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Office of
Pesticides and Toxic Substances
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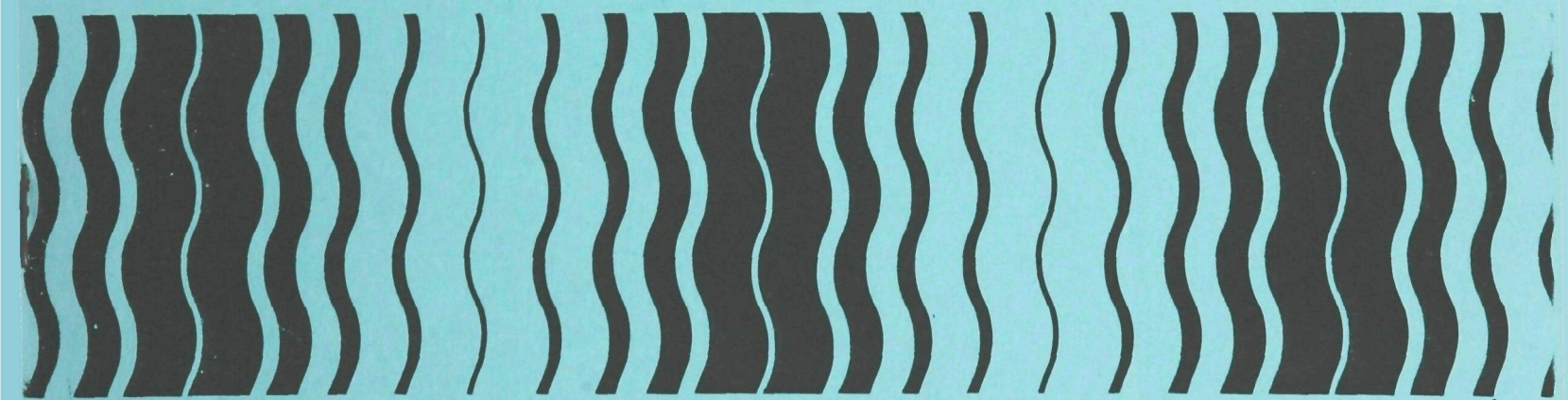
Pesticides

EPA

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



GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

AMITRAZ

AS THE ACTIVE INGREDIENT

EPA Case No. 234

CAS NUMBER 33089-61-1

October 1987

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1]The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Regulatory Position and Rationale section. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicologic and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify

the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical and Use Profile

Amitraz is the American National Standards Institute's (ANSI) acceptable common name for N'-(2,4-dimethylphenyl)-N-[[(2,4-dimethylphenyl)imino]methyl]-N-methylmethanimidamide. Other names and code designations are: Estrella, Azadieno, Baam, Mitac, Taktic, JA 119, Triazid, Triatox and Azaform. The current Chemical Abstract Service (CAS) registry number for amitraz is 33089-61-1 and the EPA Shaughnessy number is 106201.

Technical amitraz is a straw colored crystalline solid. Its melting point is 86-87°C. Amitraz at 25°C is extremely soluble in xylene (66.6g/100ml) and acetone (50g/ 100ml) and relatively insoluble in methanol (2.38g/100ml) and water (<1ppm). The empirical formula is $C_{19}H_{23}N_3$ and the molecular weight is 293.

Technical amitraz is imported into this country from England by Nor-Am Chemical Company. This pesticide is not produced domestically. There are six products currently registered which contain amitraz as an active ingredient. Two are technical amitraz products (93%) and the other four are end-use products. These are all single active ingredient formulations.

Amitraz end-use formulations are an emulsifiable concentrate and a wettable powder. There are no intra-state registrations for amitraz. Amitraz is registered to control insects and mites

on pears, ticks on cattle and lice on hogs. There are proposed tolerances and applications for registration for apples and citrus. Amitraz is currently a restricted-use pesticide and applicators must be certified or be under the direct supervision of applicators certified to apply amitraz. However, the Agency has reevaluated the basis for the restricted use designation and determined that it is not warranted as described below in section C (4).

B. Regulatory Background

Amitraz was first registered in 1975 as a 93% technical to be used in the preparation of experimental miticide/insecticide formulations. The first application for registration for an end-use product for use on apples and pears was made in 1976. In April 1977, before the registration of these uses, the Agency published in the Federal Register (42 FR 18299) a notice of a rebuttable presumption against registration (RPAR, and currently known as a Special Review) of pesticide products containing amitraz on the basis that amitraz met the risk criteria for oncogenic effects (40 CFR 162.11(a)(3)(ii)(A)). An 80-week mouse oncogenicity study showed a significant increase in the incidence of lymphoreticular tumors in mice.

In January, 1979, the Agency published in the Federal Register (44 FR 2678-2682) a notice of determination and availability of Position Document 2/3. This position document presented the Agency's analysis of the risks and benefits resulting from the

proposed use of amitraz on apples and pears, analyzed the rebuttals received from interested parties and proposed a decision to conclude the RPAR process. The Agency concluded that there is "weakly positive evidence" that amitraz is a possible human carcinogen based on the positive effects demonstrated in the mouse study although there were questions raised regarding the reliability of the study. The Agency also concluded that the proposed use of amitraz on apples and pears might pose a very small risk of cancer to certain exposed groups. To determine that risk the Agency conducted a dietary and occupational risk assessment.

The Agency, in its assessment of dietary and occupational risks associated with the use on pears, calculated two scenarios for exposure, one conservative and the other more realistic. The conservative scenario used the assumptions that: all pears were treated annually; all fresh and processed pears had residues of of amitraz at the tolerance level (3.0 ppm); and mixers, loaders and applicators did not wear protective clothing. These conservative assumptions led to calculated risks of 9×10^{-6} (10^{-5}) from dietary exposure and 10^{-4} to 10^{-6} from occupational exposure. The more realistic scenario included the following assumptions: only 40-50% of the pear acreage is treated annually, fresh pears average 1.0 ppm and processed pears average 0.25 ppm of amitraz residues and mixers, loaders and applicators are required to wear protective clothing. This more realistic scenario leads to risks of 10^{-6} for dietary and 10^{-5} to 10^{-6}

for occupational exposure. In reviewing the benefits and risks, the Agency determined that there would be significant benefits from the use on pears since there was no viable registered alternative to amitraz for control of the pear psylla. However, there were little or no benefits from the use on apples since there were suitable alternatives. After weighing the benefits and risks, the Agency in the PD 2/3 proposed to issue a conditional registration for four years for use of amitraz on pears provided that the company agreed to certain terms and conditions. These were (1) to submit additional benefits data on pears, (2) submit a new mouse oncogenicity study and (3) implement several changes on the proposed label. The label changes were: classification of all amitraz products as restricted use; additional precautionary changes including protective clothing for applicators; and, a 24-hour reentry interval and a 7-day pre-harvest interval.

2. Conclusion of RPAR

In October, 1979, the Agency published in the Federal Register (44 FR 59939-59946) a notice of its intent to conditionally register amitraz for use on pears and not to issue registration for use on apples. This FR Notice also announced the availability of Position Document 4. In this notice the Agency proposed to conditionally register amitraz for use on pears for four years under section 3(c)(7)(C) of FIFRA with the conditions that the registrants make certain label changes

and that an additional mouse oncogenicity study and benefits data be submitted within four years from the date of registration.

This section of FIFRA allows conditional registration of a pesticide product containing unregistered active ingredients only if the registration would not cause unreasonable adverse effects and would be in the public interest. The Agency determined that the registration of amitraz for use on pears would not cause unreasonable adverse effects and would be in the public interest because it would result in substantial benefits which outweighed risks. The Agency determined that it could not grant registration of amitraz for use on apples because the requirements of section 3(c)(7)(C) of FIFRA had not been met. The Agency concluded that this use would result in little or no benefits and would therefore not be in the public interest. Amitraz was granted a conditional registration in January, 1980, for four years only for use on pears. At the same time, the Agency established a 0.0 ppm tolerance for residues of amitraz in or on apples, and the fat, meat by-products, and meat of cattle, goats, hogs, horses, and sheep to effect the decision to prohibit the use on apples. (Waste from processed apples is fed to livestock.)

3. Reassessment Based on New Data

The conditions under which amitraz was conditionally registered have been satisfied. The benefits data were reviewed and found to substantiate the benefits of the use on pears. A new mouse oncogenicity study was referred to the Agency's Cancer Assessment

Group (CAG) for evaluation. The results of this study showed an increase in the incidence of hepatocellular tumors in female mice. Based on this study and the first mouse study, CAG determined that amitraz had carcinogenic activity in the mouse. The second study did not appreciably change the Agency's quantitative assessment of the potency of amitraz from the first mouse study. Based on the weight of evidence, CAG concluded that amitraz should be considered a possible human carcinogen in the lower portion of the group "C" range. In reaching this conclusion CAG considered the following information:

There is no positive epidemiology carcinogenicity data for amitraz.

The positive carcinogenic effects were found in only one species, the mouse.

Tumors were discovered mostly in terminally sacrificed groups.

The rat was negative for oncogenic effects at doses as high as 200 ppm.

Also, the mutagenic potential of amitraz had been determined to be negative in the gene mutation, hostmediated and dominant lethal test systems. Additional negative studies including the Ames Bacterial Test, a Mouse Lymphoma Assay, and an Unscheduled DNA Synthesis in Human Embryonic Cells have been conducted with amitraz. In addition, several metabolites were also tested with their mutagenic potential also reported to be generally negative. The Agency is not aware of any other pesticide that is structurally related to amitraz that shows carcinogenicity. However, the parent compound does metabolize to substituted anilines, some of which as a class are oncogenic.

The chronic toxicology data base for amitraz is complete. The toxicological data considered in support of this registration standard included a 2-year rat feeding/oncogenicity study which was negative for oncogenic effects with a no-observable-effect-level (NOEL) of 200 ppm; a three-generation rat reproduction study with a NOEL of 15 ppm; rat and rabbit teratology studies which were negative; and a 2-year mouse oncogenicity study which demonstrated an increase in the incidence of hepatocellular tumors in female mice.

4. Presentation to the Scientific Advisory Panel

On February 12, 1986 the Agency presented its conclusions and rationale to the FIFRA Scientific Advisory Panel (SAP) on the carcinogenicity of amitraz. The Agency stated that it "recognizes that Group C covers a broad range of oncogenic properities of limited evidence in animals and views amitraz to be in the lower portion of the Group C range". This means the classification is near the C/D interface for which no clear evidence of oncogenic potential has been demonstrated.

Industry also presented its position which included their view that (1) the second mouse study may have exceeded the maximum tolerated dose and therefore compromised the mice physiologically and (2) data support the hypothesis that there is an indirect hormonal mechanism for tumorigenesis at the high dose which dose which does not exist a lower doses.

After considering all of the evidence and presentations, the SAP

concluded that amitraz should be classified in Group "D", (not classifiable as to human carcinogenicity) because they believed the weight of the evidence was inadequate to clearly categorize the oncogenic potential of amitraz.

The Agency has reassessed its own position in light of the industry presentations and the SAP opinion and has now concluded that amitraz is a borderline Class C/D carcinogen considering the following information:

- the increase in liver tumors is found in only 1 sex, one species, and one dose, i.e., female mice at the high dose only.
- a two year acceptable rat oncogenicity study is negative for oncogenic potential;
- there is an essentially negative gene toxicity data base;
- the high dose administration in the second mouse study may have exceeded the maximum tolerated dose (MTD) and therefore compromised the females physiologically;
- data presented support an indirect hormonal mechanism for tumorigenisis at the high dose which may not be operative at lower doses.

For the same reasons stated above, the Agency believes that a quantitative risk assessment for amitraz would not provide useful enough information on which to base a reasonable regulatory decision. Therefore, a quantitative risk assessment will not be performed. The risks from use of amitraz can only be assessed in a qualitative way; i.e., there is weak evidence that amitraz may be a carcinogen in laboratory animals and therefore may pose some unquantifiable risk to people exposed to amitraz through the diet or during application.

In this registration process the Agency has reconsidered the risks and benefits associated with the use on pears in view of the reassessment of the data base including the new oncogenicity study and benefits data. The assessment of these data has led the Agency to change its opinion of amitraz'z oncogenic potential; i.e., it is a Class C/D carcinogen instead of a Class C carcinogen. The benefits of use of amitraz remain essentially the same and the benefits outweigh the qualitative risks.

III. REGULATORY POSITION AND RATIONALE

A. Summary Of Regulatory Position and Rationales

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

1. All products containing amitraz as a sole active ingredient may continue to be registered or sale, distribution, reformulation, and use on pears, cattle and hogs subject to the terms and conditions specified in this Guidance Document. Registrants must provide, or agree to develop, additional data, as specified in Tables A and B in order to maintain existing registrations or to permit new registrations.

   Rationale: Under FIFRA, the Agency may choose not to cancel or withhold registration if data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3 (c)(7)). The issuance of this standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary. In addition, the Agency made a regulatory decision in 1980 to conditionally register amitraz for use on pears because a risk/benefit assessment demonstrated that the benefits from the use outweighed the risks. A current evaluation of the benefits from the use of amitraz on pears indicates that the benefits have not changed. No viable alternative to amitraz for control of the pear psylla has been registered by the Agency since the original benefits assessment. The

Agency has since registered amitraz for use on hogs and cattle. As discussed above, the Agency has not quantified the risks due to the use of amitraz but has reevaluated the evidence which indicates it to be a Class C/D carcinogen. Although exposure to amitraz may pose some unquantifiable oncogenic risk, the Agency believes it continues to be in the best interest of the public to continue the registration of amitraz; the benefits of use of amitraz outweigh the qualitative risks.

2. The Agency cannot issue tolerances for the proposed use of amitraz on apples and citrus at this time. The Agency will consider new uses for amitraz on a case-by-case basis.

Rationale:

The toxicology data base for amitraz is complete. The environmental data base for amitraz is largely incomplete. However, there are uses which would have minimal impact on the environment. Available residue data submitted in support of the proposed apple and citrus uses indicate that food additive (409) tolerances for apple pomace and citrus molasses and pulp must be established. There is weakly positive evidence that amitraz is a carcinogen. At this time the Agency can not establish these food additive tolerances because of the Delaney Clause within Section 409 of the Federal Food, Drug and Cosmetic Act. The Delaney Clause in Section 409 of the FFDCA bars the establishment of food/feed additive regulations for substances which induce

cancer in man or test animals, with certain exceptions. The Agency is currently developing a position relative to the Delaney Clause and FIFRA. Once this policy has been established, the proposed apple and citrus tolerances will be reevaluated. Other uses will be evaluated on a case by case basis.

3. The Agency is requiring environmental fate studies to characterize amitraz's fate in the environment, including its potential to leach through soil.

Rationale: Data are not sufficient either to assess the environmental fate of amitraz or to characterize its leaching potential for contamination of ground water. The preliminary data indicate that amitraz may have the potential to leach through soil. A leaching study (although not adequate by Agency standards) indicates that amitraz is moderately mobile in sandy loam, silt loam and clay soils and very mobile in sandy soils. Additional studies are being required. The Agency has become increasingly concerned about the presence of pesticide chemicals in ground waters in the United States. Although amitraz was not included in the Special Data Call-In Notice the Agency issued on March 31, 1984 the Agency is concerned over the potential of amitraz to leach. The data required under this Guidance Document will allow the Agency to characterize the potential of amitraz to contaminate ground water.

4. The Agency has determined that end use products containing amitraz will no longer be classified as restricted use products.

Rationale: The Agency required that all end-use amitraz products be classified for restricted use when amitraz was conditionally registered for use on pears in an effort to reduce worker exposure. However, upon reassessment of the carcinogenic potential of amitraz, the Agency has concluded that it is a borderline Class C/D carcinogen, on the line between "possible human carconogen" and "not classifiable as to human carcinogenicity" (the animal evidence is inadequate) Therefore, because the hazard could not be well defined, a quantitative risk assessment would not be appropriate. Because of this reassessment, the Agency believes it would be unreasonable to restrict the use of amitraz, since the weight of the evidence is inadequate to clearly catagorize the oncogenic potential. Continuation of the restricted use classification is not warranted. Because there are no other reasons to restrict amitraz products at this time, the Agency via this Standard is removing the restricted use classification for amitraz end-use products. For the same reasons, the Agency will not impose a cancer label warning for amitraz products; the evidence does not warrant such a warning.

5. The Agency will continue to require a reentry interval of 24 hours for the pear use of amitraz.

Rationale: Amitraz meets the toxicity and exposure criteria for reentry as defined under the Pesticide Assessment Guidelines. In order to minimize exposure of this acutely toxic pesticide to workers entering treated areas pending the receipt and evaluation of reentry data, the 24-hour reentry interval will be continued. Through this Guidance Document studies are being required to further evaluate amitraz's exposure potential. Upon receipt and review of these data, the Agency will reevaluate the reentry interval established for amitraz.

6. The Agency is requiring a study to determine the effects of amitraz on avian reproduction.

Rationale: Acute toxicity studies indicate that amitraz is slightly toxic to birds. A one-generation avian reproduction study, although inadequate, demonstrated that amitraz would affect avian reproduction at less than 40 ppm. A NOEL was not established with that study. Therefore, a new study is being required. Also, sufficient environmental fate data are not available to permit assessment of avian exposure to amitraz residues. Based on Agency receipt and review of the avian reproduction data and the environmental fate data required by this Guidance Document, the Agency will be able to determine if amitraz poses a hazard to bird reproduction.

7. The Agency is requiring additional plant metabolism data since the metabolism of amitraz in plants has not been adequately described.

Rationale: Heretofore, the parent compound, amitraz and its metabolites containing the 2,4-dimethylaniline moiety have been considered to be the residues of concern in plants. However, reexamination of existing data indicate that about 60% of the residues were unidentified. Should the required metabolism data indicate the presence of additional metabolites of concern, the tolerance definition will have to be altered accordingly. In addition, the Agency is concerned over the possibility of amitraz to hydrolyze and form dimethylamine which has been shown to cause liver tumors in mice. The Agency cannot determine whether amitraz does hydrolyze to dimethylamine and if so, the amount, until the plant metabolism data are submitted.

8. The Agency is not imposing label statements at this time with regard to endangered species.

Rationale: The limited available data indicate that technical amitraz is slightly toxic to birds. Although an avian reproduction study indicates a potential chronic hazard to birds is possible if there is sufficient exposure from the use of amitraz, the effect on birds including endangered species cannot be assessed until a new avian reproduction study and the environmental fate data required by this Guidance Document

are received and evaluated. The available data also suggest that the estimated residues that could occur in water as a result of the pear use of amitraz do not result in an endangered aquatic species concern. The Agency will address the need for an endangered species label statement when the environmental fate and avian reproduction data are received and evaluated.

9. Registrants of end-use products must submit revised labeling which incorporates the label precautions found in Section G.

Rationale: The Agency believes that the label statements prescribed in this Standard should minimize the hazards associated with exposure to users of amitraz and to aquatic organisms.

B. Criteria for Registration Under This Standard

To be covered under this Guidance Document products must contain amitraz the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section F of this document.

The application for registration or reregistration of manufacturing-use products subject to this Guidance Document must comply with all terms and conditions described in it, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, commitment to fill data gaps on the schedule specified by the Agency and, when applicable, offer to pay compensation as required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136(c)(2)(D).

C. Acceptable Ranges and Limits

1. Product Composition Standard

To be covered under this Guidance Document manufacturing-use products must contain amitraz as the sole active ingredient. Each manufacturing-use product formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active and intentionally added inert ingredients which may be present in products.

2. Acute Toxicity Limits

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

3. Use Patterns

To be registered under this Standard, manufacturing-use products containing amitraz may be labeled for formulation into other manufacturing-use products or into end-use products only for the use on pears. The attached index entry provides the approved maximum application rate and frequencies.

D. Required Labeling

All manufacturing-use and end-use amitraz products must bear appropriate labeling as specified in 40 CFR 162.10, PR Notices 83-2, 83-3, 87-4, 87-5, and below. Appendix II contains further information on label requirements.

Pesticide products containing amitraz as the active ingredient may not be released for shipment by the registrant after October 31, 1988 unless the product bears amended labeling which complies with the requirements of this standard.

Pesticide products containing amitraz as the active ingredient may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered to any person after October 31, 1989 unless the product bears amended labeling which complies with the requirements of this Standard.

All Products

1. Ingredient Statement

The ingredient statement for manufacturing-use products and end-use products must list the active ingredient as:

Amitraz: N'-(2,4-dimethylphenyl)-N-[[2,4-dimethylphenyl)=imino]methyl]-N-methylmethanimidamide

Manufacturing Use Products

1. Use Pattern Statement

All manufacturing-use amitraz products must state that they are intended for formulation into other manufacturing-use products or into end-use products for use only on pears.

2. Environmental Hazards

The following revised environmental hazard statement must appear on all MP labels:

> "This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

End-Use Products

1. Reentry Statement

The reentry statement below must appear in the use directions of labels of all amitraz products with directions for use for use on pears:

> "Do not reenter treated areas for 24 hours without protective clothing."

2. Protective Clothing and Equipment

The worker protection statements listed below must appear as part of the precautionary statements for all end-use amitraz products:

> "During mixing/loading or application wear a protective suit which has long sleeves and long pants. Wear chemical resistant gloves; a hat, boots and goggles or face shield. A helmet with visor may be substituted for the hat and goggles during aerial application. Mixer/loaders should also wear a chemical resistant apron when handling the concentrated product. Wash thoroughly with soap and water after handling and before eating, urinating, or smoking. Remove and wash clothing before reuse. Clothing should be laundered separately from household articles. Replace gloves frequently. Clothing which has been drenched and used gloves should be disposed of in accordance with state or local regulations. Instead of clothing and equipment specified above, the applicator can use an enclosed tractor cab or cockpit with properly filtered air supply."

3. Environmental Hazards

The following environmental hazards statement listed below must appear on each end-use label in the Environmental Hazards section:

> "This product is toxic to fish. Do not apply directly to water. Drift and runoff from treated areas may be hazardous to fish in adjacent sites. Do not contaminate water by cleaning of equipment or disposal of wastes."

E. Tolerance Reassessment Summary

U.S. tolerances for residues of amitraz in or on the raw agricultural commodities are as follows:

3.0 ppm in or on pears

0.1 ppm cattle, fat

0.3 ppm cattle, mbyp

0.05 ppm cattle, meat

0.03 ppm milk

0.3 ppm milk, fat

0.1 ppm hogs, fat

0.2 ppm hogs, kidney and liver

0.3 ppm hogs, mbyp

0.05 ppm hogs, meat

0.0 ppm in or on apples, and the fat, meat by-products, and meat of goats, horses, and sheep

The zero tolerances were established administratively as a result of the RPAR as an affirmative action to emphasize the Agency's decision not to permit the use of amitraz on apples. Interim Codex Maximum Residue Limits have been established for amitraz as follows: in or on pome fruits at 0.5 ppm; in or on oranges at 0.5 ppm; and, in or on the carcase meat of cattle and pigs at 0.05 ppm, cattle, pig, and sheep meat by-products at 0.2 ppm and milk at 0.01 ppm. There are no Canadian or Mexican tolerances established for amitraz. The metabolism of amitraz in plants has not been adequately

described. Should the required metabolism data indicate the presence of additional metabolites of concern, the tolerance definition will be revised accordingly. The available pear residue data support the established tolerance level for amitraz residues in or on pears.

There are no finite tolerances established for amitraz residues on crops involving livestock feed items. At this time, data pertaining to the metabolism of amitraz in food animals for purposes of this Registration Standard are not required.

The acceptable daily intake (ADI) for amitraz is 0.0025 mg/kg/day based on the 2-year chronic dog feeding study with a no observed effect level (NOEL) of 10 ppm and a safety factor of 100. The maximum permitted intake (MPI) (based on a 60 kg person) is 0.15 mg/day. The theoretical maximum residue contribution (TMRC) resulting from the published tolerancesis 0.0723 mg/day which accounts for 48.20% of the ADI.

IV. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing amitraz as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section III.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

V. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

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

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission.

The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. <u>You request a waiver of the data requirement</u>. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. <u>You request that EPA amend your registration by deleting the uses for which the data are needed</u>. You are not required to submit data for uses which are no longer on your label.

6. <u>You request voluntary cancellation of the registration of your product(s) for which the data are needed</u>.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time

extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting

such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VI. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section V.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or V.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

VIII. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

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

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

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

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

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

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

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

E. Addresses

The required information must be submitted to the following address:

Dennis H. Edwards, Jr. PM 12)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

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

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

APPENDIX I

DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

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

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

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

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data must Be Submitted Within Time Frames Listed Below [1]
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	[X]	[ ]		6 Months
63-8 - Solubility	TGAI or PAI	R	[ ]	[X]		
63-9 - Vapor Pressure	PAI	R	[ ]	[X]		
63-10 - Dissociation constant	PAI	R	[ ]	[X]		
63-11 - Octanol/water partition coefficient	PAI	R	[X]	[ ]		6 Months
63-12 - pH	TGAI	R	[X]	[ ]		6 Months
63-13 - Stability	TGAI	R	[X]	[ ]	7	15 Months
Other Requirements:						
64- 1 - Submittal of samples	TGAI, PAI	CR	[ ]	[X]		

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

§158.120 Product Chemistry (Continued)

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

2. Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
   - 6 Month Due Date is _____.
   - 15 Month Due Date is _____.

3. Details of the manufacturing process including the relative amounts of beginning materials, description of reaction conditions, duration of each step of the process and quality control measures for the stabilized 93% technical must be submitted. The name and address of the manufacturer or producer of each starting material for the stabilized 93% technical must be submitted. In addition, a copy of all available technical specifications, data sheets, and all other documents by which the manufacturer, producer or supplier of the beginning material describes its composition and properities must be submitted.

4. A discussion of each impurity believed to be present at >0.1% based on knowledge of any contamination such as migration of components of packaging materials into the product and contaminants resulting from earlier use of production equipment to produce other products or substances must be submitted.

5. Five or more representative samples should be analyzed for the amount of active ingredient and each impurity present >0.1%. Analysis for nitrosoamine impurities should include volatile and non-volatile nitrosoamines.

6. Not required because the 93% stabilized technical is a solid at room temperature.

7. Insufficient information was provided as to the sensitivity of the 93% stabalized technical to metal ions and metal, therefore additional data are required.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirements	Composition [1]	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission [2]
§158.125 Residue Chemistry				
171-2 - Chemical Identity	TGAI	Yes	GS00234015;GS00234016	No
171-3 - Directions for Use	--	Yes	GS00234017	No
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partial	00028664;00028666 00055718;GS00234011 GS00234012	Yes[3] 18 Months
- Livestock	PAIRA and Plant Metabolites	No	-	Reserved[4]
171-4 - Residue Analytical Method				
- Plant residues	TGAI and Metabolites	Yes	00046030;00051930 00051929;GS00234013	No[5]
- Animal residues	TGAI and Metabolites			Reserved[4]
- Storage stability	TGAI and Metabolites	Partial	00046029;GS00234014	Yes[6] 15 Months
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
- Pears	TEP	Yes	00046029;00051717	No

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirement	Composition [1]	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames for Data Submission [2]
§158.125 Residue Chemistry - Continued				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
-- Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	No	-	Reserved[4]
171-5 - Reduction of Residue	Residue of Concern	No	-	No[7]
171-6 - Proposed Tolerance	Residue of Concern	No	-	No[7]
171-7 - Reasonable Grounds in Support of Petition	--	No	-	No[7]
171-13 - Submittal of Analytical Reference Standards	PAIRA	Yes	-	No[7]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

§158.125 Residue Chemistry - Continued

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

2. Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
   ° 15 Month Due Date is _____.
   ° 18 Month Due Date is _____.

3. The available plant metabolism data are not adequate because a large fraction (>60%) of ^{14}C-residues recovered from mature pears was not identified. Data reflecting the distribution and metabolism of ^{14}C-amitraz labeled in both benzene rings in mature pears harvested 7 days after the last of a series of prebloom and foliar applications (at least 10) at 1.5lb. AI/A is required. It may be necessary to apply exaggerated rates to obtain sufficient residues for identification. Analyses should include hydrolysis and reextraction of plant residues and aqueous fractions to determine conjugated ^{14}C-residues of amitraz. ^{14}C amitraz treated pears should also be analyzed by enforcement "cold" methodology to determine whether conjugated metabolites of concern are determined by the method and to verify detection of all 2,4-dimethylaniline.

4. There are no finite tolerances established for amitraz residues on crops involving livestock feed items. Therefore, data are not required at this time.

5. If additional metabolites of toxicological concern are found then additional validated methods for data collection and tolerance enforcement will be required.

6. Data are required reflecting the stability of metabolites III, IV, and V in or on pears stored at freezing temperatures for intervals up to 42 days.

7. Not applicable.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission [3]
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A	No	-	Yes	9 Months
Photodegradation						
161-2 - In water	TGAI or PAIRA	A	No	-	Yes	9 Months
161-3 - On soil	TGAI or PAIRA	A	No	-	Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A	No	-	No[4]	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A	No	-	Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	A	No	-	No[4]	
162-4 - Aerobic Aquatic	TGAI or PAIRA	A	No	-	No[4]	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A	Partial	00114229	Yes[5]	12 Months
163-2 - Volatility (Lab)	TEP	A	No	-	Yes	12 Months
163-3 - Volatility (Field)	TEP	A	No	-	Yes	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

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

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

§158.130 Environmental Fate - Continued

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. Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
   - 9 Month Due Date is _____.
   - 12 Month Due Date is _____.
   - 15 Month Due Date is _____.
   - 27 Month Due Date is _____.
4. Not required based on use pattern.
5. Although this study is scientifically sound, this study does not fulfill this data requirement because of the following deficiencies: the test soils were not completely characterized; the purity of the test substance was not reported; the incubation temperature was not reported; degradates were not identified; and values of soil/water relationships (K_d) were not reported. This information must be submitted to upgrade the study or another study must be conducted.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral Toxicity - Rat	TGAI	A	Yes	00041539	No
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A	Yes	00040862	No
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A	Yes	00029963	No
81-7 - Delayed Neurotoxicity - Hen	TGAI	A	No	-	No[4]
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding : - Rodent, and	TGAI	A	Yes	00028712;00028715	No[5]
- Non-rodent (Dog)		A	Yes	00028716	No
82-2 - 21-Day Dermal - Rabbit	TGAI	A	Yes	00029972	No
82-3 - 90-Day Dermal - Rabbit	TGAI	A	No	-	No
82-4 - 90-Day Inhalation: - Rat	TGAI	A	No	-	No
82-5 - 90-Day Neurotoxicity: - Hen	TGAI	A	No	-	No[4]
-Mammal		A	No	-	No[4]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.135 Toxicology - Continued					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species:	TGAI				
- Rodent, and		A	Yes	00044585	No
- Non-rodent (Dog)		A	Yes	00044586	No
83-2 - Oncogenicity - 2 species:	TGAI				
- Rat (preferred), and		A	Yes	00044485	No
- Mouse (preferred)		A	Yes	00139552;00111886	No
83-3 - Teratogenicity - 2 species:	TGAI				
- Rat		A	Yes	00029959;00029960	No[5]
- Rabbit		A	Yes	00029961	No
83-4 - Reproduction - Rat 2-generation	TGAI	A	Yes	00029962	No
MUTAGENICITY TESTING					
84-2 - Gene Mutation (Ames Test)	TGAI	A	Yes	00029459;00029953	No[5]
84-2 - Structural Chromosomal Aberration	TGAI		Yes	00029954;00029955 00029957	No[5]
84-4 - Other Genotoxic Effects	TGAI	A	Yes	00029958;GS00234007	No[5]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.135 Toxicology - Continued					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A	Yes	00028685;00028674 00028667;00028675 00028668;00028676 00028671;00041503 00028669;00041497 00028672;00041499 00041500;00041498 00041501;00028682 GS00234006	No[5]
86-1 - Domestic Animal Safety	Choice	A	Yes	00041513;00044591	No[5]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

§158.135 Toxicology - Continued

1. Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2. The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3. Data must be submitted within the indicated time frame, based on the date of the Guidance Document....
   ° 12 Month Due Date is _____.

4. Amitraz is not an organophosphate compound and is not structurally related to a substance that causes delayed neurotoxicity.

5. All references must be cited to satisfy this data requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A	No	-	Yes[4] 27 Month
132-1 - Soil Dissipation	TEP	A	No	-	No[5]
133-3 - Dermal Exposure	TEP	A	No	-	No[5]
133-4 - Inhalation Exposure	TEP	A	No	-	No[5]
§158.142 Spray Drift					
201-1 - Droplet Size Spectrum	TEP	A	No	-	No[5]
201-1 - Drift Field Evaluation	TEP	A	No	-	No[5]
Special Testing					
Glove Permeability Study	TEP	A	No	-	Yes[6] 6 Months

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

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

3. Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
   - 6 Month Due Date is _____.
   - 27 Month Due Date is _____.

158.140 Reentry Protection
158.142 Spray Drift
Special Testing (continued)

4. An interim 24-hour reentry interval is being imposed until the foliar dissipation data are received and reviewed by the Agency.

5. Not required because the criteria that would trigger these requirements have not been exceeded.

6. Because of the oncogenicity potential of amitraz, data are required detailing the permeability and breakthrough times of materials used in "protective" gloves. Data are required to support liquid amitraz formulations. A description of this study can be found in ASTM 739-81- Standard Test Method for Resistance of Protective Materials To Permeation by Hazardous Liquid Chemicals.

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TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission [3]
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A	Yes	00030451	No	
71-2 - Avian Subacute Dietary Toxicity						
- Upland Game Bird, and	TGAI	A	Partial	00030452	Yes[4]	9 Months
	U-40481	A	No		Reserved[5]	
- Waterfowl	TGAI	A	Yes	00030453	No	
71-3 - Wild Mammal Toxicity	TGAI	A	No	-	No	
71-4 - Avian Reproduction	TGAI					
- Upland Game Bird, and		A	Partial	00072412	Yes[6]	24 Months
- Waterfowl		A	Partial	00072411	No[6]	24 Months
71-5 - Simulated Field Testing	TEP					
- Mammals, and		A	No	-	Reserved[7]	
- Birds		A	No	-	Reserved[7]	
- Actual Field Testing	TEP					
- Mammals, and		A	No	-	Reserved[7]	
- Birds		A	No	-	Reserved[7]	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.145 Wildlife and Aquatic Organisms - Continued AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish Toxicity					
a. Coldwater Fish Species,	TGAI	A	Yes	00030446;00030445	No
b. Coldwater Fish Species	TEP	A	Partial	00030445	Yes[9] 9 Months
	U-40481	A	No	-	Reserved[5]
c. Warmwater Fish Species	TGAI	A	Partial	00030447;00030448 00030444	Yes[8] 9 Months
d. Warmwater Fish Species	TEP	A	Partial	00030447;00030448 00030444	No[8]
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A	Yes	GS00234021	No
	TEP	A	No	-	Yes[10] 9 Months
	U-40481	A	No	-	Reserved[5]
72-3 - Acute Toxicity to Estuarine and Marine Organisms					
- Fish	TGAI	A	No	-	Yes[11] 12 Months
	U-40481	A	No	-	Reserved[5]
- Mollusk	TGAI	A	Yes	GS00234022;00030450	No[11]
	U-40481	A	No		Reserved[5]
- Shrimp	TGAI	A	Yes	GS00234022;00030450	No[11]
	U-40481	A	No	-	Reserved[5]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.145 Wildlife and Aquatic Organisms - Continued AQUATIC ORGANISM TESTING					
72-3 - Acute Toxicity to Estuarine and Marine Organisms (continued)					
- Fish	TEP	A	No	-	No[11]
- Mollusk	TEP	A	No	-	No[11]
- Shrimp	TEP	A	No	-	No[11]
72-4 - Fish Early Life Stage, and	TGAI	A	No	-	Yes 15 Months
- Aquatic Invertebrate Life-Cycle		A	No	-	Yes 15 Months
72-5 - Fish - Life-Cycle	TGAI	A	No	-	Reserved[13]
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	A	No	-	Reserved[13]
- Crustacean					
- Fish					
- Insect Nymph					
- Mollusk					
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	A	No	-	Reserved[12]
- Actual Field Testing	TEP	A	No	-	Reserved[12]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

§158.145 Wildlife and Aquatic Organisms - Continued

1. Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product; U-40481 = degradation product of amitraz

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

3. Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
   - 9 Month Due Date is _____.
   - 12 Month Due Date is _____.
   - 15 Month Due Date is _____.
   - 24 Month Due Date is _____.

4. The Japanese quail is not a recommended species. A study using the bobwhite quail is required.

5. Available data shows that a degradation product of amitraz (U-40481) is substantially more toxic than the parent. Testing with this degradation product may be required depending upon requested environmental fate data and the results of the requested ecological effects studies on amitraz.

6. An NOEL was not established in either the bobwhite or mallard duck study. However, only one avain reproduction study needs to be repeated, preferably with an upland gamebird (the bobwhite quail is preferred).

7. Reserved pending receipt of requested environmental fate data and/or the results of the avian reproduction data.

8. The referenced studies do not fulfill guideline requirements because the harlequin fish and the carp are not recommended test species. Also, in one study the test containers were lined with polyethylene plastic.

9. This study does not fulfill guideline requirements because it is only a 48-hr study instead of the required 96-hour and the test levels were not measured. This study is required because the test results suggest that amitraz in the 20% EC formulation is more toxic to fish than technical amitraz.

10. A 48-hour aquatic invertebrate study with the 20% EC is required because test results suggest that amitraz in the 20% EC formulation is more toxic to fish than technical amitraz.

11. Marine/estuarine testing is not required for the pear use. Present data fulfill requirements for oyster and shrimp, but the estuarine fish study would be required for future uses.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

§158.145 Wildlife and Aquatic Organisms - Continued

12. Reserved pending the results of requested environmental fate data

13. Reserved pending the results of the early life stage and aquatic invertebrate life-cycle studies and requested environmental fate studies.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

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

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.150 Plant Protection (continued)					

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

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

3. These data are not required in accordance with §158.150.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirement	1 Composition	Use 2 Pattern	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact toxicity	TGAI	A	Yes	00074486	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A	No	-	No[3]
141-4 - Honey bee subacute feeding study	(Reserved)				
141-5 - Field testing for pollinators	TEP	A	No	-	No[3]

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TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: AMITRAZ

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.155 Nontarget Insect - Continued					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects					(Reserved)
142-1 - Aquatic insect life-cycle study					(Reserved)
142-3 - Simulated or actual field testing for aquatic insects					(Reserved)
143-1 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES thru 143-3					(Reserved)

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

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

3. Due to the low toxicity demonstrated by the honey bee acute toxicity study, no further testing is required.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL: AMITRAZ

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

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL: AMITRAZ

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

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL: AMITRAZ

Data Requirement	Composition [1]	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [2]	
§158.135 Toxicology					
ACUTE TESTING					
81-1 - Acute Oral Toxicity - Rat	MP	Yes	00041539	No[3]	
81-2 - Acute Dermal Toxicity - Rabbit	MP	Yes	00040862	No[3]	
81-3 - Acute Inhalation Toxicity - Rat	MP	Yes	00029963	No[3]	
81-4 - Primary Eye Irritation - Rabbit	MP	No	-	Yes[3]	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	No	-	Yes[3]	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	No	-	Yes[3]	9 Months

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1. Composition: MP = Manufacturing-use product.

2. Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
   ° 9 Month Due Date is _____.

3. Data will support both manufacturing-use products 45639-51 and 129.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL: AMITRAZ

§158.120 Product Chemistry (Continued)

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

1. Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
   - 6 Month Due Date is _____.
   - 12 Month Due Date is _____.
   - 15 Month Due Date is _____.

2. An upper limit must be provided (and certified) for amitraz in the stabilized 93% technical product. An upper and lower limit must be provided (and certified) for the intentionally added inert in the stabilized 93% technical produt. Also, upper limits must be provided (and certified) for each impurity >0.1% (w:w) in the stabalized 93% technical product. Finally, any nitrosamines must be identified and quantified in six samples of the 93% stabalized technical; two samples of each must be analyzed shortly after production, three months after production, and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be established and certified for any nitrosamines found to be present.

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APPENDIX II

LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. 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.

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

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

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

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

Classification Labeling Requirements

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

1. All uses restricted.

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

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

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

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

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

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

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

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

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

Item 10C. 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. [40 CFR 162.10]

COLLATERAL LABELING

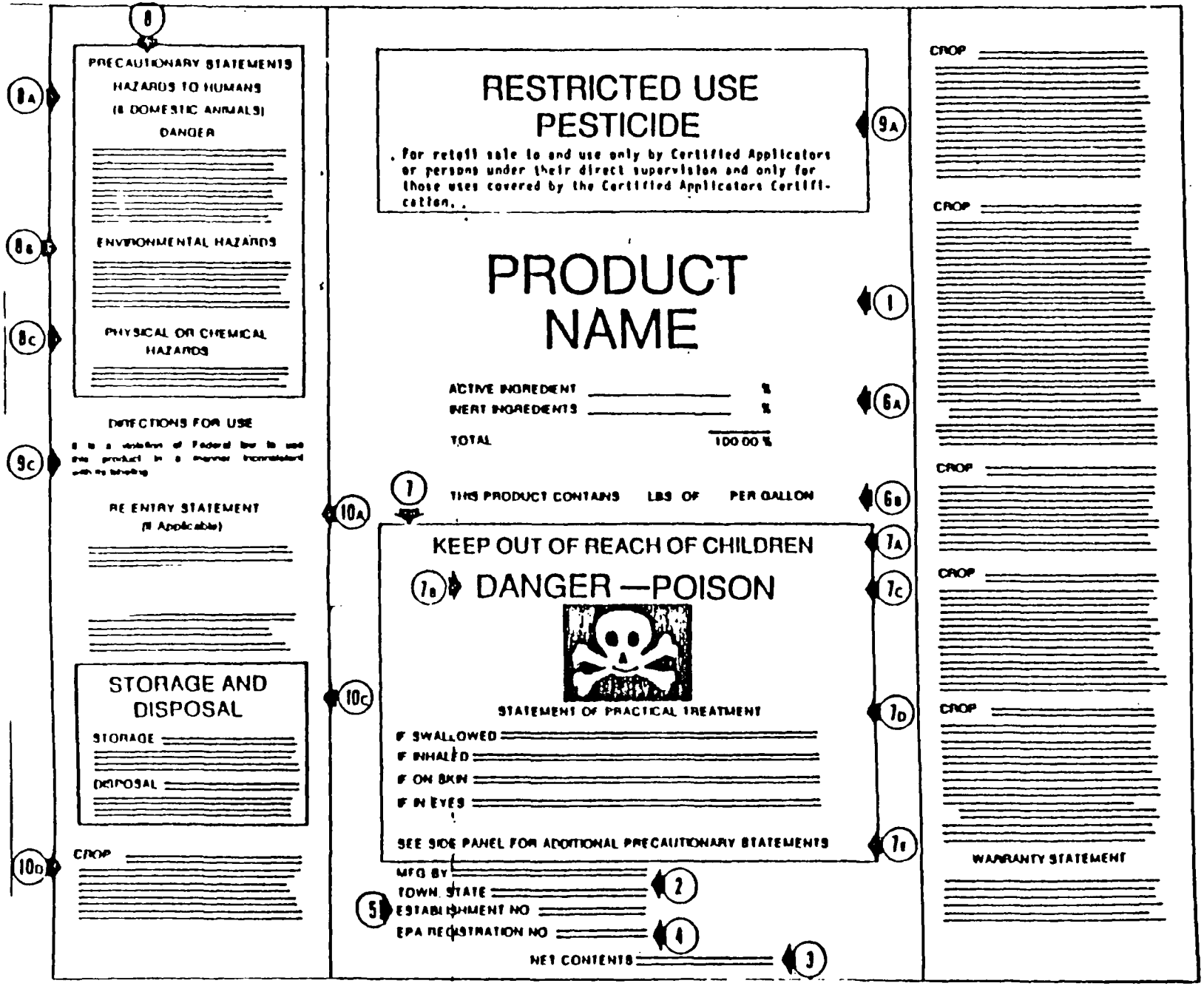
Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted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

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

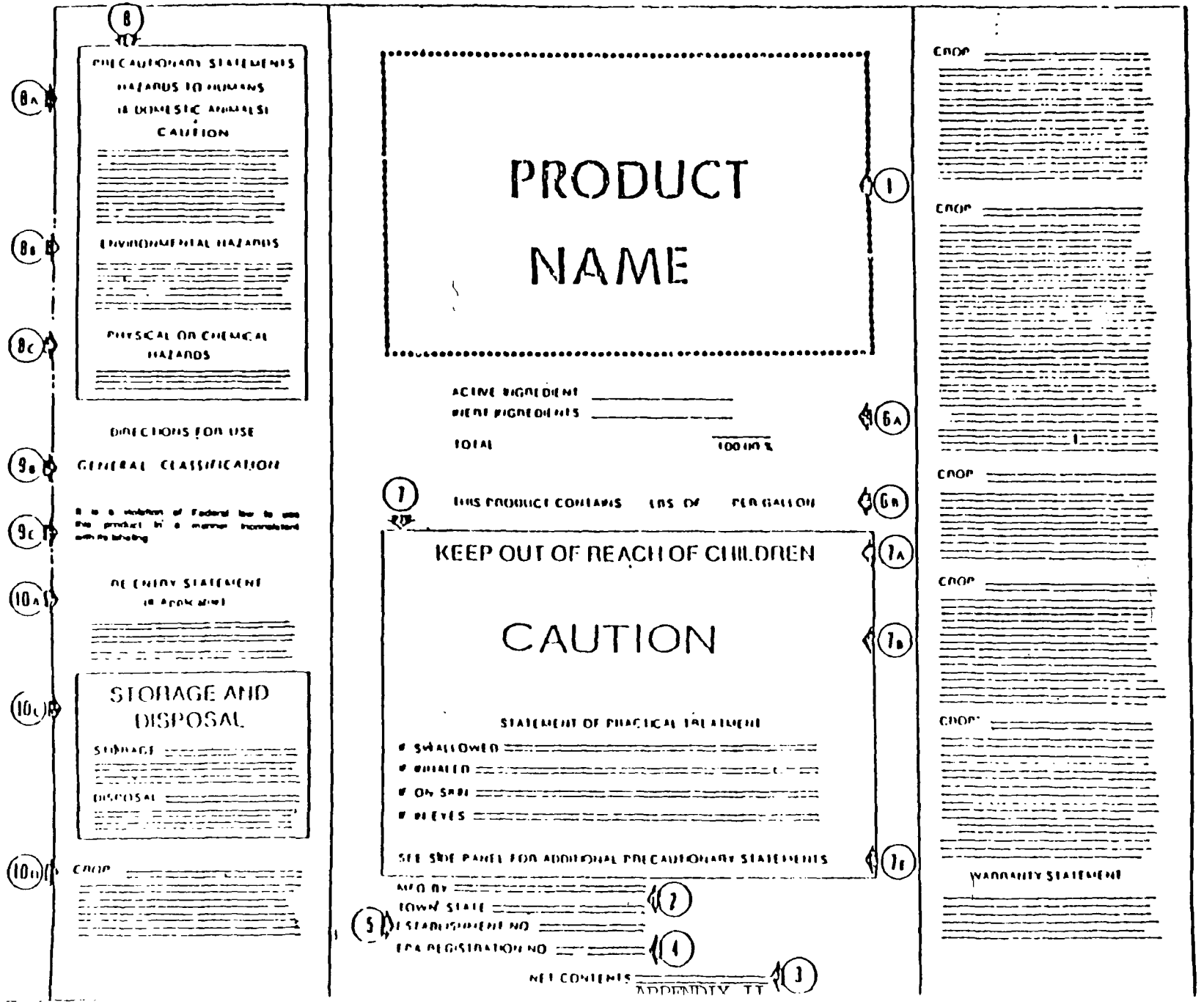
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "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 Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. 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 statement 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 or First Aid	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	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED U PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	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. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units


8
8A
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER
8B
ENVIRONMENTAL HAZARDS
8C
PHYSICAL OR CHEMICAL
HAZARDS
DIRECTIONS FOR USE
9C
RE ENTRY STATEMENT
(If Applicable)
STORAGE AND
DISPOSAL
STORAGE
DISPOSAL
10C
10D
CROP
RESTRICTED USE
PESTICIDE
. 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 Applicators Certification. .
9A
PRODUCT
NAME
1
ACTIVE INGREDIENT
INERT INGREDIENTS
%
6A
TOTAL
100.00 %
7
10A
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
KEEP OUT OF REACH OF CHILDREN
7A
7B
DANGER —POISON
7C
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
7D
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7E
MFG BY
TOWN, STATE
2
5
ESTABLISHMENT NO
EPA REGISTRATION NO
4
NET CONTENTS
3
CROP
CROP
CROP
CROP
CROP
WARRANTY STATEMENT

APPENDIX II



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APPENDIX TT

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 practi-

cal 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	8	6
Above 5 to 10	10	8
Above 10 to 15	12	9
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 precaution or statement of practical treatment to minimize such hazard and avoid injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient

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

(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

(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 (45) days from the date such notice is sent to submit evidence in rebuttal of the presumption; provided, however, that for good cause shown the Administrator may grant an additional sixty

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 that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, 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."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C 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."

4. 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."

5. 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."

PESTICIDE ACTIVE INGREDIENTS THAT ARE ACUTE HAZARDOUS WASTES

I. PESTICIDES ON THE "E" LIST (with RCRA # and CAS #)

[40 CFR 261.33(e)]

Acrolein	P003	107-13-1
Aldicarb	P070	116-06-3
Aldrin	P004	309-00-2
Allyl alcohol	P005	107-18-6
Aluminum phosphide	P006	1302-45-0
4-Aminopyridine (Avitrol)	P008	504-24-5
Arsenic acid	P010	7778-39-4
Arsenic pentoxide	P011	1303-28-2
Arsenic trioxide	P012	1327-53-3
Calcium cyanide	P021	592-01-8
Carbon disulfide	P022	75-15-0
p-Chloroaniline	P024	106-47-8
Cyanides (soluble cyanide salts not otherwise specified)	P030	
Cyanogen chloride	P031	506-77-4
Dieldrin	P037	60-57-1
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate (disulfoton)	P039	298-04-4
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos®)	P040	297-97-2
Dimethoate	P044	60-51-5
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)	P071	298-00-0
4,6-Dinitro-o-cresol and salts	P047	534-52-1
4,6-Dinitro-o-cyclohexylphenol	P034	131-89-5
Dinoseb	P020	88-85-7
Endosulfan	P050	115-29-7
Endothall	P088	129-67-9
Endrin	P051	72-20-8
Famphur	P097	52-85-7
Fluoroacetamide	P057	640-19-7
Heptachlor	P059	76-48-8
Hexachlorohexahydro-exo,exo-dimethanonaphthalene (Isodrin)	P069	465-73-6
Hydrocyanic acid	P063	74-90-8
Methomyl	P066	16752-77-5
alpha-Naphthylthiourea (ANTU)	P072	86-88-41
Nicotine and salts	P075	54-11-5
Octamethylpyrophosphoramide (OMPA, schradan)	P085	152-16-9
Parathion	P089	56-38-2
Phenylmercuric acetate (PMA)	P092	62-38-4
Phorate	P094	298-02-2
Potassium cyanide	P098	151-50-8
Propargyl alcohol	P102	107-19-7
Sodium azide	P105	26628-22-8
Sodium cyanide	P106	143-33-9
Sodium fluoroacetate	P058	62-74-8

Strychnine and salts	P108	57-24-9 60-41-3
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)	P109	3689-24-5
Tetraethyl pyrophosphate	P111	107-49-3
Thallium sulfate	P115	7446-18-6
Thiofanox	P045	39196-18-4
Toxaphene	P123	8001-35-2
Warfarin (>0.3%)	P001	81-81-2
Zinc phosphide (>10%)	P122	1314-84-7

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II. PESTICIDES DERIVED FROM TRI-, TETRA-, AND PENTACHLOROPHENOLS [40 CFR 261.31]

2-Chloroethyl 2-(2,4,6-trichlorophenoxy) ethyl ether	F027	5324-22-1
Dehydroabietylammonium pentachlorophenoxide	F027	35109-57-0
Erbon	F027	136-25-4
O-ethyl O-(2,4,5-trichlorophenyl) ethylphosphonothioate	F027	327-98-0
2,2'-Methylenebis (3,4,6-trichlorophenol) (Hexachlorophene)	F027	70-30-4
--Potassium salt of	F027	67923-62-0
--Sodium salt of	F027	3247-34-5
--Disodium salt of	F027	5736-15-2
Pentachlorophenol	F027	87-86-5
--Potassium salt of	F027	7778-73-6
--Sodium salt of	F027	131-52-2
--Zinc salt of	F027	2917-32-0
--Zinc salt of N-alkyl (C_{16}-C_{18})-1,3-propanediamine	F027	
--Pentachlorophenyl laurate	F027	3772-94-9
Potassium trichlorophenate (2,4,6)	F027	2591-21-1
Potassium trichlorophenate (2,4,5)	F027	35471-43-3
Silvex	F027	93-72-1
--2-Butoxyethyl ester	F027	19398-13-1
--Butoxypolypropoxypropyl ester	F027	53404-07-2
--Butoxypropyl ester	F027	25537-26-2
--Diethanolamine salt	F027	51170-59-3
--Diisopropanolamine salt	F027	53404-09-4
--Dimethylamine salt	F027	55617-85-1
--Dipropylene glycol isobutyl ether ester	F027	53535-26-5
--Ethanolamine salt	F027	7374-47-2
--2-Ethylhexyl ester	F027	53404-76-5
--Isooctyl ester	F027	53404-14-1

--Isopropanolamine salt	F027	53404-13-0
--Monohydroxylaluminum salt	F027	69622-82-8
--Polypropoxypropyl ester	F027	83562-66-7
--Potassium salt	F027	2818-16-8
--Propylene glycol isobutyl ether ester	F027	53466-84-5
--Sodium salt	F027	37913-89-6
--Triethanolamine salt	F027	17369-89-0
--Triethylamine salt	F027	53404-74-3
--Triisopropanolamine salt	F027	53404-75-4
--Tripropylene glycol isobutyl ether ester	F027	53535-30-1
Sodium 2-(2,4,5-trichlorophenoxy) ethyl sulfate	F027	3570-61-4
Tetrachlorophenols	F027	25167-83-3
--Alkylamine*amine salt (as in fatty acids of coconut oil)	F027	
--Potassium salt	F027	53535-27-6
--Sodium salt	F027	25567-55-9
2,4,5-Trichlorophenol	F027	95-95-4
2,4,6-Trichlorophenol	F027	88-06-2
2,4,5-Trichlorophenol salt of 2,6-bis[(dimethylamino)methyl] cyclohexanone	F027	53404-83-4
2,4,5-Trichlorophenol, sodium salt	F027	136-32-3
2,4,6-Trichlorophenol, sodium salt	F027	3784-03-0
2,4,5-Trichlorophenoxyacetic acid	F027	93-79-8
--Alkyl C-12 amine salt	F027	53404-84-5
--Alkyl C-13 amine salt	F027	53404-85-6
--Alkyl C-14 amine salt	F027	53535-37-8
--N,N-diethylethanolamine salt	F027	53404-86-7
--Dimethylamine salt	F027	6369-97-7
--N,N-dimethyllinoleylamine salt	F027	53404-88-9
--N,N-dimethyloleylamine salt	F027	53404-89-0
--N-oleyl-1,3-propylene diamine salt	F027	53404-87-8
--Sodium salt	F027	13560-99-1
--Triethanolamine salt	F027	3813-14-7
--Triethylamine salt	F027	2008-46-0
--Alkyl (C3H7 - C7H9) ester	F027	
--Amyl ester	F027	120-39-8
--Butoxyethoxypropyl ester	F027	1928-58-1
--2-Butoxyethyl ester	F027	2545-59-7
--Butoxypropyl ester	F027	1928-48-9
--Butyl ester	F027	93-79-8
--Dipropylene glycol isobutyl ether ester	F027	53535-31-2
--2-Ethylhexyl ester	F027	1928-47-8
--Isobutyl ester	F027	4938-72-1

--Isopropyl ester	F027	93-78-7
--Propylene glycol isobutyl ether ester	F027	53466-86-7
--Tripropylene glycol isobutyl ether ester	F027	53535-32-3
4-(2,4,5-Trichlorophenoxy)butyric acid [2,4,5-TB]	F027	93-80-1
2-(2,4,5-Trichlorophenoxy)ethyl hydrogen sulfate [2,4,5-TES]	F027	69633-04-1
1,4',5'-Trichloro-2'-(2,4,5-trichlorophenoxy) methanesulfonanilide [Edolan U]	F027	69462-14-2

PESTICIDES THAT ARE TOXIC HAZARDOUS WASTES

PESTICIDES ON THE "F" LIST [40 CFR 261.33(f)]	RCRA #	CAS #
Acetone	U002	67-64-1
Acrylonitrile*	U009	107-13-1
Amitrole	U011	61-82-5
Benzene*	U019	71-43-2
Bis(2-ethylhexyl)phthalate	U028	117-81-7
Cacodylic acid	U136	75-60-5
Carbon tetrachloride*	U211	56-23-5
Chloral (hydrate) (chloroacetaldehyde)	U034	302-17-0
Chlordane, technical*	U036	57-74-9
Chlorobenzene*	U037	108-90-7
4-Chloro-m-cresol	U039	59-50-7
Chloroform*	U044	67-66-3
o-Chlorophenol	U048	95-57-8
Creosote	U051	8021-39-4
Cresylic acid (cresols)*	U052	1319-77-3
Cyclohexane	U056	110-82-7
Cyclohexanone	U057	108-94-1
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one (Kepone, chlordecone)	U142	143-50-0
1,2-Dibromo-3-chloropropane (DBCP)	U066	96-12-8
Dibutyl phthalate	U069	84-74-2
S-2,3-(Dichloroallyl diisopropyl-thiocarbamate) (diallate,Avadex)	U062	2303-16-4
o-Dichlorobenzene*	U070	95-50-1
p-Dichlorobenzene*	U072	106-46-7
Dichlorodifluoromethane (Freon 12®)	U075	75-71-8
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb®)	U192	23950-58-5
Dichloro diphenyl dichloroethane (DDD)	U060	72-54-8
Dichloro diphenyl trichloroethane (DDT)	U061	50-29-3
Dichloroethyl ether	U025	1191-17-9
2,4-Dichlorophenoxyacetic, salts and esters (2,4-D)*	U240	94-75-7
1,2-Dichloropropane	U083	8003-19-8
1,3-Dichloropropene (Telone)	U084	542-75-6
Dimethyl phthalate	U102	131-11-3
Epichlorohydrin (1-chloro-2,3-epoxypropane)	U041	106-89-8
Ethyl acetate	U112	141-78-6
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)	U038	510-15-6

*Proposed for deletion by TCLP proposal

Ethylene dibromide (EDB)	U067	106-93-4
Ethylene dichloride*	U077	107-06-2
Ethylene oxide	U115	75-21-8
Formaldehyde	U122	50-00-0
Furfural	U125	98-01-1
Hexachlorobenzene*	U127	118-74-1
Hexachlorocyclopentadiene	U130	77-47-4
Hexachloroethane*	U131	67-72-1
Hydrofluoric acid	U134	7664-39-3
Isobutyl alcohol*.	U140	78-83-1
Lead acetate	U144	301-04-2
Lindane*	U129	58-89-9
Maleic hydrazide	U148	123-33-1
Mercury	U151	7439-97-6
Methoxychlor*	U247	72-43-5
Methyl alcohol (methanol)	U154	67-56-1
Methyl bromide	U029	74-83-9
Methyl chloride	U045	74-87-3
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene) [acute waste per 261.31]	U132	70-30-4
Methylene chloride*	U080	75-09-2
Methyl ethyl ketone*	U159	78-93-3
4-Methyl-2-pentanone (methyl isobutyl ketone)	U161	108-10-1
Naphthalene	U165	91-20-3
Nitrobenzene*	U169	98-95-3
p-Nitrophenol	U170	100-02-7
Pentachloroethane	U184	76-01-7
Pentachloronitrobenzene (PCNB)	U185	82-68-8
Pentachlorophenol* [acute waste per 261.31]	U242	87-86-5
Phenol*	U188	108-95-2
Pyridine*	U196	110-86-1
Resorcinol	U201	108-46-3
Safrole	U203	94-59-7
Selenium disulfide	U205	7488-56-4
Silvex [acute waste per 261.31]	U233	93-72-1
1,1,2,2-Tetrachloroethane*	U209	79-34-5
Tetrachloroethylene*	U210	127-18-4
2,3,4,6-Tetrachlorophenol* [acute waste per 261.31]	U212	
Thiram	U244	137-26-8
Toluene*	U220	108-88-3
1,1,1-Trichloroethane* (methyl chloroform)	U226	71-55-6
Trichloroethylene*	U228	79-01-6
Trichloromonofluoromethane (Freon 11®)	U121	75-69-4
2,4,5-Trichlorophenol* [acute waste per 261.31]	U230	95-95-4
2,4,6-Trichlorophenol* [acute waste per 261.31]	U231	88-06-2

2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)* [acute waste per 261.31]	U232	93-76-5
Warfarin (<0.3%)	U248	81-81-2
Xylene	U239	1330-20-7
Zinc phosphide (<10%)	U249	1314-84-7

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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 not 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.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

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."

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 occur

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.

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

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

1. Domestic use products 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. All other products must bear container disposal instruction based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or punctur and dispose of in a sanitary landfill, or b other procedures approved by state and loca authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or punctur 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.
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.

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 that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, 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."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C 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."

4. 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."

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

APPENDIX III

USE INDEX APPENDIX

106201

AMITRAZ*

TYPE PESTICIDE: Insecticide, Acaricide

FORMULATIONS:
Tech (93%)
WP (50%)
EC (1.5 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. Do not re-enter treated areas until 24 hours after application unless protective clothing is worn. Do not tank mix with bordeaux mixtures, detergents, dodine, ferbam, 1-napthaleneacetic acid (NAA), sulfur, or other highly alkaline materials. During mixing/loading or application wear a protective suit which has long sleeves and long pants. Wear chemical resistant gloves; a hat, boots, and goggles or face shield. A helmet with visor may be substituted for the hat and goggles during aerial application. Mixer/loaders should also wear a chemical resistant apron when handling the concentrated product. Instead of clothing and equipment specified above, the applicator can use an enclosed tractor cab or cockpit with properly filtered air supply. Amitraz is toxic to fish. Do not apply directly to water. Drift and runoff from treated areas may be hazardous to fish in adjacent sites. Do not contaminate water by cleaning of equipment or disposal of wastes.

Beneficial Insect Caution:
Amitraz is toxic to predacious mites such as Typhlodromus accidentalis, Amblyseius fallacis, and stigmaeid mites.

Agricultural Crop Tolerances:
Apples - 0 ppm

Livestock Tolerances:
0 ppm (meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep)

Definition of Terms:
Claims for pest control limited to suppression of population are indicated by parenthesized pest name.

*N'-(2,4-dimethylphenyl)-N-[[(2,4-dimethylphenyl)imino]methyl]-N-methyl-methanimidamide

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AMITRAZ

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
04003AA	Pear		3 ppm 7 day preharvest interval through 1.5 pounds per acre for foliar application. Do not apply more than 10.5 pounds per acre during the growing season. Do not allow livestock to graze treated areas. Do not apply emulsifiable concentrate formulation as a summer spray west of the Rocky Mountains when cool, moist, poor drying conditions exist or when night temperatures are below the dew point, as fruit injury may result.
LAVASA TBGAZA LAVAYA LAVBEA	European red mite (Codling moth) (McDaniel spider mite) (Twospotted spider mite)	0.75-0.94 lb/A [400 gal/A] [concentrate spray] or 0.188-0.234 lb/100 gal (1.5 lb/gal EC)	Prebloom and foliar applications. Apply when the majority of overwintering European red mite eggs have hatched and repeat as needed.
RAXALA TBGAZA LAVAYA LAVBEA	Pear psylla (Codling moth) (McDaniel spider mite) (Twospotted spider mite)	0.75-1.5 lb/A [400 gal/A] [concentrate spray] or 3-6 oz/100 gal [0.75-1.5 lb/A] (50% WP) (1.5 lb/gal EC)	Prebloom application. Application must occur during a precise point in the pest's life cycle. Apply after eggs have moved into the female pear psyllas oviduct, but prior to heavy egg laying. Apply when daily maximum temperatures exceed 50 F (10.0 C). If weather or orchard conditions do not permit treatment before heavy egg laying, apply after the majority of the first generation eggs have hatched. Consult local Cooperative Agricultural Extension Service for more specific timing information. May be tank mixed with dormant oil. Foliar application. Apply when majority of pests are in the adult or young nymphal stages of development.

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AMITRAZ

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Pear (continued)		
LAJAOA TBGAZA LAVAYA LAVBEA	Pear rust mite (Codling moth) (McDaniel spider mite) (Twospotted spider mite)	0.75-1.5 lb/A [400 gal/A] [concentrate spray] or 0.188-0.375 lb/100 gal (1.5 lb/gal EC)	Prebloom and foliar applications. Apply when the mites become active in the spring and repeat as needed.

Listing of Registered Pesticide Products by Formulation

093.0001 93% technical chemical
amitraz (106201)
001023-00058 045639-00051

050.0006 50% wettable powder
amitraz (106201)
001023-00061

101.5012 1.5 lb/gal emulsifiable concentrate
amitraz (106201)
001023-00059 043142-00045

APPENDIX IV

BIBLIOGRAPHY APPENDICES

GUIDE TO USE OF THIS BIBLIOGRAPHY

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

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

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

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

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

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

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. The date of the earliest known submission appears immediately following the word "received."

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

(3) Submitter. The third element is the submitter, 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 26th, 123456-Z; and the 27th, 123456-AA.

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APPENDIX V

FORMS APPENDICES

OMB Approval No. 2070-0057
Expires 11/30/89

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

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

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

EPA Form 8580-6

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: _____

Registrant's Name and Address: _____

_____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____ concerning a requirement for submission of "generic" data on the active ingredient _____ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated _____ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _____ and their registration number(s) is/are _____ .

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: _____
(Signature)

Dated: _____ _____
(Typed)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No. _____ Date _____

Guidance Document for _____

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 Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 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				

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 Number or EPA Accession Number	Submitting Data (Attached)	
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 toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				