United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington, DC 20460

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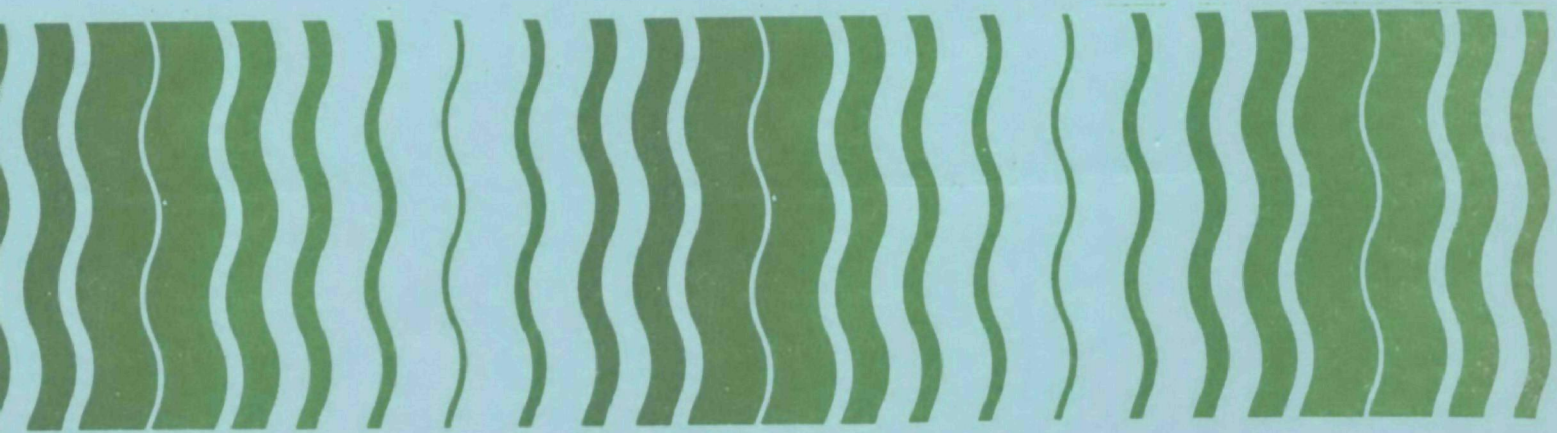
Pesticides

EPA

Daminozide

Pesticide Registration Standard and Guidance Document



Fact Sheet #:
Dated:

CHEMICAL INFORMATION FACT SHEET FOR DAMINOZIDE

Description of Chemical

Common Name: Daminozide
Chemical Name: Butanedioic acid mono(2,2-dimethylhydrazine), Succinic acid 2,2-dimethylhydrazide
Trade Name: Alar, Kylar, SADH, B-nine, B-995, aminozide,
EPA Shaughnessy Code: 035101
Chemical Abstracts Service (CAS) Number: 1596-84-5
Pesticide Type: Plant Growth Regulator
Chemical Family: Amino Acid Derivative
U.S. and Foreign Producers: Uniroyal and Aceto Chemical

Use Patterns and Formulations

Daminozide is a plant growth regulator registered as a 5 percent water soluble liquid or 85 percent water soluble dry concentrate formulation. The amount of daminozide that is applied as a field spray ranges from 0.9 to 6.8 pounds active ingredient per acre per year, depending of the crop, time of application and desired effects. Daminozide controls the vegetative and reproductive growth of orchard crops such as apples, cherries, nectarines, peaches, prunes and pears. In addition, daminozide use enhances shorter and more erect peanut vines or modifies the stem length and shape of ornamental plants. Other minor uses of daminozide include: Brussels sprouts (California), cantaloupes (California and Arizona), grapes, and tomatoes.

Scientific Findings

o Summary Science Statement

Daminozide is a white, water soluble solid. Data indicate that daminozide has low acute toxicity, low dermal irritation potential and is neither teratogenic nor mutagenic. Daminozide and its UDMH contaminant cause oncogenic effects. A tolerance reassessment cannot be performed at this time. Daminozide leaches from soil, but is not persistent. Daminozide is not an acute toxicant to fish and wildlife.

o Chemical Characteristics

Daminozide is a white, crystalline solid with slight to no odor. Daminozide is soluble in water, methanol and acetonitrile, but insoluble in xylene and aliphatic hydrocarbons. Daminozide has a melting point range from 154 to 156°C. Technical daminozide contains at least 99 percent active ingredient.

o Toxicological Characteristics

The LD50 and Toxicity Categories for daminozide are: acute oral (8.4 g/kg, IV), acute dermal (>16 g/kg, III), acute inhalation (>147 mg/kg, IV), primary eye irritation (mild, none at this time), dermal irritation (mild, IV). Daminozide does not produce mutagenic or teratogenic effects. Data are insufficient to judge the effects of daminozide on reproduction. Daminozide causes oncogenic effects in laboratory animals.

o Physiological and Biochemical Behavioral Characteristics

Data indicate that daminozide is rapidly absorbed through the leaves, roots and stems. Daminozide is translocated in plants and can accumulate in roots, fruit, etc. Adequate methods are available to detect daminozide. A method to detect the UDMH metabolite down to 1 ppb must be validated to confirm the presence of UDMH residues in plants. Components of the final residues have not been adequately identified or quantified. The majority of daminozide residues ingested by milk animals is rapidly excreted in the urine and feces.

o Environmental Characteristics

Degrades in water to unsymmetrical 1,1-dimethylhydrazine (UDMH), a known oncogen. Daminozide appears to resist photodegradation, but is degraded by soil microorganisms. Daminozide appears to leach, but since it does not persist in soil, the potential for ground water contamination is small. Daminozide does not bioconcentrate in fish nor does it accumulate in rotational crops.

o Ecological Characteristics

Daminozide has low acute toxicity to fish and terrestrial wildlife. No data are available to assess the ecological hazard from the UDMH hydrolysis product/contaminant. Problems with Endangered Species: None known at this time.

o Tolerance Assessment

A final reassessment of all tolerances cannot be made at this time until the data gaps specified by the Standard are filled.

o Problems with Use

Extended storage of solutions of daminozide result in excessive hydrolysis of the active ingredient to UDMH.

Regulatory Position & Rationale

o Use Clasiification

Daminozide is classified as a General Use Pesticide.

o Use Restrictions

None.

o Unique Warning Statements

Solutions of daminozide must be used within 24 hours after preparation.

o Benefit Analysis

Approximately 825,000 pounds of daminozide are produced annually with apples and peanuts accounting for 600,000 pounds and 225,000 pounds of the annual usage, respectively. Without daminozide, short term revenue losses are projected to range up to $30 million annually for apples and from $4.3 to $10.7 million annually for peanuts.

o Risk Analysis

Significant exposure to daminozide and UDMH can occur via consumption of raw and processed agricultural commodities treated with daminozide. The Agency's preliminary estimate of oncogenic dietary risk for daminozide is high. There are insufficient data to quantify the oncogenic dietary risk of UDMH at this time. The oncogenic nondietary risk for daminozide and UDMH may not be significant.

o Special Review

Registrants of daminozide products are notified, via the Guidance Document, that daminozide meets the oncogenicity risk criterion in 40 CFR 162.11(a) and will undergo a Special Review. The Agency will not reregister any current products and it will not register any new products containing daminozide until Special Review is completed and the Agency has received commitment to fulfill data requirements.

Summary of Major Data Gaps

Data gaps and time [in months] allowed to perform studies: toxicology (chronic testing [48], teratology [12], reproduction [24], general metabolism [12] and mutagenicity [6]), product chemistry (product identity, analysis and certification of product ingredients, physical and chemical characteristics) [6], environmental fate (degradation [6], photodegradation [6], metabolism [24], mobility [6], dissipation [24], accumulation [24] and reentry [24], residue chemistry (metabolism in plants and animals [12], analytical methods and residue data [12], residue data [12]), and ecological effects (avian and mammalian testing and aquatic organism testing) [48].

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Disclaimer

The information presented in this Chemical Information Fact Sheet is for informational purposes only and may not be used to fulfill data requirements for pesticide registration and reregistration.

GUIDANCE FOR THE INTERIM REGISTRATION OF PESTICIDE PRODUCTS CONTAINING DAMINOZIDE AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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APPENDICES

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme, giving preference 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. A thorough review of the product performance data base has not been performed for all pesticides, in keeping with the efficacy waiver policy for non-public health uses of pesticides. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position 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 poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, 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 find serious concerns, we will bring end-use products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that registrants submit data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, it is the Agency's policy under §3(c)(2)(B) that these data are not required to be submitted by those registrants who qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic suppliers of

the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted 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 discontinue the registration of any of your products subject to the interim registration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time-frames outlined. EPA may issue a notice of intent to cancel or suspend the registration of any currently registered product or deny any application for registration of a product if you fail to comply with the requirements set forth in this Guidance Document for Interim Registration

This Guidance Document for Interim Registration will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Acting Administrator, EPA was enjoined from implementing §3(c)(1)(D) of FIFRA. EPA has decided that as long as this injunction is in effect, it will, for most pesticides, proceed with the requirements in this Guidance Document for Interim Registration which do not require compliance with the provisions of §3(c)(1)(D). EPA will not require current registrants to apply to amend their product registrations to make changes in the labeling, packaging, or composition for this chemical at this time. The Agency will supplement this Document for Interim Registration with additional guidance when this litigation concludes. Failure to comply with the provisions of the subsequent guidance may also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time 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.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) FOR MAINTENANCE OF INTERIM REGISTRATION
I. Products Not Qualifying For A Formulator's Exemption A. Single Active Ingredient Products*	These products must obtain registration by compliance with the labeling, packaging & data requirements stated in the Guidance Document for Interim Registration.
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 Guidance Document, will be required and some labeling precautions may also be required.
II. Products Qualifying For A 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 handled 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 need not obtain interim regiatration, provided that the registrant fulfills the requirements in the Guidance Document for Interim Registration. Such end-use products are subject to the label changes required for products in "II" above. If there are no manufacturing-use products registered by any company, end-use products must comply with the Guidance Document for Interim Registration.
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 POSITION AND RATIONALE

A. INTRODUCTION

This chapter describes the regulatory position of the Environmental Protection Agency ("the Agency") on daminozide, based on an evaluation of all registered manufacturing-use products (MUP's) containing daminozide as the sole active ingredient. Future requests for registrations of substantially similar products will be covered by this Standard. Dissimilar products will require amendments to the Standard. This Standard provides the rationale for the Agency's position, the criteria for registration and also discusses labeling requirements and tolerances.

In developing its regulatory position, the Agency determines whether available data indicate that a pesticide has met the criteria for unreasonable adverse effects found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations (CFR). Pesticides meeting these criteria are candidates for a Special Review, which is a modification of the intensive risk/benefit analysis known as the Rebuttable Presumption Against Registration (RPAR) process. The Agency's determination whether any criteria have been met and its rationale for any regulatory action are summarized in the regulatory position of this standard.

"Daminozide" is the accepted common name for butanedioic acid mono (2,2-dimethylhydrazide) recognized by the American National Standards Institute. Trade and other names for daminozide include Alar®-85, Alar®, SAD 85®, Kylar®-85, B-nine®-SP, Succinic acid, 2,2-dimethylhydrazide and N-(dimethylamino)succinamic acid. The Chemical Abstracts Service (CAS) Registry number is 1596-84-5. The Office of Pesticides Program's internal control number (EPA Shaughnessy number) is 035101.

B. USE PROFILE

Daminozide is a plant growth regulator registered as a 5 percent water soluble liquid concentrate or 85 percent soluble dry concentrate formulation for use in controlling the vegetative and reproductive growth of orchard crops such as apples, cherries, nectarines, peaches, prunes and pears. In addition, daminozide use enhances shorter and more erect peanut vines or modifies the stem length and shape of ornamental plants. Other minor uses of daminozide include: Brussels sprouts (California), cantaloupes (California and Arizona), grapes, and tomatoes (pre-harvest treatments are limited to Florida).

C. REGULATORY POSITION

Based on a review and evaluation of all available data and other relevant information on daminozide, the Agency has made the following determinations:

1. Daminozide has demonstrated oncogenic effects in laboratory animals and is contaminated with and hydrolyzes to unsymmetrical 1,1-dimethylhydrazine (UDMH), a known animal oncogen. Registrants of daminozide products are hereby notified that daminozide has met the oncogenicity risk criterion in 40 CFR 162.11(a) and will undergo a Special Review. A Notice announcing the initiation of a Special Review will be published in the Federal Register.

2. The oncogenic dietary risk of daminozide is high. Additional oncogenic risk occurs as a result of UDMH dietary exposure. The continued use of daminozide may cause unreasonable adverse effects on the environment. The oncogenic nondietary risk of daminozide and UDMH does not currently appear to be sufficiently high to cause concern for the Agency.

3. The Agency will not reregister any current products and it will not register any new uses of daminozide until the Special Review is completed and the Agency has received a commitment to fulfill all data requirements.

4. Registered manufacturing-use products containing daminozide as a sole active ingredient may be sold, distributed, formulated and used in the United States, subject to the terms and conditions specified in this Standard. Registrants with products that do not conform to this Standard must apply to amend the Standard in order to obtain interim registration. Mixtures and end-use products containing daminozide are covered under this Standard for the purposes of labeling. The use patterns of the end-use products are considered for purposes of determining generic data requirements for daminozide.

5. Registrants not qualifying for a formulator exemption must provide or agree to develop all data specified in the tables of this Standard to maintain existing registrations. The Agency may amend this Standard or initiate further regulatory actions after it has reviewed the submitted data and concluded the Special Review. All data must be generated according to the Good Laboratory Practices specified in 48 FR 53946. All data must be initiated as soon as possible after receipt of the Guidance Document. Registrants must

notify the Agency of any information which indicates possible adverse effects, as specified under Section 6(a)(2) FIFRA.

D. REGULATORY RATIONALE

At this time, the Agency has determined that it will not reregister existing use patterns of daminozide for the following reasons:

1. Daminozide has demonstrated oncogenic potential in laboratory animals. Additionally, daminozide is contaminated with and hydrolyzes to UDMH, a chemical known to cause oncogenic effects in laboratory animals.

2. Significant exposure to daminozide and UDMH can occur via consumption of raw and processed agricultural commodities treated with daminozide as well as during application.

3. Dietary risk estimates for daminozide and UDMH indicate that an unacceptable risk may exist from consumption of raw and processed agricultural commodities treated with daminozide.

4. There are no data to establish reentry exposure to daminozide and UDMH for individuals entering areas treated with daminozide. However, the Agency has established an interim 24 hour reentry interval. The Agency will evaluate the reentry interval after it has reviewed data required by this standard.

5. Available data are insufficient to fully assess the environmental fate of daminozide and UDMH. A complete environmental fate assessment will be performed after the data, required by this document, are reviewed by the Agency.

6. There are insufficient data to characterize the toxic effects of the end-use products containing daminozide and UDMH to aquatic organisms. A complete hazard assessment will be performed after additional ecological effects data are submitted to the Agency.

7. Data available on both human or wildlife poisoning incidents through the Pesticide Incident Monitoring System (PIMS) through July, 1980 indicate only a single report, a case of skin irritation. PIMS data, though, provide no information on chronic health effects from exposure to this or other chemicals.

E. CRITERIA FOR INTERIM REGISTRATION UNDER THIS STANDARD

All manufacturing-use products which contain daminozide as the sole active ingredient are subject to this Standard. All products subject to this Standard must either comply with the acute toxicity limits, product composition and use pattern requirements listed in Section F or submit data and a justification to amend the Standard to encompass such products.

The Agency will not reregister any current products and it will not register any new products until the Special Review has been completed and the Agency has received commitments to fulfill all data requirments.

F. ACCEPTABLE RANGES AND LIMITS

1. Product Composition

Technical grade products must contain at least 99 percent daminozide as the sole active ingredient. All manufacturing-use product formulations must be fully described with an appropriate certification of limits. Any manufacturing-use daminozide product not meeting these requirements will be consider a new product and will not be reregistered until completion of the Special Review and the Agency has received a commitment to fulfill all data requirements.

2. Acute Toxicity Limits

Technical grade and manufacturing-use products containing daminozide must be labeled according to the following acute toxicity categories: Acute Oral (IV), Acute Dermal (III), Acute Inhalation (IV) and Primary Dermal Irritation (IV).

3. Use Patterns

Manufacturing-use products containing daminozide must be labeled for formulation only into end-use products for use as a growth regulator used on apples, cherries, peanuts, nectarines, peaches, prunes, pears, brussel sprouts (California), cantaloupes (California and Arizona), grapes, tomatoes (Florida) and ornamentals.

G. REQUIRED LABELING

All technical grade, manufacturing-use and end-use products containing daminozide must bear appropriate labeling as specified in 40 CFR 162.10. The following labeling requirements apply to technical, manufacturing-use and end-use products.

1. Manufacturing-Use Product Statements

a. Use Patterns

Products intended for formulation into end-use products must bear the following statement:

"For formulation only into end-use plant growth regulator products intended for use on apples, cherries, nectarines, peaches, prunes, pears, brussel sprouts (California), cantaloupes (California and Arizona), grapes, tomatoes (Florida), peanuts and ornamentals."

"Avoid breathing dusts and contact with skin."

All products must bear the following statements:

"Each formulator is responsible for obtaining EPA registrations for its formulated product(s)."

b. General Warning

"Do not discharge into lakes, streams, ponds, or public waters unless in accordance with NPDES permit. For guidance, contact your Regional Office of the EPA."

2. End-Use Product Statements

"Do not contaminate water by cleaning of equipment or disposal of wastes. Do not apply directly to water or wetlands."

"Do not allow spray solution to touch skin and wear protective clothing to protect hands, arms and legs both when diluting and applying this product."

"Do not reenter treated areas until 24 hours after application, unless wearing protective clothing."

"Avoid breathing dusts. Wear a protective mask during mixing/loading operations."

"Use spray and stock solutions within 24 hours. Do not store solutions. Immediate use is appropriate, if another component is added to spray mixture."

H. TOLERANCE REASSESSMENT

A listing of the tolerances in the United States for residues of daminozide in or on raw agricultural commodities may be found in 40 CFR 180.246, in processed foods may be found in 21 CFR 193.410 and in animal feeds when applied to growing crops may be found in 21 CFR 561.360. There are no Codex entries for residues of daminozide.

The several registration and FIFRA § 3(c)(2)(B) tolerance data requirements which are outstanding and the few available residue data preclude a final reassessment of all daminozide tolerances at this time. Until these data gaps are filled, the Agency is unable to satisfactorly estimate the contribution of actual residues of daminozide and its UDMH contaminant/ hydrolysis product to the diet.

I. PRELIMINARY ANALYSIS OF CURRENT BENEFITS AND RISKS

1. Current Benefits Review

a. Introduction

Under Section 3 of FIFRA, the Agency's decisions on pesticide use must consider benefits as well as risks. In an attempt to quantify the benefits from the use of daminozide as a growth regulator, biological and economic data were compiled on apples and peanuts, the two predominant use sites.

b. Usage Estimates by Site

Approximately 600,000 pounds active ingredient of daminozide are applied to 125,000 to 130,000 apple acres (25 percent of U.S. apple acreage), with usage concentrated on fruit intended for the fresh market. For peanuts, about 225,000 pounds active ingredient of daminozide are used for 250,000 acre treatments of which 175,000 to 180,000 acres are in the eastern U.S..

For all other registered sites, the estimated annual usage is 35,000 pounds active ingredient, or approximately 4 percent of the total national usage of daminozide. No benefits were estimated for daminozide use on these latter sites. It should not be assumed that no benefits from daminozide uses are derived at these minor sites simply because they are not included in this current benefits evaluation.

c. Summary of Findings

i) Apples

Daminozide, formulated as an 85 percent soluble dry concentrate, is used as a single application foliar spray for apples. The registered application rates range from 3.4 to 6.8 lbs/A.I./ acre/yr in 400 gallons of water/acre for "Spring" treatment, 2.6 to 5.1 lbs/A.I./acre/yr in 400 gallons of water/acre for "Mid-Season" treatment, and 1.7 to 5.1 lbs/A.I./acre/yr in 400 gallons of water/acre for "Summer" treatment. The types of desired plant growth regulator effects determine the selected seasonal timing of application. Tree size and vigor are factors that determine the specific rate selected within the range of the application rates.

Daminozide is currently the only registered apple plant growth regulator that provides all of the following multiple effects:

- o Increases fruit color (on red varieties),
- o Delays fruit maturity (ripening), thereby extending the harvest period,
- o Prevents preharvest drop,
- o Maintains fruit firmness, thereby reducing handling and storage bruises,
- o Delays development of watercore primarily in Red Delicious and Stayman varieties up to 7 days,
- o Reduces scald, weather check, bitterpit, cork spot, fruit cracking, apple size and vegetative growth,
- o Promotes flower bud initiation in the following spring, thereby, increasing return blossoms, fruit set and subsequent yields.

Other registered apple plant growth regulators with similar, but limited claims include:

- o NAA - Prevents preharvest fruit drop of short duration. Application must be repeated at 5 to 10 day intervals and be delayed until just prior to harvest.
- o Silvex - Increases red color and prevents preharvest fruit drop, as does daminozide. Silvex, however, accelerates fruit ripening and softening, necessitating harvest within 2 weeks after application to prevent overripening of the fruit. Additionally, silvex may not be applied closer than 14 days prior to harvest. In addition, this use of Silvex is subject to a Notice of Intent to cancel registrations. Silvex is currently undergoing cancellation hearings.
- o Ethephon - Promotes red color development and flower initiation on young non-producing trees, as does daminozide. Major disadvantages include accelerated fruit ripening and, in the mid-Atlantic states, accelerated watercore development. Ethephon is often tank mixed with daminozide to offset these undesirable effects. The use of ethephon alone is not recommended for the storage of fresh fruit.
- o Diphenylamine - Prevents scald development if applied as a post-harvest spray or dip within 7 days prior to storage. This chemical is considered to be more effective than daminozide for scald control.

- o Ethoxyquin - Prevents scald development if applied as a post-harvest spray or dip prior to storage. This chemical is considered to be more effective than daminozide for scald control.

Daminozide offers a major advantage for application timing over NAA or silvex for pre-harvest drop control. Daminozide may be applied early enough in the season to afford assurance against apple drop in the time period prior to harvest, a time period before NAA and silvex may be applied to the crop.

Daminozide is currently the only registered plant growth regulator that provides the specific following benefits:

- o Delays fruit maturity,
- o Maintains fruit firmness,
- o Delays watercore development (primarily in the mid-Atlantic states),
- o Reduces apple size (used on the Rome Beauty variety to accomodate coring and peeling machine processing).

Without daminozide, fresh market Red Delicious and McIntosh apple producers would incur substantial losses in the short run, with possible losses in net revenue ranging up to $30 million per year. U.S. farm value of fresh apple production was approximetley $597 million in 1982. Of the above loss, growers of McIntosh apples would lose up to $18.83 million in annual net revenue on 37,300 affected acres. Losses of this intensity suggest either that alternative apple varieties would be planted over a prolonged period of time, or that some unknown proportion of McIntosh producers would leave the apple industry.

Short term annual income losses on 70,000 affected acres of Red Delicious apples were estimated at $11.22 million, or about $159 per acre. Consumers could encounter reduced quality in fresh apples, as well as a shorter term duration of fresh fruit availability due to reduced apple storage life. Alternatively, a greater quantity of processed apples could be expected at lower than current prices.

ii. Peanuts

Daminozide, formulated as an 85 percent soluble dry concentrate, is spray applied over-the-top-of peanuts to produce shortened, more erect vines, and to enhance green coloration as well as yields. One to six applications are applied per growing season, with total seasonal active ingredient usage ranging from 0.80 to 1.3 pounds per acre, while current use practices indicate one to three applications per season. Current permissible treatment requires a 30 day preharvest interval.

The total number of applications in a given season is variable and often dependant on factors that influence rapid vine growth (e.g. rainfall, irrigation practices and peanut variety). No other growth regulators are registered for this use. Without daminozide, U.S. peanut growers (mostly in the southeast) could be expected to sustain short term reductions in net revenue, ranging from $4.3 to $10.7 million annually, or from $23.95 to $59.50 per impacted acre. U.S. farm value of peanut production was $856 million in 1982. While impacts of this intensity could represent a substantial financial impact to affected growers, total U.S. production could decline from 1.0 to 1.7 percent, causing no appreciable effect on farm or retail prices. Moreover, it is likely that any serious production shortfalls could be alleviated by increases in allowable production in that poundage quotas will be in effect through 1985.

d. Limitations of Analysis

The specific site analyses provide an overview of use/usage, the availability and efficacy of alternative controls, and the likely economic consequences in the absence of daminozide for only the most important sites (e.g. apples and peanuts). These analyses are preliminary, were developed with data readily available to the Agency, and do not quantify all of the "enhancement effects" attributable to daminozide. These analyses are subject to future revision by the Agency.

2. Preliminary Risk Analysis

a. Introduction

The Agency has completed its review of the data base for daminozide and has concluded that daminozide and its UDMH hydrolysis product are oncogenic in laboratory rats and mice. One study indicated that feeding of daminozide caused adenocarcinomas and leiomyosarcomas of the uterus in female rats, hepatocellular carcinomas in male mice, and alveolar/ bronchiolar carcinomas and adenomas in male and female mice and female rats (NCI, 05007997). In a second study, administration of daminozide in drinking water resulted in statistically significant incidences of blood vessel tumors and lung tumors in both male and female mice, as well as a significant incidence of kidney and liver tumors in the male mice (Toth, 05009679). Analysis of the drinking water in this latter study indicated that the UDMH hydrolysis product increased as a function of time. In a third study (Toth, GS032001), administration of drinking water containing UDHM resulted in statistically significant incidences of blood vessel and lung tumors in both male and female mice. Kidney and lung tumors were also noted in this study, but at a lower rate than the blood vessel and lung tumors.

The Agency is concerned with the presence of unsymmetrical 1,1-dimethylhydrazine (UDMH) that is associated with the use of daminozide. UDMH causes oncogenic effects in laboratory animals. UDMH has demonstrated mutagenic activity in both the presence and absence of metabolic activation. UDMH is a contaminant in technical products and formulated products. Hydrolysis of formulated products, as diluted for use can form additional UDMH. Hydrolysis of daminozide residues to UDMH, following the boiling of apples, was first identified and reported by Newsome (1980, MRID 005021600). UDMH was also found in apple juice.

The Agency currently has insufficient data to make a complete assessment of risk from daminozide and UDMH. The Agency requested and received commitments to generate studies to address risk, via a request under section 3(c)(2)(B) FIFRA dated August 25, 1983. The requested data include:

- o In-vitro hydrolysis study simulating the conditions in the human stomach to determine the mechanism and rate of conversion of daminozide to UDMH,
- o In-vivo radiolabeled metabolism study in an appropriate species with a stomach pH similar to the human,
- o Residue study on apples treated with daminozide,
- o C_{14} plant metabolism study to determine the fate of daminozide and UDMH in plants,
- o Residue study on all raw agricultural commodities listed in 40 CFR 180.246, and for each food or feed listed in 21 CFR 193.410 and 561.360,
- o A study to examine conversion of daminozide to UDMH during food preparation and processing,
- o C_{14} metabolism study in ruminants and poultry,
- o Tiered animal residue study in ruminants and poultry, and
- o Tiered in vitro and in vivo study to determine the fate of bound residues.

The Agency has evaluated residue data, the only data submitted under § 3(c)(2)(B) FIFRA. The Agency has concluded that these few residue data do not adequately reflect the amount of UDMH formed in apples, apple sauce or apple juice from the maximum recommended and registered use of daminozide on apples and other raw agricultural commodities because data are not available to allow the Agency to determine whether daminozide was applied at the maximum registered application rate. These and other data will be discussed in the Special Review.

b. Dietary Exposure

i) General Assumptions

The estimated dietary exposure of humans to pesticide residues from registered uses is a function of several factors:

- o The pesticide residues remaining in or on a commodity (in ppm, usually at the established tolerance level) to calculate the Theoretical Maximum Residue Contribution (TMRC) to the diet,
- o The mean percentage of a commodity in a daily diet of 1.5 kg (food factor),
- o The assumed average body weight of a person is 60 kg.

When these factors are substituted into a formula, human exposure to pesticide residues in a commodity is found in terms of mg of pesticide per kg of body weight per day.

ii) Daminozide

The Agency has estimated the potential dietary exposure to daminozide by the U.S. population from treated fruits and vegetables. In making these estimates, the Agency had to choose between two basic approaches. The first approach was to assume that the national population might be exposed to the average of residue levels actually measured in field tests. The second was to assume that the U.S. population could be exposed to the highest residues of daminozide that would be legally permissible, which would be at the tolerance level, and to calculate the maximum residue exposure for each individual. The available data are not adequate to calculate actual residue levels. The dietary exposure assessment, therefore, has been based on the current tolerances for daminozide.

The Agency's dietary estimates on raw agricultural commodities assume equal distribution of treated crops among the U.S. population and an average daily consumption of fruit by individuals. An individual's exposure could, of course, vary considerably depending upon eating habits and geographic location. For example, in some areas all of the apples sold may have been treated with daminozide or a person may consume more than the average portion of fruit in his daily diet. But since the reverse may occur as well, in some areas none of the fruit sold may have been treated or a person may eat less than the average portion of fruit, the values are considered representative for the total U.S. population over a lifetime.

The human dietary exposure estimates to daminozide are based on the established tolerance levels (40 CFR, 180.246) and are estimated to be 3.92 mg/day (0.0655 mg/kg body weight for a 60 kg person). A summary of the Agency's dietary exposure analysis for daminozide is presented below.

DIETARY EXPOSURE TO DAMINOZIDE[1/]

Crop	Tolerance (ppm)	Food Factor (% of Daily Diet)2/	Daily Intake (mg/1.5 kg diet/day)
Cherries	55	0.10	0.08
Plums(incl. prunes)	50	0.13	0.10
Tomatoes	40	2.87	1.72
Apples	30	2.53	1.14
Nectarines	30	0.03	0.01
Peaches	30	0.90	0.40
Peanuts	30	0.36	0.16
Brussels Sprouts	20	0.03	0.01
Pears	20	0.26	0.08
Grapes (not raisins)	10	0.45	0.07
Melons	3	2.00	0.09
Peppers	1	0.12	0.00
Meat (incl. poultry)	0.2	13.85	0.04
Eggs	0.2	2.77	0.01
Milk	0.02	28.62	0.01
		TOTAL	3.92

1/ Based on tolerance levels.
2/ Mean daily percentage.

iii) UDMH

There are few data on UDMH residues in or on raw agricultural commodities in the diet. Of major concern to the Agency is the potential for breakdown of daminozide residues to UDMH, a carcinogen. A 1980 study (Newsome, MRID 005021600) indicated that boiling of apples treated with daminozide resulted in a significant fraction of the daminozide residues coverting to UDMH. This study indicates that 5.1 percent of daminozide applied to the apples converted to UDMH. The measurement of field treated apples containing a lower level of daminozide showed an even higher conversion level to UDMH of 7.7 percent.

The Agency has reviewed residue data submitted to-date. Daminozide and UDMH residues in processed apple juice ranged from 0.5 to 10.5 ppm and 4.0 to 220 ppb, respectively. Daminozide and UDMH residues in processed apple sauce ranged from 0.5 to 10.9 ppm and 4.9 to 383 ppb, respectively. The combined data to-date indicate that daminozide residues in

apples will breakdown to UDMH by cooking and processing procedures. Daminozide residues in processed apples have ranged from 1.0 to 21 ppm.

Additional market basket studies of commercially processed apple sauce detected daminozide and UDMH ranging from <1 ppm to 1.5 ppm and <1 ppb to 69 ppb, respectively. Analysis of commercially processed apple juice detected daminozide and UDMH ranging from <1 ppm to 1.6 ppm and <1 ppb to 51 ppb, respectively. The results of this "market basket survey" indicate the presence of daminozide and UDMH at significant levels.

The Agency is concerned about UDMH and daminozide dietary exposure to special groups of individuals (especially young children) who consume large quantities of apple products. Exposure of these types of individuals will be an area of discussion in the Special Review.

c. Non-Dietary Exposure

i) General Assumptions

Daminozide is applied primarily by air blast equipment to orchards, by ground boom equipment to vegetable crops and by a hand carried three-gallon power sprayer in greenhouses. Available data indicate that daminozide leaches, but is not persistent. Thus, exposure of humans to daminozide through contamination of ground water is unlikely. Likewise, exposure to aquatic organisms through runoff and leaching is considered unlikely. Exposure of workers to daminozide occurs by dermal and inhalation routes during mixing, loading, and spraying.

ii) Daminozide

Worker exposure was measured in two studies submitted by Uniroyal Inc. (MRID GS0032012 and MRID GS0032024) using procedures developed by Durham and Wolfe (1962, MRID GS0032015) for the assessment of pesticide exposure during agricultural operations. Worker exposure was measured at six apple growing sites, three greenhouses and one peanut growing site. Daminozide was mixed with water prior to use and applied under actual use conditions by volunteer workers.

Worker exposure in apple orchards was measured using both concentrate and dilute sprays of daminozide at several different application rates including the maximum label rate. Exposure values for apple workers were calculated from these studies. The exposure estimate for peanuts is based on only one sample and reflect an application rate less than the maximum recommended rate. Applicator exposure to daminozide in greenhouses was also estimated.

The following assumptions were made to calculating worker exposure for daminozide:

- All daminozide collected on respirator pads was inhaled by the worker,
- Workers wore a short-sleeved shirt and long pants so that dermal exposure was the sum of exposures of unprotected skin (face, neck, forearms and hands),
- Results of analysis of shoulder pad (in ug/cm^2) were used to estimate facial exposure based on 650 cm^2 of facial surface area,
- Results of analysis of back and chest pads were used to estimate neck exposure based on a surface area of $150cm^2$ for front of neck and $110cm^2$ for back of neck.
- Exposure to forearms was calculated based on $1210cm^2$ surface area,
- Exposure to hands was the sum of analysis (in mg) of two handwashings following application.

The following table presents the Agency's estimate of non-dietary exposure.

WORKER EXPOSURE TO DAMINOZIDE[1/]

Unit Exposure	Dermal (mg/hr)	Inhalation (mg/hr)	Total (mg/hr)	Time (hr/yr)	Exposure[2/] mg/kg/yr
Apples[3/]					
Max	77.6	0.0169	77.6	4.8 - 6.0	5.3 - 6.7
Ave	33.7	0.0029	33.7	4.8 - 6.0	2.3 - 2.9
Min	12.4	0.0002	12.4	4.8 - 6.0	0.9 - 1.1
Peanuts[4/]	2.3	0.0011	2.31	18 - 72	0.6 - 2.4
Ornamentals[5/]					
Max	8.5	0.0043	8.5	27	3.3
Ave	7.1	0.0016	7.1	27	2.7
Min	5.5	N.D.	5.5	27	2.1

[1/]Based on Uniroyal applicator exposure studies [Ball and Cummings (MRID GS032012), Ball (MRID GS032024)] uncorrected for absorption. Assume applicator wears shoes, socks, long trousers, a shortsleeved open-necked shirt, but no hat or gloves.

[2/]Assume a person weighs 70 kg.

[3/]Exposure time based on Stone (MRID GS0032021). The low figure represents treatment of 50 acres of apples (150 gallons/acre) using a concentrate sprayer. The high figure represents treatment of 50 acres of apples (400 gallons/acre) using a dilute solution sprayer.

[4/]Exposure time based on Russell (MRID GS0032018). The low figure represents three treatments per year, 6 hours per treatment to an average 53 acre peanut farm. The high figure represents three treatments per year, 24 hours per treatment to a common size 200 acre peanut farm.

[5/]Exposure time based on Petrie (MRID GS032014). This figure represents an average of three crops per year with two treatments per crop.

iii) UDMH

Exposure to the impurity UDMH has been calculated based on the estimate by Von Schmeling (MRID GS0032003) that technical daminozide contains 0.005 percent UDMH. The dermal exposure estimates for applicators are presented in the following table and were calculated by multiplying the corresponding values from the field exposure study by 5×10^{-5} (the percent of UDMH expressed as a decimal). As inhalation exposure is negligible when compared to dermal, it has not been estimated. These exposure values do not account for any UDMH formed as a result of hydrolysis of daminozide in the spray tank.

WORKER EXPOSURE TO UDMH FROM PRODUCT IMPURITY

Crop	Exposure (mg/kg/yr)
Apples	
Max	3.5×10^{-4} - 3.0×10^{-4}
Ave	1.0×10^{-4} - 1.0×10^{-4}
Min	5.0×10^{-5} - 6.0×10^{-5}
Peanuts	3.0×10^{-5} - 1.2×10^{-4}
Ornamentals	
Max	2.3×10^{-4}
Ave	1.0×10^{-4}
Min	1.0×10^{-4}

Exposure to UDMH due to hydrolysis of daminozide after mixing has also been estimated using the results of Wright (1981, GS0032022). These estimates give some indication of exposure to UDMH for applicators as a result of hydrolysis of daminozide.

The concentration of UDMH during spraying is the average of UDMH level present at the beginning of spraying and UDMH level present at the end of spraying. For both apples and peanuts daminozide is generally mixed in the spray tank and applied immediately.

If a 500 gallon spray tank were used in an apple orchard, a concentrate sprayer (150 gallons per acre) would be refilled every 30 minutes and dilute sprayer (400 gallons per acre) would be refilled every 25 minutes while spraying. For spraying peanuts a 150 gallon tank capacity sprayer delivering 10 gallons per acre would be refilled every 1.7 hours.

Based on the data from the hydrolysis study by Wright, the concentration of UDMH which is produced from the hydrolysis of daminozide can be estimated from the equation $X = A(1-e^{-KT})$ where:

- o A is the concentration of daminozide at time 0,
- o K is the rate constant for hydrolysis = 1.2×1^{-4},
- o T is the number of hours after addition of water to the daminozide powder, and
- o X is the concentration of UDMH.

Current label directions for greenhouse application state: "After mixing, allow to stand for one hour or so before using." It is assumed that the daminozide solution is allowed to stand one and one-half hours before spraying begins and spraying takes one half hour. Then the concentration of UDMH

during spraying is the average of UDMH levels present at one and one half hours after mixing and 2 hours after mixing. The Agency believes that longer times will cause higher concentrations of UDMH to form in the spray solution and result in higher risk. The following table summarizes estimates of worker exposure to UDMH.

WORKER EXPOSURE TO UDMH DUE TO HYDROLYSIS[1/2/3/]

Crop	UDMH Concentration(ppm) Initial	Final	Average	Exposure (mg/hr)	(hr/yr)	(mg/kg/yr)
Apples (Dilute Spray)						
2,500 ppm	0	0.075	0.038	$5x10^{-4}$	9.9	$7.1x10^{-5}$
Apples (Concentrated Spray)						
5,000 ppm	0	0.3	0.15	$1x10^{-3}$	7.8	$1.1x10^{-4}$
Peanuts						
10,000 ppm	0	2.0	1.0	$2x10^{-4}$	72	$2.0x10^{-4}$
Ornamentals						
3,000 ppm	0.54	0.72	0.63	$1x10^{-3}$	27	$3.9x10^{-4}$
7,500 ppm	1.3	1.8	1.6	$2x10^{-3}$	8	$2.3x10^{-4}$

1/The average UDMH concentration was used to calculate exposure.
2/Exposure was calculated for a 70 kg person.
3/Exposure times are those used for daminozide exposure estimation.

The total amount of worker exposure to UDMH is the sum of exposure to both impurity and hydrolysis. Workers applying daminozide in apple orchards could be exposed to UDMH ranging from $1x10^{-4}$ mg/kg/year to $5x10^{-4}$ mg/kg/year. While applying daminozide to peanuts, workers could be exposed to UDMH ranging from $2x10^{-4}$ to $3x10^{-4}$ mg/kg/year. Workers applying daminozide in greenhouses could be exposed to UDMH ranging from $3x10^{-4}$ to $6x10^{-4}$ mg/kg/yr.

c. Risk Estimates

i) Introduction

The Agency's Interim Cancer Assessment Guidelines (41 FR 21402) state that when a chemical is judged to be a potential human carcinogen, the Agency must estimate its possible impact on public health at current and anticipated levels of exposure. The Agency recognizes that the available techniques for assessing the magnitude of the cancer risk to human populations based on animal data are, at best, uncertain due to the need to extrapolate the dose response data to very low dose levels and to differences in levels of susceptability of animals and humans. Accordingly, these risk estimates are neither scientific certainties nor absolute upper limits on the risk of cancer from the exposure to daminozide and its UDMH

contaminant. Rather, these estimates should be viewed as a health hazard index that incorporates the degree of carcinogenic activity and human exposure to daminozide and its UDMH contaminant/hydrolysis product. The Agency has estimated risk from exposure to daminozide via the dietary and nondietary routes.

ii) Risk Assumptions

Ingestion of several of the raw agricultural commodities (e.g. cherries, plums, tomatoes, apples, peanuts, peaches, pears and nectarines) may result in exposure to high levels of UDMH by hydrolysis of daminozide during processing or cooking. Information concerning the possible hydrolysis of daminozide to UDMH in the processing or home preparation of fruits and vegetables bearing residues of daminozide and/or UDMH is lacking with the exception of the apple commodity. Therefore, the UDMH dietary risk estimate has been limited to consumption of apple products.

iii) Summary of Risk Estimates

1) Dietary Risk

The Agency has estimated risk separately for exposure to both daminozide and UDMH.

A) Daminozide

The Agency's estimate of a risk for daminozide at the Theoretical Maxium Residue Contribution (TMRC) to the daily diet is presented below.

DAMINOZIDE DIETARY RISK ESTIMATES

TMRC Exposure (mg/kg bw/dy)	Q*1 (mg/kg bw/dy)	Risk
6.53×10^{-2} [1/]	4.7×10^{-3} [2/]	3×10^{-4}

1/ TMRC exposure = 3.93 mg/dy of daminozide in a 1.5 kg diet for a 60 kg adult. Exposure is assumed to be a worst case estimate for daminozide at tolerance levels.

2/ Estimated potency factor was calculated using the blood vessel tumors from both sexes of mice and a one-hit multistage model and was uncorrected for the shorter lifetime of the treated animals (MRID 005009679).

B) UDMH

The Agency has insufficient data to estimate the amount of UDMH which may be present in raw agricultural commodities. Therefore, no risk estimate for UDMH can be performed at this time.

The Agency is concerned about UDMH and daminozide dietary exposure to special groups of individuals (especially young children) who consume large quantities of apple products. Dietary risk estimates for processed apples for age groups between birth and adult (maturity) vary considerably. The Agency cannot estimate risk from such a relatively short and varying exposure at this time. However, it should be recognized that the food consumption for these 1 to 2 year old age groups are many times greater than those typical for the 60 kg adults. The risk associated with these types of individuals will be an area of discussion in the Special Review.

2) Nondietary Risk

The Agency's estimates of risk from apple orchard application are presented below.

APPLICATOR RISK ESTIMATES

Exposure Range 1/ (mg/kg bw/dy)	Q*1 (mg/kg bw/dy)	Risk Range
Daminozide		
1.6×10^{-3} to 1.8×10^{-2}	4.7×10^{-3}	7.5×10^{-6} to 8.4×10^{-5}

1/ Assumes 100 percent absorption.

While few data currently are available on exposure to UDMH and daminozide, the Agency currently believes that the risk associated with nondietary exposure to these chemicals may not result in unreasonable adverse effects. Dermal absorption of daminozide is expected to be low as this water soluble chemical has a low fat solubility. Additionally, a dermal LD-50 study indicates that little, if any, daminozide passes through the skin.

d. Conclusions

The Agency has made a preliminary determination that orally dosed daminozide is an oncogen and is contaminated with and hydrolyzes to UDMH, a known oncogen. Daminozide has exceeded the oncogenicity risk criterion for Special Review.

Daminozide possesses numerous unique plant growth regulatory effects for apples. Without daminozide, fresh market Red Delicious and McIntosh apple producers would incur substantial net revenue losses in the short run, ranging up to $30 million per year. No other plant growth regulators are registered for use on peanuts. Without daminozide, peanut growers could be expected to sustain short term reductions in net revenue, ranging from $4.3 to $10.7 million annually.

The Agency estimates that the dietary risk from daminozide residues is high. Additionally, the Agency believes that dietary exposure from UDMH residues will also occur. The Agency believes that the risk associated with nondietary exposure to daminozide is less significant, since data indicate dermal absorption may be low.

Pending further review, registration of new products and reregistration of current products containing daminozide cannot be permitted until the Agency has completed the Special Review, has received a commitment to fulfill the data required by this standard and has reviewed the data requested by the Agency on August 25, 1983 under section 3(c)(2)(B) FIFRA.

DATA REQUIREMENT TABLES

TABLE A
GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

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 Section 3(c)(2)(B)? When?2/
§158.120 Product Chemistry				
Product Identity				
61-1 - Identity of Ingredients	TGAI	partially	00009540	yes 5/
61-2 - Statement of Composition	TGAI	partially	GS032003,00009511 00009514	yes 5/
61-3 - Discussion of Formation of Unintentional Ingredients	TGAI	partially	GS032003 GS032040	yes 3/4/5/
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	partially	GS032040	yes 5/
62-2 - Certification of Limits	TGAI	partially	GS032040	yes 5/
62-3 - Analytical Methods for Enforcement of Limits	TGAI	partially	00022043,00009423 00009540,00009511	yes 5/

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ All data must be submitted within 6 months after receipt of the Guidance Document.
3/ A quantitative depiction of the unintentional ingredients, present in the technical material, up to 0.1% of the total weight have to be provided.
4/ A description of the methodology used in the identification and/or quantification of the unintentional ingredients in the registered technical material should be provided.
5/ Data are available from Uniroyal Chemical, but no data are available from Aceto Chemical Company for this specific data requirement. Aceto Chemical must submit this data.

TABLE A
GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

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 Section 3(c)(2)(B)? When?2/
Physical and Chemical Characteristics				
63-2 - Color	TGAI	partially	00009540	yes 3/
63-3 - Physical State	TGAI	partially	00009540	yes 3/
63-4 - Odor	TGAI	partially	00009540	yes 3/
63-5 - Melting Point	TGAI	partially	00009540	yes 3/
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	no	-	yes 4/
63-8 - Solubility	TGAI	partially	00009540	yes 3/
63-9 - Vapor Pressure	TGAI	no	-	yes 4/
63-10 - Dissociation Constant	TGAI	partially	00009540	yes 3/
63-12 - pH	TGAI	partially	00009540	yes 3/

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ All data must be submitted within 6 months after receipt of the Guidance Document.
3/ Data are available from Uniroyal Chemical, but no data are available from Aceto Chemical Company for this specific data requirement. Aceto Chemical must submit this data.
4/ This data gap pertains to both Uniroyal and Aceto Chemical Corp.

TABLE A
GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

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 Section 3(c)(2)(B)? When?2/
§158.120 (cont'd)				
63-13 - Stability	TGAI	partially	00009540	yes 3/
63-14 - Oxidizing or Reducing Action	TGAI	no	-	yes 4/
63-16 - Explodability	TGAI	no	-	yes 4/
63-17 - Storage Stability	TGAI	partially	00009511	yes 3/

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

2/ All data must be submitted within 6 months after receipt of the Guidance Document. D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ No data are available from Aceto Chemical Company for this specific data requirement. Aceto Chemical must submit this data.

4/ This data gap pertains to both Uniroyal and Aceto Chemical Corp.

TABLE A
GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

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 Section 3(c)(2)(B)? When?
§158.130 Environmental Fate					
Degradation - Laboratory					
161-1 - Hydrolysis	TGAI or PAIRA	A	Partially	GS032022,00009707	Yes/6 months 3/4/
Photodegradation					
161-2 - In Water	TGAI or PAIRA	A	No	-	Yes/6 months 3/
161-3 - On Soil	TGAI or PAIRA	A	No	-	Yes/6 months 3/
161-4 - In Air	TGAI or PAIRA	A	Partially	00009707	Yes/6 months 3/
Metabolism - Laboratory					
162-1 - Aerobic Soil	TGAI or PAIRA	A	No	00009417,00009708	Yes/24 months 3/
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes/24 months 3/
Mobility					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A	Partially	00009707,00009708	Yes/6 months 5/
163-2 - Laboratory Volatility	TEP	A	No	-	Yes/6 months
163-3 - Field Volatility	TEP	A	No	-	Reserved 6/

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.
3/ Analysis for UDMH, hydrazine and 1,1-dimethylnitrosamine required. If radiolabeled studies will be conducted, nitrogen labeling is preferred.
4/ Analysis to be performed at pH 1, 5, 7 and 9.
5/ Aged soil must be used in this study. Metabolites must be identified.
6/ Pending results of the Laboratory Volatility data requirement (163-2).

TABLE A
GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

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 Section 3(c)(2)(B)? When?
Dissipation Studies - Field					
164-1 - Soil	TEP	A	Partially	00009707,00009577	Yes/24 months 3/
164-5 - Soil, Long-term	TEP	A	No	-	Reserved 4/
Accumulation					
165-1 - Rotational Crops (Confined)	PAIRA	A	Partially	00009726	Yes/24 months 5/
165-2 - Rotational Crops (Field)	TEP	A	No	-	Reserved 6/
165-4 - Fish (Laboratory)	TGAI or PAIRA	A	Partially	00009725	Reserved 7/
165-5 - Aquatic Non-Target Organisms (Field)	TGAI or PAIRA	A	No	-	Reserved 8/
Subpart K					
Reentry	TEP	A	No	-	Yes/24 months 9/

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.
3/ Analysis for UDMH required in this study.
4/ Requirement for this study depends on results of the Soil Dissipation data requirement (164-1).
5/ Metabolite identification required.
6/ Requirement for this study depends on results of the Confined Rotational Crop data requirement (165-1).
7/ Requirement depends on results of octanol/water coefficient. If required, metabolite identification in fish required and analysis of water for UDMH is required.
8/ Requirement for this study depends on results of the Fish Accumulation data requirement (165-4).
9/ An interim reentry interval of 24 hours is required until data have been reviewed by the Agency. Registrants must submit foliar dissipation data.

GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

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 Section 3(c)(2)(B)? When?
§158.135 Toxicology					
Acute Testing					
81-1 - Oral LD50 (rat)	TGAI	A,B,F	Yes	00009737	No
81-2 - Dermal LD50	TGAI	A,B,F	Yes	00009737	No
81-3 - Inhalation LD50 (rat)	TGAI	A,B,F	Yes	00009737	No
81-4 - Primary Eye Irritation	TGAI	A,B,F	Partially	00009679	Yes/6 Months
81-5 - Primary Dermal Irritation	TGAI	A,B,F	Yes	00009682	No
Subchronic Testing					
82-1 - 90 Day Feeding (rodent)	TGAI	A,B,F	Yes	00009727	No
Chronic Testing					
83-1 - Chronic Toxicity Two Species (rodent & nonrodent)	TGAI	A,B,F	Partially	00009413	Yes/48 months 3/
83-2 - Oncogenicity Two Species (rat and mouse)	TGAI	A,B,F	Yes	00009413,05007997 05009679	No
83-3 - Teratogenicity Two Species	TGAI	A,B,F	Partially	05018829,GS032002	Yes/12 months 4/

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.

3/ Rodent and non-rodent studies are required.

4/ A study utilizing a second mammalian species (mouse, hampster or rabbit) must be performed.

TABLE A
GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

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 Section 3(c)(2)(B)? When?
83-4 - Reproduction - Two Generation	TGAI	A,B,F	Partially	00009413	Yes/24 months
Mutagenicity					
84-2 - Gene Mutation	TGAI	A,B,F	Yes	00009681	No
84-2 - Chromosomal Aberration	TGAI	A,B,F	No	-	Yes/6 months
84-2 - Dominant Lethal	TGAI	A,B,F	Yes	00009683	No
Metabolism					
85-1 - General Metabolism	PAI or PAIRA	A,B,F	Partially	00009414	Yes 3/
Contaminant					
- Rodent Oncogenicity	Anal. Grade UDMH	A,B,F	Yes	GS032001,05009679	No

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.

3/ This study was requested under section 3(c)(2)(B) FIFRA on August 25, 1983. This study must be submitted to the Agency by June 30, 1985.

TABLE A
GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

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 Section 3(c)(2)(B)? When?4/
§158.145 Wildlife and Aquatic Organisms					
Avian and Mammaliam Testing					
71-1 - Avian Oral LD50	TGAI	A,B,F	No	-	Yes
	UDHM	A,B	No	-	Yes
71-2 - Avian Dietary LD50 -					
a. Waterfowl	TGAI	A,B	Yes	00009703	No
	UDMH	A,B	No	-	Yes
b. Upland Gamebird	TGAI	A,B,F	Yes	00009705	No
	UDMH	A,B	No	-	Yes
71-3 - Wild Mammal Toxicity	TGAI				3/
71-4 - Avian Reproduction	TGAI				3/
71-5 - Simulated & Actual Field Testing (Mammals/Birds)	TEP				3/
Aquatic Organism Testing					
72-1 - Freshwater Fish LC50 -					
a. Warmwater	TGAI	A,B,F	No	-	Yes
	UDMH	A,B	No	-	Yes
b. Coldwater	TGAI	A,B	Yes	00009706	No
	UDMH	A,B	No	-	Yes
72-2 - Acute LC50 Freshwater Invertebrates	TGAI	A,B,F	No	-	Yes
	UDMH	A,B		-	Yes

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.
3/ Not applicable at this time.
4/ All data must be submitted within 48 months after receipt of the Guidance Document.

TABLE A
GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

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 Section 3(c)(2)(B)? When?
Aquatic Organism Testing (Cont'd)					
72-3 - Acute LC50 Estuarine & Marine Organisms	TGAI				3/
72-4 - Fish Early Life Stage & Aquatic Invertebrate Life-cycle	TGAI				3/
72-5 - Fish Life Cycle	TGAI				3/
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product				3/
72-7 - Simulated or Actual Field Testing (Aquatic Organisms)	TEP				3/

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.
3/ Not applicable at this time.

TABLE A
GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

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 Section 3(c)(2)(B)? When?7/
§158.125 Residue Chemistry					
Metabolism					
- Plants	PAIRA		partially	05012551,GS032041, 00009474,GS032042, 00009527,00009470, 00009586,GS032003, GS032022,05021600, 05013980,05016127, 05012420,05012407, GS032023	yes 3/6/8/
- Livestock	PAIRA & plant metabolites		partially	GS032043,00009528, 00009586	yes 4/
Analytical Methods					
- Plant Residues	TGAI & metabolites		partially	05015547,00010338, 05004402,00009470, 00009586	yes 5/
- Animal Residues	TGAI & metabolites				yes

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.
3/ Additional data should be submitted indicating whether UDMH is present at the 1 to 10 ppb level in raw agricultural commodities resulting from application of daminozide.
4/ Additional data is requested on the formation and presence of daminozide metabolites in tissues and milk.
5/ A reliable analytical method, sensitive from 1 to 10 ppb, must be submitted for the determination of UDMH in raw agricultural commodities, tissues, milk and eggs.
6/ Further testing for N-nitrosodimethylamine is not necessary at this time.
7/ All data must be submitted within 12 months after receipt of the Guidance Document, except as noted.
8/ Animal and plant metabolism data must be submitted to the Agency by June 1, 1984.

TABLE A
GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

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 Section 3(c)(2)(B)? When?5/
Storage Stability Data	PAI	-	no		yes
Residue Data					
- Crops	TEP	A			
o Apples			yes	00009709,00009716,00009472,00009471,00009422	yes 3/4/
o Pears (WA & OR, only)			yes	GS032021	yes 3/4/
o Sour Cherries			yes	00009551	yes 3/4/
o Sweet Cherries			yes	00009595	yes 3/4/
o Peaches			yes	00009594	yes 3/4/
o Nectarines			yes	00009465	yes 3/4/
o Fresh Prunes (French Variety, CA only)			yes	00009432	yes 3/4/
o Dried Prunes			yes	00009432	yes 3/4/

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.
3/ Residue data on UDMH must be submitted on these commodities.
4/ All residue data were submitted by Uniroyal, Inc. No residue data were submitted by Aceto Chemical Co., Inc.
5/ All data must be submitted within 12 months after receipt of the Guidance Document.

TABLE A
GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

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 Section 3(c)(2)(B)? When?6/
Residue Data					
- Crops	TEP	A			
o Brussel Sprouts			yes	00009429	yes 3/4/
o Grapes			yes	00009422	yes 3/4/5/
o Canteloupes (AZ & CA, only)			yes	00009431	yes 3/4/
o Tomatoes (Field Grown Transplants)			yes	00009422,00009550	yes 3/4/
o Peanuts			yes	00022055,00009582, 00022053,00009660, 00009755,00009660, 00009647	yes 3/4/

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.
3/ Residue data on UDMH must be submitted on these commodities.
4/ All residue data were submitted by Uniroyal, Inc. No residue data were submitted by Aceto Chemical Co., Inc.
5/ The label restriction "Use on Concord Grapes only" should be returned to the label. Otherwise, residue data for raisins, raisin waste and grape pomace are required.
6/ All data must be submitted within 12 months of the receipt of the Guidance Document.

TABLE A
GENERIC DATA REQUIREMENTS FOR DAMINOZIDE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 6/	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? When?5/
§158.125 Residue Chemistry (cont'd)					
- Processed Crops	TEP	A			
o Apple Pomace			yes	00009709	yes 3/
o Raisins, Raisin Waste, & Grape Pomace			no		yes 4/
o Tomato Products (concentrated)			partially	GS032023	yes 3/
o Tomato Pomace			no		yes 3/
o Peanut Hulls			yes	00022055	yes 3/
o Peanut Hay			yes	00009513	yes 3/
o Peanut Oil & Meal			yes	00009583	yes 3/
- Meat and Milk	TEP		yes	00009516,00009462	yes 3/
- Poultry	TEP		yes	00009516,00009462	yes 3/
- Eggs	TEP		yes	00009516,00009462	yes 3/

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.
3/ Residue data on UDMH must be submitted on these commodities.
4/ Registration carried an initial restriction for use on concord grapes only. This restriction no longer remains on the label. Registrant must submit the referenced data or return to previous restriction.
5/ All data must be submitted within 12 months after receipt of the Guidance Document.
6/ All residue data were submitted by Uniroyal, Inc. No residue data were submitted by Aceto Chemical Co., Inc.

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix I) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice 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 Section 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 ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted[2/]. Any necessary studies must be conducted in accordance with acceptable protocols, examples of which are contained in EPA's Pesticide Assessment Guidelines[3/], and, for the most part, in the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

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 (or all such products having a certain use pattern), regardless of any such product's unique composition or 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/ U.S. EPA, 1982. Pesticide Registration; Proposed Data Requirements - Part 158. FEDERAL REGISTER of November 24, 1982 (47 FR 53192).

3/ U.S. EPA, 1983. Pesticide Assessment Guidelines, National Technical Information Service, Springfield, VA.

Also 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 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: The "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 IV 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] 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 Registration 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.

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.

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 III)*/

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.)

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*/ FIFRA Section 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
(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed.

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. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA will consider your request, you remain subject to the deadlines for submitting the required data until EPA grants your request.

(Footnote continued from previous page)
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.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data 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 not 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 is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. 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. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This chapter applies only to manufacturing-use products, not 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 IV) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This chapter applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix V-1 an V-2], as indicated by the following paragraphs of this chapter of the guidance document.

You must submit the revised labeling set forth in this guidance package within 90 days of receipt of this guidance package.

A. Label Contents

40 CFR §162.10 (Appendix V-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix V-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. See Appendix V-2. [40 CFR §162.10(b)]

Item 2. COMPANY NAME, ADDRESS AND PHONE NUMBER - The name, address and phone number 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. See Appendix V-2. [40 CFR §162.10(c)]

Item 3. AVERAGE NET CONTENTS - An average net content statement is required on all labels. 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 average net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the

largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix V-2. [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 V-2. [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 registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix V-2. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and nominal percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients as indicated in your certification of limits. The preferred location is immediately below the product name. The ingredient 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 V-2. [40 CFR 162.10(g)]

Item 6A. 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 - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
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 - All labels are required to have the statement "KEEP OUT OF REACH OF CHILDREN" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix V-2. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix V-2. [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, inhalation, or dermal 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 V-2. [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 V-2. [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 V-2. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as 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 V-2. [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 taken to avoid accident, injury or damage. See Appendix V-2. [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 V-2. [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 V-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) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

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

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (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 submitted in accordance with 40 CFR §163.61-10(c) 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 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix V-2. [40 CFR §162.10(l)(2)(ii)]

Item 10A. 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. Make certain that the statement you use pertains specifically to your product. 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 V-4 for the latest specific storage and disposal product label statements.

Item 10B. 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 V-2. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other 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

All applications prepared in response to this Notice should be addressed as follows:

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

For each product for which continued registration is desired:

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 and revised labeling. Refer to Appendix II with appropriate attachments.

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

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

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

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1).

APPENDIX I

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 materials 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 known 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.

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

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

(1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission.

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

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 25th 123456-Z; and the 27th, 123456-AA.

INDEX OF CITATIONS USED IN THE DATA REQUIREMENT CHARTS
REFERENCES LISTED IN NUMERIC ORDER

MRID No.	Author
GS032001	Toth, 1973
GS032002	Knickerbocker, 1979
GS032003	Von Schmelling, 1981
GS032021	Uniroyal, 1972
GS032022	Wright, 1981
GS032023	Uniroyal, 1975
GS032040	Von Schmelling, 1983
GS032041	Dahgren, 1963
GS032042	Sachs, 1967
GS032043	Tyer, 1967
00009413	Oser, 1966
00009414	Ryer, 1966
00009417	Ames, 1966
00009422	U.S. Rubber Co., 1966
00009423	Uniroyal, 1975
00009429	Uniroyal, 1972
00009431	Uniroyal, 1972
00009432	Uniroyal, 1972
00009465	Uniroyal, 1969
00009470	Newell, 1968
00009471	Uniroyal, 1967
00009472	Edgerton, 1967
00009474	Reed, 1965
00009511	Uniroyal, 1972
00009514	Uniroyal, 19??
00009527	Chin, 1970
00009528	St. John, 1969
00009540	U.S. Rubber Co., 1966
00009550	Uniroyal, 1968
00009551	Uniroyal, 1968
00009577	Dannals, 1972
00009582	Uniroyal, 1971
00009586	Sisken, 1970
00009594	Uniroyal, 1968
00009595	Uniroyal, 1968
00009681	Brusick, 1977
00009682	Griffiths, 1977
00009683	Palmer, 1973
00009703	Beavers, 1977
00009705	Beavers, 1977
00009706	Kuc, 1977
00009707	Kucharczyk, 1971
00009708	Dannals, 1972
00009709	Lind, 1975
00009725	Sleight, 1973
00009726	Erdmann, 1978
00009727	Carson, 1964
00009737	Carson, 1963

INDEX OF CITATIONS USED IN THE DATA REQUIREMENT CHARTS
REFERENCES LISTED IN NUMERIC ORDER

MRID No.	Author
00009716	State University College of New York, 1972
00009725	Sleight, 1973
00009726	Erdmann, 1978
00009727	Carson, 1964
00009737	Carson, 1963
00009755	Uniroyal, 1975
00010338	Edgarton, 1967
00022043	Uniroyal, 1969
00022053	Uniroyal, 1969
00022055	Uniroyal, 1966
05004402	Lynch, 1969
05007997	NCI, 1978
05009679	Toth, 1977
05012407	Shutak, 1968
05012420	Martin, 1964
05012551	Martin, 1966
05013980	Dicks, 1973
05015547	Looney, 1972
05016127	Takahasi, 1969
05018829	Khera, 1979
05021600	Newsome, 1980

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Daminozide Registrations

MRID No.	Citation
000009417	Ames, R.B.; Smith, A.E.; Stone, G.M. (1966) Persistence of Alar-85 in Soil. Method dated Nov 17, 1966. (Unpublished study received Dec 15, 1966 under 7F0552; submitted by United States Rubber Co., Naugatuck, Conn.; CDL:090684-K)
000009703	Beavers, J.B. (1977) Final Report: Acute Oral LD50 --Mallard Duck: Project No. 117-121. (Unpublished study received Aug 25, 1977 under 400-79; prepared by Wildlife International, Ltd., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:096322-A)
000009705	Beavers, J.B. (1977) Final Report: Eight-Day Dietary LC50--Bobwhite Quail: Project No. 117-126. (Unpublished study received Aug 25, 1977 under 400-79; prepared by Wildlife International, Ltd., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:096322-C)
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000009527	Chin, W.T.; Stone, G.M. (1970) Fate of Alar in Peanut Plants and Peanuts. (Unpublished study received Feb 11, 1971 under 0F0990; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:091704-M)

GS0032041 Dahlgren and Simmerman (1965) Science 148:485.

000009708 Dannals, L.E.; Puhl, R.J.; Kucharczyk, N. (1972) Environmental Fate Studies on Alar (R)*: Second Status Report on PR 70-15: Work on Succinic acid 2,2-dimethylhydrazide (Alar-85, Kylar-85, Kylar). (Unpublished study received Apr 20, 1972 under 400-79; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:120367-A)

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000010338 Edgerton, L.J.; Rockey, M.L.; Arnold, H.; et al. (1967) Colorimetric determination of Alar residues in apples. Journal of Agricultural and Food Chemistry 15(5):812-813. (Also In unpublished submission received Feb 7, 1968 under 8F0704; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:093010-B)

000009726 Erdmann, M.R.; Jackson, C.E.; Meck, R.D.; et al. (1978) Alar (R)●14C Rotational Crop Study: Project No. 7701. (Unpublished study received Sep 29, 1978 under 400-49; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:097590-A)

000009682 Griffiths, J.; Babish, J.G. (1977) Report: Primary Skin Irritation Study with Rabbits. (Unpublished study received Mar 10, 1978 under 400-117; prepared by Food and Drug Research Laboratories, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL: 233200-E)

005018829 Khera, K.S.; Whalen, C.; Trivett, G.; Angers, G. (1979) Teratologic assessment of maleic hydrazide and daminozide, and formulations of ethoxyquin, thiabendazole and naled in rats. Journal of Environmental Science and Health, Part B 14(6):563-577.

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000009528 St. John, L.E., Jr.; Arnold, H.; Lisk, D.J. (1969) Metabolic studies with Alar growth regulator in the dairy cow. Journal of Agricultural and Food Chemistry 17(1):116-117. (Also In unpublished submission received Feb 11, 1971 under 0F0990; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:091704-R)

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000022043 Uniroyal, Incorporated (1969) Control Test AC-1031: Neutralization Equivalent of Alar Tech. Rev. Method dated Sep 8, 1969. (Unpublished study received May 8, 1974 under 4F1504; CDL:093986-D)

000009511 Uniroyal, Incorporated (1972) Alar (R)®, Succinic acid 2,2-dimethylhydrazide: Alternate Names--B995, B-9, B-Nine (R)®. (Unpublished study received May 8, 1974 under 4F1504; CDL: 093986-A)

000009423 Uniroyal, Incorporated (1975) Alar-85: Analysis for Alar in Alar-85 and Kylar-85 (via Bromide/Bromate Titration). Method AC-1060-C dated Jun 24, 1975. (Unpublished study including letter dated Jul 10, 1975 from A.W. Mitlehner to Robert J. Taylor, received Jul 16, 1975 under 2F1271; CDL:095331-A)

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000009431 Uniroyal, Incorporated (1972) The Effects of EPA Tolerance Pesticides upon the Recovery of Alar (R)* Residues from Melons. (Unpublished study received Oct 3, 1972 under 2F1271; prepared in cooperation with Morse Laboratories and State Univ. College of New York--Oswego, Lake Ontario Environmental Laboratory; CDL: 091801-C)

000009432 Uniroyal, Incorporated (1972) The Effects of EPA Tolerance Pesticides upon the Recovery of Alar (R)* Residues from Prunes. (Unpublished study received Oct 3, 1972 under 2F1271; prepared in cooperation with Morse Laboratories CDL:091801-D)

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GS0032040 Von Schmelling, B. (1983) Uniroyal submission of May 27, 1983. (Accession Number 250943, MRID No. 00130644)

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APPENDIX II

OMB Approval No. 2070-0060 ; Expires 12-31-93

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

APPENDIX III

OMB Approval No. 2000-0468 (Expires: 12-31-33)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

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

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

APPENDIX IV

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				

63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

APPENDIX V-1

cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).

(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:

(1) The data the applicant has submitted to EPA under paragraph (b) of this section;

(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and

(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.

(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:

(1) A notification of the applicant's intent to apply for registration, including the proposed product name;

(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);

(3) An identification of the item(s) of data to which the offer applies;

(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and

(5) The applicant's name, address, and telephone number.

(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:

(1) All data submitted or specifically cited by the applicant in support of the registration; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of any such active ingredient; and

(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27953, May 11, 1979]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by

any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run par-

allel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity, irritation reversible within 7 days	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the

placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) 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. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* 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. Examples of the hazard statements and the circum-

stances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F. if there is a flashback at any valve opening	Extremely flammable Contents under pressure Keep away from fire, sparks, and heated surfaces Do not puncture or incinerate container Exposure to temperatures above 130° F may cause bursting
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable Contents under pressure Keep away from heat, sparks, and open flame Do not puncture or incinerate container Exposure to temperatures above 130° F may cause bursting
All other pressurized containers	Contents under pressure Do not use or store near heat or open flame Do not puncture or incinerate container Exposure to temperatures above 130° F may cause bursting
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable Keep away from fire, sparks, and heated surfaces
Above 20° F and not over 80° F	Flammable Keep away from heat and open flame
Above 80° F and not over 150° F	Do not use or store near heat or open flame

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* 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.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended

for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. 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." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing—* (1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five

APPENDIX V-2

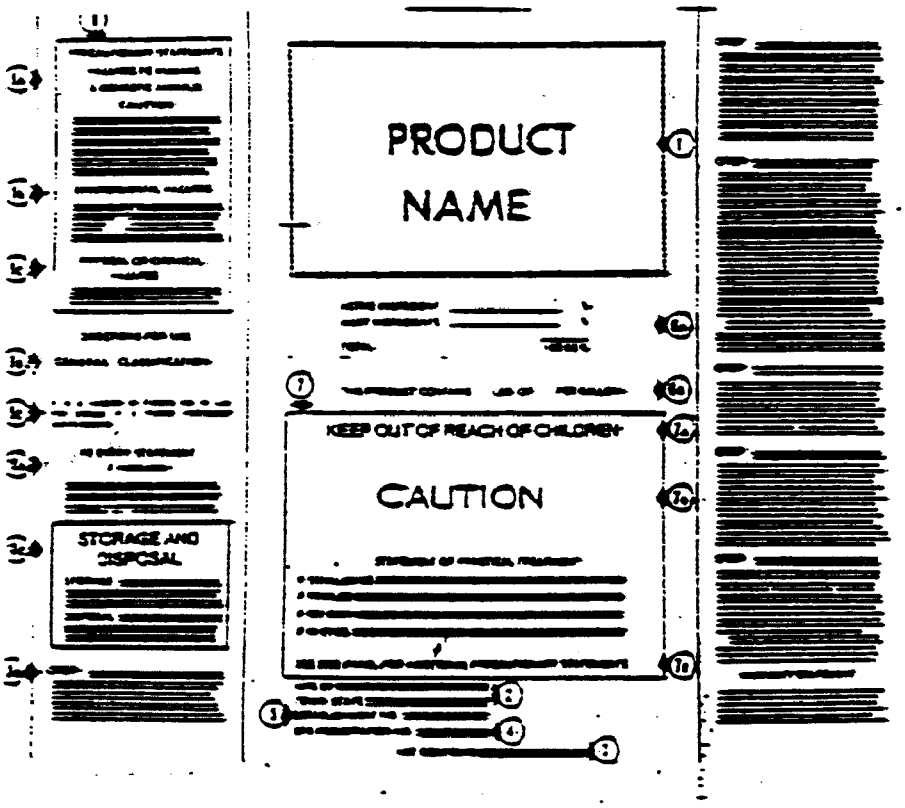
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

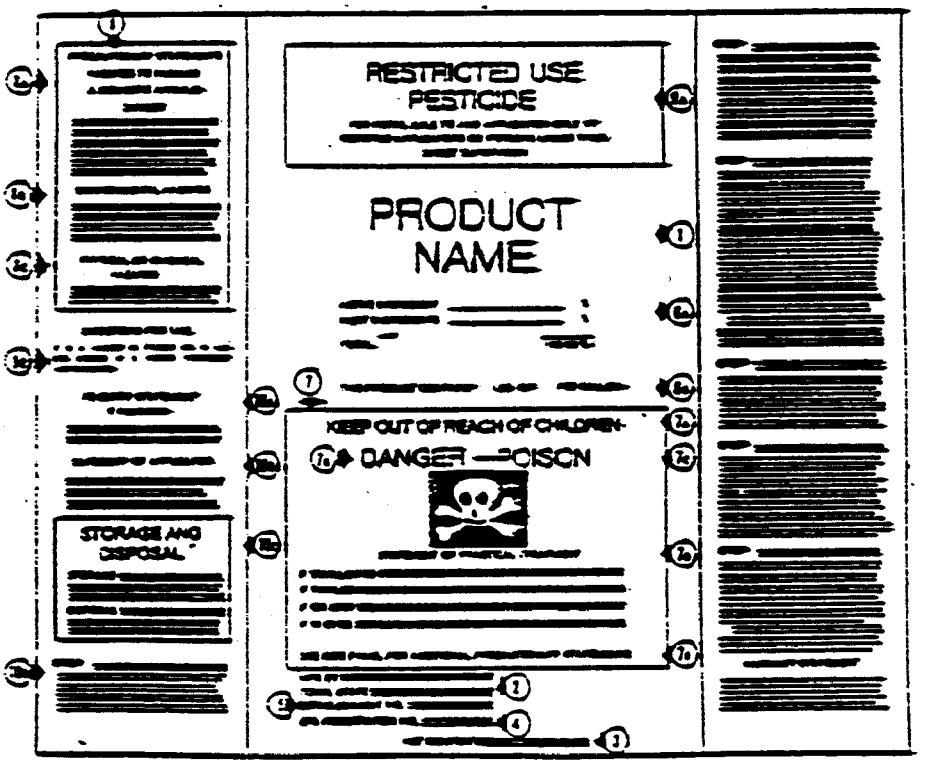
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

SAMPLE LABELS



General Use Pesticide



Restricted Use Pesticide

APPENDIX V-3

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

APPENDIX V-4

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, O,O-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene