GUIDANCE FOR THE

REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

DICOFOL

AS THE ACTIVE INGREDIENT

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

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INTRODUCTION

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

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the end-use (formulated) products that contain the active ingredient. If we find serious concerns, we will bring end-use products under the provisions of the Registration Standards program to the extent necessary to protect the public.

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

the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

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

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

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

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

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

I. REGULATORY POSITION AND RATIONALE

A. Introduction
B. Chemical Description and Use Summary
C. Regulatory Position
D. Regulatory Rationale
E. Criteria for Registration and Reregistration under this Document
F. Acceptable Ranges and Limits
G. Required Labeling
H. Tolerance Reassessment
I. Special Studies

A. INTRODUCTION

This Guidance Document describes the Agency's regulatory position on manufacturing-use products containing dicofol. The Agency's position addresses a number of regulatory requirements -- labeling requirements, tolerances, and the data requirements -- that must be met to register or reregister products covered by this Guidance Document.

As part of developing its regulatory position on a pesticide, the Agency makes a determination whether any of the criteria in 40 CFR 162.11 have been met and whether a Special Review[1/] should be initiated. This document serves to notify the registrants that a Special Review will be initiated. The Special Review process will be explained briefly below, as well as the Agency's concerns and rationale for initiating the Special Review.

In addition to the basic regulatory decision and rationale, this Document includes the following: criteria for the registration or reregistration of

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1/ Special Review is the new name for the Rebuttable Presumption Against Registration (RPAR) process. This name will be proposed in regulations in the near future.

dicofol products under the Guidance Document; acceptable ranges and limits for product composition, acute toxicity and use patterns; required labeling; and a tolerance reassessment.

B. CHEMICAL DESCRIPTION AND USE SUMMARY

The chemical name for dicofol is 1,1-bis(chlorophenyl)-2,2,2-trichloroethanol; for convenience in writing this Guidance Document, the name dicofol will be used instead of the chemical name. Use of the name dicofol implies no endorsement of any product containing the active ingredient. There is no common name for the chemical accepted by the American National Standard Institute.

The Chemical Abstracts Registry (CAS) number for dicofol is 115-32-2. The EPA Shaughnessey number is 010501. The chemical formula is $C_{14}H_9Cl_5O$, and the molecular weight is 370.51.

Trade names and other names for dicofol include: Acarin®, Carbax®, CAS 115-32-2, CPCA, Decofol®, Dichlorokelthane, DIMC, ENT-23648, FW-293, Kelthane®, Kelthane A®, p,p'-Kelthane, Kelthanethanol, Mibol®, Mitigan®, and NCI-000486. Other chemical names for dicofol are:

1. Benzenemethanol, 4-chloro-alpha-(4-chlorophenyl)-alpha-(trichloromethyl)-
2. Benzhydrol, 4,4'-dichloro-alpha-(trichloromethyl)-
3. 1,1-Bis(4-chlorophenyl)-2,2,2-trichloroethanol
4. 4,4'-Dichloro-alpha-(trichloromethyl)benzhydrol
5. Di-(p-chlorophenyl)trichloromethylcarbinol
6. 2,2,2-Trichloro-1,1-di(4-chlorophenyl)ethanol

Manufacturing-use dicofol is a non-flowable liquid (or waxy solid) at room temperature. It ranges from dark to yellow-brown in color. It is stable under cool and dry conditions, and is practically insoluble in

water, but readily soluble in most organic solvents. Its melting point ranges from 58°C to 78°C.

Dicofol was first registered as a pesticide in 1957. Manufacturing-use dicofol products are not produced domestically. Rather, all dicofol used in domestically registered pesticides is imported. Dicofol is used in acaricides to control mites on agricultural crops and ornamentals and in or around agricultural and domestic buildings. End-use products containing dicofol are made in a variety of formulations, and marketed as emulsifiable concentrates, wettable powders, dusts, ready-to-use liquids, and aerosol sprays. The products act on the surfaces of the sites of application to control mites.

There are currently six registered manufacturing-use products consisting of the technical grade of dicofol (80 - 85%) and four formulation intermediates, one of which is a multiple active ingredient product. There are seven registered manufacturers of these manufacturing-use products: Rohm and Haas Company, Makhteshim Beer-Shiva, Aceto Chemical Company, Agan Chemical Manufacturers, Drexel Chemical Company, Tricon Chems International, and Ida, Inc.

End-use products containing dicofol as their sole active ingredient include 66 section 3 Federal registrations and 37 Intrastate products. End-use products containing dicofol plus other active ingredients include 130 section 3 Federal registrations and 49 Intrastate products.

Certain unintentional impurities have been identified in manufacturing-use dicofol products which are the result of the manufacturing process. The identified contaminants of concern include the p,p' and o,p' isomers of DDT, DDE, DDD (TDE), and a compound known as "extra-chlorine DDT" (Cl-DDT). The chemical names for these contaminants are as follow:

1. 1,1-bis-(p-chlorophenyl)-2,2,2-trichloroethane [p,p' DDT]
2. 1-(p-chlorophenyl)-1-(o-chlorophenyl-2,2,2-trichloroethane [o,p' DDT]
3. 1,1-bis-(p-chlorophenyl)-2,2-dichloroethylene [p,p' DDE]

4. 1-(p-chlorophenyl)-1-(o-chlorophenyl)-2,2-dichloroethylene [o,p' DDE]
5. 1,1-bis-(p-chlorophenyl)-2,2-dichloroethane [p,p' DDD]
6. 1-(p-chlorophenyl)-1-(o-chlorophenyl)-2,2-dichloroethane [o,p' DDD]
7. 1,1-bis-(p-chlorophenyl)-1,2,2,2-tetrachloroethane [p,p' Cl-DDT]
8. 1-(p-chlorophenyl)-1-(o-chlorophenyl)-1,2,2,2-tetrachloroethane [o,p' Cl-DDT]
9. 1-(2,4-dichlorophenyl)-2-(4-chlorophenyl)-1,2,2,2-tetrachloroethane
10. 1-(2,4-dichlorophenyl)-2-(4-chlorophenyl)-1,,2,2-tetrachloroethane

In this Document, the term DDTr will be used to denote any or all of these DDT analogs. Though an environmental effects and fate data base for Cl-DDT is unavailable, the Agency assumes that this chemical is potentially a DDE precursor.

C. REGULATORY POSITION

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

1. The Agency has determined that the risk criterion in 40 CFR 162.11 regarding an adverse wildlife effect has been met by certain outdoor uses of dicofol products. These products appear to contain a sufficient quantity of DDT contaminants to cause significant adverse ecological effects. The Agency focused on the potential to cause eggshell thinning in documenting the basis for Special Review but recognizes, and is gathering evidence about, a wide range of other effects associated with DDT and related compounds. A Special Review of all outdoor dicofol end-use products containing detectable amounts of DDTr will be initiated.

2. No new registrations for dicofol products intended for outdoor use will be issued which would further increase the amount of DDTr in the environment.

3. Registrants and applicants for registration of manufacturing-use dicofol products must provide or agree to develop the additional data specified in Tables A and B of this Document in order to maintain existing registrations. Tables A and B include special studies, explained in Section I below, which are needed to address the concerns above. The health effects data required must be conducted and submitted in accordance with the FIFRA Good Laboratory Practice Regulations (48 FR 53946). Manufacturing-use products containing dicofol as the sole active ingredient may be registered or reregistered subject to the terms and conditions specified in this Guidance Document.

4. Registrants and applicants for registration must submit data regarding the composition of their product and in particular the concentration of DDTr contaminants in their manufacturing products. The Agency is concerned about the presence of these contaminants at levels substantially below one percent of the technical dicofol product because a no-effect-level has not been determined for reproductive effects in certain species of birds and because environmental modeling indicates that current usage may produce residues in fish that exceed the known effect for these reproductive effects (Balcomb, 1983b).

5. Because available residue data are inadequate and no definitive toxicity data are available, a tolerance reassessment cannot be performed at this time. A complete reassessment will be performed when the data specified in Tables A and B are supplied. There are also insufficient data to determine how much DDTr is contributed to the human diet when dicofol products are used. Special studies must be conducted to measure whether DDTr residues are present in or on food and feed crops and whether tolerances for DDTr are needed.

D. REGULATORY RATIONALE

The following section provides the Agency's rationale to support the regulatory position described above.

1. Initiation of the Special Review

The Agency has concluded in its review of data during the reregistration process that dicofol, when used for certain outdoor applications, meet the risk criterion for unreasonable adverse effects (40 CFR 162.11(a)(3)(ii)(C)) because dicofol is contaminated with DDTr at levels which have unreasonable adverse effects on the environment. The risks of concern and the economic importance of pests controlled by dicofol products are summarized in the sections that follow. A Special Review will be initiated to examine the risks and benefits of these and other uses and to reach final regulatory conclusions.

Even though a Special Review will be initiated for dicofol, all current or prospective registrants of dicofol manufacturing-use products are still required to satisfy the requirements established by this Guidance Document. In particular, current registrants are responsible for generating and providing additional data required by the Guidance Document. Once the data being required by the Guidance Document have been submitted and reviewed, the Agency will determine whether those data warrant any changes in the Agency's current regulatory position.

2. Rationale and Procedures for Lowering DDTr Concentration

The risks of DDTr to the environment are well documented (see Section 4 A). The intention of the Special Review will be to reduce or eliminate these risks. One way to alleviate these risks is to reduce or eliminate the DDTr in the dicofol products. However, current manufacturing methods apparently preclude the production of dicofol without DDTr contamination. The Agency does not have adequate information to judge the level to which the registrants can feasibly reduce DDTr. Therefore, the Agency is requiring data on manufacturing methods, the levels of DDTr contamination in products, and updated Confidential Statements of Formula. It is the Agency's opinion that it would be prudent for registrants to modify their

manufacturing processes to reduce the DDTr contamination to non-detectable levels in the technical product.

In order to develop a complete risk/benefit assessment evaluating dicofol use, the Agency will need data on the cost of altering the dicofol manufacturing process to reduce DDTr contamination. If registrants provide estimates of both capital costs and changes in operating costs necessitated to reduce DDTr in the manufacturing-use products, the Agency will consider this information in its final regulatory decision.

3. 1972 DDT Cancellation Order (37 FR 13369)

In 1972, the uses of nearly all pesticide products containing DDT and TDE were cancelled. However, products containing dicofol were not specifically mentioned under this Order. The Agency will evaluate the risks and benefits associated with each outdoor use of dicofol in the Special Review to determine whether revisions must be made to the terms and conditions of registration.

4. Preliminary Risk Assessment for DDTr Contaminants

a. Ecological Hazards Associated with DDT (Balcomb, 1983a)

Dicofol products contain DDT, DDD and DDE. It also contains a structurally similar chemical (Cl-DDT) of unknown toxicity that reportedly degrade to DDE. The Agency's assessment of the use of dicofol has considered risks that may result from the introduction of DDT, DDD, DDE and related compounds into the environment.

Historically, the use of DDT has adversely affected many terrestrial and aquatic organisms. DDE is of special concern because its long-term persistence and tendency to bioaccumulate in terrestrial and aquatic organisms allows for widespread exposure of wildlife. The use of DDT prior to

1972 resulted in mortality of certain species of birds, bats, fish and nontarget invertebrates. It has also had profound chronic effects in many animal species. Severe population reductions in birds and fish have been related to DDT's effects on reproduction.

Though dicofol outdoor uses are concentrated in certain regions of the United States, the resulting environmental contamination by DDTr may reach other areas. Because DDTr bioaccumulates in individual organisms and biomagnifies through some food chains (particularly those involving aquatic organisms), it is reasonable to assume that higher trophic level aquatic organisms and birds may be particularly impacted. Contamination, however, will not likely be confined only to use areas. One of the major reasons that virtually all uses of DDT were cancelled in 1972 is that its widespread use in the U.S. contributed to the nationwide DDTr burden. Elevated and possibly harmful DDE residues have recently been detected in wildlife in major dicofol use areas.

There is evidence that the level of DDT-related contamination, on a nationwide basis, is declining. Nonetheless, residues remain ubiquitous and may be high enough in some areas to affect bird and fish reproduction. Risk assessment for dicofol is therefore complicated in that its use in some areas may result in residues high enough to cause adverse effects, regardless of ambient concentrations, while other uses in other locations may incrementally increase ambient levels such that effects occur. It is not clear at this time that such distinctions can be made scientifically.

Because of the Agency's concerns that fish-eating birds may be exposed to residues of DDTr exceeding dietary levels known to impair reproduction, the Agency developed a model to estimate the level of DDTr residues in water (Hitch and Reinert, 1983). The simulation relies upon the Exposure Analysis Modeling System (EXAMS). The Arroyo Colorado waterway of southern Texas was chosen because of the high level of dicofol used on citrus and the important aquatic bird habitats in the drainage

area. Under the conditions of steady-state chemical loading this model predicts the equilibrium concentration in a water body. The chemical input to the river system was estimated based on the following assumptions:

1) The amount of dicofol used each year in this drainage basin is 100,000 pounds. This is based on the estimate of 25,000 acres of citrus with drainage into the Arroyo Colorado, and the estimate that up to four pounds of dicofol active ingredient are used on citrus. Using this estimate, the highest label rate for a single application compensated for the legal use of multiple applications at less than the maximum rate.

2) For purposes of this simulation, the water in the river basin is assumed to be free of DDTr prior to the introduction of contaminated dicofol, which yields the EXAMS steady state concentration. Even though it is documented that background levels of DDTr occur ubiquitously throughout all matrices of the environment, this assumption is necessary to calculate the DDTr burden in fish that results solely from the use of dicofol.

3) The amount of DDTr added to the environment was arbitrarily factored in at 10% of the dicofol active ingredient applied. The model's residue predictions are a direct linear function of the loading so that aquatic residues for any level of product contamination can be estimated by proportionality.

4) The physical characteristics of DDT and DDE vary slightly and the modeling capabilities required the choice of one set of chemical parameters. From a calculation standpoint, counterbalancing factors mitigated the importance of choosing the physical properties of DDT or DDE for the purpose of aquatic fate modeling to predict the eventual concentration of DDE precursors in fish. For the EXAMS model, the physical parameters for p,p'-DDT, the most extensively studied analog, were used throughout the simulation and the environmental exposure assessment.

5) The Agency assumed that most of the DDTr reaching the Arroyo Colorado was transported by surface water running off the immediate drainage area in which dicofol had been used. A recent review of the available literature on pesticide runoff concluded that DDT consistently shows losses of 2 to 3% of the amount applied. Therefore, 2% of the DDT applied was assumed to reach the Arroyo Colorado as a consequence of surface water runoff.

Using the assumptions noted above, EXAMS predicted a steady state water column concentration of 9 parts per trillion (ppt) DDTr[2/]. Whole fish concentrations of 9 ppm DDTr were estimated to occur via bioaccumulation and biomagnification[3/]. Levels of DDTr contamination reported in the registrant's Confidential Stantement of Formula were then compared with the model's predictions. It was concluded that levels of reported DDTr contamination, if contained in dicofol products used in accordance with the model's assumptions, would generate DDTr residue levels in fish that would exceed dietary levels shown experimentally to reduce eggshell thickness. Effects on avian reproduction have been documented experimentally at dietary levels as low as 0.6 ppm DDE (wet weight). Monitoring studies of brown pelicans have indicated reproductive effects at lower dietary concentrations. Because all of the constituants of DDTr are known or

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2/ Significant uncertainty is necessarily associated with the type of quantitative exposure assessment presented. This uncertainty results from the difficulties in describing the geophysical environment, from incomplete physical-chemical parameters of the chemicals, and from an inability to completely describe with the EXAMS model the environmental processes that affect the transport and fate of the DDTr in this simulation. However, in the absence of monitoring data from a habitat receiving known loadings of DDTr, the use of a simulation model was considered to be the best available means of quantitatively estimating exposure to aquatic birds.

3/ Bioaccumulations of 1,000,000 have been determined in field studies.

expected to degrade to DDE, the Agency concludes that the residue levels of DDTr in fish pose a significant risk.

Caution must be used in extrapolating the values calculated for the Arroyo Colorado to other water basins due to the many location specific factors which can affect the magnitude of aquatic DDTr levels and the observed trends in the changes in environmental levels.

b. Oncogenicity of Dicofol and DDT

The potential oncogenicity of dicofol per se is unknown due to the unavailablity of adequate studies. The data available do suggest possible oncogenicity in male mice. However, the study is unacceptable due to the reported decomposition of the test material during the study. Additional testing is required before a conclusion can be reached.

Laboratory tests have indicated that both DDT and DDE can cause tumors in mice. As indicated in the 1972 DDT cancellation decision, DDT should be considered a potential human carcinogen. However, adequate dietary exposure data are not available to estimate the potential risks to humans through dietary exposure to DDT contaminants in dicofol products. These data are being required from registrants, and when they are submitted, an assessment of the carcinogenic risk to humans will be made.

5. Groundwater Contamination

Dicofol residues are relatively immobile in soil. It does not leach below a depth of two inches in sandy loam soil, and in a soil runoff study, dicofol was found to be essentially immobile when incorporated into the top inch of a silt loam soil. Therefore, there is no expectation of groundwater contamination.

6. Current Benefits Review for Dicofol[4/]

An estimated 2 million pounds of dicofol active ingredient are used annually as an acaracide in the United States (Devine, 1983; Luttner, 1981; Scheid, 1980). The major dicofol use sites are citrus and cotton[5/]. These sites accounted for an estimated two-thirds of the dicofol usage during the 1980-1981 period.

The farm level value of U.S. orange, grapefruit, and lemon production was approximately $1.8 billion for the 1980-1981 citrus season. Dicofol is used throughout the citrus growing regions for control of spider mites. Spider mite nymphs and adults damage citrus foliage, limiting the trees' vigor and, therefore, ability to produce maximum yields of good marketable fruit. Other species of mites damage twigs and young limbs of citrus trees as well as damaging fruit and causing early fruit drop.

Uncontrolled mite populations reduce yield and quality of citrus and increase the average cost of citrus production. Although alternative acaricides to dicofol are available, dicofol's widespread use suggests that alternatives are less cost effective and/or preferable than dicofol for control of mite populations under specific circumstances.

The farm level value of U.S. cotton production is approximately $4 billion annually. Dicofol is used for spider mite control on cotton primarily in the state of California which produces approximately $1 billion of cotton annually. In general, the nymph and adult spider mites

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4/ More detailed information on dicofol use, usage, and economic benefits can be found in two Agency documents prepared under the registration standards process. Sutherland and Gross, 1983, dicusses the biological aspects of dicofol use. Vlier, 1983, presents a preliminary review of the economic benefits of dicofol use on cotton and citrus.

5/ Most dicofol use on cotton occurs in the San Joaquin Valley.

damage cotton foliage, stems, and fruit. Sustained, uncontrolled spider mite populations may build up and cause defoliation, bract desiccation, and shedding of cotton squares and bolls. Heavy feeding can cause reduced lint quality and yield, as well as, lowered cotton seed production and viability.

Uncontrolled mite populations would therefore increase the average unit cost of cotton. As in the case of citrus, although alternative acaricides to dicofol are available, dicofol's use, particularly in the the San Joaquin Valley, suggests that alternatives are less cost effective and/or less preferable than dicofol for control of mite populations under specific circumstances.

E. CRITERIA FOR PRODUCTS SUBJECT TO THIS GUIDANCE DOCUMENT

To be covered by this Guidance Document, products must contain dicofol as 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 applicant for registration or reregistration of products subject to this Document must comply with all terms and conditions described herein. These include making a commitment to fill data gaps on a schedule specified by the Agency. Also, applicants for registration under this Document must contact the Agency for specific instructions, including updated information on data requirements and companies whose data satisfy the Agency's data requirements. Applicants for registration or reregistration must follow the instructions contained in this Guidance Document and complete and submit the appropriate forms within the time specified.

F. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be fully covered under this Guidance Document, manufacturing-use products must contain dicofol as the sole active ingredient. Each manufacturing-use product formulation proposed for registration or re-registration must be fully described and an appropriate certification of limits must be included. The label must also state the nominal concentration for the active ingredient. However, because the Agency is concerned about DDT and related compounds as impurities in the manufacturing-use product, quantification of these impurities must be at a level of detection below 0.1% of the manufacturing-use product using the best suitable analytical methods (preferably gas liquid chromatography or high pressure liquid chromotography). The registrant must identify the analytical methods use.

2. Acute Toxicity Limits

The Agency will consider for registration any manufacturing-use product whose any acute toxicity category is supported by adequate acute toxicology data and labeling, including appropriate precautionary statements.

3. Use Patterns

To be covered under this Guidance Document, manufacturing-use products must be labeled for formulation into end-use products which are registered by the U.S. Environmental Protection Agency.

G. REQUIRED LABELING

All dicofol products must bear appropriate labeling as specified in 40 CFR 162.10. Because of the absence of data required to assess the

environmental and health hazards of dicofol, the Agency is not able to evaluate the adequacy of all precautionary and required statements on manufacturing-use product labels. This Guidance Document does not require changes in the current precautionary statements and environmental hazard labeling. The Agency may, after review of data to be submitted in response to this Document, require additional revisions to current labels, and may impose additional label requirements.

All manufacturing-use product labels must bear the following statement:

"For Formulation into End-Use Products Intended Only for Uses Accepted by the U.S. Environmental Protection Agency."

H. TOLERANCE REASSESSMENT

U.S. tolerances are established for residues of dicofol in or on raw agricultural products as follows (40 CFR 180.163):

30 ppm in or on hops;

25 ppm in or on peppermint hay and spearmint hay;

10 ppm in or on apricots, grapefruit, kumquats, lemons, limes, nectarines, oranges, peaches, tangerines;

5 ppm in or on apples, beans (dry), snap beans (succulent), lima beans (succulent), blackberries, boysenberries, bushnuts, butternuts, cantaloupes, cherries, chestnuts, crabapples, cucumbers, dewberries, eggplant, figs, filberts, grapes, hazelnuts, hickory nuts, loganberries, melons, muskmelons, pears, pecans, peppers, pimentos, plums (fresh plums), pumpkins, quince, raspberries, summer squash, strawberries, tomatoes, walnuts, watermelons, winter squash;

0.1 ppm in or on cottonseed.

Tolerances for dicofol commodities may be expressed as residues of dicofol and its metabolites. Some of the metabolites have yet to be identified. Therefore, following their identification, all existing tolerances for dicofol must be reassessed. If the requested additional residue data indicate the presence of residues of DDTr in or on raw agricultural commodities resulting from the the registered uses of dicofol on these raw agricultural commodities, then residue tolerances for DDTr for these commodities may be required.

Current labels allow for maximum application rates greater than those established with the above tolerances. Thus, current tolerances do not reflect the current use rates, with the exception of mint and strawberries.

Further, there are no established tolerances for dicofol residues on currants, gooseberries, peanuts, field corn and sugar beets (roots and tops). All of the dicofol products used on these commodities are intrastate products, that is they were registered State labels. In addition, the following commodities, which appear on labels of federally registered dicofol products, have no tolerance: almonds, caneberries, olallieberries, potatoes, prunes, and tangelos. Residue data described in Table A of this Document must be generated for these commodities, and petitions for tolerances must be submitted.

Processing studies will be required to show the amount of residues in the following processed commodities: apple pomace, tomato pomace, tomato waste, citrus pulp, citrus oil, grape pomace, raisin waste, cottonseed by-products (i.e. cottonseed meal and hulls, cottonseed oil).

If the processing causes residues to concentrate at levels that would exceed the tolerance established for the raw agricultural commodity, a food additive tolerance for the by-product will be required.

Animal feeding studies with large ruminants and poultry are required to establish the extent of transfer of residues to meat, milk, poultry, and eggs.

Two uses, for alfalfa and clover seed crops, are designated as food uses of dicofol and require tolerances under the Federal Food Drug and Cosmetic Act.

The Theoretical Maximum Residue Contribution (TMRC) is 1.607 mg/day as dicofol, assuming a 1.5 kg diet, based on the tolerances and food factors for all commodities for which U.S. tolerances are established. A report by the Food and Drug Administration's Regulatory Enforcement Program shows that residues of dicofol found on many agricultural crops during FY 1976, 1977, 1978, 1979, and 1980 did not exceed the residue tolerances for these crops.

No Acceptable Daily Intake (ADI) or Maximum Permissible Intake (MPI) figures have been established, due to the absence of acceptable toxicological data for dicofol. The ADI will be established when appropriate testing data are available. Until all required data have been submitted and reviewed, the current U.S. tolerances for dicofol will remain in effect.

I. SPECIAL STUDIES

The following special studies are required to resolve the questions regarding the environmental fate, effects, and product chemistry of DDTr compounds.

1. Environmental Fate

Environmental fate studies utilizing Cl-DDT as the test substance will be required to support the registration of all manufacturing-use products containing this compound. These environmental fate studies shall

include all tests cited in Table A (Generic Data Requirements for Dicofol), except for the crop rotation tests. (Note: The tendency of Cl-DDT to accumulate in rotational crops will be evaluated in the appropriate studies with dicofol technical). Additionally, it is noted that the aerobic and anaerobic aquatic metabolism and aquatic field dissipation studies listed in §158.130 are needed because of a significant potential for transport to water has been demonstrated.

Protocols for these studies must be submitted to the Agency within three months of the receipt of this Guidance Document by registrants. These studies must be designed so as to clearly indicate the chemical fate of Cl-DDT in the environment. The Agency recognizes that certain impurities must necessarily occur in any sample of Cl-DDT which the registrant might select as a test substance. The protocols utilized by the registrant must, therefore, clearly indicate how the degradation products of Cl-DDT can be distinguished from the impurities and their derivatives.

2. Ecological Effects

No effects data are available for Cl-DDT, therefore chronic toxicity studies with birds, fish, and aquatic invertebrates are required (Data Requirements Table A).

Estimated environmental residues of DDTr (from the EXAMS model) are within the range of concentration showns to cause effects in monitoring and experimental studies with DDTr. If registrants are able to substantially reduce the DDTr in dicofol to levels that would indicate environmental exposures below that for which the Agency can predict effects with the existing data base (no-effect levels are not yet known), extensive ecological effects testing would be required to overturn the Agency's presumption that such low levels may be harmful.

Field monitoring which would disprove a possible linkage between dicofol use and environmental effects of DDTr such as, for example, egg-shell thinning or impairment of fish reproduction, may be impossible or too impractical to conduct. Factors such as ambient DDTr contamination, differential species sensitivity, latency of effects, chemical persistance and mobility, and the varied biological and physical make-up of potential use sites, which all must be taken into consideration in a general proof may confound such studies or require that they be unreasonably complex.

3. Product Chemistry

Registrants certifying the presence of Cl-DDT in their manufacturing-use products are required to submit measurements of the octanol-water partition coefficient (K_{ow}), water solubility, and vapor pressure for this chemical.

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix I) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

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

B. What Generic Data [1/] Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted[2/]. Any necessary studies must be conducted in accordance with acceptable protocols, examples of which are contained in EPA's Pesticide Assessment Guidelines[3/], and, for the most part, in the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

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

2/ U.S. EPA, 1982. Pesticide Registration; Proposed Data Requirements - Part 158. FEDERAL REGISTER of November 24, 1982 (47 FR 53192).

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

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

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

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

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

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

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

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

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree (Footnote continued at bottom of next page)

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

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

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

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)
to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

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

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

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

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

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

TABLE A

GENERIC DATA REQUIREMENTS FOR DICOFOL

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional[2/] Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	No	-	Yes[3/]
61-2 - Statement of Composition	TGAI	No	-	Yes[3/]
61-3 - Discussion of Formation of Impurities	TGAI	Partially	Confidential Statement of Formula	Yes[4/]
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	No		Yes[5/]
62-2 - Certification of Limits	TGAI	Partially	Confidential Statement of Formula	Yes[6/]
62-3 - Analytical Methods for Enforcement of Limits				
- Active Ingredient	MP	Yes	05005142, 00004348[a/] 05014643, 05017499 00004340, 05004951 05005964, 05006333 05005167, 00004336[b/] 05015278, 05020221 05005274, 05004878 05005279, 05015625 05017892	No
- Impurities	MP	Yes	05004176	No
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00004358[c/], 00004339[d/]	No[7/]
63-3 - Physical State	TGAI	Yes	00004358[c/], 00004339[d/]	No
63-4 - Odor	TGAI	No	-	Yes
63-5 - Melting Point	TGAI	Yes	00004358[c/], 00004339[d/]	No[7/]
63-6 - Boiling Point	TGAI	No	-	Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR DICOFOL

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry (continued)				
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00004358 c/, 00004339 d/	No
63-8 - Solubility	TGAI or PAI	Partially	00004358 c/, 00004339 d/	Yes 8/
63-9 - Vapor Pressure	PAI	No	-	Yes
63-10 - Dissociation constant	PAI	No	-	Yes
63-11 - Octanol/water partition coefficient	PAI	No	-	Yes
63-12 - pH	TGAI	No	-	No 7/9/
63-13 - Stability	TGAI	No	-	Yes
Other Requirements:				
64- 1 - Submittal of samples	Choice	No	-	Yes

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than April, 1984.
3/ Updated information must be supplied by all companies on identity and quantity of impurities and inert ingredients. Special attention must be given to identifying and quantifying the DDT impurities. The name and address of the producer of the starting materials, the manufacturing process, and the reaction conditions are needed.
4/ Special testing is required on the impurity known as Cl-DDT. These tests are the octanol-water partition coefficient water solubility, and vapor pressure.
5/ Five or more representative samples should be analyzed for the amount of active ingredient and each impurity present in the technical material for which a certified limit is required.
6/ Upper and lower limits must be provided and certified for the dicofol concentrations and each impurity > 0.1 percent.
7/ Aceto Chemical did not submit any physical/chemical properties. Rohm & Haas and Makhteshim Beer-Shiva did report some of these properties for their technical products.
8/ Solubility should be expressed in grams/100 ml solvent or ppm at 20°C.
9/ Not soluble in water.

a/ Data submitted by Intrachem, S.A. These data may be compensable.
b/ Data submitted by Aceto Chemical Company. These data may be compensable.
c/ Data submitted by Rohm and Haas Company. These data may be compensable.
d/ Data submitted by Makhteshim Beer-Sheva Chemical Works, Limited. These data may be compensable.

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partially	05000993, 05006528 00004275, 00004321 05004877, 05006219	Yes 3/
- Livestock	PAIRA and plant metabolites	No		Yes
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolites	Partially	05005274, 00004420 05005165, 00004341a/ 05005167, 05004945 05004951, 05005141 05006330, 00004371 00004426, 05017942 05005537, 05006312 05012262, 05019781	Yes 4/
- Animal residues	TGAI and metabolites	No		Yes
171-4 - Storage Stability Data	PAI	No	-	Yes
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Peppermint Hay	TEP	Yes	00004324, 00004323 00021700, 00021701 00004272, 00004322	No
Mint Oil	TEP	Yes	00004321, 00021701	No
Spearmint Hay	TEP	Yes	00004324, 00021700 00004272	No
Strawberries	TEP	Yes	00004305	No
Hops		Partially	00004305	Yes 5/
Apricots, nectarines, peaches		Partially	00004305	Yes 5/
Grapefruit, kumquats, lemons, oranges, tangerines		Partially	00004305	Yes 5/

TABLE A
GENERIC DATA REQUIREMENTS FOR DICOFOL

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue studies for each food use				
Apples, crabapples, pears, quinces		Partially	00004504	Yes
Blackberries, boysenberries, dewberries, loganberries, raspberries		Partially	00004305	Yes 5/
Cherries, plums, prunes		Partially	00004305	Yes 5/
Beans (dry)		Partially	00004305	Yes 5/
Snap beans, lima beans (succulent form)		Partially	00004305, 00019894	Yes 5/
Cantaloupes, melons, muskmelons, pumpkins, watermelons, winter squash		Partially	00004305	Yes 5/
Cucumbers and summer squash		Partially	00004305	Yes 5/
Bushnuts, butternuts, chestnuts hazelnuts, hickorynuts, pecans, walnuts, filberts		Partially	00004305	Yes 5/
Tomatoes, eggplants, peppers, pimentos		Partially	00004305	Yes 5/
Grapes, figs		Partially	00004305	Yes 5/
Cottonseed		Partially	00004305	Yes 5/
Field corn		No		Yes
Alfalfa and clover		No		Yes
Potable water	TEP	No		Yes
Fish	TEP	-	-	No
Irrigated crops	TEP	-	-	No
Food Handling	TEP	-	-	No

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue studies for each food use				
Residue studies in food-producing animals				
- Meat	TEP	Partially	05004708	Yes 6/
- Milk	TEP	No	-	Yes
- Poultry	TEP	Partially	05026372, 05005377	Yes 6/
- Eggs	TEP	No	-	Yes

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 no later than December, 1986.
3/ It has been concluded by the Agency that the metabolic fate of dicofol in or on plants has not been adequately demonstrated. Further testing will be required using C^{14}dicofol to identify the metabolites and/or degradation products in the final residue.
4/ Since there is no adequate profile of the fate of dicofol residues in or on plants and animals, no opinion can be offered about whether or not there are adequate methods to collect the residue data and to enforce the established tolerances. When they are revised, the dicofol tolerances may have to be expressed in terms of residues of dicofol and its metabolites, or degradation products. Methods in that case will have to be available to determine the metabolites, or degradation products.
5/ Although for most crops residue data were submitted, due to the changes of application rates and pre-harvest intervals, these outdated data are not adequate to support the registered uses under present day standards, and the established tolerances are not supported.
6/ It is the Agency's opinion that proper feeding studies with large ruminants and poultry should be performed, indicating at what feeding level residues start to appear in meat, milk, poultry and eggs.

a/ Data submitted by Makhteshim Beer-Sheva Chemical Works, Limited. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR DICOFOL

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,E,F,H	Partially	GS021003 a/	Yes 4/
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B	No	GS021005 a/	Yes 5/
161-3 - On soil	TGAI or PAIRA	A	No	-	Yes
161-4 - In Air	TGAI or PAIRA	A	No	-	Yes
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,E,F,H	Partially	GS021001 a/, GS021004 a/	Yes 6/
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes
162-3 - Anaerobic Aquatic	-	-	-	-	No 7/
162-4 - Aerobic Aquatic	-	-	-	-	No 7/
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,E,F,H	Yes	GS021002 a/, GS021007 a/	No
163-2 - Volatility (Lab)	TEP	A,E,F	Yes	05011076	No
163-3 - Volatility (Field)	TEP	A,E,F	No	-	Yes
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B,H	Partially	GS021008 a/, GS021004 a/	Yes 8/
164-2 - Aquatic (sediment)	-	-	-	-	No 7/
164-3 - Forestry	-	-	-	-	No 9/
164-4 - Combination and Tank Mixes	-	-	-	-	No 10/
				a/	a/ 11/

Data Requirement

§158.130 Environmental Fate
(continued)

ACCUMULATION STUDIES:

165-1 - Rotational Crops (Confined)	PAIRA	A	Partially	05012142, GS021013 a/	Yes 12/
165-2 - Rotational Crops (Field)	TEP	A	No	-	Yes
165-3 - Irrigated Crops	-	-	-	-	No 13/
165-4 - In Fish	TGAI or PAIRA	A,B	Partially	GS021013 a/	Yes 14/
165-5 - In Aquatic Nontarget Organisms	TGAI or PAIRA	A,B	No	-	Yes

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than December, 1986.
4/ The study partially satisfies the data requirement for hydrolysis by providing information on the rate of hydrolysis of dicofol in buffered solutions at one concentration, one temperature, and three pHs (acidic, neutral, and basic). A material balance and identification of all degradation products greater than 10% of the initial dicofol concentrat could not be determined. One additional study at a different concentration and temperature at acidic, neutral, and basic pHs is required. The study should include a material balance and the identification of all degradation produc greater than 10% of the initial dicofol concentration.
5/ The photolysis study was conducted on silica gel-coated thin layer plates, which is no longer a data requirement. F the use patterns identified for dicofol, photodegradation studies are required to be conducted in distilled or de-ionized water, on soil, and in air.
6/ Sufficient data on dicofol aerobic soil metabolism in silt loam are available, which is one of the three soil types required. Two additional soil types must be tested, one should be a sandy loam and the other should be appropriate to the intended use areas.
7/ There are no registered aquatic uses for dicofol.
8/ Field dissipation studies are required to be conducted under actual use conditions, using the representative formula product. However, the submitted studies were conducted using ^{14}C-dicofol formulated into an emulsifiable concentra Since the results of the studies provided data on the material balance, in addition to data on persistence, mobilit and identification of degradation products, the Agency will accept the studies as satisfying the data requirement f silt loam, which is one of the four soil types required. Three additional field dissipation studies are required using soil types appropriate to the intended use areas. One of the three types of soil should be sandy loam.
9/ There are no registered forestry uses for dicofol.
10/ This Guidance Document deals only with single active ingredients.
11/ Long term field dissipation studies are required to be conducted under actual use conditions, using the representat formulated product. However, the submitted studies were conducted using ^{14}C-dicofol formulated into an emulsifiabl concentrate. Since the results of the studies provided data on the material balance, in addition to data on persis ence, mobility, and identification of degradation products, the Agency will accept the studies as satisfying the d

(footnotes continued on next page)

requiremen for silt loam, which is one of the four soil types required. Three additional field dissipation studies are required using soil types appropriate to the intended use areas. One of the three types of soil should be sandy loam.

' Results of the submitted rotational crop study indicated that there is a potential for dicofol and its residues to accumulate in rotational crops. However, the sampling intervals in the confined rotational crop studies were inappropriate to assess the potential uptake of dicofol and its residues at 30 days, four months, and one year after the last dicofol application. Therefore, an additional confined rotational crop study with the appropriate sampling interals is required. This study should be conducted using the manufacturing-use product as the test substance. The analytical method utilized in the study must be capable of separating and measuring dicofol, its residues, and its impurities (DDTr) in the confined rotational crops. Alternatives to conducting the confined rotational crop study are: 1) rotational crop studies conducted under actual use conditions, 2) a label restriction that prohibits crop rotation with crops other than those specified on the label, or 3) a tolerance for the nontarget crop.

' Dicofol is not registered for intentional application to irrigation water.

' The protocol for the submitted ecosystem study is inappropriate to assess the potential accumulation of dicofol and its residues in fish, because the exposure period was not long enough, nor was there a depuration period included in the protocol to assess elimination of dicofol and its residues from fish. A flowthrough system fish accumulation study is required. This study should be conducted using the manufacturing-use product as the test substance. The identity of the test substance should be specified (qualitative and quantitative description of the chemical composition). The analytical method utilized in the study must be capable of separating and measuring the DDT* impurities in the test substance.

/ Data submitted by Rohm and Haas Company. These data may be compensable.

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	A,B,E,F,H,I	Yes	00004373, 00004365 05002571, 00004374	No
81-2 - Dermal LD_{50}	TGAI	A,B,E,F,H,I	Yes	00004366	No
81-3 - Inhalation LC_{50} - Rat	TGAI	A,B,E,F,H,I	No	-	Yes
81-7 - Acute Delayed Neurotoxicity - Hen	-	-	-	-	No 4/
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,B,E,F,H,I	Partially	00004429	Yes 5/
82-2 - 21-Day Dermal	TGAI	A,B,E,F,H,I	No	-	Yes
82-3 - 90-Day Dermal	TGAI	-	No	-	No 6/
82-4 - 90-Day Inhalation - Rat	TGAI	A,B,E,F,H,I	No	-	Reserved 7/
82-5 - 90-Day Neurotoxicity-Hen/Mammal	-	-	No	-	No 4/
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,B,E,F,H,I	No	-	Yes
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A,B,E,F,H,I	No	GS021051	Yes 8/
83-3 - Teratogenicity - 2 species	TGAI	A,B,E,F,H,I	No	-	Yes
83-4 - Reproduction, 2-generation	TGAI	A,B,E,F,H,I	Yes	00004424, 00004312	No

TABLE A
GENERIC DATA REQUIREMENTS FOR DICOFOL

ta Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
58.135 Toxicology (continued)					
UTAGENICITY TESTING					
4-2 - Gene Mutation	TGAI	A,B,E,F,H,I	No	-	Yes 9/
4-2 - Chromosomal Aberration	TGAI	A,B,E,F,H,I	No	-	Yes 9/
4-2 - Other Mechanisms of Mutagenicity	TGAI	A,B,E,F,H,I	No	-	Yes 9/
PECIAL TESTING					
5-1 - General Metabolism	PAI or PAIRA	A,B,E,F,H,I	No	05002571	Yes 10/
5-2 - Domestic Animal Safety	Choice	-	-	-	No

1/ Composition: TGAI = Technical grade of the active ingredient. PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis. Due to the uncertainties of the dicofol impurities (DDTr), and their contribution, if any to a possible risk potential, all TGAI dicofol must be similar in composition. Any variation of the levels of impurities may result in additional toxicology data testing and requirement The Agency shall make data testing decisions on a case-by-case basis for each submitted statement of formula.

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

3/ Data must be submitted no later than December, 1986.

4/ This test is not required because dicofol does not depress cholinesterase acivity, and it is not structurally related to a compound that induces neuropathy or delayed neurotoxicity.

5/ The rat study submitted was adequate, testing in a second species, preferably the dog, is required.

6/ This test is not required because dicofol in not intentionally applied to the skin and its use will not result human exposure similar to that caused by swimming pool additives or pesticide-impregnated fabrics.

7/ 90-day inhalation toxicity testing requirement is reserved pending results from the acute inhalation test.

8/ The data available on oncogenicity do suggest possible oncogenicity in male mice. However, the study is unacceptable due to the reported decomposition of the test material during the study.

9/ The minimum standard for mutagenicity testing is: 1) Two different tests that are sensitive for point mutations, one for a mammalian system (in vivo or in vitro), 2) Two tests for chromosomal damage, and 3) one auxillary test for DNA damage on a test appropriate for other mechanisms of toxicity, i.e. DNA repair, induct test.

10/ A metabolism study comparing DDT and dicofol in the rat was started but not completed (various tissues removed for examination were not identified and assays were not reported, identification of purity and/or contaminants in the test substance were not reported). A request for a final report was made, however the registrant replied that the study was never completed.

Data Requirement	Composition 1/	Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	-	-	-	Reserved 4/
132-1 - Soil Dissipation	TEP	-	-	-	Reserved 4/
133-3 - Dermal Exposure	TEP	-	-	-	Reserved 4/
133-4 - Inhalation Exposure	TEP	-	-	-	Reserved 4/

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 no later than December, 1986.
4/ These tests are reserved pending the receipt of additional data (inhalation, chronic feeding, oncogenicity, and teratogenicity).

TABLE A
GENERIC DATA REQUIREMENTS FOR DICOFOL

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	A,B,H	Yes	00004315, 00004314	No
71-2 - Avian Dietary LC_{50}	TGAI	A,B,H	Yes	GS021052	No
71-3 - Wild Mammal Toxicity	-	-	-	-	No 4/
71-4 - Avian Reproduction	TGAI	A,B,H	Partially	GS021014	Yes 5/
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A,B,H	No	-	No 4/
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	A,B,H	Partially	GS021048, GS021049 GS021063 GS021046 GS021047	Yes 6/
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B,H	Partially	GS021060	Yes 7/
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A,B,H	Partially	05005326	Yes 8/
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A,B,H	Yes	GS021062	No
72-5 - Fish Life-Cycle	TGAI	A,B,H	No	-	Yes
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	A,B,H	No	-	Yes
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	-	No	-	No 9/

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than December, 1986.
4/ This test is required only on a case-by-case basis when hazards to nontarget vertebrates are likely. Lowered tiered testing does not indicate a potential hazard to nontarget vertebrates.
5/ The avian reproduction requirement involves testing with two species (mallard and bobwhite). Testing with mallards has been received but it does not fulfill the requirements; mallard and bobwhite testing are required.
6/ Testing is required on a coldwater fish species.
7/ There are insufficient data available in the submitted study to permit a statistical validation.
8/ Dose mortality data are not provided in the original citation.
9/ This test is required on a case-by-case basis when hazards to nontarget aquatic organisms are likely.

TABLE A
GENERIC DATA REQUIREMENTS FOR DICOFOL

Data Requirements	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
158.150 Plant Protection					
21-1 - TARGET AREA PHYTOTOXICITY	EP	-	-	-	No 4/
ONTARGET AREA PHYTOTOXICITY					
TIER I					
22-1 - Seed Germination/ Seedling Emergence	TGAI	-	-	-	No 4/
22-1 - Vegetative Vigor	TGAI	-	-	-	No 4/
22-2 - Aquatic Plant Growth	TGAI	-	-	-	No 4/
TIER II					
23-1 - Seed Germination/ Seedling Emergence	TGAI	-	-	-	No 4/
23-1 - Vegetative Vigor	TGAI	-	-	-	No 4/
23-2 - Aquatic Plant Growth	TGAI	-	-	-	No 4/
TIER III					
24-1 - Terrestrial Field	TEP	-	-	-	No 4/
24-2 - Aquatic Field	TEP	-	-	-	No 4/

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/ Data must be submitted no later than December, 1986.
4/ This study is not required because dicofol has not been shown to cause phytotoxicity problems.

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	A,B,H	Yes	05001991, 05008989 05008900, 05009244	No
141-2 - Honey bee - toxicity of residues on foliage	-	-	-	-	No 4/
141-3 - Wild bees important in alafala pollination - toxicity of residues on foliage	-	-	-	-	No 4/
141-4 - Honey bee subacute feeding study	-	-	-	-	Reserved 5/
141-5 - Field testing for pollinators	-	-	-	-	No 4/
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	-	-	-	-	Reserved 5/
142-2 - Aquatic insect life-cycle study	-	-	-	-	Reserved 5/
142-3 - Simulated or actual field testing for aquatic insects	-	-	-	-	Reserved 5/
143-1 thru 143-3 - NONTARGET INSECT TESTING- PREDATORS AND PARASITES	-	-	-	-	Reserved 5/

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than December, 1986.
4/ Although dicofol is registered for use on alfalfa grown for seed, dicofol has been shown to be relatively nontoxic to bees. This study is not required.
5/ [illegible]

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

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry				
Product Identity				
61-1 - Identity of Ingredients	MP	No		Yes 3/
61-2 - Statement of Composition	MP	No		Yes 3/
61-3 - Discussion of Formation of Impurities	MP	No	Confidential Statement of Formula	Yes 4/
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MP	No		Yes 5/
62-2 - Certification of Limits	MP	Partially	Confidential Statement of Formula	Yes 6/
62-3 - Analytical Methods for Enforcement of Limits				
- Active Ingredient	MP	Yes	05005142, 00004348 a/ 05014643, 05017499 00004340, 05004951 05005964, 05006333 05005167, 00004336 b/ 05015278, 05020221 05005274, 05004878 05005279, 05015625 05017892	No
- Impurities	MP	Yes	05004176	No
Physical and Chemical Characteristics				
63-2 - Color	MP	Partially	00004358 c/, 00004339 d/	Yes 7/
63-3 - Physical State	MP	Partially	00004358 c/, 00004339 d/	No
63-4 - Odor	MP	No		Yes
63-7 - Density, bulk density, or [redacted]	[redacted]	Partially	00004358 c/, 00004339 d/	Yes 7/

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DICOFOL

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional 2/ Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
63-14 - Oxidizing or reducing potential	MP	No		Yes
63-15 - Flammability	MP	Yes	00004358 c/, 00004339 d/	Yes 7/
63-16 - Explodability	MP	No		Yes
63-17 - Storage Stability	MP	Yes	00004358 c/, 00004339 d/	Yes 7/
63-18 - Viscosity	-			No 9/
63-19 - Miscibility	MP	No		Yes
Other Requirements				
64- 1 - Submittal of Samples	Choice			

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than April, 1984.
3/ Updated information must be supplied by all companies on identity and quantity of impurities and inert ingredients. Special attention must be given to identifying and quantifying the DDT impurities. The name and address of the producer of the starting materials, the manufacturing process, and the reaction conditions needed.
4/ Special testing is required on the impurity known as Cl-DDT. These tests are the octanol-water partitian coefficient, water solubility, and vapor pressure.
5/ Five or more representative samples should be analyzed for the amount of active ingredient and each impurity present in the technical material for which a certified limit is required.
6/ Upper and lower limits must be provided and certified for the dicofol concentrations and each impurity > 0.1 percent.
7/ Aceto Chemical did not submit any physical/chemical properties. Rohm & Haas and Makhteshim Beer-Shiva did report some physical/chemical properties for the technical product.
8/ Not soluble in water, therefore no pH data are required.
5/ Not applicable because the material is not a liquid.

a/ Data submitted by Intrachem, S.A. These data may be compensable.
b/ Data submitted by Aceto Chemical Company. These data may be compensable.
c/ Data submitted by Rohm and Haas Company. These data may be compensable.
d/ Data submitted by Makhteshim Beer-Sheva Chemical Works, Limited. These data may be compensable.

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

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	Yes	00004373; 00004365 05002571; 00004374	No
81-2 - Dermal LD_{50}	MP	Yes	00004366	No
81-3 - Inhalation LC_{50} - Rat	MP	No		Yes
81-4 - Primary Eye Irritation - Rabbit	MP	No		Yes 3/
81-5 - Primary Dermal Irritation	MP	No		Yes
81-6 - Dermal Sensitization	MP	No		Yes

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than December, 1986.
3/ Based on the primary eye irritation data available on formulation intermediates, manufacturing-use dicofol is considered a potentially severe eye irritant. If the registrants agree that it is a severe eye irritant, the formulation intermediate data will suffice. Otherwise, the study must be conducted with a manufacturing-use product.

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

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

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

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

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

A. Label Contents

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

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix V-2. [40 CFR §162.10(b)]

Item 2. COMPANY NAME 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. See Appendix V-2. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds

and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix V-2. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix V-2. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix V-2. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and 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 ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix V-2. [40 CFR 162.10(g)]

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

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

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

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix V-2. [40 CFR §162.10(h)(1)(ii)]

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

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix V-2. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix V-2. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix V-2. [40 CFR §162.10(h)(1)(iii)]

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

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

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

Item 8C. PHYSICAL OR CHEMICAL HAZARD

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

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

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

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

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

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

      ii. There is no flash back; and

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

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix V-2. [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix V-4 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix V-2. [40 CFR §162.10]

B. Collateral Information

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

V. INSTRUCTIONS FOR SUBMISSION

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

Jay Ellenberger (PM 12)
Phone No. (703)-557-2386
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

For each product for which continued registration is desired:

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

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

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

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

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

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

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

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

APPENDIX I

Guide to Use of This Bibliography

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

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

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

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

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

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

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

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

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

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

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

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION GUIDANCE DOCUMENT BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under this Guidance Document

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APPENDIX II

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

APPENDIX III

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

APPENDIX IV

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

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

63-20	Corrosion characteristics				
63-21	Dielectric break-down 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 sensitiza-tion				

APPENDIX V-1

cacy, 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 27952, May 11, 1979]

§ 162.10 Labeling requirements.

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

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

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

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

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

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

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

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

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

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

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

(ii) All required label text must:

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

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

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

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

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

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

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

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

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

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

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

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

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

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.

(i) *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.

(ii) *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.

(iii) *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.

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

(v) *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	Required signal word, all capitals	"Keep out of reach of Children"
	Points	Points
5 and under	8	6
Above 5 to 10	10	8
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

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

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

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

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

(ii) *Environmental hazards.* Where a hazard exists to non target organisms (excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precau-

tions 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:

(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

Flash point	Required text
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, 1978, 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 definition of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing directions 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 5736, Feb. 9, 1978]

APPENDIX V-2

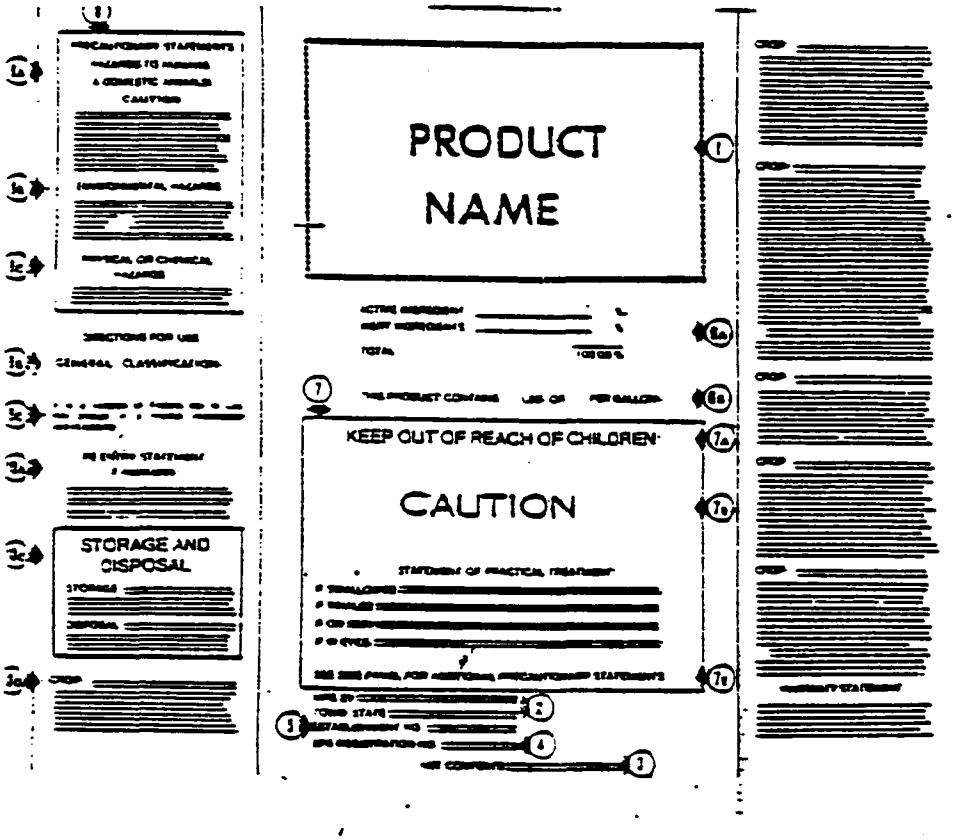
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

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

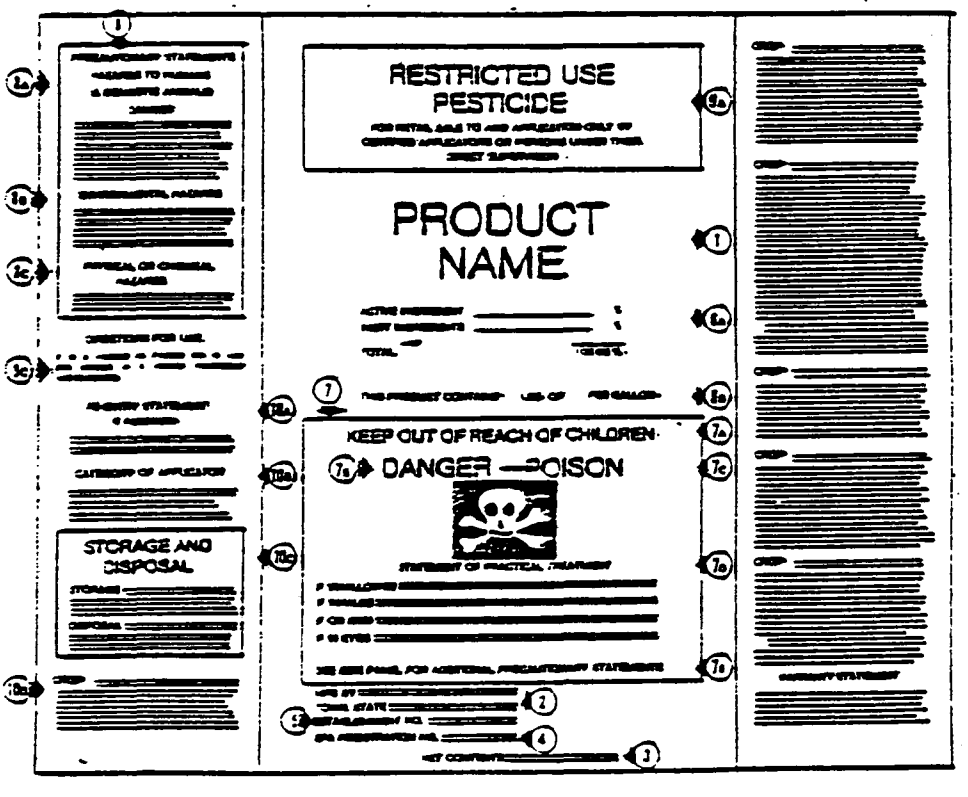
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical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

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

SAMPLE LABELS



General Use Pestticide



Restricted Use Pesticide

APPENDIX V-3

PHYSICAL-CHEMICAL HAZARDS

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

APPENDIX V-4

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

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

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

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

A. Storage Instructions:

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

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

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

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

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

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

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

B. Pesticide Disposal Instructions:

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

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

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

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

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

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

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

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

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

C. Container Disposal Instructions

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

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

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

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

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

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

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

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

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

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

"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