

Attachment 6. List of All Registrants Sent This Data Call-In 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	b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	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

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

Please fill in blanks below.

Company Name	Company Number

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-90)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-94-026 September 1994

R.E.D. FACTS

Bentazon

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 0182, bentazon, which includes bentazon technical and sodium bentazon, the active ingredient in end-use pesticide products.

Use Profile

Bentazon, also known by its trade name Basagran, is a selective herbicide that is used after seedlings have emerged to control broadleaf weeds and sedges among food and feed crops including alfalfa, beans, corn, peanuts, peas, peppers, peppermint, rice, sorghum, soybeans and spearmint. Bentazon also is registered for use on ornamental lawns and turf. Most bentazon used in the U.S. (73%) is applied to soybean crops.

Bentazon may be applied either aerially or using ground equipment (except to lawns and turf, which may be treated using ground equipment only). Formulations include a flowable concentrate and a soluble concentrate/liquid. Use practice limitations prohibit applying bentazon through any type of irrigation system; discharging effluent containing the product into sewage systems or bodies of water; using treated plants for feed or forage; and treating crops/sites within 30 to 75 days of harvest or 12 to 50 days of grazing.

Regulatory History

EPA issued a Registration Standard for bentazon in September 1985 (NTIS #PB86-159563). An August 1990 Data Call-In (DCI) required additional data on terrestrial and aquatic animal effects, environmental fate, toxicology, residue chemistry, and plant protection. Products currently registered contain bentazon alone or in combination with atrazine.

Human Health Assessment

Toxicity

Bentazon is slightly acutely toxic by the oral, dermal and inhalation routes, and has been placed in Toxicity Category III (the second-to-lowest of four categories) for these effects. It is a skin sensitizer in guinea pigs.

In a subchronic toxicity study using rats, bentazon caused a variety of effects at the highest dose tested including reductions in body weight gain, an increase in blood clotting times, and increased kidney and liver weights.

A chronic toxicity study in beagle dogs produced adverse effects at the two highest dose levels including clinical signs of toxicity, anemia-like changes in blood, depressed body weight gains, intestinal inflammation and congestion of the small intestine and spleen.

In two combined chronic toxicity and carcinogenicity studies using rats and mice, bentazon caused no compound-related increases in tumors. Numerous other adverse effects were observed at the highest dose levels, however, including effects on blood clotting and to the testes, pancreas and liver, changes in kidney, thyroid and pituitary gland weights, reduced body weight gain, and hemorrhage in the liver and heart. Based on these studies, bentazon was classified as a "Group E" carcinogen, that is, a compound that shows evidence of non-carcinogenicity for humans.

In a developmental toxicity study using rats, bentazon did not cause maternal toxicity but at the highest dose tested caused an increase in postimplantation loss and effects on bone development in fetuses. In rabbits, bentazon caused some evidence of both maternal toxicity and developmental toxicity. In a reproductive toxicity study using rats, at the highest dose levels, bentazon caused a decrease in body weights of pups during lactation and reductions in food consumption and weight gain, as well as kidney and liver effects in parents. Bentazon is not mutagenic.

Dietary Exposure

People may be exposed to residues of bentazon through the diet. Tolerances or maximum residue limits have been established for raw agricultural commodities including various types of beans, corn, mint, peanuts, peas, peppers, rice, sorghum and soybeans (please see 40 CFR 180.355(a)); for animal commodities including milk, eggs, and the fat, meat and meat byproducts of cattle, goats, hogs, poultry and sheep (see 40 CFR 180.355(b); and for the processed commodity spent mint hay (see 40 CFR 186.375). A tolerance for rice hulls is proposed. EPA has reassessed the existing bentazon tolerances and found that several changes and corrections are needed, as explained in the RED document.

EPA has assessed the acute and chronic dietary risks posed by bentazon. In the chronic risk analysis, the Agency used a Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime, of 0.03 mg/kg bwt/day (milligrams/kilogram of bodyweight/day). This RfD is based on a No Observed Effects Level (NOEL) of 3.2 mg/kg

bwt/day established in the dog feeding study described earlier, plus an uncertainty factor of 100. For the overall U.S. population and 22 subgroups, exposure from all current tolerances represents 2.2% of the RfD. The exposure level of the most highly exposed subgroup, non-nursing infants less than one year old, represents 8.1% of the RfD. Based on these estimates, chronic dietary risk is not of concern.

In the acute dietary risk analysis, EPA used a NOEL derived from the developmental toxicity study in rats, described earlier. The subgroup of most interest in terms of developmental toxicity, females aged 13 and above (women of child bearing age), have a margin of exposure (MOE) of 500. This means they receive approximately $1/500^{th}$ the amount that represents the NOEL in animals. Thus, acute dietary risk from bentazon is not of concern.

Occupational and Residential Exposure

Based on current use patterns, workers may be exposed to bentazon during and after applications in agricultural and other settings. The Agency was concerned about developmental toxicity effects resulting from this exposure. Margins of Exposure (MOEs) were estimated for short and intermediate term exposure scenarios involving mixing, loading and applying bentazon using both ground and aerial application methods. The resulting MOEs ranged from 1,714 to 100,000; all are well over 100, the margin regarded as acceptable from a safety standpoint. Therefore, the personal protective equipment (PPE) required for early entry is the minimum PPE required under the Worker Protection Standard (WPS): coveralls, chemical-resistant gloves, shoes and socks.

The risk to homeowners who handle bentazon is expected to be lower than that of people who handle the pesticide occupationally.

Human Risk Assessment

Bentazon is slightly acutely toxic by all routes (Toxicity Category III) and is a skin sensitizer. It is classified as a "Group E" carcinogen--a chemical showing evidence of non-carcinogenicity to humans, but causes some developmental toxicity effects in rats and rabbits.

Bentazon is used on a variety of food crops, and people may be exposed to residues through their diets. Based on EPA's acute and chronic dietary risk assessments, however, dietary exposure to the bentazon uses supported for reregistration is not of concern.

Although the Agency has concerns about possible developmental toxicity effects among workers exposed to bentazon, these concerns are minor based on our assessment that worker risks are low. There are no concern that warrant the establishment of personal protective equipment (PPE) requirements beyond those required by the Worker Protection Standard (WPS) or appearing on existing product labels for non-WPS uses.

Environmental Assessment

Environmental Fate

Dissipation of bentazon is dependent on microbe-induced degradation, leaching and surface water runoff. Bentazon is moderately resistant to degradation in aerobic mineral soils. Degradation in aquatic environments is dependent on photolysis. Degradation in soil is controlled by processes involving microbes in the presence of oxygen. Bentazon has a low binding affinity to soil and therefore may leach into ground water and runoff into surface waters. Leaching did not appear to be a major route of dissipation in field studies, however. Bentazon dissipates rapidly under typical use conditions.

The soil degradates of bentazon include AIBA, which is very mobile but not persistent, and N-methylbentazon which is not mobile. These compounds should not pose a threat to ground water.

Environmental Fate Assessment

EPA concludes that, in addition to surface runoff, leaching through the soil profile also is a major route of dissipation for bentazon in the environment. Bentazon exceeds levels of concern for ground water quality, and also may impact the quality of surface water. Possible chronic effects of long-term drinking water exposure prompted EPA's Office of Water to establish a lifetime Health Advisory (HA) of 20 parts per billion (ppb), which will likely be increased to 200 ppb soon. However, bentazon is not regulated under the Safe Drinking Water Act (SDWA), no Maximum Contaminant Level (MCL) has been established, and water supply systems are not required to sample or analyze for its residues.

Bentazon has been detected in well water in four out of eight states sampled including California (with the greatest number of detections, extending over 11 counties), Florida, Missouri and Virginia. EPA is requiring a small-scale prospective ground water monitoring study to establish the conditions under which bentazon is prone to leach to ground water during normal agricultural use. The Agency also is requiring a ground water label advisory for bentazon to minimize its adverse effects on ground water. The registrant has agreed to prepare educational materials for end users, dealers and distributors regarding ground and surface water protection.

EPA also is requiring spray drift studies as confirmatory information, and in the future may require drift-related labeling statements for bentazon products applied aerially to agricultural crops.

Ecological Effects

Bentazon is slightly toxic to birds on an acute oral and subacute dietary basis, and exceeds the level of concern for avian chronic effects. Bentazon is slightly toxic to small mammals on an acute basis, and is practically nontoxic to honeybees. Bentazon also is practically nontoxic to cold and warm water fish, aquatic invertebrates and estuarine/marine organisms. Bentazon poses a low risk to aquatic plants but may represent a hazard to terrestrial and semi-aquatic plants.

Ecological Effects Risk Assessment

EPA concludes that the use of bentazon as an herbicide will not pose a serious environmental threat. Bentazon poses a chronic reproductive health risk to birds. However, the registrant has agreed to lower the maximum seasonal application rate from four to two pounds per acre, to reduce the potential for this risk. Although it is slightly toxic to birds and small mammals on an acute and subacute basis, bentazon is expected to pose minimal acute/subacute risks to both endangered and nonendangered birds and mammals as a result of its current uses. Since it is a herbicide, bentazon is expected to pose a risk to non-target terrestrial and semi-aquatic plants near treated sites. No hazard to aquatic animals or honeybees is anticipated.

Additional Data Required

EPA is requiring additional generic product chemistry, residue chemistry, toxicology, environmental fate and ecological effects studies to confirm its regulatory assessments and conclusions regarding bentazon. 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 bentazon end-use products must comply with EPA's current pesticide product labeling requirements. The following statements, some of which may be on some existing product labels, are now required on all labels as specified below.

Environmental Hazard Statement

Non-residential end-use product labeling must bear the following statement for crayfish and catfish commercial farms:

> "For terrestrial uses only, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

Ground Water Label Advisory

To minimize bentazon contamination of ground water, the following statement is required on all end-use product labeling:

> "This chemical is known to leach through soil into groundwater under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination."

Worker Protection Requirements

- The following entry restriction is required for all non-WPS occupational uses of bentazon:

"Do not enter or allow others to enter the treated area until sprays have dried."

- The following entry restriction is required for all homeowner products:

"Do not allow persons or pets to enter the treated area until sprays have dried."

- The following labeling statements are required for all bentazon products intended primarily for occupational use, including uses both within and not in the scope of the WPS.

Application Restrictions:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Engineering Controls:

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If there are no such instructions for washables, 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."

- Because bentazon is a skin sensitizer, the following statement must be placed in the "Hazards to Humans and Domestic Animals" section of the Precautionary Statements on the labeling of all end-use products:

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

Reduction in Application Rate

All bentazon labels must be amended to reflect a maximum seasonal application rate of 2 lbs ai/a (2 pounds active ingredient per acre).

Products Registered for Residential Use Only

The following label statement is required for all products intended for use on lawns and turf:

> "Do not apply directly to water. Do not contaminate water when disposing of equipment washwater or rinsate."

Regulatory Conclusion

The use of currently registered pesticide products containing bentazon 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.

Bentazon products will be reregistered once the required confirmatory generic data, product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA.

Products that contain the active ingredient atrazine in addition to bentazon will be reregistered when atrazine also is eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for bentazon 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.

Following the comment period, the bentazon RED document 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 bentazon RED, or reregistration of individual products containing bentazon, 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.