CASE NUMBER 234

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

AMITRAZ

AS THE ACTIVE INGREDIENT
106201

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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APPENDICES

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

II. REGULATORY POSITION AND RATIONALE

A. Introduction

This chapter contains the Agency's regulatory position on products containing the pesticide amitraz as the sole active ingredient. The Agency bases its position and rationale on a consideration of all uses of amitraz appearing on pesticide products registered under Sections 3 and 24(c) of the FIFRA as well as on products authorized for distribution in intrastate commerce under 40 CFR 162.17. The Agency has reviewed the known chemical, environmental, and toxicological characteristics of this pesticide and its established tolerance for residues in or on pears. From these considerations the Agency sets forth the the data and labeling requirements that must be met by registrants and applicants for registration of amitraz products in order for their products to be registered or reregistered under this Guidance Document. Unique labeling requirements and certain data needs for end-use products (EP's) containing amitraz are also established by this Standard.

Only those data and labeling requirements for current and future substantially similar MPs and EPs are addressed here. Future products that differ appreciably from those described in this Guidance Document may be subject to additional data and/or labeling requirements.

B. 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 only on pears. There are proposed tolerances and applications

for registration for hogs, cattle, apples and citrus. Amitraz is a restricted-use pesticide and applicators must be certified or be under the direct supervision of applicators certified to apply amitraz.

C. 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

positive 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} 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 with little or no benefits from the use on apples since there were suitable alternatives.

After weighing the benefits and risks, the Agency 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.

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 the label changes at registration and 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 and very small 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 affect the decision to prohibit the use on apples. (Waste from processed apples is fed to livestock.)

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. The new mouse oncogenicity study was referred to the Agency's Cancer Assessment Group (CAG) for evaluation. The results of this study show an increase in the incidence of hepatocellular tumors in female mice and an increase in lung tumors in male mice. Based on this study and the first mouse study, CAG has determined that amitraz has 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 of analysis, CAG concluded that amitraz should be considered a possible human (a Group "C") carcinogen.

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 has 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 have also been 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 and increase in lung tumors in male mice. 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. Since the assessment of these data has not led the Agency to change its opinion of amitraz's oncogenic potential or benefits, the Agency concludes that the risks and benefits remain the same for the pear use and that there is no reason to act against the registration of that use.

D. Regulatory Position and Rationale

Based on a review and evalution 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 for sale, distribution, reformulation, and use on pears 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: 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. The Agency has reevaluated that decision and concludes that the risks and benefits as discussed

above are substantially the same as those reached in the RPAR process. The risks have been reassessed using the results of a second mouse oncogenic study. The dietary risk from consuming amitraz treated pears is 10^{-6} and the occupational risk is between 10^{-5} and 10^{-6}. These risks are essentially the same as those that were calculated when amitraz was initially registered using the first mouse oncogenic study. 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 believes that it continues to be in the best interest of the public to continue the registration of the pear use.

2. The Agency has decided not to issue tolerances for the proposed use of amitraz on apples and citrus. The Agency will consider other uses on a case-by-case basis.

Rationale:

The toxicology data base for amitraz is complete except for a dermal penetration study. The Agency (CAG) has classified amitraz as a Group "C" carcinogen based on positive effects demonstrated in two mouse oncogenicity studies coupled with the negative rat oncogenicity study.

The environmental data base for amitraz is largely incomplete. However, there are uses which would have minimal impact on the environment.

There are currently four proposed uses for amitraz pending

with the Agency. These are apples, citrus, cattle and swine. 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. At this time the Agency will not establish these food additive tolerances because of the Delaney Clause within Section 409 of the Federal Food, Drug and Cosmetic Act. The proposed cattle and swine uses will be considered. Data supporting these particular uses are in review.

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. However, the available data are insufficient to fully characterize the leaching potential of amitraz. 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. All end-use products containing amitraz shall continue to be classified for restricted use and the restricted use label statement will be revised to specify that the reason for this classification is because of the oncogenicity of amitraz and concern over worker exposure to amitraz. A cancer warning statement will also be added to manufacturinguse product labels.

   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. Since the Agency is regulating amitraz as a possible human carcinogen, continuation of the restricted use statement because of its oncogenicity potential is warranted. In addition, the Agency believes that a cancer statement will further emphasize the precautions that must be taken when handling amitraz, especially for the end-use products.

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

Rationale: In order to minimize exposure to workers entering treated areas pending the receipt and evaluation of reentry data, a 24-hour reentry interval was required when amitraz was conditionally registered for use on pears. Because of amitraz's oncogenic potential, this reentry interval is being retained. Through this Guidance Document studies are being required to further evaluate amitraz's exposure potential. Upon receipt and review of these data, the Agency may impose a different reentry interval.

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.

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).

F. Acceptable Ranges and Limits

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.

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.

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.

G. Required Labeling

All manufacturing-use and end-use amitraz products must bear appropriate labeling as specified in 40 CFR 162.10. The guidance document for this Standard contains information on label requirements.

° 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

° 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.

° Precautionary Statements

Statement For Manufacturing-Use Products

1. Labels for manufacturing-use amitraz products must bear precautionary statements, as specified in 40 CFR 162.10, reflecting the compound's acute human toxicity. Amitraz is in Toxicity Category II by the acute dermal route of exposure.

2. The following statement must be place on the front panel of

all manufacturing-use amitraz products:

"The use of this product may be hazardous to your health. This product contains amitraz which has been determined to cause tumors in laboratory animals. Use of protective clothing and equipment can reduce risk."

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

" Environmental Hazards

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 in writing. For guidance contact your State Water Board or Regional Office of the EPA."

Statements For End-Use Products

1. All end-use products must bear the restricted-use statement:

"RESTRICTED USE PESTICIDE

"Because amitraz has been shown to cause tumors in laboratory mice, this product may be applied only by certified applicators or persons under their direct supervision. Use of protective clothing and equipment and following the use precautions below can reduce risk."

2. 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."

3. 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."

4. 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."

H. Tolerance Reassessment Summary

U.S. tolerances for residues of amitraz in or on the raw agricultural commodities are as follows (40 CFR 180.287):

> 3.0 ppm in or on pears
>
> 0.0 ppm in or on apples, and the fat, meat by-products, and meat of cattle, goats, hogs, 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 published tolerance for pears given a

theoretical maximum residue contribution (TMRC) to the daily diet of 0.0115 mg/day (for an average 1.5kg daily diet) which accounts for 7.66% of the ADI.

c106201

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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Provisional Update: 8-06-85

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.
ILAVASA ITBGAZA ILAVAYA ILAVBEA	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.
IRAXALA ITBGAZA ILAVAYA ILAVBEA	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)		
ILAJAOA ITBGAZA ILAVAYA ILAVBEA	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.

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AMITRAZ

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

Issued: 10-01-81

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? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames for Data Submission [2]
§158.125 Residue Chemistry - Continued				
171-4 - 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? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission [3]
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	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? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral Toxicity - Rat	TGAI	A	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? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.135 Toxicology - Continued					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species:	TGAI				
- Rodent, and		A	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? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission [3]
§158.135 Toxicology - Continued						
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]	
85-2 - Dermal Penetration	Choice	A	No	-	Yes	12 Months
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=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....
   ° 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 descripti of this study can be found in ASTM 739-81- Standard Test Method for Resistance of Protective Materials To Permeation by Hazardous Liquid Chemicals.

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 tc 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]

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

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.

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

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.

REQUIREMENT FOR SUBMISSION OF GENERIC DATA

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

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

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

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

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

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

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

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

C. Options Available for Complying With Requirements to Submit Data

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

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

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

OR

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

OR

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

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

(Footnote continued on next page)

OR

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

OR

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

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

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

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

(Footnote continued from previous page)

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

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

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

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

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

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

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

IV. SUBMISSION OF REVISED LABELING

Note: This section applies to end use products only to the extent described in Section I (Regulatory Position and Rationale). Otherwise, the following information pertains exclusively to manufacturing use products.

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

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

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

A. Label Contents

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 8C. PHYSICAL OR CHEMICAL HAZARD

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

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

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

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

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

i. The flame extension is zero inches;

ii. There is no flashback; and

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

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

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

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

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

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

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

Classification Labeling Requirements

If Section I of this Guidance Document indicates that your product has been classified for restricted use, the following label requirements apply:

1. Front panel statement of restricted use classification.

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

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

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

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

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

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

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

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

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

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

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

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

B. Collateral Labeling

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

V. INSTRUCTIONS FOR SUBMISSION

A. For Manufacturing Products (MP) containing Amitraz as an active ingredient.

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

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

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

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

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

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

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

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

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

B. For Manufacturing Use Products containing Amitraz in combination with other active ingredients

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

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

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

C. For End Use Products containing Trimethacarb alone or in combination with other active ingredients:

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

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

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

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

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

c. Two copies of any required product-specific data. (Refer to Table C).

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

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

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

D. For intrastate products containing Amitraz either as the sole active ingredient or in combination with other active ingredients

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

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

Jay S. Ellenberger Product Manager 12
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460
Phone No. (703) 557-2386

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

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

Appendix II-1

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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OMB Approval No. 2000-0468 (Expires 12-31-83)

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 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

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 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

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

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

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;

APPENDIX IV-I
(continued)

(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 precautions to avoid potential accident, 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 with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

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

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

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

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

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

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

APPENDIX IV-1 (continued)

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

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

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

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

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

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

(iii) *Exceptions to requirement for direction for use.*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) Rotational crop restrictions.

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

(D) [Reserved]

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

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

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

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

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

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

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

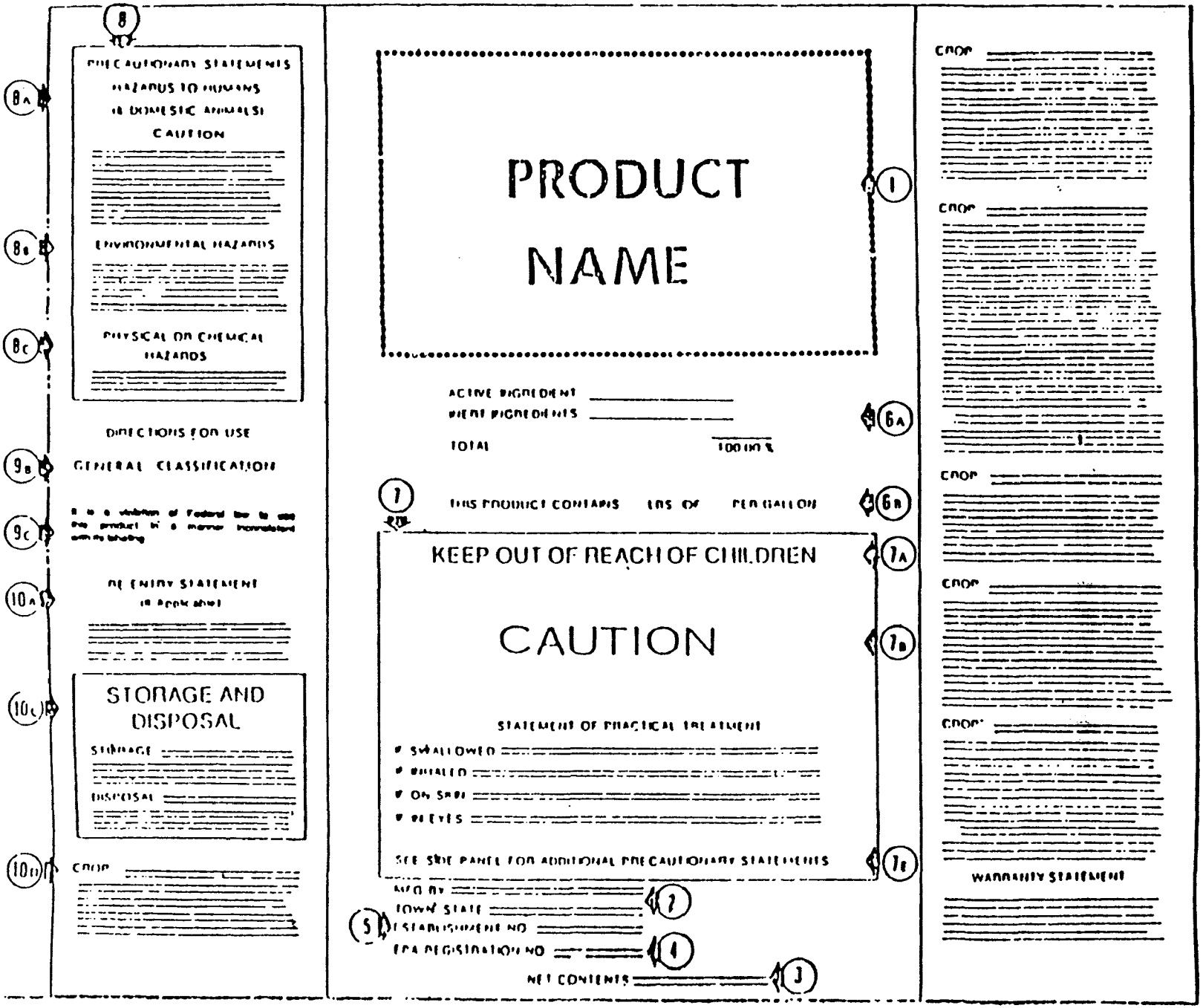
(k) *Advertising.* [Reserved]

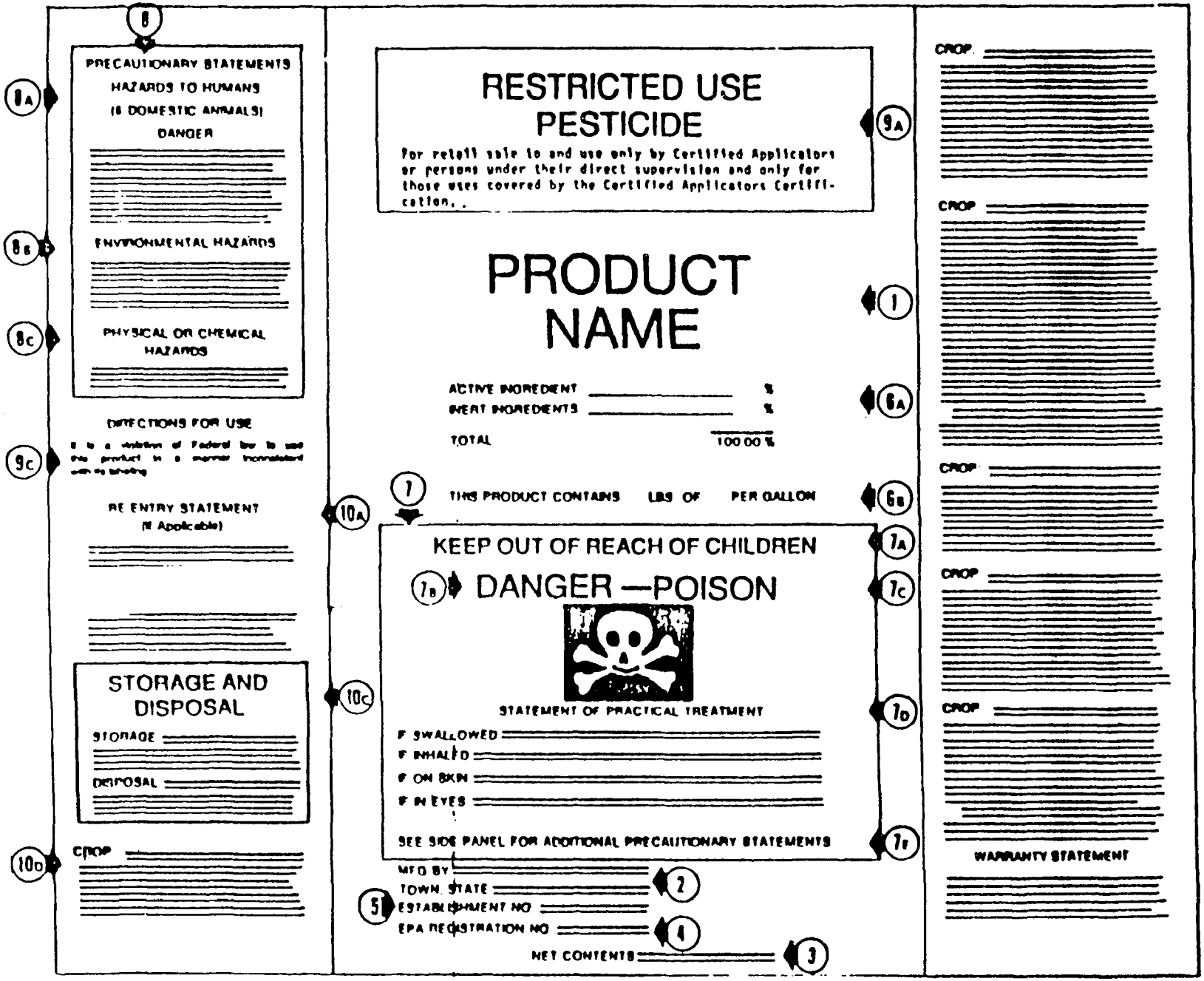
[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing.*

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


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


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
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
TOTAL
100.00 %
6A
1
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
10A
KEEP OUT OF REACH OF CHILDREN
7A
1B
DANGER —POISON
7C
10C
STATEMENT OF PRACTICAL TREATMENT
7D
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
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

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 statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

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

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

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.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

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

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

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

A. Storage Instructions:

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

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

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

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

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

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

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

B. Pesticide Disposal Instructions:

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

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

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

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

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

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

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

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

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

C. Container Disposal Instructions

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

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

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

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

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

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

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

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

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

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

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

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

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

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

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

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