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Office of
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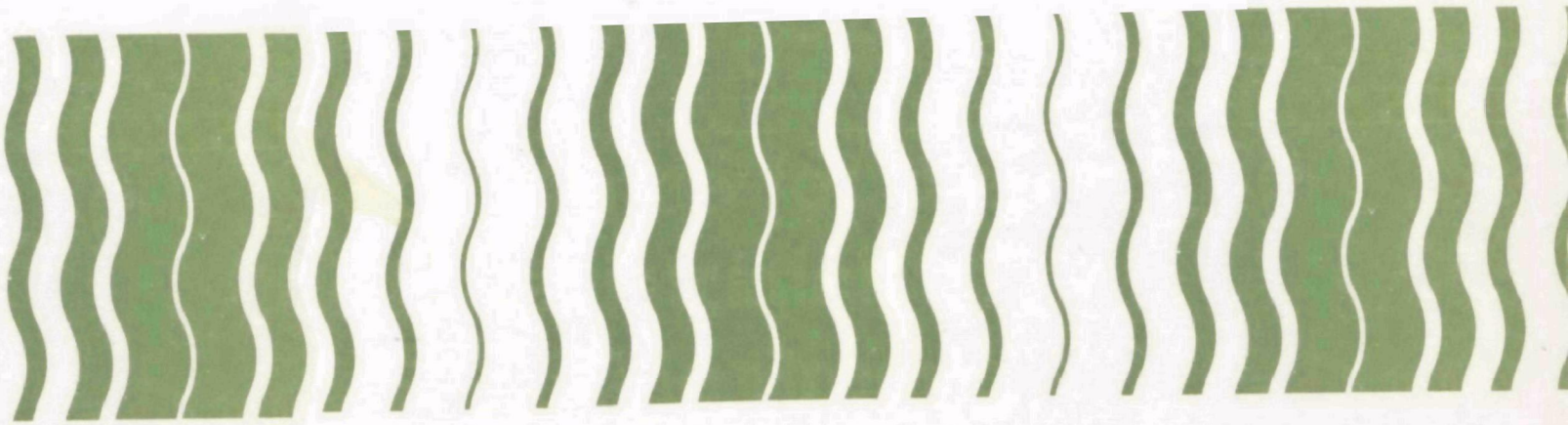
Pesticides

EPA

Guidance for the Reregistration of Pesticide Products Containing Bentazon as the Active Ingredient



GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING BENTAZON AS THE ACTIVE INGREDIENT

EPA CASE NUMBER: 182

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g)) directs EPA to reregister all pesticides as expeditiously as possible.

To carry out this task, EPA has established the Registration Standards program, which will review all pesticide products containing active ingredients first registered before January 1, 1977. Pesticides will be reviewed in use clusters which have been ranked to give earliest review to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. EPA's reassessment results in the development of a regulatory position, contained in a Registration Standard, on each pesticide and its uses. The Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide will not result in adverse effects on the environment.

The scientific review, which is not contained in this Guidance Package but is available from the National Technical Information Service, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the end use (formulated) products that contain the active ingredient. If we have serious concerns, we will address end use products as part of the Registration Standards program and will propose regulatory actions to the extent necessary to protect the public.

EPA has the authority under FIFRA sec. 3(c)(2)(B) to require registrants to submit data that will answer our questions regarding the hazard that may result from the intended use of a pesticide. Although sec. 3(c)(2)(B) provides that all registrants are responsible for these data, the Agency generally imposes generic data requirements only on the registrants of the manufacturing use products (basic suppliers

of the active ingredient) and other producers who do not qualify for the formulator's exemption.*

A producer who wishes to qualify for the formulator's exemption may change his source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. A registrant may do so by submitting a new Confidential Statement of Formula, EPA Form 8570-4, identifying the registered source of the active ingredient, to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document. If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product which does not comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

*The formulator's exemption applies to a registrant of an product if the source of his active ingredient(s): (1) is a registered product and (2) is purchased from a source which does not have ownership in common with the registrant's firm.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY ASSESSMENT

A. INTRODUCTION

This Registration Standard describes the regulatory position and rationale of the Environmental Protection Agency (the "Agency") for all registered manufacturing-use products (MPs) containing sodium bentazon as the sole active ingredient. This Standard also will require cetain changes on the labels of end-use products (EPs) containing sodium bentazon. The Agency bases its position and rationale on an evaluation of all MPs, and Section 3, 24(c), and intrastate uses registered for sodium bentazon. After briefly describing the chemical and its uses, this chapter presents the Agency's regulatory position and rationale, the criteria for registration, acceptable ranges and limits, labeling requirements, and the current tolerances.

B. DESCRIPTION OF CHEMICAL

Bentazon is the acceptable common name (approved by the American National Standards Institute and the Weed Science Science Society of America) for the herbicide with the chemical name of 3-(1-methylethyl)-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide. The Chemical Abstracts Service (CAS) Registry number for bentazon is 50723-80-3 while the EPA Office of Pesticide Program's Chemical Code Number is 275200.

All products currently marketed in the U.S. contain the sodium salt of bentazon as the active ingredient, referred to as sodium bentazon. Sodium bentazon MP is marketed under the name "Bentazon Manufacturer's Concentrate". Sodium bentazon single active ingredient EP is marketed under the name "Basagran" Postemergence Herbicide". A multiple active ingredient EP (mixture with atrazine) is marketed under the name "Laddock" Postemergence Flowable Herbicide". The EPA Office of Pesticide Program's Chemical Code Number is 103901 for sodium bentazon.

The chemical formula for bentazon is $C_{10}H_{12}N_2O_3S$ and the molecular weight is 240.3. Pure analytical standard (i.e., purer than technical) bentazon is white. Technical grade bentazon (isolated before formation of the sodium salt) is an odorless, non-volatile solid with a melting point of 137-139°C. Its solubility (g/100 g solvent, 20°C) is 0.05 in water and 150.7 in acetone. Sodium bentazon is considerably more soluble in water than bentazon, with a solubility of 230 g/100 g in water.

Sodium bentazon is a post-emergence contact herbicide used to control selected broadleaf weeds and sedges. It is applied by ground or air as a broadcast foliar spray following weed emergence. Various tank mixes are also permitted. See the EPA Index entry in this guidance package for additional label information, including the use sites for which sodium bentazon is registered.

C. Regulatory Position and Rationale

1. The available data do not indicate that any of the risk criteria listed in § 162.11 (a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the uses of sodium bentazon at the present time. However, substantial data gaps exist.

Rationale:

(Note: Agency data requirements for reregistration are described in 40 CFR Part 158. The data tables in this guidance package relate these specifically to bentazon and sodium bentazon.)

Human/Domestic Animal Hazard

Sodium bentazon belongs in Toxicity Category III (defined in 40 CFR 162.10) based upon acceptable acute oral and acute dermal data. An acute inhalation study is supplementary (valid but does not meet EPA guideline requirements) and will need to be repeated.

Subchronic data are supplementary (90-day rat feeding study and 13-week dog study; bentazon) or invalid (21-day dermal study; sodium bentazon), and will require replacement. Compound-related effects were seen at 300 and 3000 ppm test levels in the dog study (numerous effects at 3000 ppm; prostatitis at 300 ppm was basis of lowest-effect-level of 300 ppm and no-effect-level of 100 ppm). A one year dog study is required for hazard assessment.

All chronic toxicity data for bentazon are supplementary or invalid, and will require replacement. 24-month rat and 18-month mouse studies have been invalidated, and a "for cause" laboratory audit requested, due to substantial deficiencies. In a supplementary mouse oncogenicity study, no specific clinical or pathological symptoms could be associated with bentazon exposure.

A rat 3-generation reproduction study found no compound-related effects up to a dietary level of 180 ppm. However, without effects at the highest dose, the dose selection is considered inadequate and an additional reproduction study is required.

The available rat and rabbit teratogenicity studies are inadequate, but do not suggest that bentazon is a potent teratogen or fetotoxic agent. Terata were observed in one rat study at a dose of 200 mg/kg/day, but the utility and validity of these data are in question. Additional teratology studies in the rat and rabbit are required.

A variety of mutagenicity studies (analytical grade bentazon; or sodium bentazon) have been reviewed, but none are adequate for regulatory purposes. This is also the case for metabolism studies with labeled bentazon.

Ecological Effects

Technical bentazon is considered slightly toxic to birds based on subacute dietary testing. Formulated bentazon is considered slightly toxic to birds based on acute oral testing with a 50% a.i. wettable powder. Avian reproduction testing did not show effects up to the highest dietary level tested, but the studies were found to lack vital information and do not presently meet EPA guideline requirements.

Technical bentazon is characterized by EPA as practically nontoxic to both coldwater and warmwater fish, and slightly toxic to aquatic invertebrates, based on review of acute testing. Formulated bentazon is considered practically nontoxic to coldwater and warmwater fish based on acute testing with a 48% a.i. liquid product.

Applications of sodium bentazon on registered use sites are considered unlikely to result in acute hazard to most nontarget organisms because of the generally low toxicity seen in technical and formulated product testing, and low applicati rates. However, a final risk assessment is deferred due to lack of critical environmental chemistry data and certain ecological effects data.

Biological opinions (covering all registered pesticides) have been received from the U.S. Fish and Wildlife Service Office of Endangered Species (OES) for three of the crops for which sodium bentazon is registered: corn, sorghum, and soybeans. To avoid jeopardy to the Valley Elderberry Longhorn Beetle (Desmoceru californicus dimorphus), OES indicates that herbicides should be prohibited from designated areas in California in order to protect the host plant, elderberry (Sambucus spp.). Labeling developed by EPA to implement this prohibition is included in Section F below.

These opinions also stated that "...to avoid jeopardy to Solano grass...the use of any herbicides toxic to graminoides should be prohibited within..." certain defined geographic areas of California, because of concerns with spray drift and runoff from agricultural areas. Solano grass (Tuctoria (= Orcuttia) mucronata) is an endangered plant species found in a vernal lakebed in Solano County, California. Since no grass species are claimed on existing labeling to be controlled with sodium bentazon and the herbicide is used on various grass crops, Ecological Effects Branch (with informal consultation with OES) did not consider there to be a threat to Solano grass from the registered use of this chemical. Subsequently, information has been located indicating that sodium bentazon may affect certain germinating grass species with direct exposure at full dosage rates, but that it does not affect grasses after germina Solano grass germinates in March and April. The earliest planting date for corn, sorghum, or soybeans is for corn, which can be planted as early as April 1 Since sodium bentazon is applied postemergence to the weeds, there may be little opportunity for an application that could affect Solano grass. Further consultation with OES will be initiated. Label restrictions, as above, and/or plant protection data requirements (under § 158.150) may be imposed.

An oyster study and further environmental chemistry data are required, in part, to evaluate whether there is any hazard to endangered mussel species from sodium bentazon use.

The Agency is not aware of any other data which would suggest that the risk criteria of § 162.11 have been met or exceeded for the uses of sodium bentazon at the present time.

2. The existing manufacturing-use pesticide product containing sodium bentazon as the sole active ingredient may continue to be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Standard. The registrant must provide or agree to develop the additional data specified in Tables A and B of this guidance document to maintain the existing MP registration or to permit new registrations of substantially similar sodium bentazon MPs.

Rationale:

There are substantial data gaps in support of existing sodium bentazon registrations. The Agency has discretion to cancel or deny registrations because data are missing or inadequate. The Agency has elected to use the issuance of this Standard as the mechanism for identifying data needs. The Agency will complete its hazard evaluation, or determine what further data are necessary to do so, upon review of the data being called in under this Registration Standard. The Agency will determine at that time if such data will affect the registrations of bentazon.

If such review determines that criteria for determinations of unreasonable adverse effects are met or exceeded (as specified under §162.11), a rebuttable presumption shall arise that a notice of intent to cancel registration(s) pursuant to FIFRA §6(b)(1) (or a notice of intent to hold a hearing to determine whether the registration(s) should be cancelled) may be issued. If, at any time, review of the data indicates that an imminent hazard (as defined by FIFRA § 2(l)) is posed by bentazon use, immediate suspension procedures may be initiated as per FIFRA §6(c)(1).

3. The term TGAI (technical grade of the active ingredient) in the data tables refers to the technical grade of bentazon, not sodium bentazon. On a case-by-case basis, testing using sodium bentazon may be acceptable for fulfilling TGAI testing requirements. Clarification or verification of all test materials used in studies submitted by the registrant is required. The Agency reserves the right to impose additional testing of either bentazon or sodium bentazon following review of this information and/or review of new studies submitted to fulfill data gaps identified in this Standard.

Rationale:

Residue chemistry review has indicated that the moiety of concern (due to detectable residues) is bentazon, not sodium bentazon, and thus all tolerances have been established for bentazon (combined with certain of its metabolites). It is possible that, in addition to testing with bentazon, further testing with sodium bentazon will be required to evaluate exposure specifically to sodium bentazon. In many cases, the test material used in studies submitted to the Agency is not fully identified, and it is essential that this information be submitted to enable assessment. Note that, in addition to testing with TGAI, certain testing is specifically required using the MP (sodium bentazon), PAI (bentazon pure active ingredient), PAIRA (pure active ingredient, radiolabelled) TEP (typical end-use product), and metabolites.

4. No new uses of sodium bentazon will be permitted until the data base is adequate to complete a hazard assessment.

Rationale:

In accordance with Conditional Registration Interim Final Regulations (FR Vol. 44, No. 93, May 11, 1979), no new uses or new products may be registered without "data sufficient to allow the Agency to determine that approval of the application would not cause a significant increase in the risk of unreasonable adverse effects on the environment". For bentazon/sodium bentazon, the entire subchronic and chronic toxicology data base (required to evaluate hazard to humans/domestic animals from existing uses) is invalid or otherwise inadequate, and thus totally insufficient for evaluation of any new uses. The Agency is unable to complete a tolerance reassessment of bentazon/sodium bentazon because of these gaps, as well as residue chemistry data gaps.

The Agency is unable to fully assess potential human exposure, potential for groundwater contamination, or complete an ecological effects hazard assessment of existing sodium bentazon uses because of exposure assessment/environmental chemistry data gaps. There are also certain product chemistry, wildlife/aquatic organism, and nontarget insect data gaps that prevent full assessment of existing use.

5. The MP and EP manufacturer must make labeling changes specified in this guidance document. These include grazing restrictions, a rotational crop restriction, prohibition of sodium bentazon use where commercial crayfish or catfish farming are practiced, and restrictions regarding use of bentazon- or sodium bentazon-contaminated water for irrigation.

Rationale:

Residue chemistry review indicates a need for grazing restrictions for corn and peanut forage to ensure residues are below established tolerance levels of 3 ppm for these forage items at the time of grazing.

To complete an exposure assessment, rotational crop data, residue data on crops receiving irrigation water from sodium bentazon-treated rice fields, and residue data on crayfish and catfish that are farmed in rice fields are among the data required. Pending submission and review of this data, the cited restrictions are required.

Ecological effects review specifies the modified/updated environmental hazard statements as per Proposed Rule 40 CFR §156.55: Federal Register Vol. 49, No. 1(September 26, 1984.

6. Based on review of available data, bentazon itself is not considered likely to contaminate groundwater. However, data are required to determine the potential for bentazon metabolites to contaminate groundwater. Bentazon does have the potential to contaminate surface waters.

Rationale:

Review indicates that bentazon is very mobile in soil but that rapid degradation is likely to prevent groundwater contamination. An aged leaching study is needed to determine the potential for metabolites to contaminate groundwater. Bentazon has the potential to contaminate surface waters because of 1) its rice use pattern that involves either direct application to water or application to fields prior to flooding, and 2) runoff from treated areas for other uses.

D. CRITERIA FOR REGISTRATION UNDER THE STANDARD

To be covered under this Standard, products must contain sodium bentazon as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section E of this document.

The applicant for registration or reregistration of manufacturing-use products subject to this Standard must comply with all terms and conditions described in it, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, commitment to fill data gaps on the schedule specified by the Agency and, when applicable, offer to pay compensation as required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136(C)(2)(D). Registration applicants must contact the Agency for specific instructions, including updated information on data requirements and companies whose data have been used in support of registration.

Registrants of end-use products who do not qualify for the Formulator's Exemption must satisfy labeling, packaging, and data requirements in accordance with this guidance package. Registrants of end-use products who qualify for the Formulator's Exemption must comply with the unique labeling statements identified in Section F.

E. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be covered under this Standard, manufacturing-use products must contain sodium bentazon as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient which may be present in products.

2. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use products containing sodium bentazon, provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products containing sodium bentazon may be labeled for formulation into end-use products only for the commodities listed below. The attached index entry lists all registered uses, as well as approved maximum application rates and frequencies.

-Terrestrial, non-domestic, food uses: beans (dry or succulent), Bohemian chili peppers, corn (field, sweet, or popcorn), grain sorghum, peanuts, peas (dry or succulent), peppermint, soybeans, spearmint.

-Aquatic, non-domestic, food use: rice

-Terrestrial, non-domestic, non-food use: established ornamental turf (bahiagrass, bentgrass, bermudagrass, bluegrass, centipedegrass, fescue, ryegrass, St. Augustinegrass, zoysiagrass)

-Terrestrial, domestic, non-food use: established ornamental turf species listed above.

F. REQUIRED LABELING

All MPs and EPs containing sodium bentazon must bear appropriate labeling as specified in 40 CFR §162.10. The guidance package for this Standard contains information on label requirements. All labeling changes must appear on all products released for shipment by 9/86. All labeling changes must appear on all products in channels of trade by 9/87.

In addition, the following restrictions are required:

1. Manufacturing-Use Products

a) When citing the bentazon equivalent, the chemical name for bentazon should be written as "3-(1-methylethyl)-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2 dioxide".

b) "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the U.S. Environmental Protection Agency."

2. End-Use Products

a) "Do not graze treated corn fields for at least 12 days after the last sodium bentazon treatment."

b) "Do not graze treated peanut fields for at least 50 days after the last sodium bentazon treatment."

c) "Do not rotate crops used for food or feed, which are not registered for use with sodium bentazon, on areas previously treated with this chemical."

d) "Do not use sodium bentazon on rice fields in which the commercial cultivation of catfish or crayfish is practiced."

e) "Do not use water containing bentazon or sodium bentazon residues from rice cultivation to irrigate crops used for food or feed unless sodium bentazon is registered for use on these crops."

f) For all uses except rice: "Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes."

g) For rice use: "Do not contaminate water by cleaning of equipment or disposal of wastes."

h) "Notice: It is a violation of federal laws to use any pesticide in a manner that results in the death of an endangered species or adverse modification of their habitat.

"The use of this product may pose a hazard to certain federally designated endangered species known to occur in specific areas within the CALIFORNIA counties of Merced, Sacramento, and Solano. Before using this product in these counties you must obtain the EPA Endangered Species Bulletin specific for these areas. The bulletin (EPA/ES-85-8) is available from either your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters, or the Regional Office of the U.S. Fish and Wildlife Service (Portland, Oregon). THIS BULLETIN MUST BE REVIEWED PRIOR TO PESTICIDE USE. THE USE OF THIS PRODUCT IS PROHIBITED IN THESE COUNTIES UNLESS SPECIFIED OTHERWISE IN THE BULLETIN."

i) Where bentazon equivalent is cited on the label, the chemical name should be as in 1 (a) above.

TOLERANCES

In the United States, tolerances are currently established in 40 CFR §180.355 for

a) combined residues of bentazon (3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites in or on agricultural commodities as follows:

Commodity	parts per million
Beans (except soybeans), dried	0.05
Beans (exc. soybeans), dried, vine hays	3
Beans (exc. soybeans), forage	3
Beans, lima (succulent)	0.05
Beans, succulent	0.5
Bohemian chili peppers	0.5*
Corn, fodder	3
Corn, forage	3
Corn, grain	0.05
Corn, fresh (incl. sweet K+CWHR)	0.05
Mint	1
Peanuts	0.05
Peanuts, hay	3
Peanuts, hulls	0.3
Peanuts, forage	3
Peas (dried)	0.05
Peas (dried), vine hays	3
Peas, forage	3
Peas, succulent	0.5
Rice	0.05
Rice, straw	3
Sorghum, fodder	0.05
Sorghum, forage	0.20
Sorghum, grain	0.05
Soybeans	0.05
Soybeans, forage	3
Soybeans, hay	0.3

and

b) combined residues of bentazon (3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one-2,2-dioxide) and its metabolite 2-amino-N-isopropyl benzamide in raw agricultural commodities as follows:

Commodity	parts per million
Cattle, fat	0.05
Cattle, mbyp	0.05
Cattle, meat	0.05
Eggs	0.05
Goats, fat	0.05
Goats, mbyp	0.05
Goats, meat	0.05

(cont.)

Commodity	parts per million
Hogs, fat	0.05
Hogs, mbyp	0.05
Hogs, meat	0.05
Milk	0.02
Poultry, fat	0.05
Poultry, mbyp	0.05
Poultry, meat	0.05
Sheep, fat	0.05
Sheep, mbyp	0.05
Sheep, meat	0.05

*The misprinted tolerance of 0.5 ppm for Bohemian chili peppers will be corrected to read 0.05 ppm.

Tolerance reassessment cannot be conducted because of toxicology and residue chemistry data gaps.

International Tolerances

There are 0.1 ppm Canadian tolerances for bentazon on soybeans, beans, peas, corn, rice, and peanuts. Presently, there are no Mexican or Codex Alimentarius tolerances for bentazon.

EPA Compendium of Acceptable Uses

BENTAZON, SODIUM SALT*

TYPE PESTICIDE: Herbicide

FORMULATIONS:
Tech (46%)
FlC (1.66 lb/gal)
SC/L (4 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: A selective herbicide for postemergence control of certain broadleaf weeds and sedges. It is effective mainly through contact action and foliar absorption. Rainfall or overhead irrigation within 8 hours after application may nullify its effectiveness. Apply in 20 to 50 gallons of water per acre at 40 to 80 psi of pressure with ground equipment; the higher rates are for use in dense crop or weed foliage. Use a minimum of 5 gallons of water per acre and a maximum of 40 psi of pressure with aerial applications. Do not use flood, whirl chamber, or controlled droplet applicator (CDA) nozzles. Do not cultivate within 5 days before or after application in the following northern and western states: AZ, CA, CO, CT, ID, IL, IN, IA, KS, KY, ME, MA, MI, MN, MO, MT, NB, NV, NH, NJ, NY, ND, OH, OR, PA, RI, SD, UT, VT, WA, WV, WI, WY. Do not apply to crops that have been subjected to stress conditions such as hail damage, flooding, drought, injury from other herbicides, or widely fluctuating temperatures, as crop injury may result. It may be necessary to irrigate prior to application to ensure active weed growth; weeds growing under drought conditions are usually not satisfactorily controlled.

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Not located.

PHYTOTOXICITY TO CROPS: Some leaf-speckling and leaf-bronzing may occur under certain conditions.

MODE OF ACTION: Inhibition of photosynthesis and particularly, the Hill reaction.

Livestock Tolerances: 0.02 ppm in milk; 0.05 ppm in eggs and in meat, fat and meat byproducts of cattle, goats, hogs, poultry and sheep.

BROADLEAF WEEDS CONTROLLED:

Balloonvine	(a)(c)
Bristly starbur	(a)(c)(d)
Canada thistle	(a)(b)(d)(f)(g)
Coffee senna	(a)(c)
Common cocklebur	(a)(c)(d)(e)(f)(g)
Common groundsel	(b)

*Bentazon
3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide (sodium salt)
Basagran

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BROADLEAF WEEDS CONTROLLED (continued)

PBDAEBA	Common lambsquarters	(a)(b)(d)(f)
PEDADBA	Common purslane	(a)(f)(g)
PBFAEBA	Common ragweed	(a)(b)(c)(d)(f)
PBFBUBA	Common sunflower	(a)(c)(d)(f)(g)
PBGAFBM	Cypressvine morningglory	(a)(c)(d)
PBEABAA	Dayflower	(a)(c)(d)(e)
PBFAOBE	Devils beggarticks	(a)(c)(d)
PBGAFBV	Entireleaf morningglory	(a)(c)(d)
PBGACBB	Field bindweed	(a)(d)(f)
PBFBOAA	Galinsoga	(a)(d)(f)
PBFAEBE	Giant ragweed	(a)(c)(d)(f)(g)
PAUAEBA	Gooseweed	(e)
PEWAIBG	Hairy nightshade	(b)(f)(g)
PBGACBD	Hedge bindweed	(a)(d)(f)
PCQBSBB	Hemp sesbania	(a)
PBGAFBG	Ivyleaf morningglory	(a)(c)
PEWADBD	Jimsonweed	(a)(c)(d)(f)(g)
PBDAIBA	Kochia	(b)
PEAAGBP	Ladysthumb	(a)(b)(d)(f)(g)
PBGAFBS	Palmleaf morningglory	(a)(c)(d)
PEAAGBO	Pennsylvania smartweed	(a)(b)(c)(d)(f)(g)
PBGAFBU	Pitted morningglory	(a)(c)(d)
PDAAJBF	Prickly sida	(a)(c)(d)(f)(g)
PBGAFBT	Purple morningglory	(a)(c)(d)
PCYABBA	Redstem	(e)
PEYABBA	Redweed	(a)(e)
PBFDKAA	Salsify	(b)
PBKAHBA	Sheperdspurse	(a)(f)(g)
PBGAGBB	Smallflower morningglory	(a)(c)(d)
PEAAGAD	Smartweed	(e)
PDAACBA	Spurred anoda	(a)(c)(d)
PBGAFBL	Tall morningglory	(a)(c)(d)
PBVAEBB	Tropic croton	(a)(c)(d)
PDCABBA	Unicorn-plant	(a)(c)(f)
PDAABBB	Velvetleaf	(a)(c)(d)(f)
PDAAEBC	Venice mallow	(a)(d)
PBFDBBF	Western goldenrod	(b)
PEAAGBH	Wild buckwheat	(a)(d)
PBKBKBB	Wild mustard	(a)(b)(d)(f)(g)
PBVAGBU	Wild poinsettia	(a)

(a) in soybeans
(b) in mints
(c) in peanuts
(d) in corn and grain sorghum
(e) in rice
(f) in beans
(g) in peas

BENTAZON, SODIUM SALT

GRASSES AND OTHER MONOCOTS CONTROLLED:

PBMAEBH	Largespiked spikerush	(e)
PBMADBI	Yellow nutsedge	(a)(b)(c)(d)(e)(f)(h)

(a) in soybeans
(b) in mints
(c) in peanuts
(d) in corn and grain sorghum
(e) in rice
(f) in beans
(h) in ornamental turf

AQUATIC WEEDS CONTROLLED:

PAEABBB	Common waterplantain	(e)
PECACBB	Ducksalad	(e)
PBMAGBG	Ricefield bulrush	(i)
PBMAGBF	River bulrush	(i)
PAEADAA	Sagittaria	(e)
PBMADBF	Smallflower umbrella sedge	(i)

(e) in rice
(i) in CA rice

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP	
	(Agricultural Crops)	
15001AA 15002AA 15003AA	**Beans, Dry or Succulent**	0.05 ppm (beans, dry) 0.05 ppm (beans, lima (succulent)) 0.5 ppm (beans, succulent) 3.0 ppm (beans, dry, vinehay) 3.0 ppm (beans, forage) 30 day preharvest interval in succulent beans. Do not apply more than 2 pounds active ingredient per acre in one season. General Information: Do not apply to bean fields until beans have at least the first trifoliate leaf fully expanded because severe crop damage may occur. Tolerant bean types are navy, pinto, pinks, great northern, kidney, red, whites, cranberry, black turtle soup, small limas, large limas, and snap beans.
	0.75-1.0 (4 lb/gal SC/L)	Postemergence. Broadcast. Apply when weeds are small and actively growing. Certain weed problems may require the use of the higher dosage and repeat treatments, or the use of an oil concentrate. The addition of oil may increase crop injury and reduce yields.
	1.0-1.5 (4 lb/gal SC/L)	Use limited to IL, IN, KY, MI, and OH. Postemergence. Broadcast. For suppression of field and hedge bindweed. Apply with an oil concentrate when the bindweed vines are a maximum of 10 inches long.

BENTAZON, SODIUM SALT

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
28005AA	Corn	0.05 ppm (grain) 0.05 ppm (fresh corn (including sweet corn kernel plus cob with husk removed)) 3.0 ppm (fodder and forage) Do not apply more than 2 pounds active ingredient per acre in 1 season. General Information: Corn is tolerant at all stages of growth, but applications generally correspond to the corn growth stages of 1 to 5 leaves. Seed corn producers should consult tolerance of seed production inbred lines to bentazon.
	0.75-1.0 (4 lb/gal SC/L)	Postemergence. Broadcast. Apply when weeds are small and actively growing. Certain weed problems may require the use of the higher dosage and repeat treatments, or the use of an oil concentrate.
	0.50-0.75 (1.66 lb/gal FlC) (4 lb/gal SC/L)	Postemergence. Broadcast. Apply when weeds are small and actively growing. Do not make more than 1 application per season. Oil concentrate must be added to the spray mixture. Formulated with or tank mixed with atrazine.
	1.0-1.5 (4 lb/gal SC/L)	Use limited to all other than the following southern states: AL, AR, FL, GA, LA, MS, NC, OK, SC, TN, TX, VA. Postemergence. For partial control of annual morninglories not larger than 4 true leaves. Apply with an oil concentrate.
	1.0-1.5 (4 lb/gal SC/L)	Use limited to IL, IN, KY, MI, and OH. Postemergence. Broadcast. For suppression of field and hedge bindweed. Apply with an oil concentrate when the bindweed vines are a maximum of 10 inches long.
	1.0-1.5 (4 lb/gal SC/L)	Postemergence. Broadcast. To provide partial control of cocklebur where earlier treatments were either not made or not successful. Use a thorough spray coverage of cocklebur plants up to 24 inches tall. Make a single application as shown, or apply 0.75 pound active ingredient per acre and repeat 10 to 14 days later.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
'28015AA	Peanuts	0.05 ppm (peanuts) 0.3 ppm (hulls) 3.0 ppm (forage and hay) Do not apply more than 2 pounds active ingredient per acre in 1 season. General Information: Peanuts are tolerant at all stages of growth, but applications generally correspond to the peanut growth stages of bunching to pegging.
	0.75-1.0 (4 lb/gal SC/L)	Postemergence. Broadcast. Apply when weeds are small and actively growing. Certain weed problems may require the use of the higher dosage or repeat treatments, or the use of an oil concentrate. May be tank mixed with 4-(2,4-dichlorophenoxy)-butyric acid, dimethylamine salt for postemergence control of morninglories; or with acifluorfen (except in OK and TX).
	1.0-1.5 (4 lb/gal SC/L)	Postemergence. Broadcast. To provide partial control of cocklebur where earlier treatments were either not made or not successful, use a thorough spray coverage of cocklebur plants up to 24 inches tall. Make a single application, or apply 0.75 pound active ingredient per acre and repeat 10 to 14 days later.
'28074AA	Peas (dry or succulent)	0.05 ppm (peas, dry) 0.5 ppm (peas, succulent) 3.0 ppm (peas, dry, vinehay) 3.0 ppm (peas, forage) Do not apply more than 2 pounds active ingredient per acre in 1 season. General Information: Peas are tolerant to bentazon after 3 pairs or leaves (or 4 nodes) are present. Tolerant pea types are garden peas and southern peas. Do not use on blackeyes grown in CA or to garbanzo beans at any stage of growth, as severe crop damage will occur. Do not add oil to any bentazon application to peas.
	0.75-1.0 (4 lb/gal SC/L)	Postemergence. Broadcast. Apply when weeds are small and actively growing. Certain weed problems may require the use of the higher dosage and repeat treatments.

BENTAZON, SODIUM SALT

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/28012AA	Peppermint Spearmint	1 ppm (mint) Do not apply more than 4 pounds active ingredient per acre in 1 season.
	1.0-2.0 (4 lb/gal SC/L)	Broadcast to established crops when weeds are small and actively growing. Certain weed problems may require the use of the higher dosage and repeat treatments, or the use of an oil concentrate.
/28072AA	Rice	0.05 ppm (rice) 3.0 ppm (straw) Do not apply more than 3 pounds active ingredient per acre in 1 season (maximum of 2 pounds active ingredient per acre in first crop and 1 pound active ingredient per acre in second ratoon crop). General Information: Do not apply with ground equipment when field is flooded because splashing will wash the chemical off weed leaf surfaces and minimize control. When making aerial applications, orient all nozzles straight down. Bentazon may be used on the first and second (ratoon) crop.
	0.75-1.0 (4 lb/gal SC/L)	Early postemergence. Broadcast. In an alternate flooding culture, apply when there is not water on the field and at least 24 hours prior to flooding. The weed growth stages at this time generally correspond to rice that is tillering (stooling). In a continuous flooding culture or when treating after permanent flood, apply when weeds are above the surface of the water. For early treatment, water may be partly or completely drained to expose more weed growth. Do not raise water level for at least 24 hours after application. In CA add nonphytotoxic oil (containing emulsifier) to the spray mixture.
	0.75 (4 lb/gal SC/L)	Postemergence. Tank mix with 3',4'dichloropropionanilide for control of mixed populations of grasses and broadleaf weeds. Apply by ground or air to drained fields only. Do not apply on the second (ratoon) crop.

BENTAZON, SODIUM SALT

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
'28019AA	Sorghum, Grain	0.05 ppm (grain, fodder) 0.2 ppm (forage) Do not apply more than 1 pound active ingredient per acre in 1 season. Do not apply to grain sorghum that is heading or blooming. General Information: Grain sorghum is tolerant at all stages of growth up to and including early boot stage, but applications generally correspond to the crop growth stages of 1 to 5 leaves.
	0.75-1.0 (4 lb/gal SC/L)	Postemergence. Broadcast. Apply when weeds are small and actively growing. Certain weed problems may require the use of the higher dosage or the addition of an oil concentrate.
	0.5-0.75 (4 lb/gal SC/L)	Postemergence. Broadcast. Apply when weeds are small and actively growing. Do not make more than 1 application per season. An oil concentrate must be added to the spray mixture. Tank mix with atrazine.
'28023AA	Soybeans	0.05 ppm (soybeans) 0.3 ppm (hay) 3.0 ppm (forage) Do not apply more than 2 pounds active ingredient per acre in 1 season. General Information: Soybeans are tolerant to bentazon at all stages of growth, but applications generally correspond to the growth stages of unifoliate to 2 expanded trifoliate leaves. May be tank mixed with, or applied sequentially to sethoxydim; or acifluorfen, or sethoxydim and acifluorfen. The determination of tank mix or sequential application should be made by the stage of the weeds being controlled by each chemical.
	0.75-1.0 (4 lb/gal SC/L)	Postemergence. Broadcast. Apply when weeds are small and actively growing. Certain weed problems may require the use of the higher dosage and repeat treatments, or the use of an oil concentrate.
	1.0-1.5 (4 lb/gal SC/L)	Use limited to all other than the following southern states: AL, AR, FL, GA, LA, MS, NC, OK, SC, TN, TX, VA. Postemergence. For partial control of annual morningglories not larger than 4 true leaves. Apply with an oil concentrate.

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Soybeans (continued)	
1.0-1.5 (4 lb/gal SC/L)	Use limited to IL, IN, KY, MI, and OH. Postemergence. Broadcast. For suppression of field and hedge bindweed. Apply with an oil concentrate when the bindweed vines are a maximum of 10 inches long.
1.0-1.5 (4 lb/gal SC/L)	Postemergence. Broadcast. To provide partial control of cocklebur where earlier treatments were either not made or not successful, use a thorough spray coverage of cocklebur plants up to 24 inches tall. Make a single application, or apply 0.75 pound active ingredient per acre and repeat 10 to 14 days later.
0.75-1.0 (4 lb/gal SC/L)	Postemergence. Broadcast. Tank mix with 4-(2,4-dichlorophenoxy)butyric acid, dimethylamine salt for postemergence control of morninglories. Apply when weeds are actively growing and before annual morninglory vines are a maximum of 6 inches long in the south (AL, AR, FL, GA, LA, MS, NC, OK, SC, TN, TX, VA) and a maximum of 10 inches long in all other states. Do not add oil to the tank mix. Do not make more than 1 application of the tank mix per season.
Spearmint	See Peppermint cluster.
TERRESTRIAL NON-FOOD CROP	
(Ornamental Plants and Forest Trees)	
'33015AA Bahiagrass	
'33016AA Bentgrass	
'33017AA Bermudagrass	
'33019AA Bluegrass	
'33023AA Centipedegrass	
'33031AA Fescue	
'33049AA Ryegrass	
'33050AA St. Augustinegrass	
'33056AA Zoysia Grass	
1.0-2.0 (4 lb/gal SC/L)	Broadcast. Yellow nutsedge control. Apply to established turf when yellow nutsedge is actively growing under good soil moisture conditions. If desired control is not obtained with the first application, make additional applications at inter-

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Bahiagrass cluster (continued)	
	vals of 10 to 14 days. Do not apply more than 3 pounds active ingredient per acre in any 1 season. Plan the initial application for when most yellow nutsedge has emerged. In unmowed turf, make first application after yellow nutsedge emergence but before it is 8 inches tall. Do not mow 3 to 5 days before or after application. Do not apply to golf course greens or collars. Avoid over-the-top spraying of adjacent ornamentals. Spraying near the base of established ornamentals should not result in injury.

AERIAL AND TANK MIX APPLICATIONS

9001500 AAAAAAA	Aerial Application	
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) All Sites
9900300 AAAAAAA	Tank Mix	
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Corn, Peanuts, Rice, Sorghum, Soybeans

BENTAZON, SODIUM SALT

Listing of Registered Pesticide Products by Formulation

046.0001 46% technical chemical
bentazon, sodium salt (103901)
007969-00042

101.6614 1.66 lb/gal flowable concentrate
bentazon, sodium salt (103901) plus atrazine (080803)
007969-00054

104.0015 4 lb/gal soluble concentrate/liquid
bentazon, sodium salt (103901)
007969-00045

Appendix A

Listing of Common Chemical Names Used on the Entry

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
121001	sethoxydim (ISO)	2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)-propyl]-3-hydroxy-2-cyclohexen-1-one

Listing by Site/Pest and Site/Formulation/Registration Number

BROADLEAF WEEDS CONTROLLED:

?EQABBA	Balloonvine
?BFABBB	Bristly starbur
?BFAWBB	Canada thistle
?CQAMBG	Coffee senna
?BFDQBD	Common cocklebur
?BFCXBK	Common groundsel
?BDAEBA	Common lambsquarters
?EDADBA	Common purslane
?BFAEBA	Common ragweed
?BFBUBA	Common sunflower
?BGAFBM	Cypressvine morningglory
?BEABAA	Dayflower
?BFAOBE	Devils beggarticks
?BGAFBV	Entireleaf morningglory
?BGACBB	Field bindweed
?BFBOAA	Galinsoga
?BFAEBE	Giant ragweed
?AUAEBA	Gooseweed
?EWAIBG	Hairy nightshade
?BGACBD	Hedge bindweed
?CQBSBB	Hemp sesbania
?BGAFBG	Ivyleaf morninglory
?EWADBD	Jimsonweed
?BDAIBA	Kochia
?EAAGBP	Ladysthumb
?BGAFBS	Palmleaf morningglory
?EAAGBO	Pennsylvania smartweed
?BGAFBU	Pitted morningglory
?DAAJBF	Prickly sida
?BGAFBT	Purple morningglory
?CYABBA	Redstem
?EYABBA	Redweed
?BFDKAA	Salsify
?BKAHBA	Sheperdspurse
?BGAGBB	Smallflower morningglory
?EAAGAD	Smartweed
?DAACBA	Spurred anoda
?BGAFBL	Tall morningglory
?BVAEBB	Tropic croton
?DCABBA	Unicorn-plant
?DAABBB	Velvetleaf
?DAAEBC	Venice mallow
?BFDBBF	Western goldenrod
?EAAGBH	Wild buckwheat
?BKBKBB	Wild mustard
?BVAGBU	Wild poinsettia

Listing by Site/Pest and Site/Formulation/Registration Number (continued)

GRASSES AND OTHER MONOCOTS CONTROLLED:

?BMAEBH Largespiked spikerush
?BMADBI Yellow nutsedge

AQUATIC WEEDS CONTROLLED:

?AEABBB Common waterplantain
?ECACBB Ducksalad
?BMAGBG Ricefield bulrush
?BMAGBF River bulrush
?AEADAA Sagittaria
?BMADBF Smallflower umbrella sedge

TERRESTRIAL FOOD CROP

(Agricultural Crops)

/15001AA Beans, Dry or Succulent
/15002AA
/15003AA

Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

/28005AA Corn
Pest (see lists above)
(1.66 lb/gal FlC)
007969-00054

(4 lb/gal SC/L)
007969-00045

/28015AA Peanuts
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

/28074AA Peas (dry or succulent)
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

Listing by Site/Pest and Site/Formulation/Registration Number (continued)

/28012AA Peppermint
Spearmint
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

/28072AA Rice
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

/28019AA Sorghum, Grain
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

/28023AA Soybeans
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

TERRESTRIAL NON-FOOD CROP

(Ornamental Plants and Forest Trees)

/33015AA Bahiagrass
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

/33016AA Bentgrass
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

/33017AA Bermudagrass
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

/33019AA Bluegrass
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

Listing by Site/Pest and Site/Formulation/Registration Number (continued)

33023AA Centipedegrass
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

33031AA Fescue
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

33049AA Ryegrass
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

33050AA St. Augustinegrass
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

33056AA Zoysia Grass
Pest (see lists above)
(4 lb/gal SC/L)
007969-00045

REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B). The tables following this section list the data required for maintaining the registrability of each product.

EPA has determined that additional generic data described in Table A must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data[1/] Must be Submitted. You may determine which generic data you must submit by consulting Table A at the end of this chapter. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines [2/] or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you do not wish to develop data in support of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

For certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient, regardless of the product's unique composition or specific use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: "Typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

OR

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

OR

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager.

(Footnote continued from previous page)
In EPA's opinion, joint data development by all registrants subject to a data requirement or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it should encourage joint testing rather than duplicative testing, and that suspension should be withheld in certain cases. to further this goal. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

The extension request should state the reasons why you believe that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry						
Product Identity:						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	R	[X]	[ ]	2	6 months
61-3 - Discussion of Formation of Impurities	TGAI	R	[X]	[ ]	2	6 months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	CR	[X]	[ ]	2	12 months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	R	[ ]	[X]		
63-3 - Physical State	TGAI	R	[ ]	[X]		
63-4 - Odor	TGAI	R	[ ]	[X]		
63-5 - Melting Point	TGAI	R	[ ]	[X]		
63-6 - Boiling Point	TGAI	R	[ ]	[X]		

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	[X]	[ ]		6 months
63-8 - Solubility	TGAI or PAI	R	[ ]	[X]		
63-9 - Vapor Pressure	PAI	R	[ ]	[X]		
63-10 - Dissociation constant	PAI	R	[X]	[ ]		6 months
63-11 - Octanol/water partition coefficient	PAI	R	[X]	[ ]		6 months
63-12 - pH	TGAI	R	[X]	[ ]		6 months
63-13 - Stability	TGAI	R	[ ]	[X]		
Other Requirements:						
64- 1 - Submittal of samples 3/	TGAI, PAI	CR	[ ]	[ ]		

TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient; R = Required; CR = Conditionally Required

1/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
° 6 Month Due Date is 27 MAR 1986.

2/ Update as per current product chemistry guidelines (Subdivision D).

3/ The Agency will request samples if/when needed. If requested, the time permitted for submittal will be 6 months.

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frames For Data Submission 2/
§158.125 Residue Chemistry					
171-2 - Chemical Identity	TGAI	partially		yes 3/	6 months
171-3 - Directions for Use	--	partially		yes 4/	6 months
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	partially	00040517, 00051652, 00039657, 00051653, 00106221, 00051655, 00106230, 00040516, 00108281, 00039852, 00052052, 00052050, 00039282, 00051656, 00040518, 00039285, 00039284, 00039283, 00039656, 00039668, 00039666, 00039671, 00039661, 00039660, 00039664, 00039670, 00039672, 00039280, 00039669, 00051654, 00039665, 00039281, 00039667, 00040519, 00039659, 00040184, 00039852, 00039278, 00040188, 00084714, 00039279, 00052055, 00084715	yes 5,6/	18 months
- Animals	PAIRA and Plant Metabolites	partially	Cows 00039850, 00044781, 00039851, 00040110, 00039848, 00039849,	yes 7,8/	18 months

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission 2/
§158.125 Residue Chemistry - Continued				
			Goats	
			00039853, 00039854, 00039848, 00040111,	
			Poultry	
			00039856, 00044782, 00039848, 00039855, 00039857,	
			Swine	
			00137904	
			Laboratory Animals	
			Rat	
			00051652, 00039848, 00039853, 00040111, 00063615	
			Rabbit	
			00039861, 00039860	
			Mice	
			00039862	

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames for Data Submission 2/
§158.125 Residue Chemistry - Continued				
171-4 - Residue Analytical Method				
- Plant residues	TGAI and Metabolites	yes	(plant and animal) 00051657, 00106263, 00023509, 00040521, 00039851, 00044782, 00039658, 00040522, 00040185, 00040517, 00040186, 00040187, 00040785	reserved 9/
- Animal residues	TGAI and Metabolites	partially	incl. above	yes 9,10/ 15 months
171-4 - Storage stability		yes	00039290, 00040189 00040193	reserved 9/
171-4 - Magnitude of the Residue- Residue Studies for Each Food Use				
- Crop Group #1 - Legume Vegetables (Succulent or Dried)				
o Soybeans				
-- Crop field trials	TEP	yes	(crop and processed) 00106228, 00040172, 00040182, 00040177, 00040181, 00040176, 00079082, 00040180, 00040174, 00051658, 00031796, 00040183, 00106263, 00040178, 00023507, 00040179, 00040173, 00040186, 00040184	reserved 9/
-- Processed Food/Feed	EP	yes		reserved 9/

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames for Data Submission 2/
§158.125 Residue Chemistry - Continued				
o Beans, succulent and dried				
Beans, succulent (except lima beans)				
-- Crop Field Trials	TEP	yes	00106243, 00106263, 00023507, 00026208,	reserved 9/
-- Processed Food/Feed	EP	no		yes 9,11/ 24 months
Beans, dried				
-- Crop Field Trials	TEP	yes	00106243, 00106263, 00040520, 00023507,	reserved 9/
Beans, lima				
-- Crop Field Trials	TEP	yes	00106231, 00023507, 00106263, 00051911, 00040520	reserved 9/
o Peas, succulent and dried				
Peas, succulent				
-- Crop Field Trials	TEP	yes	00106263, 00051912, 00040521, 00023507, 00040520, 00106243	reserved 9/
Peas, dried				
-- Crop Field Trials	TEP	partially	00051912	yes 9,12/ 18 months

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TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Submission 2/
§158.125--Residue Chemistry, cont.				
Crop Group #2--Foliage of Legume Vegetable Group				
o Soybean forage				
-- Crop Field Trials	TEP	partially	00040183, 00040176, 00079082, 00051658, 00106227,	yes 9,13/ 18 months
o Soybean hay				
-- Crop Field Trials	TEP	yes	00079082, 00040183, 00031796, 00051658, 00106236, 00106228,	reserved 9/
o Bean forage and hay				
-- Crop Field Trials	TEP	yes	00051911, 00106236, 00106231, 00106243, 00040521, 00051912,	reserved 9/
o Pea Forage and Vine Hay				
-- Crop Field Trials	TEP	yes	00106243, 00051912,	reserved 9/
Crop Group #3--Fruiting Vegetable Group (except cucurbits)				
o Bohemian chili peppers				
-- Crop Field Trials	TEP	yes	00106245	reserved 9/

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Fr Submission 2/
§158.125 Residue Chemistry - Continued				
Crop Group #4--Cereal Grains Group				
o Corn, grain				
-- Crop Field Trials	TEP	yes	(crop and processing) 00023507, 00106252 00023508, 00106254 00106263, 00106251 00023511, 00108303	9/ reserved
-- Processed Food/Feed	EP	yes		reserved
o Corn, fresh (incl. sweet corn)				
-- Crop Field Trials	TEP	yes	00023511, 00106238 00106253, 00040171	9/ reserved
-- Processed Food/Feed	EP	no		9/ reserved
o Rice, grain				
-- Crop Field Trials	TEP	yes	(crop and processing) 00106238, 00040831, 00040829, 00040820, 00040822, 00040819, 00040833, 00052053, 00040824, 00040834, 00040828, 00040823, 00040832, 00040830, 00040825, 00040821, 00084711, 00040824,	9/ reserved
-- Processed Food/Feed	EP	yes	incl. above	9/ reserved
o Sorghum, grain				
-- Crop Field Trials	TEP	yes	00126689	9/ reserved
-- Processed Food/Feed	EP	no		9/ reserved

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(b)? Time Frame for Submission 2/
§158.125 Residue Chemistry, cont.				
Crop Group #5--Forage, Fodder, and Straw of Cereal Grains Group				
o Corn forage and fodder				
-- Crop Field Trials	TEP	yes	00106254, 00106252 00106253, 00106251, 00040171, 00106238, 00108303, 00023511, 00106263	reserved 9/
o Rice straw				
-- Crop Field Trials	TEP	yes	00040833, 00040825, 00106238, 00040821, 00040834, 00040822, 00052053, 00040820, 00040823, 00040831, 00040827, 00040832, 00040829, 00040829	reserved 9/
o Sorghum fodder and forage				
-- Crop Field Trials	TEP	yes	00126689	reserved 9/
Miscellaneous Crops Not Included in Any Crop Grouping				
o Peanuts (kernels)				
-- Crop Field Trials	TEP	yes	(crop and processing) 00106263, 00023507, 00106237, 00023511,	reserved 9/
-- Processed Food/Feed	EP	yes	incl. above	reserved 9/

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(b)? Time Frame for Submission 2/
§158.125 Residue Chemistry, cont.				
o Peanut hulls				
-- Crop Field Trials	TEP	yes	00023511, 00106237	reserved 9/
o Peanut forage and hay				
-- Crop Field Trials	TEP	yes	00106237, 00023511	reserved 9/
o Mint				
-- Crop Field Trials	TEP	yes	(crop and processing) 00023511, 00106241, 00106263, 00023507	reserved 9/
-- Processed Food/Feed	EP	yes		reserved 9/
Magnitude of Residue in Meat, Milk Poultry, Eggs	TGAI or Plant Metabolites	yes	00108303, 00039849, 00039856, 00039855, 00039844, 00137904	reserved 14/
Food Handling	EP	N/A 18/		no
171-5 - Reduction of Residue	Residue of Concern			yes 19/ 9 months
171-6 - Proposed Tolerance 20/	Residue of Concern	yes	see 171-4	reserved 21/
171-7 - Reasonable Grounds in Support of Petition	--			
171-13 - Submittal of Analytical Reference Standards 22	PAIRA			

TABLE A

11 . GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(b)? Time Frame for Submission 2/

§158.125 Residue Chemistry, cont.

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
- 6 Month Due Date is 27 MAR 1986.
- 15 Month Due Date is 27 DEC 1986.
- 18 Month Due Date is 27 MAR 1987.
- 24 Month Due Date is 27 SEP 1987.

3/ See Product Chemistry Table (61-2 and 62-3).

4/ A restriction against grazing is required for at least 12 days after the last treatment of corn forage/fodder. A 50-day grazing restriction is required for peanut forage and hay.

5/ The residues in plants, not extractable with MeOH and composing 50-67% of total, should be better characterized.

6/ The 6-hydroxy and the 8-hydroxy metabolites are residues of toxicological concern and are to be included with bentazon in the tolerances on crops.

7/ The metabolism in animals is not understood as the acid hydrolysis procedure was not run on any of the methanol extracts of eggs and poultry tissues. This is a data gap and must be corrected.

8/ Tolerance for residues in animal products must be expressed in terms of combined residues of AIBA plus bentazon. There are no residues of the 6- and 8-hydroxy metabolites in animals which would require representation in the tolerances for animal products.

9/ In light of the need for additional metabolism data noted above, it is possible that additional residue studies for new metabolites of concern will be required. If needed, these studies should reflect representative growing regions, the maximum registered use, sample chromatographs, and methodology which determines the terminal residue of concern. If the residue samples are stored for a long period of time, storage stability studies for parent and metabolites of concern will be needed. If detectable residues of bentazon or metabolites of toxicological concern occur in grain, a milling study will be needed to show the distribution of these residues in the milled fractions. These are potential data gaps.

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

§158.125 Residue Chemistry, cont.

10/ The recoveries of bentazon from milk at fortifications of 0.05 and 0.1 ppm are not acceptable and must be improved.

11/ Data on residues in cannery waste are required.

12/ Testing is required in Idaho and Washington.

13/ Testing is required in Tennessee and Missouri.

14/ Methods and quantitative analyses will be needed if residues of toxicological concern are identified from requested metabolism studies.

18/ Sodium bentazon is not labeled for use in food/feed handling establishments or other indoor sites where food/feed could be contaminated.

19/ Reduction of residue data are required when the assumption of tolerance level residues would result in predicted exposure at an unsafe level. Data on the level of residue in food as consumed will be used to obtain a more precise estimate of potential dietary exposure. The Agency recommends that such data be generated to support all pesticides requiring a tolerance in case new data are revealed which indicate that the pesticide is more toxic than initially determined — 40 CFR §158.125(b)(11).

20/ Includes filing fee.

21/ Changes may be required, depending on the outcome of requested studies.

22/ The Agency will request analytical reference standards if/when needed.

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	ABC	no		yes	9 months
Photodegradation						
161-2 - In water	TGAI or PAIRA	ABC	no		yes	9 months
161-3 - On soil	TGAI or PAIRA	A	no		yes	9 months
161-4 - In Air	TGAI or PAIRA	N/A			no 4/	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	AB	partial	00040204, 00040208 00051659	yes 5	27 months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	yes	00040204, 00040208	no	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C	no		yes	27 months
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	no		yes	27 months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	ABC	partial	00041081	yes 6/	12 months
163-2 - Volatility (Lab)	TEP	N/A			no 4/	
163-3 - Volatility (Field)	TEP	N/A			no 4/	

TABLE A
.GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES--FIELD:						
164-1 - Soil	TEP	AB	no		yes[7/]	27 months
164-2 - Aquatic (Sediment)	TEP	C	no		yes	27 months
164-3 - Forestry	TEP	N/A				
164-4 - Combination and Tank Mixes		N/A			no[8/]	
164-5 - Soil, Long-term	TEP	A			no[9/]	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	no		yes[10/]	30 months
165-2 - Rotational Crops (Field)	TEP	A	no		yes[10/]	39 months
165-3 - Irrigated Crops	TEP	C	no		yes[11/]	30 months
165-4 - In Fish	TGAI or PAIRA	ABC	partial	00108300 12/	yes[12/]	12 months
165-5 - In Aquatic Non-Target Organisms	TEP	N/A				

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

§158.130 Environmental Fate, cont.

3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
- 9 Month Due Date is 27 JUN 1986.
- 12 Month Due Date is 27 SEP 1986.
- 27 Month Due Date is 27 DEC 1987.
- 30 Month Due Date is 27 MAR 1988.
- 39 Month Due Date is 27 DEC 1988.

4/ Data are not required due to the relatively low vapor pressure of bentazon.

5/ Additional work should be done to chemically identify, if feasible, other soil metabolites that may have formed.

6/ Data on leaching of unaged bentazon in sandy clay loam and loamy sand soils are acceptable. The following additional data are required: (1) leaching studies on parent compound and degradation products for two more soil types; (2) data on the leaching of degradation products for the two soil types already accepted for column leaching; and (3) adsorption/desorption studies on sediment.

7/ The following studies would be acceptable if data are submitted to indicate that the test material used was a typical end-use product: MRID 00108287, 00108288, 00044405, 00044400, 00044390, 00106226, 00044404, 00044401, 00044402, 00108296.

8/ Data requirements for combination products and tank mixes are not addressed in this standard.

9/ Data are not required since results of valid aerobic soil metabolism and terrestrial field dissipation studies indicate that 50% of residues dissipate prior to recommended subsequent application.

10/ For crops rotated on treated areas, any one of the following will apply:

(a) A tolerance must be obtained for the rotated crop.

(b) The product label must include a restriction against the rotation of crops used for food or feed which are not registered for use with sodium bentazon.

(c) Data must be provided to determine time intervals at which rotated crops planted on treated areas will be free of pesticide residues.

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

§158.130 Environmental Fate, cont.

11/ For sodium bentazon use on rice, any one of the following will apply:

(a) A tolerance must be obtained for any crop used for food or feed that is exposed to irrigation water containing bentazon or sodium bentazon residues.

(b) The product label must include a restriction against the use of irrigation water containing bentazon or sodium bentazon residues on crops grown for food or feed.

(c) Data must be provided to demonstrate conditions under which rice irrigation water can be used on other crops without resulting in illegal plant residues.

12/ Data on residue accumulation in fish are required; a study on catfish is preferred. The chemical name and structure of the bentazon residue "NISAA" mentioned in the crawfish uptake study (MRID 00108300) is needed.

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,C	yes	00064314	no	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B,C	yes	00041088	no	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A,B,C	no		yes	9 months
81-7 - Delayed Neurotoxicity - Hen	TGAI	N/A[4]	no		no	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding :	TGAI					
- Rodent, and		A,B,C	no		yes	15 months
- Non-rodent (Dog)		A,B,C	no		yes	18 months
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B,C	no		yes	12 months
82-3 - 90-Day Dermal - Rabbit	TGAI	N/A[5]			no	
82-4 - 90-Day Inhalation:	TGAI					
- Rat		N/A[5]			no	
82-5 - 90-Day Neurotoxicity:	TGAI					
- Hen		N/A[6]			no	
-Mammal		N/A[6]			no	

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.135 Toxicology - Continued						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species:	TGAI					
- Rodent, and		A,B,C	no		yes	50 months
- Non-rodent (Dog)		A,B,C	no		yes 7/	50 months
83-2 - Oncogenicity - 2 species:	TGAI					
- Rat (preferred), and		A,B,C	no		yes	50 months
- Mouse (preferred)		A,B,C	no		yes	50 months
83-3 - Teratogenicity - 2 species:	TGAI					
- Rat		A,B,C	no		yes	15 months
- Rabbit		A,B,C	no		yes	15 months
83-4 - Reproduction - Rat 2-generation	TGAI	A,B,C	no		yes	39 months
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B,C	no		yes	9 months
84-2 - Structural Chromosomal Aberration	TGAI	A,B,C	no		yes	12 months
84-2 - Other Genotoxic Effects	TGAI	A,B,C	no		yes	12 months
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,B,C	no		yes 8/ 9/	24 months

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.135 Toxicology - Continued					
86-1 - Domestic Animal Safety	Choice	N/A 10/			no

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
- 9 Month Due Date is 27 JUN 1986.
- 12 Month Due Date is 27 SEP 1986.
- 15 Month Due Date is 27 DEC 1986.
- 18 Month Due Date is 27 MAR 1987.
- 24 Month Due Date is 27 SEP 1987.
- 39 Month Due Date is 27 DEC 1988.
- 50 Month Due Date is 27 NOV 1989.

4/ Bentazon is neither an organophosphate, nor an analog of a neurotoxic compound, hence no delayed neurotoxicity study is required.

5/ This study is not applicable to exposure conditions.

6/ This study is not applicable to exposure conditions. See footnote #4 above.

7/ A one-year dog study is required.

8/ Metabolism testing using sodium bentazon is also required to determine whether there is any difference from bentazon.

9/ Although the Agency does not have a chronic data base, there is indication of possible teratogenicity, for example. It is important to examine dermal absorption at this time to better understand potential exposure. This will enable the Agency to determine whether adequate margins of safety exist, should adverse effects be seen in required studies.

10/ There is no evidence of high acute or subacute toxicity.

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	N/A			no
132-1 - Soil Dissipation	TEP	N/A			no
133-3 - Dermal Exposure	TEP	N/A			no
133-4 - Inhalation Exposure	TEP	N/A			no
§158.142 Spray Drift					
201-1 - Droplet Size Spectrum	TEP	N/A			no
201-1 - Drift Field Evaluation	TEP	N/A			no

1/ Composition: TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,C	partially	00041804, 00041077	yes 4/ 9 months
71-2 - Avian Subacute Dietary Toxicity	TGAI				
- Upland Game Bird, and		A,B,C	partially	00108851	yes 4/ 9 months
- Waterfowl		A,B,C	partially	00108850	yes 4/ 9 months
71-3 - Wild Mammal Toxicity	TGAI		no		no
71-4 - Avian Reproduction	TGAI				
- Upland Game Bird, and		A,B,C	partially	00083345	yes 4,6/ 9 months
- Waterfowl		A,B,C	partially	00124702	yes 4,6/ 9 months
71-5 - Simulated or Actual Field Testing	TEP				
- Mammals, and		A,B,C	no		no
- Birds		A,B,C	no		no
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish Toxicity					
- Coldwater Fish Species	TGAI	A,B,C	partially	00041075	yes 4/ 9 months
	TEP	C	partially	00041076	yes 4/ 9 months

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms - Continued					
and - Warmwater Fish Species	TGAI	A,B,C	partially	00041075	yes 4/ 9 months
	TEP	C	partially	00041076	yes 4/ 9 months
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,C	partially	00106240	yes 4/ 9 months
	TEP	C	no		yes 9 months
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI				
- Fish		A,B,C	no		no
- Mollusk		A,B,C	no		yes 5/ 12 months
- Shrimp		A,B,C	no		no
72-4 - Fish Early Life Stage, and	TGAI	A,B,C	no		reserved 6/
- Aquatic Invertebrate Life-Cycle	TGAI	A,B,C	no		reserved 6/
72-5 - Fish - Life-Cycle	TGAI	A,B,C	no		reserved 6/
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product				
- Crustacean			no		no
- Fish		A,B,C	no		yes 7/
- Insect Nymph		A,B,C	no		no
- Mollusk		A,B,C	no		no

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms - Continued					
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	A,B,C	no		reserved 6/
- Actual Field Testing -Aquatic Organisms	TEP	A,B,C	no		reserved 6/

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
- 9 Month Due Date is 27 JUN 1986.
- 12 Month Due Date is 27 SEP 1986.

4/ The composition of the test material, including percent active ingredient, must be clarified/verified.

5/ An oyster study is required regarding the rice use (aquatic) and the turf, corn, and soybean uses (since there are greater than 300,000 acres of each of these in coastal counties). This study is also needed to evaluate the potential for hazard to endangered mussel species. Fish and shrimp studies are not required at this time due to the low toxicity seen in other aquatic studies.

6/ This study is not required for hazard assessment at the present time. Following Agency review of product and environmental chemistry data requested in this Registration Standard, reevaluation of ecological effects data requirements will be made.

7/ See requirement in table under §158.130.

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP		3/		
NONTARGET AREA PHYTOTOXICITY TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI	A	3/		
122-1 - Vegetative Vigor	TGAI	A	3/		
122-2 - Aquatic Plant Growth	TGAI	A	3/		
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI		3/		
123-1 - Vegetative Vigor	TGAI		3/		
123-2 - Aquatic Plant Growth	TGAI		3/		
TIER III					
124-1 - Terrestrial Field	TEP		3/		
124-2 - Aquatic Field	TEP		3/		

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ These data are not required at this time, in accordance with §158.150.

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact toxicity	TGAI	A,B,C	no		yes	9 months
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B,C	no		no	
141-4 - Honey bee subacute feeding study	(Reserved)					
141-5 - Field testing for pollinators	TEP					
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects	(Reserved)					
142-1 - Aquatic insect life-cycle study	(Reserved)					
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)					

TABLE A
GENERIC DATA REQUIREMENTS FOR BENTAZON/SODIUM BENTAZON

§158.155 Nontarget Insect - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
° 9 Month Due Date is 27 JUN 1986.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: Unless stated otherwise in Section I, Regulatory Position and Rationale, this Section applies only to manufacturing use products, not to end use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill gaps identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

Table B--Product-Specific Data Requirements for Manufacturing Use Products--lists the product specific data you must submit. Data that are required to be submitted are identified in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING SODIUM BENTAZON

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	R	[X]	[ ]	2	6 months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	R	[X]	[ ]	3	6 months
61-3 - Discussion of Formation of Impurities	MP	R	[X]	[ ]	3	6 months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	CR	[X]	[ ]	3	12 months
62-2 - Certification of Limits	MP	R	[X]	[ ]	3	12 months
62-3 - Analytical Methods to Verify Certified Limit	MP	R	[X]	[ ]	3	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	R	[ ]	[X]		
63-3 - Physical State	MP	R	[ ]	[X]		
63-4 - Odor	MP	R	[ ]	[X]		

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING SODIUM BENTAZON

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Cont.)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	[X]	[ ]	3	6 months
63-12 - pH	MP	CR	[X]	[ ]	3	6 months
63-14 - Oxidizing or Reducing Action	MP	CR	[X]	[ ]	3	6 months
63-15 - Flammability	MP	CR	[ ]	[X]		
63-16 - Explodability	MP	R	[X]	[ ]	3	6 months
63-17 - Storage Stability	MP	R	[ ]	[X]		
63-18 - Viscosity	MP	CR	[ ]	[X]		
63-19 - Miscibility	MP	CR	[ ]	[X]		
63-20 - Corrosion Characteristics	MP	R	[X]	[ ]	3	15 months
Other Requirements:						
64- 1 - Submittal of samples 4/	MP	CR	[ ]	[ ]		

MP = Manufacturing-use Product; R = Required; CR = Conditionally Required

1/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
- 6 Month Due Date is 27 MAR 1986.
- 12 Month Due Date is 27 SEP 1986.
- 15 Month Due Date is 27 DEC 1986.

2/ An updated statement of composition is needed from BASF Wyandotte Corporation.

3/ Update as per current Product Chemistry guidelines (Subdivision D).

4/ The Agency will request samples if/when needed. If requested, the time permitted for submittal will be 6 months.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING SODIUM BENTAZON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 2/
§158.135 Toxicology					
ACUTE TESTING					
81-1 - Acute Oral Toxicity - Rat	MP	yes	00064314	no	
81-2 - Acute Dermal Toxicity - Rabbit	MP	yes	00041088	no	
81-3 - Acute Inhalation Toxicity - Rat	MP	no		yes	9 months
81-4 - Primary Eye Irritation - Rabbit	MP	3/		3/	
81-5 - Primary Dermal Irritation - Rabbit	MP	3/		3/	
81-6 - Dermal Sensitization - Guinea Pig	MP	no		yes	9 months

1/ Composition: MP = Manufacturing-use product.

2/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.

° 9 Month Due Date is 27 JUN 1986.

3/ No additional data is required at this time using MP. Available studies in these categories have not been re-reviewed for this Registration Standard.

IV. SUBMISSION OF REVISED LABELING

Note: This section applies to all products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling information complying with this section (supplemented by requirements described in Section I, Regulatory Position and Rationale), EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section I indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. Front panel statement of restricted use classification.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B [There is no Item 9B].

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B [There is no Item 10B].

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4, IV-5, and IV-6 to determine the storage and disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

A. For Manufacturing Products (MP) containing (name of pesticide) as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division at the address given at the end of this section the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit to the Product Manager on the Registration Division:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data (See Tables B).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten

text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 for latest requirements.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

B. For Manufacturing Use Products containing (name of pesticide) in combination with other active ingredients

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

C. For End Use Products containing (name of pesticide) alone or in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product-Specific Data Report, EPA Form 8580-4 (Appendix III-1), if applicable (if Table C lists required product-specific data).

c. Two copies of any required product-specific data, if applicable (if Table C lists required product-specific data).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. Labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8 1/2 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, submit all generic data, unless you are eligible for the formulator's exemption.

D. For intrastate products containing (name of pesticide) either as the sole active ingredient or in combination with other active ingredients

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

Applications and other required information should be submitted to the following address:

Robert Taylor, Product Manager (25)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460
Phone No. (703) 557-1800

The address for submission to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460

Guide to Use of This Bibliography

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

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

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

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

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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