GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

CHLOROBENZILATE

AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

DECEMBER 30, 1983

TABLE OF CONTENTS

APPENDICES

INTRODUCTION

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

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

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. 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

A. INTRODUCTION

This guidance document describes the Agency's regulatory position on registration of manufacturing use products (MPs) containing the miticide chlorobenzilate. The Agency's position is based on an evaluation of all registered uses and registered MP's with chlorobenzilate as the sole active ingredient. The document also considers known chemical and toxicological properties of this chemical as well as the established tolerances for residues in or on food and feed commodities. From these considerations the Agency sets forth the data and labeling requirements that must be met by registrants and applicants of chlorobenzilate products in order for the products to be reregistered or registered under this document. In order to be registrable under this document, technicals and manufacturing use products must list chlorobenzilate as the sole active ingredient. The tables accompanying this document list the data gaps which must be satisfied through submission of additional information. Future MPs that differ appreciably from those described in this document may require that amendments be made to this document to reflect the differences.

B. DESCRIPTION OF CHEMICAL AND USE PROFILE

Chlorobenzilate- $C_{16}H_{14}Cl_2O_3$; mol. wt. 325.20;
C.A.S. # 510-15-6, Shaughnessy # 028801.

Chlorobenzilate is the accepted common name for ethyl 4,4'-dichlorobenzilate. Trade names and other names include Acaraben™, Akar™, Folbex™, Geigy 338, Benzilan, Rospin and Kop-Mite.

Technical chlorobenzilate is a brownish viscous liquid. It has a boiling point of 141-142°C at 0.06mm Hg and a melting point of 35-37°C (pure material). At a temperature of 19.4°C, 86.9 grams of the technical material is soluble in 100 ml. of xylene. The material is virtually insoluble in water and infinitely miscible in benzene, acetone and other organic compounds. Under normal conditions, chlorobenzilate is stable at room temperature.

This miticide is produced in the United States by the Ciba-Geigy Corp. The chemical is also produced overseas by Nippon Kayaku Co., Japan and Makhteshim Beer-Sheva, Israel.

The federally registered formulated (end use) products containing chlorobenzilate are single active ingredient formulations. There are no mixtures with other active ingredients. Chlorobenzilate is commercially formulated as a four pound emulsifiable concentrate and the only registered use for the chemical is on citrus. This use is restricted to the states of Arizona, California, Florida and Texas. Foreign uses also include smokestrips for use in honey bee hives to control the bee-mite Acarapis woodi. In addition to the federal registrations, there remain three Florida intrastate products for use on citrus. There are no active Special Local Need registrations.

C. REGULATORY POSITION

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

1. Neither this Agency nor the state of California has established a reentry interval for field workers entering treated fields. Considering acute toxicity alone, chlorobenzilate would not normally require a reentry interval. However, in keeping with established Agency policy for chemicals having an inadequate data base for evaluation of reentry exposure, and which have chronic toxic effects, a 24-hour reentry interval is now required. The registrant can either accept this interval or submit data to establish a different interval. This interval is considered provisional and the Agency reserves the right to revise this reentry interval and to impose additional label requirements after receipt and review of the data required in Table A and B of this Guidance Document.

2. Although the Agency is unable to complete a full tolerance reassessment because of certain residue chemistry and toxicology data gaps, the Agency concludes that no change in the present tolerance for citrus is warranted at this time. Additional residue data may necessitate a revision of this tolerance and the establishment of a food and/or feed additive tolerance(s).

3. Manufacturing-use products containing chlorobenzilate as a sole active ingredient may be registered for sale, distribution, reformulation, and use, under the terms and conditions set forth in this Guidance Document.

4. Registrants must provide or agree to develop additional data, as specified in the tables attached to this Guidance Document in order to maintain existing registrations or to obtain new registrations of substantially similar MPs.

5. On May 26, 1976, the EPA published in the Federal Register (41 FR 21517) a Notice of Rebuttable Presumption Against Registration and Continued Registration (RPAR) of pesticide products containing chlorobenzilate. The Agency concluded that the chemical induced oncogenic effects in experimental mammals. The Agency's position was not successfully rebutted.

   Since chlorobenzilate has been determined to pose an oncogenic risk, this chemical "triggers" criteria for unreasonable adverse effects listed in Section 162.11 (a) of Title 40 of the U.S. Code of Federal Regulations. The Agency has concluded, via the RPAR process (Federal Register (44 FR 9548) February 13, 1979, " Notice of Intent to Cancel Registrations and Deny Applications for registration of all non-citrus chlorobenzilate uses," that by limiting the use to citrus, classifying chlorobenzilate products for restricted use, and by upgrading the protective clothing requirements, the exposure level and risks would be lowered to acceptable levels. The benefits were determined to exceed the risks and the chemical was allowed continued use under the terms set forth in our "Notice of Intent to Cancel or Deny" published in

1979. These RPAR findings have been confirmed in this review. However, other gaps in the data base preclude the completion of the Agency's total risk assessment for this pesticide chemical. Registrants had to comply with certain labeling changes and agree to develop and submit to this Agency the following residue and exposure studies:

Residue Chemistry and Exposure Studies

*a. Citrus Fractionation Study
*b. Feeding Citrus By-Products to Cattle Study (Ruminant Feeding Study)
**c. Residue Monitoring of Milk from Pulp Fed Cattle and Residue Monitoring of By-Products of Citrus Processing
d. Citrus Pickers Exposure Study
e. Aerial Applicator Exposure Study
***f. Ground Applicator Exposure Study

The Agency received little response from registrants concerning the filling of the above data gaps. Consequently, on July 22, 1982 this Agency mailed a 3(c)(2)(B) "Data Call in Notice" to all registrants requiring that certain "generic" and the above residue and exposure

* If residues concentrate in citrus pulp additional ruminant feeding studies may be required.

** This study has been eliminated since this information can be obtained in the Citrus Fractionation and Feeding Citrus By-Product to Cattle study as proposed in protocols submitted by Ciba-Geigy in February of 1980.

*** This study has been submitted by Florida Citrus Mutual and is no longer considered a data gap.

data be filled. As outlined in that document, time frames and schedules for the submission of these data were to be maintained and periodic reports were to be prepared and sent to the Agency. To date the need for one study has been eliminated, one study has been submitted, and protocols have been received and reviewed for two studies. All registrants of chlorobenzilate products remain bound by this document and the time frames for the completion of the data have been incorporated into Table A of this guidance document. These data are indicated by an asterisk in the footnotes of the tables.

6. The Agency has received a report indicating the presence of manufacturing impurities at relatively low levels in one technical chlorobenzilate product. The identified impurities include certain isomers and analogs of DDT. However, the analytical method used in this study was not provided and did not quantify the compounds identified. Since DDT and other related compounds are of substantial concern to the Agency, all registrants will be required to quantify their contaminants at the lowest level of detection using the best available technology.

D. REGULATORY RATIONALE

The Agency has determined that the registration of chlorobenzilate should continue after considering the following:

1. Adequate studies are available to assess the acute oral and dermal toxicological effects of this chemical to humans.

2. Chlorobenzilate was found to be oncogenic. This finding was based mainly on an oncogenicity screening study reported by Kotin, Falk, Pallotta et al.(1969) and a study reported by Hazleton Laboratories (Horn, 1954). Additionally, a study by Hollingsworth, Woodard, and Woodard (1966) and an NCI report (Hazleton, 1978) were cited in the Agency's "Notice of Intent to Cancel."

Rebuttals to the oncogenicity "trigger" successfully eliminated the Horn (1954) and the Hollingsworth, Woodard and Woodard (1966) studies but not the Kotin, Falk and Pallatta et al. nor the NCI study. The Carcinogen Assessment Group (CAG) concluded that there was a small, but real, oncogenic risk to users. All uses of chlorobenzilate were cancelled except for citrus in an effort to reduce exposure. Labeling changes were required and the applicator protective clothing requirements were upgraded (see Section G) to further reduce this exposure.

The data show that the populations at risk with respect to chlorobenzilate use include pesticide applicators and citrus pickers. These populations are exposed to the chemical at the time of application and/or for a period of time following application. The Agency has selected restricted use classification and reentry intervals as a means of reducing exposure to these populations.

The key concept behind the restricted use classification is that certification can generally upgrade applicator skills and that with more skill and knowledge applicators are more likely to use pesticides carefully and efficiently. It would, therefore, be reasonable to conclude that a general upgrading of the skills of chlorobenzilate applicators would result in reduced exposure.

The data base for chlorobenzilate is inadequate for evaluation of reentry exposure to citrus pickers and other field workers. Therefore, establishment of a 24-hour reentry interval is in keeping with established Agency policy for chemicals having an inadequate data base for evaluating reentry exposure and which have chronic toxic effects.

3. A three generation rat reproduction study resulted in reduced testicular weights, however, the reproductive parameters were not affected at the dosage levels tested. The Agency in its RPAR conclusions required that registrants provide another multigeneration reproduction

study. This study has been received by the Agency and the results indicate that chlorobenzilate does not adversely affect reproductive performance nor produce "testicular atrophy" at dosage levels up to 100 mg/kg per day. This is no longer considered a data gap.

4. The current tolerance of 5 ppm on citrus is not adequately supported by residue data because the analytical procedure included an unacceptable extraction step. However, no adverse data have been submitted to the Agency suggesting that this tolerance level will not protect the public. Market basket surveys by the Food and Drug Administration show that residues in citrus have not exceeded the tolerance.

5. The most recent Pesticide Incident Monitoring Systems (PIMS) records available lists four pesticide incidents involving chlorobenzilate. However, none of these accidents could be wholly attributable to this chemical. No pesticide fatalities were involved and only two persons required medical attention.

6. The available data base is insufficient to fully assess the environmental fate of chlorobenzilate. However, since the data suggest that chlorobenzilate degrades fairly rapidly and both it and its degradates have low mobility, groundwater contamination is considered unlikely. Data on the octanol/water partition coefficient, volatility, leaching and reentry are required. Once the data gaps are filled, additional data may be required.

7. There are insufficient ecological effects data to complete a hazard assessment of the use of chlorobenzilate on citrus. When the Agency receives data from the required studies in this Guidance Document, a hazard assessment will be completed. Also, our analysis of these requested data may necessitate additional studies such as acute toxicity testing to estuarine and marine organisms. The amount of DDT and related compounds contaminating chlorobenzilate products is of special ecological concern and will mandate further investigation.

8. Under FIFRA, the Agency cannot cancel or withold registration simply because data are unavailable or inadequate (see Section 3(c) (2)(B) and 3(c)(7) of FIFRA). This Guidance Document provides a mechanism for identifying data needs and calling in these data. The data will then be evaluated and a determination will be made as to the continued registrability of this chemical.

E. Criteria for Products Subject to the Guidance Document

This Guidance Document covers pesticide products that contain chlorobenzilate as a sole active ingredient; the chart on page three describes the extent to which such products are subject to this Document. Applicants for registration or reregistration of such products must comply with all terms and conditions described herein. This includes making a commitment to fill data gaps on a schedule specified by the Agency. Also, applicants for reregistration must follow the instructions contained in this Guidance Document and complete and submit the appropriate forms within the specified times. End-use products must be in compliance with the label changes specified in this Document.

F. Acceptable Ranges and Limits

1. Product Composition Standards

To be fully covered under this Guidance Document, manufacturing use products (MP's) must contain chlorobenzilate as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits. However, because the Agency is concerned about possible DDT and related compounds as impurities in the technical material, quantification of these impurities must be at a level of detection below 0.1% of the technical using the best suitable validated analytical methods (preferably gas liquid chromatography or high performance liquid chromotography).

2. Acute Toxicity Limits

The Agency will consider for registration any MP whose acute toxicity category (I, II, III or IV) is supported by adequate acute toxicity data and labeling, including appropriate precautionary statements. The Agency has determined that the appropriate signal word for chlorobenzilate products is "CAUTION".

3. Use Patterns

To be registered under this Guidance Document, MP's may be labeled for formulation only into end-use products for citrus crops under the terrestrial nondomestic food crop uses (ground and aerial applications) grouping.

G. Required Labeling

All manufacturing-use products and end-use products containing chlorobenzilate must bear appropriate labeling as specified in 40 CFR 162.10. Additionally, these products must also comply with the labeling requirements outlined in the Agency's Notice of Intent to Cancel Registrations and Deny Applications for Registrations of Pesticide Products Containing Chlorobenzilate published in the Federal Register (44 FR 9548) February 13, 1979. Those requirements, as well as labeling requirements identified in the development of this document are set forth below.

When the data to be submitted under this Guidance Document have been reviewed, the Agency may impose additional labeling requirements.

1. Label Requirements for All Chlorobenzilate Products

"General Precautions"

"Take special care to avoid getting chlorobenzilate in eyes, on skin or on clothing. Avoid breathing vapors or spray mist If chlorobenzilate gets on clothing, remove contaminated clothing and wash affected parts of body with soap and water. If extent of contamination is unknown, bathe entire body thoroughly. Change to clean clothing. Wash hands with soap and water each time before eating, drinking or smoking. At the end of each work day, bathe entire body with soap and plenty of water. Wear clean clothes each day and launder before reusing."

"Handling Precautions"

"Heavy-duty rubber or neoprene gloves and apron must be worn during loading, unloading, and equipment clean-up."

2. Label Requirements for Manufacturing-Use Products

Statement of Environmental Hazards

"ENVIRONMENTAL HAZARDS"

"This pesticide is toxic to wildlife. Do not discharge into lakes, streams, ponds or public water except in accordance with a NPDES permit. For further guidance, contact the nearest EPA Regional Office."

3. Label Requirements for End-Use Products

a. The following "Restricted Use Statement" must be added to the label.

RESTRICTED USE PESTICIDE
For retail sale to and use only by certified applicator or persons under their direct supervision and only for those uses covered by the certified applicator's certification.

b. The labeling must state, "This product is restricted to the states of Arizona, California, Florida and Texas."

c. "Required Clothing and Equipment for Application"

"One-piece overalls which have long sleeves and long pants constructed of finely-woven fabric as specified in the USDA/EPA Guide for Commercial Applicators. Wide brimmed hat. Heavy duty fabric work gloves. Any article which has been worn while applying chlorobenzilate must be cleaned before reusing. Clothing which has been drenched or has otherwise absorbed concentrated pesticide must be buried or burned"

"Facepiece respirator of the type approved for pesticide spray applications by the National Institute for Occupational Safety and Health. Instead of clothing and equipment specified above, the applicator can use an enclosed tractor cab which provides a filtered air supply (as described by Taschenberg and Bourke, 1975), and which allows no more than 0.41 mg/day total exposure to chlorobenzilate. For aerial applicators: Aerial application may be conducted without the specified clothing and equipment."

d. Statement of Environmental Hazards

"ENVIRONMENTAL HAZARDS"

This product is toxic to wildlife. Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes.

e. Reentry Statement

"Do not enter treated citrus groves within 24 hours."

H. Tolerance Reassessment

Based on the established tolerances published in 40 CFR 180.109, the theoretical maximum residue contribution (TMRC) from chlorobenzilate residues to the human diet is calculated to be 0.7017 mg/day from a 1.5 kg food diet for a 60 kg person. Because all uses of chlorobenzilate except citrus have been cancelled, the Agency has recalculated the TMRC, Acceptable Daily Intake (ADI) and Maximum Permissible Intake (MPI). These values are 0.2859 mg/day/1.5 kg (3.81% of the ADI), 0.125 mg/ kg/day and 7.50 mg/day/60 kg, respectively. These ADI and MPI values are all considered provisional since a data gap exists for a chronic feeding study in a second species. Another reassessment and recalculation of the ADI and MPI will be done when studies required to fill the toxicology data gaps have been submitted and validated. If different values are obtained then the ratio between the MPI and TMRC will be reviewed. It is possible, at that time, that the established tolerances may be affected.

According to 40 CFR 180.109, tolerances are established on residues of chlorobenzilate in or on raw agricultural commodities as follows:

15 ppm in or on almond hulls,
5 ppm in or on apples, citrus fruits, melons and pears,
0.5 ppm in or on cottonseed,
0.5 ppm in or on meat, fat, and meat byproducts of cattle and sheep,
0.2 ppm in or on almonds and walnuts.

The tolerances for apples, melons, pears, cottonseed, almond hulls, almonds and walnuts were established for residues resulting from uses on these commodities. These uses were cancelled and the tolerances are scheduled to be revoked in fiscal year 1984. The tolerance for meat, fat, and meat byproducts of cattle and sheep will be retained to cover residues resulting from citrus use.

Residue data on citrus processed commodities (molasses, pulp, and oil) will be required showing the amount of residues present. If the residues are found to concentrate in processed commodities, a petition for a food additive tolerance(s) will have to be submitted or this use must deleted from the label This requirement was not in place when the original tolerance for citrus was approved. Also, additional ruminant feeding studies may be required.

International Tolerances

The following tolerances for residues of chlorobenzilate have been established in:

Canada:	5 ppm apples, cantaloupes, citrus fruits, pears
Mexico:	5 ppm citrus fruits, apples, melons, pears
	0.5 ppm cotton(seed)
	0.2 ppm nuts

The latest Codex Alimentarius entry and tolerances for chlorobenzilate are:

Crop	Maximum Residue limit (Mg/Kg)	
Almonds	0.2	shell-free basis
Apples	5.0	
Cantaloupe	1.0	
Citrus fruit	1.0	
Grapes	2.0	
Melons	1.0	
Milk	0.05	
Pears	2.0	
Tomato	0.2	
Walnuts	0.2	shell-free basis

The Maximum Residue Limit for citrus is not currently in harmony with the established tolerances for citrus fruit in the U.S.A., Mexico and Canada. Until the residue data requested for citrus use is submitted and reviewed to determine the appropriate tolerance level, the lowering of the current 5 ppm tolerance level is not warranted.

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.)

*/ 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.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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	TGAI	Partially	00077423, 00077438[a], GS0075080[b]	Yes[3,4]
61-2 - Statement of Composition	TGAI	Partially	00077438[a], GS0075080[b]	Yes[3,4]
61-3 - Discussion of Formation of Ingredients	TGAI	Partially	00077443[a], 00077405 00077411, GS0075080[b]	Yes[3,4]
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	Partially	GS0075080[b]	Yes[5,6]
62-2 - Certification of Limits	TGAI	Partially	GS0075080[b]	Yes[6]
62-3 - Analytical Methods for Enforcement of Limits	TGAI	Partially	00077435, 00077442[a] GS0075079[b], GS0075080[b]	Yes[10]
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00077423, 00077411	Yes[6]
63-3 - Physical State	TGAI	Yes	00077423, 00077411	Yes[6]
63-4 - Odor	TGAI	No	-	Yes
63-5 - Melting Point	TGAI	N/A	-	No[7]
63-6 - Boiling Point	TGAI	Yes	00077423, 00077411	Yes[6]
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00077423, 00077411	Yes[6]

a. Data submitted by Makhteshim Beer-Sheva Chem. Works, Ltd. These data may be compensable.
b. Data submitted by Ciba-Geigy. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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- 8 - Solubility	TGAI OR PAI	Yes	00077423, 00077411 GS0075080[b]	Yes[6]
63- 9 - Vapor Pressure	PAI	Yes	00077423, 00077411	Yes[6]
63-10 - Dissociation constant	PAI	No	-	Yes
63-11 - Octanol/water partition coefficient	PAI	No	-	Yes
63-12 - pH	TGAI	N/A	-	No[8]
63-13 - Stability	TGAI	Partially	00077423, 00077411	Yes[6]
Other Requirements:				
64- 1 - Submittal of samples	TGAI	No	-	No[9]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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)				

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 three months.
3. Updated information must be supplied on identity and quantity of impurities and inerts. A comparison of the confidential statements of ingredients show that there is a good possibility for the presence of DDT and/or related compounds (DDE) as impurities in the technical material. Quantification must be made with a sensitivity below 0.1% of the technical material.
4. Data submitted by Ciba-Geigy and Makhteshim. All others must submit these data.
5. Analysis of at least five production batches is required.
6. Data submitted by Ciba-Geigy. All others must submit these data.
7. Since the material is liquid, no data are required.
8. Since chlorobenzilate is insoluable in water, no pH data are required.
9. The Agency will request samples when the need arises.
10. No validation data for any of the methods were submitted. These data are required. If the DDT-like impurities were detected by T.L.C., a description of the method should be submitted as well as adequate validation data. (Preferrably we require data by HPLC or Mass Spec.)

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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	00077457	Yes[3]
- Livestock	PAIRA and plant metabolites	Partially	00077400	Yes[4]
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolites	Yes	00078289, 00077407	No[5]
- Animal residues	TGAI and metabolites	Yes	GS0075035, 00077402	No[5]
171-4 - Storage Stability Data	PAI	Yes	00077423, 00077411	No
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Citrus Fruits	TEP	Partially	00077457, 00077448 00077416, 00077470 00077445	Yes[6,9]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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]
§158.125 Residue Chemistry				
171-4 - Magnitude of the Residues- Residues Studies for Each Food Use (con't)				
Meat/milk/poultry/eggs	TGAI or plant metabolites	Partially	00078288, 00077434 00077384	No[7]
Processed Commodities				
Citrus Molasses	TGAI	No	-	Yes[8]
Citrus pulp, dried	TGAI	No	-	Yes[8]
Citrus oil	TGAI	No	-	Yes[8]

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 36 months .
3. Metabolism data are required which determine the extent of metabolism, degradation and/or breakdown of chlorobenzilate in citrus.
4. A ^{14}C radioactive metabolism study in a large ruminant is required.
5. If additional metabolism data show concern for the presence of possible metabolites, then alternate methodology may be required.
6. Data should be submitted which reflects resulting residue levels in or on the whole fruit (oranges, lemons, grapefruit) from the maximum recommended label rates including aerial applications and repeat (3 or more) applications.
7. Large animal and poultry radiolabelled metabolism studies are needed. Depending on the results of these studies and the results of the processing study, additional feeding studies and/or a tolerance for meat, milk, poultry and and eggs may be required.
8. If residues are found to concentrate in processed commodities, a food and/or feed additive tolerance will be required and additional ruminant feeding studies may be required.

*9. A citrus fractionation study is needed. This study must be submitted by February of 1984.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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	No	-	Yes
Photodegradation					
161-2 - In water	TGAI or PAIRA	A	No	-	Yes
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	Partially	00049143[b], GS0075041	Yes[4]
162-2 - Anaerobic Soil	TGAI or PAIRA	A	N/A	-	No[5]
162-3 - Anaerobic Aquatic	TGAI or PAIRA	A	N/A	-	No[6]
162-4 - Aerobic Aquatic	TGAI or PAIRA	A	N/A	-	No[6]
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A	No	-	Yes
163-2 - Volatility (Lab)	TEP	A	No	-	Yes
163-3 - Volatility (Field)	TEP	A	No	-	Yes

b. Data submitted by Ciba-Geigy. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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 (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A	Partially	00077368[b]	Yes[7]
164-2 - Aquatic (Sediment)	TEP	-	N/A	-	No[8]
164-3 - Forestry	TEP	-	N/A	-	No[9]
164-4 - Combination and Tank Mixes	-	-	N/A	-	No[10]
164-5 - Soil, Long-term	TEP	A	No	-	Yes
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	N/A	-	No[11]
165-2 - Rotational Crops (Field)	TEP	A	N/A	-	No[11]
165-3 - Irrigated Crops	TEP	A	N/A	-	No[12]
165-4 - In Fish	TGAI or PAIRA	A	No	-	Yes[13]
165-5 - In Aquatic Non-Target Organisms	TEP	A	No	-	Reserved[14]

b. Data submitted by Ciba-Geigy. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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 (Continued)					

. Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
. The use pattern is 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 Outdoors; I= Indoor.
. Data must be submitted no later than 36 months.
. Data are required identifying the degradation products and their rates of degradation.
. This study is not required for this use pattern in the guidelines.
. Data required only for aquatic uses.
Data are required on one, preferably two domestic soils where the pesticide is to be used.
. There are no registered aquatic impact uses.
. There are no registered forestry uses.
. This guidance document deals only with single active ingredients.
. Citrus is not considered a rotational crop.
. Not required if citrus is treated conventionally with the pesticide. This study is required if the pesticide is intentionally added to the irrigation water.
Fish accumulation studies are not required if the registrant can show that the active ingredient or its principal degradation product(s) will not reach water, persist in water or accumulate in tissues of animals.
These data are required only if data from §165-4 shows potential for residues of chlorobenzilate to accumulate.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition [1]	Use Patterns [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]
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	A	Yes	00080422A	No
81-2 - Dermal LD_{50}	TGAI	A	Yes	00080422A	No
81-3 - Inhalation LC_{50} - Rat	TGAI	A	No	-	Yes
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A	No	-	No[4]
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A	Yes	00077463	No
82-2 - 21-Day Dermal	TGAI	A	No	-	No[5]
82-3 - 90-Day Dermal	TGAI	A	No	-	No[5]
82-4 - 90-Day Inhalation - Rat	TGAI	A	No	-	No[6]
82-5 - 90-Day Neurotoxicity- Hen/Mammal	TGAI	A	No	-	No[4]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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]
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A	Partially	00077463	Yes[7]
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A	Yes	GS0075001	No
83-3 - Teratogenicity - 2 species	TGAI	A	No	-	Yes[8]
83-4 - Reproduction, 2-generation	TGAI	A	Yes	GS0075081[b]	No
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A	No	-	Yes
84-2 - Chromosomal Aberration	TGAI	A	No	-	Yes
84-2 - Other Mechanisms of Mutagenicity	TGAI	A	No	-	Yes

b. Data submitted by Ciba-Geigy. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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]
§158.135 Toxicology (continued)					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A	Yes	00075003	No
85-2 - Domestic Animal Safety	Choice	A	N/A	-	No[9]

1. Composition: TGAI= Technical grade of the active ingredient.
2. The use pattern is coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food Crop; C= Aquatic, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic, Outdoor; I= Indoor.
3. Data must be submitted no later than 36 months.
4. This study is not required because the chemical is not an organophosphate and is is not structurally related to a substance that causes delayed neurotoxicity.
5. Not required because the acute dermal toxicity is Category III.
6. Not required. This use does not result in repeated inhalation exposure.
7. Testing requires a rodent and a non-rodent species. A rodent study is still needed.
*8. These data are required to be submitted by October of 1984.
9. Not required because there are no domestic animal uses.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORBENZILATE

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	No	-	Yes
71-2 - Avian Dietary LC_{50}	TGAI	A	No	-	Yes
71-3 - Wild Mammal Toxicity	TGAI	A	No	-	Reserved[4]
71-4 - Avian Reproduction	TGAI	A	No	-	Yes
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A	No	-	Reserved[4]
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	A	No	-	Yes
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A	No	-	Yes
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A	No	-	Yes
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A	No	-	Yes
70-1(d) Reptile and Amphibian LC_{50}	TGAI	A	No	-	Reserved[4]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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 (continued)					
72-5 - Fish - Life-Cycle	TGAI	A	No	-	Yes
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	A	No	-	Reserved[4]
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A	No	-	Reserved[4]

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; H= Domestic Outdoor; I= Indoor.
3. Data must be submitted no later than 36 months.
4. Reserved pending the outcome of the five basic studies (ecological effects), environmental fate data, toxicology data and residue chemistry data. When these respective studies have been evaluated then a determination will be made as to whether or not additional studies are required in order to complete a hazard assessment of the citrus use pattern.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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	Yes	00036935	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A	No	-	No[4]
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP	A	N/A	-	No[5]
141-4 - Honey bee subacute feeding study		A	N/A	-	Reserved[6]
141-5 - Field testing for pollinators	TEP	A	No	-	No[4]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition[1]	Use 2 Pattern	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 (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects		A			Reserved[7]
142-2 - Aquatic insect life-cycle study		A			Reserved[7]
142-3 - Simulated or actual field testing for aquatic insects		A			Reserved[7]
143-1 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES thru					
143-3		A			Reserved[7]

1. Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2. The use pattern is 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 36 months.
4. An acute contact LD_{50} test shows chlorobenzilate is non-toxic to honey bees, no further testing is required.
5. Required only if pesticide is intended for foliar application to seed alfalfa.
6. Reserved pending development of test methodology.
7. Reserved pending Agency decision as to whether the data requirement should be established.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	1 Composition	2 Pattern	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	A	Partially	GS0075082	Yes[5,6]
132-1 - Soil Dissipation	TEP	A	No	-	No[4]
133-3 - Dermal Exposure	TEP	A	Partially	GS0075002, GS0075082	Yes[5,6]
133-4 - Inhalation Exposure	TEP	A	No	GS0075082	Yes[5,6]

1. Composition: TEP= Typical end use product.
2. The use pattern is as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food; C= Aquatic, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic, Outdoor; I= Indoor.
3. Data must be submitted no later than 36 months.
4. A field dissipation study is required. Those results should satisfy this requirement.
*5. Citrus picker, and aerial applicator exposure data are required. These data may suffice for this requirement. These data must be submitted by February of 1984.
6. An interim 24 hour reentry interval is required pending the submission and evaluation of reentry data.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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)?
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP	A	No	-	No[3]
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI	A	No	-	No[3]
122-1 - Vegetative Vigor	TGAI	A	No	-	No[3]
122-2 - Aquatic Plant Growth	TGAI	A	No	-	No[3]
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI	A	No	-	No[3]
123-1 - Vegetative Vigor	TGAI	A	No	-	No[3]
123-2 - Aquatic Plant Growth	TGAI	A	No	-	No[3]
TIER III					
124-1 - Terrestrial Field	TEP	A	No	-	No[3]
124-2 - Aquatic Field	TEP	A	No	-	No[3]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

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)?
§158.150 Plant Protection (Continued)					

1. Composition: TGAI= Technical grade of the active ingredient; TEP= Typical end-use product. EP= End-use product.
2. The use pattern is 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. These requirements are generally waived unless it is believed there is a phytotoxicity problem.

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 B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLOROBENZILATE

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	Partially	00077423, 00077438[a] GS0075080[b]	Yes[3,4]
61-2 - Statement of Composition	MP	Partially	00077438[a], GS0075080[b]	Yes[3,4]
61-3 - Discussion of Formation of Ingredients	MP	Partially	00077443[a], 00077405 00077411, GS0075080[b]	Yes[3,4]
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MP	Partially	GS0075080[b]	Yes[5,6]
62-2 - Certification of Limits	MP	Partially	GS0075080[b]	Yes[6]
62-3 - Analytical Methods for Enforcement of Limits	MP	Partially	00077435, 00077442[a] GS0075079[b], GS0075080[b]	Yes[9]
Physical and Chemical Characteristics				
63-2 - Color	MP	Yes	00077423, 00077411	Yes[6]
63-3 - Physical State	MP	Yes	00077423, 00077411	Yes[6]
63-4 - Odor	MP	No	-	Yes
63-7 - Density, bulk density, or specific gravity	MP	Yes	00077423, 00077411	Yes[6]

a. Data submitted by Makhtishem Beer-Sheva Chem. Works, Ltd. These data may be compensable.
b. Data submitted by Ciba-Geigy. These data may be compensable.

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

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)				
63-12 - pH	MP	N/A	-	No[7]
63-14 - Oxidizing or reducing action	MP	No	-	Yes
63-15 - Flammability	MP	No	-	Yes
63-16 - Explodability	MP	No	-	Yes
63-17 - Storage Stability	MP	No	-	Yes
63-18 - Viscosity	MP	No	-	Yes
63-19 - Miscibility	MP	No	-	Yes
Other Requirements				
64- 1 - Submittal of Samples	MP	No	-	No[8]

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 three months.
3. Updated information must be supplied on identity and quantity of impurities and inerts. A comparison of the confidential statements of ingredients show that there is a good possibility for the presence of DDT and/or related compounds (DDE) as impurities in the technical material. Quantification must be made with a sensitivity below 0.1% of the technical material.
4. Data submitted by Ciba-Geigy and Makhteshim. All others must submit these data
5. Analysis of at least five production batches is required
6. Data submitted by Ciba-Geigy. All others must submit these data.
7. Since chlorobenzilate is insoluable in water, no pH data are required.
8. The Agency will request samples when the need arises.
9. No validation data for any of the methods were submitted. These data are required. If the DDT-like impurities were detected by T.L.C., a description of the method should be submitted as well as adequate validation data. (Preferrably we require data by HPLC or Mass Spec.)

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLOROBENZILATE

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]
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	Yes	00080422A	No
81-2 - Dermal LD_{50}	MP	Yes	00080422A	No
81-3 - Inhalation LC_{50} - Rat	MP	No	-	Yes
81-4 - Primary Eye Irritation - Rabbit	MP	No	-	Yes
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 36 months.

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 (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(l)(2)(ii)]

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

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

B. Collateral Information

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

V. INSTRUCTIONS FOR SUBMISSION

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

Jay S. Ellenberger
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).

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

00017801 Kotin, P.; Falk, H.; Pallotta, A.J.; et al. (1968) Evaluation of Carcinogenic, Teratogenic, & Mutagenic Activities of Selected Pesticides and Industrial Chemicals: Vol. 1. Bethesda, Md.: Bionetics Research Laboratories. (Report No. NCI-DCCP-CG-1973-1-1; incomplete study; also In unpublished submission received Mar 17, 1976 under 38329-2; submitted by Consolidated Chemical, Co., Denver, Colo.; CDL:225259-N)

00036935 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)

00049143 Rothwell, D.F.; Wheeler, W.; Hubbell, D.H. (1970) Persistence and Microbiological Effects of Acarol and Chlorobenzilate in Two Florida Soils. (Unpublished study received Nov 10, 1980 under 100-614; prepared by Univ. of Florida, Depts. of Soil Science and Food Science, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:099692-I)

00075003 R. Schattner Company (1966) Tests with Ristex to Control Various Organisms. (Compilation; unpublished study received May 28, 1964?; Jun 9, 1966 under 8383-1; CDL:050703-B)

00075918 Horn, H.J. (1954) Final Report: Chronic Feeding Studies--Rats. (Unpublished study received Jul 5, 1955 under PP0013; prepared by Hazleton Laboratories, submitted by Geigy Chemical Corp., New York, N.Y.; CDL:090089-C)

00077368 Guth, J.A.; Senn, U.; Imhof, R. (1975) Chlorobenzilate (G-23992): Dissipation of Residues of Chlorobenzilate and Two of Its Metabolites in a Silty Loam Soil after Application of AKAR 50 EC: No. RVA 323/75. (Unpublished study received Oct 28, 1976 under 100-458; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:226572-C)

00077384 Geigy Chemical Company (1966) Chlorobenzilate Residues in Sheep and Cattle Tissues. (Unpublished study received on unknown date under 9F0779; CDL:097544-J)

00077400 Geigy Chemical Company (1964) Chlorobenzilate, Technical--Metabolic Distribution and Excretion of Chloropropylate and Chlorobenzilate in Dogs. (Unpublished study received on unknown date under 9F0779; CDL:097544-Z)

00077402 Harris, H.J. (1955) Colorimetric determination of ethyl 4,4'-dichlorobenzilate (chlorobenzilate) as a spray residue. Journal of Agricultural and Food Chemistry 3(11):939-941. (Also In unpublished submission received Dec 27, 1967 under 8F0685; CDL: 092990-D)

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

00077405 Geigy Chemical Company (19??) Name, Chemical Identity and Composition of Chlorobenzilate. (Unpublished study received Feb 4, 1966 under 9H0007; CDL:221563-A)

00077407 Geigy Chemical Corporation (19??) The Determination of Chlorobenzilate and Chloropropylate in Plant Materials. Ardsley, N.Y.: Geigy. (Analytical bulletin no. 9; also In unpublished submission received Feb 4, 1966 under 9H0007; CDL:221563-C)

00077411 Geigy Chemical Corporation (19??) Chlorobenzilate--Chloropropylate Petition: Section A: Name, Chemical Identity and Composition of Chlorobenzilate and Chloropropylate. (Unpublished study received Sep 30, 1966 under 6F0463; CDL:092752-B)

00077413 Hollingsworth, R.L.; Woodard, M.W.; Woodard, G. (1966) Chlorobenzilate Safety Evaluation by Dietary Feeding to Rats for 104 Weeks. Final rept. (unpublished study received Sep 30, 1966 under 6F0463; prepared by Woodard Research Corp., submitted by Geigy Chemical Corp., New York, N.Y.; CDL:090513-A)

00077416 Wolfenbarger, D.O. (1962) Chlorobenzilate Residues--Limes: AG-A 324. (Unpublished study received Sep 30, 1966 under 6F0463; prepared in cooperation with Univ. of Florida, Subtropical Experiment Station, submitted by Geigy Chemical Corp., New York, N.Y.; CDL:090513-D)

00077423 Geigy Chemical Corporation (19??) Chlorobenzilate Formulations. Ardsley, N.Y.: Geigy. (Chlorobenzilate technical bulletin no. 61-1; also In unpublished submission received Jun 16, 1963 under PP0379; CDL:092665-C)

00077434 Mattson, A.M.; Insler, M. (1966) Chlorobenzilate Residues in Sheep and Cattle Tissues. (Unpublished study received Nov 23, 1967 under 7F0615; submitted by Geigy Chemical Co., Ardsley, N.Y.; CDL:090801-E)

00077435 Geigy Chemical Corporation (19??) Determination of Chlorobenzilate in Commercial Formulations. Ardsley, N.Y.: Geigy. (Technical release--analytical bulletin no. 4; also In unpublished submission received May 29, 1967 under 7F0615; CDL:092907-B)

00077438 Agan Chemical Manufacturers, Limited (19??) Benzilan: Chlorobenzilate Acaricide, Especially for Mite Control in Citrus. (Unpublished study received Jul 10, 1972 under 11603-12; CDL: 014052-A)

00077442 Makhteshim Beer-Sheva Chemical Works Limited (1972) Manufacturing Instructions for Technical Benzilan. (Unpublished study received Mar 30, 1973 under 11678-13; CDL:126343-A)

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

00077443 Makhteshim Beer-Sheva Chemical Works Limited (1973) Percent Composition of the Technical Chemical Including the Percent of Each Impurity. (Unpublished study received Mar 30, 1973 under 11678-13; CDL:126343-B)

00077445 Geigy Chemical Corporation (1956) Results of Tests on the Amount of Residue Remaining Including Description of the Analytical Method Used: Chlorobenzilate. (Unpublished study received on unknown date under PP0182; CDL:092458-C)

00077448 Geigy Chemical Corporation (1955) Residue of Chlorobenzilate on Apples, Pears, Cantaloupes, Melons and Lemons. (Compilation; unpublished study received Apr 11, 1955 under PP0013; CDL: 090012-A)

00077457 Gunther, F.; et al. (19??) Persistence Residue Data for Chlorobenzilate in Peel of Field-sprayed, Washed Lemons. (Unpublished study received Feb 5, 1955 under PP0013; prepared by Univ. of California--Riverside, Citrus Experiment Station, submitted by Geigy Chemical Corp., New York, N.Y.; CDL:092297-E)

00077463 Tusing, T.W. (1965) Final Report: Two-year Dietary Feeding Study-Purebred Beagles. (Unpublished study, including letter dated Aug 6, 1965 from T.W. Tusing to Frank L. Lyman, received Oct 25, 1965 under 6F0463; prepared by Hazleton Laboratories, Inc., submitted by Geigy Chemical Corp., New York, N.Y.; CDL:090511-C)

00077470 Geigy Chemical Corporation (1957) Chlorobenzilate Residues from Grapefruit, Tangerines and Oranges. (Compilation; unpublished study received on unknown date under PP0182; CDL:090210-B)

00078288 Johnston, C.D. (1960) Examination of Milk for Residues following Feeding of Chlorobenzilate to Dairy Cows. (Unpublished study, including letter dated Nov 11, 1960 from C.D. Johnston to Joseph Marrus, received Jun 16, 1963 under PP0379; prepared by Woodard Research Corp., submitted by Geigy Chemical Co., Ardsley, N.Y.; CDL:090409-E)

00078289 Blinn, R.C.; Gunther, F.A.; Kolbezen, M.J. (1954) Microdetermination of the acaricide ethyl p , p -dicholorobenzilate (chlorobenzilate). Journal of Agricultural and Food Chemistry 2(21): 1080-1083. (Also In unpublished submission received Feb 5, 1955 under PP0013; submitted by Geigy Chemical Corp., New York, N.Y.; CDL:092297-D)

00080422 Gray, E.H. (1952) Acute Oral Toxicity, Acute Dermal Irritation, Repeated Dermal Irritation. (Unpublished study received Oct 28, 1965 under 6G0504; prepared by Hazleton Laboratories, submitted by Geigy Chemical Corp., New York, N.Y.; CDL:090588-D)

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

GS0075001 Weisburger, J. H.; Weisburger, E. K.; et al. (1978) Dietary administration for two years (rats); for 18 months (mice). Prepared by the National Cancer Institute NCI-CG-TR-75.

GS0075002 Iwata, Y., M.E. Dusch, G.E. Carman, and F.A. Gunther (1979) Worker environment research: residues from carbaryl, chlorobenzilate, dimethoate, and trichlorfon applied to citrus trees. J. Agric. Food Chem. 27(6): 1141-1145.

GS0075035 Beckman and Bebenue (1964) Microcoulometric Gas Chromatographic Analysis of Grapes and Cottonseed for chlorobenzilate Residues. J. Agric. Food Chem. 12: 183.

GS0075041 Miyazaki, S., G.M. Boush, and F. Matsumara (1970) Microbial degradation of chlorobenzlate (ethyl-4,4'- dichlorobenzilate) and chloropropylate (isopropyl- 4, 4'- dichlorobenzialte). J. Agric. Food Chem. 18(1): 87-91.

GS0075079 Ciba-Geigy (1972) Nature and extent of impurities in technical chlorobenzilate. (unpublished) Presented to the Joint Meeting of FAO/WHO in 1972. "Chlorobenzilate Joint Meeting on Pesticide Residues."

GS0075080 Ciba-Geigy (1983) Additional Information of DDT-like Impurities Found in Chlorobenzilate Technical and Supporting Methodology (unpublished).

GS0075081 Ciba-Geigy (1983) Reports of Investigations made with respect to the safety of the miticide chlorobenzilate (2-generation Reproduction Study-Rat). (unpublished study received Sep 1, 1983 under 100-533; CDL:251140,251141,251142).

GS0075082 Nigg, Herbert N., and James H. Stamper (1983) Exposure of Spray Applicators and Mixer-Loaders to Chlorobenzilate. Arch. Environ. Contam. Toxicol. 12: 477-482.

APPENDIX II-2
OMB Approval No. 2000-0468 (Expires 12-31-03)

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)(iii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

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

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

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

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-92)

APPENDIX II-3

OMB Approval No. 2000-0468 (Expires: 12-31-23)

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

(To qualify, certify ALL four items)

GUIDANCE DOCUMENT DATE	
ACTIVE INGREDIENT	

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:

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

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: Citing MRID#	I am complying with data requirements by: Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[44 FR 27953, May 11, 1979]

§ 162.10 Labeling requirements.

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

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

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

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

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

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

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

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

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

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

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

(ii) All required label text must:

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

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

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

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

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

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

(i) Is false or misleading, or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the 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:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) Rotational crop restrictions.

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

(D) [Reserved]

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

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

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

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

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

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

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

(k) Advertising. [Reserved]

[40 FR 26268, July 3, 1975; 40 FR 32320, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing.* (1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five (45) days from the date such notice is sent to submit evidence in rebuttal of the presumption; provided, however, that for good cause shown the Administrator may grant an additional sixty

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

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.

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.

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).

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.