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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

AS THE ACTIVE INGREDIENT

ACEPHATE
(103301)

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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APPENDICES

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

I. REGULATORY POSITION AND RATIONALE

A. Introduction

This chapter contains the Agency's regulatory position and rationale on products containing the pesticide acephate as a sole active ingredient. The Agency bases its position and rationale on a consideration of all uses of acephate appearing on pesticide products registered under Sections 3 and 24(c) of the FIFRA. There are no acephate products authorized for distribution in intrastate commerce under 40 CFR 162.17. The Agency has reviewed the known chemical, environmental, and toxicological characteristics of this pesticide and its established 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 for registration of Acephate manufacturing-use (MP) products in order for their products to be registered or reregistered under this Standard. Unique labeling requirements and certain data needs for end-use products (EPs) containing acephate are also established by this Standard.

Only those data and labeling requirements for current and future substantially similar MPs and EPs are addressed here. Applications to register products that differ appreciably from those described in this Standard may be subject to additional data and/or labeling requirements. No new uses of acephate will be considered until the human safety concerns raised in this Standard are satisfactorily resolved.

B. Description of Chemical

Acephate is the American National Standards Institute (ANSI) approved common name given to the chemical, O,S-dimethyl acetylphosphoramidothioate. Other names include Orthene; Ortho 12,420; RE 12,420; and Ortran. Identifying characteristics and codes are as follows:

Empirical Formula: $C_4H_{10}NO_3PS$
Molecular Weight: 183.16
CAS Registry No.: 30560-19-1
ENT Registry No.: 27,822
Shaughnessy No.: 103301

Technical acephate is an off-white crystalline solid. It has a strong pungent mercaptan-type odor. Its solubility is high in water, good in polar organic solvents and poor in aromatic solvents. It is stable at 21 °C but decomposes at its melting point (82-89 °C).

Chevron Chemical Company is the sole producer of acephate in the United States and markets its products under the trade name, Orthene. There is one technical/MP (97%) registered and two formulation intermediate MPs (85% and 75%) registered. There are 28 products registered for use in the United States under Sect. 3 of the FIFRA. These include 23 single active ingredient formulations and 5 multiple active ingredient formulations. On record as of March 13, 1985, there were 113 products containing acephate registered under Sect. 24(c) of the FIFRA.

Acephate is a systemic, organophosphate insecticide registered for use on a variety of ornamentals (by both homeowner and commercial applicator), agricultural crops, forests, pasture and rangeland, lawns and turf, indoor use in both commercial (including food handling establishments) and residential buildings; and in greenhouses. It is formulated into soluble concentrate solids, soluble concentrate liquids, granulars, pressurized liquids, and an 85% cartridge. Acephate is not a restricted use chemical and is registered for homeowner use as well as commercial and agricultural uses. Methods of application include aerial, ground, injection into tree trunks (cartridge formulation); dip treatment for ornamentals [24(c) registration]; soil incorporated granular (ornamentals), and sprinklers.

As an organophosphate, acephate exerts its toxic action by inhibiting certain important enzymes of the nervous system (cholinesterase).

C. Regulatory Position and Rationale

Based on a review and evaluation of all available data and other relevant information on acephate, the Agency has determined the following:

1. Residue reduction studies and exposure studies are required to enable the Agency to accurately assess the potential human risks from current uses of acephate. These data include:

    a. Residue studies to determine the fate of residues of acephate and methamidophos in succulent beans (during cooking and canning); dried beans (during cooking and canning; soybean oil (during the refining process); and soybeans (during processing to defatted flour).

    b. A dairy cattle feeding study to determine the fate of residues of acephate and methamidophos during pasteurization or processing into the milk fractions; nonfat milk solids, milkfat solids, and milk sugar (lactose).

    c. Applicator exposure studies for forestry application; for application to both home and commercial ornamentals; and for indoor application in homes, greenhouses, and commercial establishments.

    d. Postapplication studies of indoor exposure to inhabitants resulting from application in homes, greenhouses, and commercial establishments.

    e. Usage data (as specified on last page of Table A) and use-related exposure data (as specified in Table C) for all sites listed in (c) above in addition to cotton and lettuce.

    f. Dermal penetration data.

    g. Spray drift data for terrestrial food and nonfood sites, and for forestry uses.

h. Glove permeability study for all liquid formulations containing acephate.

i. Reentry data (dislodgeable residue decline curve data for use on cauliflower and soil residue dissipation data for use on peanuts).

The use of protective clothing including impermeable gloves, long sleeved shirt and long legged trousers, is being imposed for mixer/loaders and applicators as an interim measure to reduce exposure to users of acephate products pending submittal and evaluation of the exposure studies described above. Products registered for indoor, domestic use will be required to bear a label statement prohibiting children and pets on treated surfaces until spray has dried. Refer to section F, Required Labeling.

Rationale:

The review has identified a potential chronic effects concern. Based on the available evidence, i.e., findings from the mouse oncogenicity study and the mutagenicity assays, the Agency has classified the chemical as a category C carcinogen (a possible human carcinogen) and, as such is being regulated by the Agency as a carcinogen. The available assays indicate that acephate showed consistently positive responses in gene mutation assays, was active in about 50% DNA repair assays, was very active in one sister chromatid exchange (SCE) in Chinese hamster cell cultures and was without response in in vivo assays. The mouse oncogenicity study showed a statistically significant increase in the proportion of liver adenomas/carcinomas and hyperplastic nodules occurring only in the high dose (1000 ppm) females and only at the time of terminal sacrifice. The proposed EPA guidelines for carcinogenic risk assessment (FR November 23, 1984) were followed for the evaluation and classification of the oncogenic effect of acephate. Following the guidance set forth in the EPA proposed guidelines, the mouse oncogenic response was considered as "limited evidence." At this time the Agency is considering the impact of this concern in terms of potential human risk. To estimate this level of concern, the Agency is requiring the exposure data and residue studies as specified above.

The Agency believes that, with the use of the protective clothing, as noted above and the required labeling specified within this standard, there will be no unreasonable adverse effects in the interim until exposure assessment data are received and reviewed. Based on consideration of the following points, the Agency believes that the weight of evidence that acephate is a human carcinogen is weak.

The cancer guidelines state that sufficient evidence of carcinogenicity may be shown by an increased incidence of malignant tumors or combined malignant and benign tumors in multiple species or strains. The guidelines take the position that the mouse-liver tumor response could be considered as limited evidence of carcinogenicity when a number of factors such as the following are observed: The occurrence of tumors only in the highest dose group and/or only at the end of

the study; no substantial dose-related increase in the proportion of tumors that are malignant; the occurrence of tumors that are predominately benign; no dose-related shortening of the time to the appearance of tumors; negative or inconclusive results from a spectrum of short-term tests for mutagenic activity; and the occurrence of excess tumors only in a single sex.

° In the case of acephate, the Agency considers the evidence of carcinogenicity for acephate as limited evidence. In the following paragraphs, each of these factors is discussed as it relates to the available information on acephate.

(a) The occurrence of tumors only in the highest dose group and/ or only at the end of the study.

The statistically significant increase in the liver adenomas/ carcinomas and hyperplastic nodules were observed in only the high dose (1000.0 ppm) females and only at the end of the study. At 52 weeks there was an interim sacrifice of 40 females. No tumors were diagnosed at this time. There is no evidence of life shortening due to hepatocellular carcinomas. The study was not designed to provide definitive information regarding the time at which tumors first occurred. Thus, it is not possible to draw any definitive conclusions regarding the timing of occurrence of the tumors. However, the incidence of tumors only in the high dose females tends to support a classification of the acephate data as "limited evidence" of carcinogenicity.

(b) No substantial dose-related increase in the proportion of tumors that are malignant.

Though the tumors were predominantly malignant in the high dose females, the effect was observed only at the highest dose. Therefore, there is no observed dose-response relationship for the malignant tumors (carcinomas). However, the power of this and any other similar study does not usually allow a definitive conclusion on the absence of dose response.

(c) The occurrence of tumors that are predominantly benign, showing no evidence of metastasis or invasion.

The ratio of percentage of carcinomas to adenomas in the high dose females is 15.8% to 3.9%. This supports a conclusion that malignant tumors are the predominant tumors. Therefore, this information is supportive of a classification of "sufficient" for acephate.

(d) No dose-related shortening of the time to the appearance of tumors.

There was an interim sacrifice at 52 weeks of 40 females. No tumors were observed at this time. Tumors were observed only at the end of the study in high dose females. Thus, within the limitations of the study design, there does not

appear to be evidence of a shortened time to tumor effect. However, as indicated above, the study was not designed to provide definitive information regarding the time at which tumors first occurred.

Recognizing these limitations, the Agency believes that the evidence is adequate to conclude that there probably was not a shortening of the time to the appearance of tumors. Therefore, this factor tends to support a classification of the acephate data as "limited evidence" of carcinogencity.

(e) Negative or inconclusive results from a spectrum of short-term tests for mutagenic activity.

Acephate induces gene mutations, DNA repair and sister chromatid exchanges. It was positive or weakly positive in eight gene mutation assays with activation, and negative in two acceptable studies. It was positive in one acceptable change DNA repair assay with activation, and negative in two acceptable studies. It was positive in one acceptable sister chromatid exchange assay with activation. It has been negative in two acceptable in vivo studies. The overall conclusion is that acephate has a definitive effect in a number of mutagenic assays. The in vivo assays, which were without response are generally regarded to be of lesser sensitivity, nontheless, these negative effects show that acephate is not a strong mutagenic agent under in vivo conditions, while moderately mutagenic in cellular systems (prokariots and eukariots). Therefore, this information is supportive of a classification of "sufficient" for acephate.

(f) The occurrence of excess tumors only in a single sex.

The tumors occurred only in the female mice. Therefore, this supports a "limited evidence" of carcinogenicity classification for acephate.

(g) Other data:

The rat oncogenicity study showed an increased incidence of medullary neoplasms in the adrenal gland (pheochromocytomas) of the acephate-treated male rats when related to the concurrent controls.

The incidence of pheochromocytomas in the acephate-treated male rats, however was within the ranges reported for the historical control male rats of the same strain. Following extensive analysis, Agency scientists concluded that the rat study is not indicative of an oncogenic response to acephate.

° Available studies on the metabolism of acephate by rats, dairy cattle, pigs and goats have shown that acephate is excreted essentially unchanged in mammalian urine. The excretion is rapid and there is no accumulation of acephate in tissues.

Serious consideration was given to the initiation of a Special Review because of the potential human safety concern identified during the Standard review process. As noted, the Agency believes the weight of the evidence that acephate is a human carcinogen is limited. Further, it has been determined that a Special Review could not now be usefully conducted because of the gaps in important data, particularly exposure data, listed in items C. 1(a) through (i) above. These data are necessary to enable the Agency to complete a risk assessment under the Special Review process and to make a determination regarding the registration status of acephate. Once these data are received, the Agency will initiate an expedited review and evaluation of the data.

Therefore, because the Agency believes required measures will prevent unreasonable adverse effects in the interim until exposure data are received and reviewed, because the Agency considers that the weight of evidence that acephate is a human carcinogen is weak, because additional studies are needed to accurately determine the potential risk to humans and because the required time and resources do not justify a Special Review at this time, the Agency is not placing acephate into Special Review at this time.

In making future decisions on acephate, the Agency will also take into consideration results of the toxicity studies for acephate's cholinesterase-inhibiting metabolite, methamidophos* which have been received and are now under review by the Agency. These studies include a mouse oncogenicity study, a rat chronic feeding/oncogenicity study, a dog chronic study, a rat teratology study, a rat reproduction study and mutagenicity studies. Until these studies are reviewed, particularly the chronic feeding, oncogenic and mutagenic studies, the possibility that the high-dose oncogenic effect of acephate may be due to methamidophos cannot be unequivocally eliminated. A preliminary review of the submitted oncogenic studies for methamidophos indicate that they are negative, but further reviews are necessary to confirm this preliminary finding. Technical acephate contains 0.9 to 1.2% w/w of methamidophos. A portion of acephate (generally, from 0.6 to 10%) can also be converted to methamidophos by microorganisms in mammalian gut (and be absorbed) and by plants.

Available residue data are not sufficient to allow the Agency to complete its assessment of the potential dietary risk to consumers of acephate-treated food commodities. Data are needed to determine the fate of residues of acephate and its metabolite, methamidophos, during processing of these commodities.

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* The Registration Standard for methamidophos was issued by the Agency September 30, 1982.

Available data suggest that cooking and canning would be a potential route of dietary exposure reduction. For example, in two canned succulent bean samples, residues of acephate and methamidophos, represented 12-58% and 34-65% respectively, of the residues determined in/on the raw agricultural commodity. Although there are limited cooking and canning data available, the results are inconclusive and, moreover, the percentage of residues lost during cooking or canning is expected to depend upon the commodity in question and, therefore, studies need to be conducted on each crop individually.

Thus, the residue studies on food prepared for consumption for the specified commodities as cited in C.1(a) and (b) above are needed to accurately assess the dietary risk from use of acephate as described in this document. Until the required studies are received and the Agency has completed its evaluation of the dietary risks posed by the current established tolerances, no additional tolerances for acephate will be considered.

Because dermal penetration data are lacking for acephate, the Agency is unable to determine the amount of dermal absorption of the material resulting from various levels of exposure. The Agency is requiring that such data be submitted.

The exposure studies and usage data cited in C.1 (c), (e), and (f) above are needed to enable the Agency to accurately assess the potential risk to applicators from the use of acephate as described in this document. As an interim precautionary measure to reduce the potential exposure to applicators, use of protective clothing including impermeable gloves, long-sleeved shirt and long legged trousers is being imposed. However, tests defining glove permeability of liquid formulations are required so that a determination can be made as to what specific glove materials are resistant to acephate formulations (including the inert ingredients) and to also determine the breakthrough times.

Additionally, the studies of indoor exposure to inhabitants are required to accurately assess the postapplication risk to nonapplicators. The current registered methods of application of acephate in indoor domestic settings are limited to localized areas. These application methods are crack and crevice, spot spray and paint brush spot treatments for use by pest control operators or service persons; and foliar treatment of house plants by homeowners. Because these uses of acephate in indoor residential settings are considered a limited use pattern in that application is limited to selective specified surfaces and does not include general treatment (application to broad expanses of surfaces such as walls, floors), it is expected that the potential exposure to inhabitants would be minimal. The current registered acephate product labels registered for indoor, domestic use carry the following restriction: Do not allow children or pets on treated surfaces until spray has dried. This restriction will continue to appear on all such acephate products to reduce exposure until a fuller assessment of risks can be made.

Spray drift data are also required to determine the potential exposure to humans who may be present in the area at time of application.

Pending submittal and evaluation of the studies necessary to evaluate the potential risk to humans from the present uses of acephate as described in this document, the Agency will not consider any new uses of acephate that would result in an increase in the current exposure or in new exposure, i.e., exposure to segments of population not previously exposed.

2. An interim reentry interval of 24 hours is being imposed for fieldworkers. Reentry prior to lapse of the 24 hour interval requires the use of protective clothing including impermeable gloves, longsleeved shirt and long legged trousers. Greenhouse workers who may be exposed to treated plant surfaces in greenhouses within 24 hours after application must wear protective clothing, including impermeable gloves, long-sleeved shirt and long legged trousers.

Rationale:

The available worker exposure data show that dislodgeable acephate residues decline rapidly from leaf surfaces with approximately half of the applied acephate dissipated within 24 hours following application.

Additional data, however, are needed for the Agency to accurately determine the potential exposure risk to field workers. These data include the dermal penetration and the reentry data described in the preceding section C.1 of this document. As an interim precautionary measure, the Agency is imposing the 24-hour reentry interval for field workers.

Although the scope of the current reentry guidelines (subdivision K), is limited to use patterns associated with growing crops and does not include interior settings, it is expected that greenhouse workers could encounter substantial dermal exposure to acephate residues in treated greenhouses. Therefore, the Agency is imposing the use of the protective clothing described above by greenhouse workers who may be exposed to treated plant surfaces within 24 hours after application of acephate, as an interim measure. As described in section C.1 of this document, data defining glove permeability of liquid formulations of acephate is being required.

As described in C.1. above, it is expected that the potential exposure to inhabitants resulting from the use of acephate in homes would be minimal.

3. To support continued registration of peppermint and spearmint uses, additional residue data for mint hay supporting a lower tolerance are required. To support continued registration of range and pastureland uses, residue data on grass hay supporting a lower tolerance are required. Pending submittal and evaluation of these data, use restrictions prohibiting the feeding of spent mint hay and grass hay to lactating dairy animals are being imposed as an interim measure. Refer to section F, Required Labeling.

Rationale:

As a part of the reregistration process, the established tolerance levels for acephate in meat, milk, poultry, and eggs have been reevaluated.

In determining the level of secondary residue likely to occur in meat, milk, poultry or eggs from ingestion of treated feed items, the proportion in the animals diet of the feed items bearing the residue must be taken into account, along with the tolerance level established for those feed items. Table II of the Residue Chemistry guidelines (Subdivision O) is used as a guide in determining the proportion of the diet of the various feed items. In the case of acephate, the amount of residues contributing to the animals diet from ingestion of acephate treated feed items, particularly spent mint hay or grass hay is larger than was previously thought.

The available swine and cattle feeding studies indicate that the tolerances for the fat, meat, and meat byproducts of swine, cattle, goats, horses and sheep are adequate. Also, the available poultry feeding data indicate that the tolerance levels in eggs and poultry fat, meat, and meat byproducts are adequate.

However, the available residue data indicate that the established tolerance level for acephate residues in milk is likely to be exceeded if maximum levels of spent mint hay or grass hay are included in the dairy animal diet.

Thus, the additional mint hay and grass hay data as cited above are needed to reduce the current tolerances in/on spent mint hay and grass hay. The label restrictions cited above are needed as an interim precautionary measure to ensure that the tolerance level for acephate residues in milk is not exceeded.

4. The following revisions in 40 CFR 180.108, 21 CFR 561.20, 40 CFR 180.315, 21 CFR 561.277 and 21 CFR 193.10 are to be initiated by the Agency.

   - 40 CFR 180.108 and 21 CFR 561.20

     The acephate tolerances currently established under these sections are to be expressed in terms of only acephate per se, with references to sections 40 CFR 180.315 and 21 CFR 561.277 indicating that tolerances for the metabolite, methamidophos are also in effect.

   - 40 CFR 180.315 and 21 CFR 561.277

     The methamidophos tolerances currently established under these sections are to be divided into parts (a) and (b) where (a) includes (1)tolerances reflecting use of methamidophos and (2) tolerances where both acephate and methamidophos formulations are used on the same crops, and

(b) includes tolerances reflecting use of acephate formulations alone, i.e., residues of methamidophos resulting from the metabolism of acephate.

- 21 CFR 193.10

  These food additive tolerances reflecting crack and crevice treatment in food-handling facilities are to be expressed in terms of only acephate per se, i.e., based on available data, no residues of the metabolite methamidophos are expected to occur (<0.001 ppm) in or on these foods.

Also, such a change in the residue definition would require deletion of the paragraph (d)(8) of 40 CFR 180.3 which states that methamidophos residues may not exceed the higher of the two tolerances established for the use of acephate or methamidophos as a pesticide.

Refer to Table 2 at the end of this chapter for the tolerance changes reflecting this change in the residue definition.

Rationale:

The change in residue definition, i.e., to change the expression for acephate tolerances from combined residues of acephate and methamidophos to residues of acephate per se, would achieve compatibility with the maximum residue levels (MRLs) of the Codex Alimentarius Commission at least in terms of residue definition. This change would also result in the U.S. tolerances and the Codex MRLs for acephate being compatible for the following commodities: cottonseed, eggs, animal tissues, lettuce, and milk. Residue data preclude decreasing the soybean acephate tolerance of 1 ppm to the Codex MRL level of 0.5 ppm. Of the methamidophos tolerances altered or created due to the recommended change in residue definition, only those for residues in animal tissues are compatible with Codex MRLs. Based on the residue data, the tolerances recommended for methamidophos in or on cottonseed, milk, and soybeans cannot be reduced to the levels of the corresponding Codex MRLs. Although the recommended change in residue definition would result in "new" tolerances for methamidophos, these tolerances merely reflect the residue levels that are already present in/on the specified crops resulting from the metabolism of acephate.

5. The Agency is requesting additional ground water data on an accelerated basis in order to evaluate the potential for ground water contamination. These studies include mobility, photodegradation, metabolism and dissipation data.

Rationale:

Due to its rapid leaching behavior, acephate has the potential for groundwater contamination. Available studies are insufficient to assess this potential. Thus, additional data are required.

Available studies show that acephate dissipates rapidly with half-lives of <3 and ~6 days in aerobic and anaerobic soils, respectively. The major metabolite was CO_2 in both types of soil. Apparently most of the applied acephate and the degradate methamidophos degrade to immobile compounds in ~ 20 days.

6. The Agency is requiring an avian residue monitoring study. The need for additional testing will depend on results of this monitoring study.

Rationale:

Although the dietary toxicity of acephate to avian species is not considered high, its metabolite, methamidophos, has been shown to be very toxic to birds in dietary exposures. Available data on methamidophos residues occurring in avian feed items from application of acephate at 1 lb active ingredient per acre, suggest that residue levels of methamidophos may occur as high as 9% to 41% of the bobwhite acute dietary toxicity value. This is of regulatory concern as published EPA regulations [162.11(c) (2)(iii)(B)] state that a pesticide would be a candidate for restricted use if dietary residues exceed 1/5 (i.e., 20%) of the avian acute toxicity value immediately after treatment. The avian residue monitoring data are required to support continued registration of the multiple application, high use rate field crops.

7. The Agency is imposing interim labeling to protect endangered species.

Rationale:

Appropriate labeling for the protection of endangered species determined to be in jeopardy has been developed by the Agency using a generic (cluster) approach.

This generic approach, which entails the analysis of the effects of all pesticides on endangered species on a crop-by-crop basis, rather than a chemical-by-chemical approach, is being developed in cooperation with Federal and State enforcement agencies, the Office of Endangered Species (OES) and the U.S. Department of Agriculture (USDA), using the extension services and the National Agricultural Chemical Association (NACA). Thus, the labeling developed under this approach will encompass all endangered species associated with use of pesticides on a particular crop.

Individual chemical reviews, such as this registration standard for acephate will, drawing on information developed in the clusters, consider all product uses and associated endangered species and impose appropriate label restrictions on a case-by-case basis. The label statements, identified in Section F, including the state-by-state listing of endangered species, must be added to the acephate label for the 1986 growing season. Additional labeling may be required if new uses are added to the label or, as the Agency continues investigations

on these issues, if additional endangered species information develops indicating a potential for hazardous exposure.

The Agency is imposing labeling restrictions for the protection of the following endangered species determined to be in jeopardy from use of acephate: masked Bobwhite, Aleutian Canada Goose, California Condor, Hawaiian Goose, Kirtland's warbler, Mississippi Sandhill Crane, Attwater's Greater Prairie Chicken, and the Whooping Crane. Refer to F.3.g. of this chapter for the labeling restrictions required to appear on acephate products labeled for use on soybeans, alfalfa, peanuts, beans, forest, pasture and rangeland.

8. The Agency is requiring a rat reproduction study utilizing a lower dosage level than that used in the current rat reproduction study.

Rationale:

Though the current study is considered a scientifically valid study, it does not fulfill the data requirement for a reproduction study in that a no-observable effect level (NOEL) was not determined.

Various reproductive effects (low pregnancy rate, high loss of total litters, high fetal losses, decreased size and weight of total litters and decreased number of live fetuses) were observed at the lowest dose level tested which was 50.0 ppm of technical acephate (93% acephate). When a 100 fold safety factor is applied to this level, it is equivalent to the current acceptable daily intake (ADI) level for acephate. The occurrence of these effects raises a question of concern over the potential risk to humans, resulting from exposure to acephate. Therefore, a rat reproduction study utilizing a lower dosage level than that used in the current study is required in order to determine a definite NOEL for reproductive effects, and to enable the Agency to evaluate the potential risk of such effects on humans from exposure to acephate. However, it should be noted the effects were seen only at levels which are substantially higher than that to which humans can reasonably be anticipated to be exposed, taking into account ample margins of safety. Therefore this data does not trigger a special review.

Should the new rat reproduction study show a lower effect level, the current ADI for acephate may be changed accordingly.

9. In summary, the results of the available toxicological studies on acephate are listed below.

Acute oral - rat: 945 mg/kg (male); and 866 mg/kg (female)
Toxicity Category III

Acute dermal - rabbit: >10,000 mg/kg (male)
Toxicity Category III

Acute inhalation - rat: >61.7 mg/kg (male and female)
Toxicity Category IV

Mouse oncogenicity: Female mice, fed 1000 ppm of technical acephate (highest dose tested), had a statistically significant higher

incidence of hepatocellular carcinomas (15.8%) and hyperplastic nodules (19.7%) than did the controls.

Rat oncogenicity: Not oncogenic to male and female rats under the conditions of the study; highest dose tested was 700 ppm (35 mg/kg).

Rat chronic feeding: NOEL = 5 ppm (0.25 mg/kg), based on the inhibition of cholinesterase activity in plasma, RBC and brain.

Dog chronic feeding: NOEL = 30 ppm (0.75 mg/kg) based on the inhibition of plasma, RCB and brain cholinesterase activity. NOEL = >100 ppm (2.5 mg/kg) for systemic toxicity.

Rabbit teratogenicity: Not fetotoxic or teratogenic at 10 mg/kg (highest dose tested).

Rat teratogenicity: Not teratogenic at 200 mg/kg (highest dose tested).

Mutagenicity: The available studies indicate that acephate can induce gene mutations, DNA repair, and sister chromatid exchanges. However, in vivo studies indicate that these effects, and structural chromosome aberrations, are not produced at a detectable level in an intact mammalian system.

10. Additional toxicological testing are required to be conducted on methylthioacetate (MTA) which occurs as an impurity in the current registered technical material.

Rationale:

Results of an acute dermal toxicity study with MTA on rabbits indicate nonreversible diminution or absence of pupillary light reflex and blindness caused by gliosis, macrophage accumulation, malacia, and papilledema of the optic nerve, optic tract, and brain between the optic chiasm and the pituitary. The dose levels tested were 1500, 2000, 2500 and 3000 mg/kg (dermal dose applied to a gauze sponge). The clinical signs reported with an interim report of a second dermal study in rabbits showed no indication of blindness. None of the other available studies on MTA showed any clinical sign of blindness.

The available data suggest that MTA, despite its generally low acute toxicity, may pose a hazard to the optic tract and pituitary gland in rabbits and other mammals at low doses. Data were not provided to demonstrate a NOEL for lesions at these target organs. Since visual impairment is inherently difficult to diagnose in animals, it is possible that this effect occurred in other studies but was not detected. In addition, a mutagenic effect was seen in the mouse lymphoma assay in the activated system. Due to the insufficiency of the submitted data to explain the toxic and mutagenic potential of MTA, the Agency requires that additional studies be performed.

These studies, which are identified in Table A located at the end of Chapter II, include a 90-day dermal in rabbits, acute oral in rat and rabbits, acute inhalation, the final report of a second acute dermal in rabbits, neurophysiological studies of the visual system and mutagenicity studies.

Results of the available toxicological studies conducted with MTA are summarized below:

Acute dermal - rabbit: 1720-2820 mg/kg: Toxicity Category II-III Clinical signs included irreversible absence/diminution of pupillary light reflex and apparent blindness.

Acute inhalation - rat: 3.47 mg/l: Toxicity Category III

Skin irritation - rabbit: 2.6 Primary Irritation Score: Toxicity Category III

Skin sensitization - guinea pig: non-sensitizing and nonirritating; dose level tested was 0.3 ml (0.3g)

Eye irritation - rabbit: Toxicity Category III; dose level tested was 0.1 ml of 93.5% MTA.

Mutagenicity - mouse lymphoma assay: mutagenic to lymphoma cells in the activated system, but not in the nonactivated system; levels tested were 1-10,000 microgram/ml (activated) and 10-5,000 microgram/ml (nonactivated).

D. Criteria For Registration Under The Standard

To be covered under this Standard, products must contain acephate as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in section E of this document.

The applicant for registration or reregistration of manufacturing-use products subject to this Standard must comply with all terms and conditions described in it, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, commitment to fill data gaps on the schedule specified by the Agency and, when applicable, offer to pay compensation as required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136(C)(2)(D). Registration applicants must contact the Agency for specific instructions, including updated information on data requirements and companies whose data have been used in support of registration.

Registrants of end-use products who do not qualify for the Formulator's Exemption must satisfy labeling, packaging and data requirements in accordance with this guidance package. Registrants of end-use products who qualify for the Formulator's Exemption must comply with the unique labeling statements identified in Section F.

E. Acceptance Ranges And Limits

1. Product Composition Standard

To be covered under this Standard, manufacturing-use products must contain acephate as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient which may be present in products.

2. Acute Toxicity Limits

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

3. Use Patterns

To be registered under this Standard, manufacturing-use products containing acephate must be labeled as limited for formulation into end-use products only for the uses listed below. The attached index entry (Appendix IV-5) lists all registered uses, as well as approved maximum application rates and frequencies.

- Terrestrial, nondomestic, food uses on: cauliflower, brussels sprouts, peanuts, peppermint, spearmint, pasture, rangeland, beans, celery, cotton, head lettuce, peppers, soybeans, cotton.

- Aquatic, nondomestic, food use on: cranberries.

- Terrestrial, nondomestic, non-food uses on: tobacco; forests; grasses and broadleaf weeds in nonbearing pistachio orchards [24(c) registration]; ornamentals (field grown, and nursery stock); wasteland; commercial turf.

- Domestic outdoor use on: lawns; ornamentals; residential turf areas (parks, recreational areas); and as a perimeter treatment adjacent to and on the surfaces of buildings.

- Domestic indoor use on: house plants; and as a spot treatment in residential, industrial, institutional, and commercial buildings and in transportation equipment.

- Nondomestic indoor use: ornamental and forest greenhouse plants

F. Required Labeling

All manufacturing-use and end-use acephate products must bear appropriate labeling as specified in 40 CFR 162.10. The guidance package for this Standard contains information on label requirements. All labeling changes, with the exception of the end-use product labeling as specified below, must appear on all products released for shipment by October, 1986. All labeling changes, with the exception of the end-use product labeling as specified below, must appear on all products in channels of trade by October, 1987.

In addition to the above, the following information must appear on the labeling:

1. Ingredient Statement

The ingredient statement for MPs must list the active ingredient as: Acephate, (O,S-dimethyl acetylphosphoramidothioate)... __%

2. Use Pattern Statements

All manufacturing-use acephate product labels must state that the products may be used for formulation into end-use products only for the aforementioned use patterns. Labeling must specify sites, which are listed in Use Patterns, Section E.3. A limiting factor will be data that support these use patterns. No use may be included on the label where the registrant fails to agree to comply with the data requirements in either Table A or Table B for that use pattern.

3. Precautionary Statements

Statements for Manufacturing-Use Products

a. Labels for manufacturing-use acephate products must bear statements reflecting the compound's acute human toxicity. Acephate is in Toxicity Category III by the oral and dermal routes of exposure and in Category IV by the inhalation route of exposure; the required precautionary statements associated with these categories are specified in 40 CFR 162.10.

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

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

c. The following interim protective clothing statement must appear on all MP labels:

> Wear protective clothing including impermeable gloves, long-sleeved shirt and long legged trousers when handling this product.

Statements for End-Use Products

The following labeling changes must appear on all end-use products released for shipment by April, 1986. The following labeling changes must appear on all products in channels of trade by October, 1986.

a. The following interim protective clothing statement must appear on all EP labels.

> During all mixing/loading operations and during application, wear protective clothing including impermeable gloves, long-sleeved shirt and long legged trousers.

b. The following restriction must appear on acephate products labeled for domestic indoor use:

> Do not allow children or pets on treated surfaces until spray has dried.

c. The following interim worker reentry interval statement must appear an acephate products labeled for use on field crops.

> Do not reenter treated fields within 24 hours following application. Should reentry prior to this time be necessary, protective clothing including impermeable gloves, long-sleeved shirt and long legged trousers must be worn.

d. The following interim protective clothing statement must appear on acephate products labeled for greenhouse use:

> Greenhouse workers who may be exposed to treated plant surfaces within 24 hours following application of acephate must wear protective clothing including impermeable gloves, long-sleeved shirt and long legged trousers.

e. The following environmental hazard statements must appear on acephate products labeled for the specified uses.

1. Agricultural and Ornamental Uses

This pesticide is toxic to birds. Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes. Cover or soil-incorporate spills.

2. Forest and Rangeland Use

This pesticide is toxic to birds. Applications may adversely affect birds in treatment areas. Do not apply directly to water or wetlands except under forest canopy. Do not contaminate water by cleaning of equipment or disposal of wastes. Cover or soil-incorporate spills.

3. Agricultural Crop Uses

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

f. Interim use restriction statements (Refer to C.3. of this chapter)

1. Peppermint and spearmint:
Do not use spent mint hay for feed for dairy animals.

2. Pasture and rangeland:
Do not graze or feed grass hay to dairy animals.

g. The following endangered species restrictions, including the state-by-state listing of endangered species specified in the following chart, must appear on acephate products labeled for the uses specified in the chart:

It is a violation of Federal laws to use any pesticide in a manner that results in the death of an endangered species or adverse modification of their habitat.

The use of this product may pose a hazard to certain Federally designated endangered species known to occur in specific areas within the following counties:

ENDANGERED SPECIES RESTRICTIONS

STATE, SPECIES, (BULLETIN NO.)	SOYBEANS	PASTURELAND & RANGELAND	ALFALFA	PEANUTS	FOREST	BEANS (lima, dried type and succulent)
Arizona Masked Bobwhite (EPA/ES-85-14)		Arizona (South of Tucson)				
California (1) Aleutian Canada Goose (EPA/ES-85-02)		Colusa Merced Stanislaus	Colusa Merced Stanislaus			Colusa Merced Stanislaus
(2) California Condor (EPA/ES-85-15)		Tulare, Kern Los Angeles Ventura Santa Barbara Obispo				
Hawaii Hawaiian Goose (EPA/ES-85-16)		Maui, Hawaii				
Michigan Kirtland's Warbler (EPA/ES-85-17)					Crawford Oscoda Iosco Montmorency Presque Isle Roscommon Alcona Kalkaska Ogemaw Otsego Wexford	

ENDANGERED SPECIES RESTRICTIONS (continued)

STATE, SPECIES, (BULLETIN NO.)	SOYBEANS	PASTURELAND & RANGELAND	ALFALFA	PEANUTS	FOREST	BEANS (lima, dried type and succulent)
Mississippi Mississippi Sandhill Crane (EPA/ES-85-18)		Jackson County				
Texas Attwater's Greater Prairie Chicken (EPA/ES-85-01)	Austin Colorado Fort Bend Victoria Arnasas Brazoria Galveston Refugio Goliad	Austin Colorado Fort Bend Golaid Victoria Arnasas Brazoria Galveston Refugio	Austin Colorado Fort Bend Golaid Victoria Arnasas Brazoria Galveston Refugio	Austin Colorado Brazoria Fort Bend		
Whooping Crane (EPA/ES-85-19)		Idaho, Utah, Wyoming, Colorado, New Mexico, N. Dakota, S. Dakota, Nebraska, Kansas, Texas, Oklahoma	Socorro and Valencia, New Mexico			

Before using this product in the above counties you must obtain the EPA Bulletin specific to your area. This Bulletin identifies areas within these counties where the use of this pesticide is prohibited, unless specified otherwise in the Bulletin. The EPA Bulletin is available either from your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters or the appropriate Regional Office of the U.S. Fish and Wildlife Service. THIS BULLETIN MUST BE REVIEWED PRIOR TO PESTICIDE USE.

G. Tolerance Reassessment

The currently established tolerances for combined residues of acephate and its metabolite methamidophos, as currently established under 21 CFR 193.10, 21 CFR 561.20, and 40 CFR 180.108, are supported by the available data in or on the following commodities or processed products: beans (dry and succulent), brussels sprouts, cauliflower, celery, cottonseed, cranberries, lettuce (head), mint hay, pasture and range grass and hay, peanuts, peanut hulls, peppers, soybeans, cottonseed meal and hulls, soybean meal, all foods exposed in food handling establishments, eggs, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep. The currently established tolerance for acephate residues in milk has been found likely to be exceeded if maximum levels of spent mint hay or grass hay are included in the dairy animal diet; refer to C.3 of this chapter for the Agency's position and rationale regarding this problem. Refer to Table I at the end of this chapter for the current tolerance levels for the U.S., Mexico, and Codex.

Additional data are required to assess human exposure to acephate-treated tobacco (aerial application data). No crop group tolerances are appropriate at the present time due to lack of sufficient data within each group.

A change in the residue definition for acephate tolerances is to be initiated by the Agency. Refer to C.4 of this chapter for details of this change. Refer also to Table 2 at the end of this chapter for the tolerance changes reflecting this change in the residue definition.

The metabolism of acephate in plants and animals is adequately understood. Available data show that the residues in or on plants resulting from acephate use may be largely or wholly intact acephate and its metabolite, methamidophos. Available animal metabolism data show that most of the radiolabeled material is rapidly eliminated from the body and that a majority of the material was excreted in the urine. Methamidophos is not the major metabolite in ruminants. About 80 percent of the radiolabeled material in the urine was associated with unchanged acephate, and less than 10 percent with the metabolite, O,S-dimethyl phosphorothioate. Most of the methamidophos formed is probably eliminated and excreted in the urine as O,S-dimethyl phosphorothioate.

The available plant metabolism studies show that acephate residues are readily absorbed by the roots and translocated throughout the plant. Data show that acephate does not accumulate in carrot plants rotated in acephate-treated soil or in fish, daphnia, or diatoms.

Acephate's Acceptable Daily Intake (ADI) for non-carcinogenic effects, is 0.0250 mg/kg/day based on the chronic rat feeding study with a NOEL of 5.0 ppm (0.25 mg/kg/day) and using a safety factor of 10. This safety factor was used because the rat NOEL level of 5.0 ppm is based on cholinesterase activity in brain, plasma and red blood cells. It is the Agency's policy to use a safety factor of 10 in such cases, since this activity is considered to be the more sensitive criteria. The maximum permissible intake (MPI) is 1.500 mg/day for a 60 kg human. The Theoretical Maximum Residue Concentration (TMRC), based on relevant food factors and established tolerances, is .4592 mg/day/1.5 kg. This figure represents 30.61 percent of the ADI. As described in C.8. of this chapter, results of the new rat reproduction study may effect the current ADI for acephate.

As described in C.1 of this chapter, additional residue studies are required to better define the dietary exposure to residues of acephate from treated food items as consumed. Pending submittal and evaluation of these data, no new tolerances including temporary tolerances, will be considered for acephate nor its metabolite, methamidophos.*

* A restriction against the establishment of further tolerances for methamidophos was previously imposed under the Methamidophos Registration Standard issued September 30, 1982.

Table I. Present Tolerances:

The following tolerances for residues of acephate exist in the United States and Mexico, and several international maximum residue limits (MRLs) have been recommended by the Codex Alimentarius Commission (listed below). No acephate tolerances are in effect in Canada. Note that U.S. tolerances cover combined residues of acephate and its metabolite methamidophos and that Mexican tolerances (presumably) and Codex MRLs cover only acephate *per se*.

Commodity	Tolerances (ppm)		
	United States[a]	Mexico	International (Codex)[b]
Alfalfa	--	--	10
Beans (dry and succulent)	3(1.0)	3	--
Broccoli	--	10	5
Brussel sprouts	3(0.5)	--	5
Cabbage	--	8	5
Cattle (fat, meat, meat byproducts)	0.1	--	0.1
Cauliflower	2(0.5)	--	5
Celery	10(1.0)	10	--
Chili pepper	--	4	--
Citrus fruits	--	1	5
Corn	--	4	--
Cottonseed	2	8(FA)[d]	2
Cottonseed hulls	4	--	--

Commodity	Tolerances (ppm) (Continued)		
	United States	Mexico	International (Codex) [b/]
Cottonseed meal	8	—	—
Cranberries	0.5(0.1)	—	—
Eggs	0.1	—	0.1
Goats (fat, meat, meat byproducts	0.1	—	—
Grapes	—	5	—
Grass	15	--	--
Grass hay	15	—	—
Hogs (fat, meat, meat byproducts)	0.1	--	0.1
Horses (fat, meat, meat byproducts)	0.1	—	—
Lettuce	10(1.0)	10	10
Melons	—	8	--
Milk	0.1	—	0.1
Mint hay	15(1.0)	—	—
Nuts	—	0.2	—
Peanuts	0.2	0.1	--
Peanut hulls	5	—	--
Peppers	4(1.0)	--	--
Potatoes	—	8	0.5
Poultry (fat, meat, meat byproducts)	0.1	—	0.1

*This table does not include the tolerance for acephate in/on macadamia nuts (0.5 ppm) which was established subsequent to completion of evaluation needed for this document. Acephate is not currently registered for use on macadamia nuts.

Commodity	Tolerances (ppm) (Continued)		
	United States	Mexico	International (Codex) [b]
Sheep (fat, meat, meat byproducts)	0.1	—	—
Soybeans	1	1	0.5
Soybean meal	4	—	—
Sugar beet, leaves	—	—	10
Sugar beet, roots	—	—	0.1
Tomatoes	—	4	5
Watermelons	—	5	--
Processed foods [c]	0.02(FA)	--	--

[a] Numbers represent combined residues of acephate and methamidophos, whereas numbers in parentheses represent the maximum residues (in ppm) of methamidophos.

[b] All Codex MRLs are Step 7.

[c] Due to treatment of food handling establishments.

[d] Unspecified whether seed, oil, meal, hulls, or any combination thereof.

Table 2. Tolerance changes reflecting the recommended change in residue definition.

Commodity	Acephate*		Methamidophos	
	Established tolerance(ppm)[a]	Recommended tolerance(ppm)[b]	Established tolerance(ppm)[c]	Recommended tolerance(ppm)[c]
Beans (succulent and dry forms)	3(1)	3	---	1
Brussels sprouts	3(0.5)	3	1	1
Cauliflower	2(0.5)	2	1	1
Celery	10(1)	10	1	1
Cottonseed	2	2	0.1	0.5
Cranberries	0.5(0.1)	0.5	---	0.1
Eggs	0.1	0.1	---	0.01
Fat, meat, and meat byproducts[d]	0.1	0.1	---	0.01
Grass(pasture and range)	15	15	---	3
Grass hay	15	15	---	3
Lettuce (head)	10(1)	10	1[e]	1
Milk	0.1	0.1	---	0.05
Mint hay	15(1)	15	---	1
Peanuts	0.2	0.2	---	0.1
Peanuts hulls	5	5	---	1.5
Peppers	4(1)	4	1[f]	1
Soybeans	1	1	---	0.2
Cottonseed hulls[g]	4	4	---	0.1
Cottonseed meal[g]	8	8	---	2.5
Soybean meal[g]	4	4	---	2
Processed foods[h]	0.02	0.02	---	---

[a] Expressed in terms of combined residues of acephate and methamidophos. If specified, limits of methamidophos are given parenthetically.
[b] Expressed in terms of acephate per se only.
[c] Expressed in terms of only methamidophos per se.
[d] Included are cattle, goats, hogs, horses, poultry, and sheep.
[e] The methamidophos tolerance covers all types of lettuce (head and leaf).
[f] The methamidophos tolerance covers all types of peppers.
[g] Feed additive tolerances in 21 CFR 561.20 (acephate) and recommendations for inclusion under 21 CFR 561.277 (methamidophos).
[h] Food additive tolerance reflecting spot and crack and crevice treatment of food areas of food handling establishments (21 CFR 193.10). There is no expectation of methamidophos residues in such foods (residues were nondetectable, <0.001 ppm, in all cases).
*This table does not include the tolerance of acephate in/on macadamia nuts (.05 ppm) which was established subsequent to completion of evaluation needed for this document. Acephate is not currently registered on macadamia nuts.

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TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: ACEPHATE

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

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: ACEPHATE

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	No	Footnote Number	Data must Be Submitted Within Timeframe Listed Below 1/
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	[x]	[ ]		6 Months
63-8 - Solubility	TGAI or PAI	R	[x]	[ ]		6 Months
63-9 - Vapor Pressure	PAI	R	[x]	[ ]		6 Months
63-10 - Dissociation constant	PAI	R	[x]	[ ]		6 Months
63-11 - Octanol/water partition coefficient	PAI	R	[ ]	[x]	3	
63-12 - pH	TGAI	R	[x]	[ ]		6 Months
63-13 - Stability	TGAI	R	[x]	[ ]		6 Months
Other Requirements:						
64- 1 - Submittal of samples	TGAI, PAI	CR	[ ]	[x]		

: :

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

1/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
- 6 Month Due Date is April 30, 1986 .
- 12 Month Due Date is October 31, 1986 .

2/ Data not required because the 97% technical material is solid at room temperature.

3/ Data not required because acephate is a polar compound.

4/ A description of the new manufacturing process yielding methylthioacetate (MTA) as an impurity, including purities of starting materials, reaction conditions, and any purification and quality control steps must be submitted.

5/ Analysis of five or more representative batches from the altered process for any impurity present at ≥0.1% by weight, MTA, and any other highly toxic and/or mutagenic/oncogenic impurity whether above or below 0.1% (w:w) including descriptions and validation of the analytical procedures used must be submitted.

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation 13/	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe For Data Submission 2/
§158.125 Residue Chemistry				
171-2 - Chemical Identity	TGAI	--	--	Yes 4/ 6 Months
171-3 - Directions for Use	NA	Partially	NA	Yes 5/ 6 Months
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Yes	00015187, 00015203 05007862, 00015188 00014990, 00015210 00014989	No
- Livestock	PAIRA and Plant Metabolites	Yes	00015222; 00014555	No
171-4 - Residue Analytical Method				
- Plant residues	TGAI and Metabolites	Yes	00014729, 00014579 00014659, 00014983 GS0042001	No
- Animal residues	TGAI and Metabolites	Yes	00014729	No
171-4 - Magnitude of the Residue- Residue Studies for Each Food Use				
- Crop Group #1 - Legume Vegetables (succulent or dried)				
o Crop 1 Beans - (dry and succulent incl. lima beans)	TEP	Partially	00014791, 00014787 00014774, 00014775 00014778, 00014777 00014776, 00014540 00014780, 00014781 00014783, 00014541 00014782, GS0042004	Yes 10/ 6/ 24 months

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation 13/	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe For Data Submission 2/
§158.125 Residue Chemistry - Continued				
171-4 - Magnitude of the Residue Residue Studies (continued)				
o Crop 2 - Soybeans	TEP	Partially	00014534, 00014533 00014532, 00015050 00015049, 00015060	Yes 10/ 24 Months
- Crop Group #2 - Leafy Vegetables (Except Brassica)				
o Crop 1 - Celery	TEP	Partially	00014770, 00014771 00014772, 00014773 00015326, 00015325 00015323, 00015328 00015324, 00015327 00014769, 00015329 00014768, GS0042005	Yes 6/ 24 months
o Crop 2 - lettuce (Crisp head type)	TEP	Partially	00015190, 00015191 00015192, 00015193 00015194, 00015293 00015294, 00014971 00015042, GS0042002 GS0042003	Yes 6/ 24 months
o Crop Group #3 - Brassica (cole) Leafy Vegetables				
o Crop 1 - Brussels Sprouts	TEP	Yes	GS0042006; GS0042002 GS0042003	No 6/
o Crop 2 - Cauliflower	TEP	Yes	GS0042007	No

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 13/	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 2/
§158.125 Residue Chemistry - Continued				
171-4 - Magnitude of the Residue Residue Studies (continued)				
- Crop Group #4 - Fruiting Vegetables (except cucurbits)				
o Crop 1 - Peppers	TEP	Yes	00014765, 00014760 00014762, 00014763 *00014764, GS0042008* GS0042047	No
- Crop Group #5 - Grass Forage, Fodder, and Hay				
o Crop 1 - Grass (pasture and range)	TEP	Partially	GS0042009	Yes 6/ 7/ 24 months
o Crop 2 - Grass Hay	TEP	Partially	GS0042009	Yes 7/ 24 months
- Crop Group #6 - Small Fruits annd Berries				
o Crop 1 - Cranberries	TEP	Yes	GS0042010	No

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation 13/	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe For Data Submission 2/
§158.125 Residue Chemistry - Continued				
171-4 - Magnitude of the Residue Residue Studies (continued)				
- Miscellaneous Crops				
o Crop 1 - Cotton	TEP	Partially	00015199, 00015198 00015206, 00014852 00015038, 00014854 00015206, 00014855 00015196, 00014853	Yes 6/ 24 months
o Crop 2 - Mint Hay (peppermint and spearmint)	TEP	Partially	00029683, GS0042048	Yes 7/ 24 months
o Crop 3 - Peanuts	TEP	Yes	GS0042011	No

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation 13/	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe For Data Submission 2/
§158.125 Residue Chemistry - Continued				
171-4 - Magnitude of the Residue Residue Studies (continued)				
- Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	Partially	GS0042015 00015183 00015225 00015222 00015230 00015245	Yes 6/ 16/ 18 Months
- Potable Water	EP	N/A		
- Fish	EP	N/A		
- Irrigated Crops	EP	No	--	No 15/
- Food Handling	EP	Yes	GS0042013 GS0042014	No 9/
171-5 - Reduction of Residue	Residue of Concern	No	--	Yes 10/ 24 Months
171-6 - Proposed Tolerance 3/ 11/	--	--	--	--
171-7 - Reasonable Grounds in Support of Petition 12/	--	--	--	--
171-11 - Tobacco	TEP	Partially	05014159 00015122 00015125 GS0042012	Yes 8/ 24 months
171-13 - Submittal of Analytical Reference Standards 14/	--	--	--	--

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

§158.125 Residue Chemistry - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product; Residue of concern = acephate and methamidophos have been identified as the residues of concern resulting from application of acephate.

2/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
- 6 Month Due Date is April 30, 1986 .
- 18 Month Due Date is April 30, 1987 .
- 24 Month Due Date is October 31, 1987.

3/ Includes filing fee.

4/ The same chemical identity data as required under §158.120 are required, with emphasis on impurities that could constitute a residue problem.

5/ Refer to Chapter II. F3f, of this document for the required interim use restriction statements for peppermint, spearmint, pasture, and rangeland.

6/ The available data (GS0042002 and GS0042003) suggest that the stability of acephate residues upon frozen storage is dependent upon the stored, treated commodity. Of the six crops tested, only lettuce and brussels sprouts have been assigned acephate tolerances. No data are available concerning residue stability in stored animal products. We do not feel that the tested commodities are representative of all crops regulated for acephate tolerances, especially in light of the erratic lettuce storage data. We, therefore, cite the following data gap which must be satisfied.

- o Weathered residues of acephate and methamidophos must be determined in and on the following commodities immediately prior to storage and at intervals approximating the maximum period of storage at subfreezing temperatures: beans, celery, cottonseed, grass, and lettuce. In addition, eggs, milk and animal tissues must be similarly tested.

7/ It is estimated that, based on available residue data, the established tolerance level for acephate residues in milk are likely to be exceeded if maximum levels of spent mint hay or grass hay are included in the dairy animal diet. To ensure that the established tolerance level in milk will not be exceeded the following data must be submitted to maintain continued registration of the use of acephate on mint (spearmint and peppermint) and pasture and rangeland:

§158.125 Residue Chemistry - Continued

7/Cont.

Mint

Submit additional mint hay residue data supporting a lower tolerance.

Pasture and rangeland

Submit additional residue data on hay supporting a lower tolerance.

8/ Tobacco residue data generated from aerial applications of acephate are required.

9/ These data are sufficient to support the current established food additive tolerance for use of acephate in food handling establishments under 21 CFR 193. Additional data and a proposed tolerance under 21 CFR 561 would be required to support use of acephate in food areas of feed handling establishments. The current registered use of acephate in food areas of food handling establishments is restricted for use in food (as opposed to feed) handling establishments.

10/ Residue data on food prepared for consumption for the following commodities are needed to estimate actual dietary exposure to residues of acephate and its metabolite, methamidophos from consumption of these foods.

Beans, succulent: Available canning data are quite variable for residues of both acephate and methamidophos and, in addition, sampling was inadequate. Canning does, however, appear to be a potential route of dietary exposure reduction. No cooking (boiling) data are available on beans. Therefore, the following data must be submitted to estimate actual dietary exposure to succulent beans:

- o Cooking (boiling) of succulent green beans according to common consumer practices. Beans must bear field-weathered, detectable residues of acephate and methamidophos. Beans must be analyzed both before and after cooking. Cooking water should also be analyzed.

- o Commercial processing (canning) of field-treated, succulent green beans bearing detectable residues of acephate and methamidophos. Beans must be analyzed both before and after canning. Canning water should also be analyzed.

Beans, dried: No canning or cooking data are available. Data are insufficient to support an increase in the PHI, if desired. The following data are required to estimate the actual dietary exposure to residues in dry beans:

§158.125 Residue Chemistry - Continued

- o Pinto and/or navy beans must be field-treated with the 75% soluble concentrate/solid formulation (SC/S) six times at 1 lb ai/A. Beans are to be allowed to dry normally, and then both boiled and canned, in separate tests, according to typical home or commercial preparation procedures. Cooking fluid and beans must be analyzed both before and after boiling and canning for residues of acephate and its metabolite methamidophos.

Soybean oil: The available processing data are not adequate to estimate the dietary exposure due to consumption of soybean oil.

Acephate residues in crude oil may be present $\leq$ 33% of the concentration in or on soybean seed. Cottonseed data indicate that further reductions in residues would occur upon refining the crude oil but data are insufficient to make a reliable estimation. Therefore, the following data must be submitted.

- o A determination of residues of acephate and methamidophos in crude oil and refined oil.

Soybean, defatted flour: There are no data available on the degree of concentration (or reduction) of residues of acephate and methamidophos in defatted flour, which is used as a component of infant formula. A four-fold residue concentration generally occurs upon processing soybeans to soybean meal (and, presumably, defatted flour), as reflected by the 1.0 ppm vs. 4 ppm tolerances in or on seed vs. meal, respectively.

Defatted flour is similar to soybean meal but has not been toasted and is more finely ground. Therefore, the following study must be submitted to refine the estimated dietary exposure due to consumption of defatted soybean flour.

- o A determination of the degree of concentration (or reduction) of acephate and methamidophos upon processing soybeans (containing field-weathered residues) to defatted flour.

11/ No new tolerance proposals are required to be submitted to support registered uses of acephate as described in this document.

12/ The rationale of how the residue data support the proposed tolerance is required to be submitted with any proposed tolerance(s). As specified in footnote 11 above, no new tolerance proposals are required.

§158.125 Residue Chemistry - Continued

13/ Where there are more than one bibliographic data citation listed for a data requirement, each study by itself only partially satisfies that data requirement.

14/ Submittal of reference standards are required to be submitted for new pesticides and thus would not need to be submitted for acephate.

15/ These data are not required because the registered use of acephate as described in this document indicate that crops are not irrigated with acephate treated water.

16/ Milk: Dairy products contribute 4.2 - 26.1% of the ADI, depending on the population under consideration. The Tolerance Assessment System (TAS) recognizes three milk fractions: nonfat milk solids, milkfat solids, and milk sugar (lactose). However, no data are available concerning the fate of residues upon pasteurization or processing into the fractions noted above. The following data are required for an actual exposure assessment:

- o A dairy cattle feeding study must be conducted in which cattle are fed acephate and methamidophos at an approximately 5:1 ratio in the diet. The feeding level should be high enough to result in detectable residues of both acephate and methamidophos in milk. Exaggerated rates would be advantageous. Residues of acephate and methamidophos must be determined in whole raw milk (containing detectable residues of each compound), pasteurized milk, and in nonfat milk solids, milkfat solids, and possibly milk sugar (lactose).

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Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation [11]	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Timeframe for Data Submission [3]
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,F,G,H	Partially	00014986	Yes[10]	9 Months
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B,C,G	Yes	00014987 00015202	No	
161-3 - On soil	TGAI or PAIRA	A,B,C,G	No	--	Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A,B,C	No	--	No[4]	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,F,H	Yes	00014991	No	
162-2 - Anaerobic Soil	TGAI or PAIRA	A,B	Yes	00014991	No	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C,G	No	--	Yes	27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	Yes	00014988 05018064	No	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C,F,G,H	Partially	00015209 00015213 00014992 00015212	Yes[5]	12 Months
163-2 - Volatility (Lab)	TEP	A,B,F	No	--	No[4]	
163-3 - Volatility (Field)	TEP	A,B,F	No	--	No[4]	

TABLE A

GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 11/	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/	
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B,H	No	--	Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	C	Partially	00015221	Yes 6/	27 Months
164-3 - Forestry	TEP	G	Yes	00014637, 00029738 00014638, 05015409 00014642 00014635	No	
164-4 - Combination and Tank Mixes 12/						
164-5 - Soil, Long-term	TEP	A,B,C,G,H	No	--	Reserved 7/	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	Partially	00015210	Yes 13/	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No	--	Reserved 8/	
165-3 - Irrigated Crops	TEP	--	No	--	No 9/	
165-4 - In Fish	TGAI or PAIRA	A,B,C,G	Yes	00015243	No	
165-5 - In Aquatic Nontarget Organisms	TEP	G	Yes	00014637, 00014496 00014638, 00015242 00014642 00014635	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

14

§158.130 Environmental Fate - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
- 9 Month Due Date is July 31, 1986 .
- 12 Month Due Date is October 31, 1986 .
- 27 Month Due Date is January 31, 1988 .
- 39 Month Due Date is January 31, 1989 .

4/ These data are not required because of the low vapor pressure of acephate.
5/ Adsorption/desorption data must be submitted.
6/ Aquatic field dissipation data reflecting the registered use of acephate on cranberries are required.
7/ The Agency will determine whether this study is required based on an evaluation of the dissipation studies required in 164-1 and 164-2 of this table. If required, the Agency will notify the registrant and will provide a time frame for submittal of the study which will be 49 months from date of notification.
8/ The Agency will determine whether this study is required based on an evaluation of the confined rotational crop data required in 165-1 of this table. If required, the Agency will notify the registrant and will provide a time frame for submittal of the study which will be 50 months from date of notification.
9/ These data are not required because the current registered use patterns as described in this Document indicate that crops are not irrigated with acephate-treated water.
10/ This study would satisfy the data requirement if documentation proving it was done with sterile (bacteria-free) water can be provided by the registrant.
11/ Where there is more than one bibliographic data citation listed for a data requirement, each study by itself only partially satisfies that data requirement.
12/ These data are not required because this Document only addresses single active ingredient products.
13/ These data are required for leafy vegetable crops.

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 11/	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/	
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,C,F,G,H,I	Yes	00014675 00029696	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B,C,F,G,H,I	Yes	00014681 GS0042023	No	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A,B,C,F,G,H,I	Yes	00015307	No	
81-7 - Delayed Neurotoxicity - Hen	TGAI	A,B,C,F,G,H,I	No	--	Yes	12 Months
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding : - Rodent, and	TGAI	--	No	--	No4/	
- Nonrodent (Dog)		--	No	--	No4/	
82-2 - 21-Day Dermal - Rabbit	TGAI	--	Yes	GS0042045	No	
82-3 - 90-Day Dermal - Rabbit	TGAI	--	No	--	No5/	
82-4 - 90-Day Inhalation: - Rat	TGAI	Tobacco	No	--	Yes6/	6 Months (Protocol)
82-5 - 90-Day Neurotoxicity: - Hen	TGAI	A,B,C,F,G,H,I	No	--	Reserved7/	
-Mammal			No	--	Reserved7/	

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 11/	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.135 Toxicology - Continued					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: - Rodent, and	TGAI	A,C	Yes	GS0042024 GS0042033	No
- Nonrodent (Dog)		A,C	Yes	00014699 GS0042025	No
83-2 - Oncogenicity - 2 species: - Rat (preferred), and	TGAI	A,B,C,F,G,H,I	Yes	GS0042024 GS0042033 GS0042032	No
- Mouse (preferred)		A,B,C,F,G,H,I	Yes	GS0042026, GS0042030 GS0042027, GS0042031 GS0042029,	No
83-3 - Teratogenicity - 2 species: - Rat	TGAI	A,C,I	Yes	00014695	No
- Rabbit		A,C,I	Yes	GS0042028	No
83-4 - Reproduction - Rat 2-generation	TGAI	A,C	No	--	Yes 10/ 39 Months
MUTAGENICITY TESTING					
84-2 - Gene Mutation (Ames Test)	TGAI	A,B,C,F,G,H,I	Yes	GS0042038, 00028625	No
84-2 - Structural Chromosomal Aberration	TGAI	A,B,C,F,G,H,I	Yes	GS0042040	No
84-4 - Other Genotoxic Effects	TGAI	A,B,C,F,G,H,I	Yes	GS0042039	No

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 11/	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Timeframe for Data Submission 3/
§158.135 Toxicology - Continued						
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,C	Yes	00014219 00014518 00014994	No	
85-2 - Dermal Penetration	Choice	A,B,C,F,G,H,I	No	--	Yes 8/	6 Months (Protocol)
86-1 - Domestic Animal Safety	Choice	--	--	--	No 9/	

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

§158.135 Toxicology - Continued

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
- 6 Month Due Date is April 30, 1986 .
- 12 Month Due Date is October 31, 1986 .
- 39 Month Due Date is January 31, 1989 .

4/ These data are not needed to support registration of acephate because the available 28-month rat feeding and the 2-year dog feeding studies (83-1) are adequate to assess human exposure via the oral route.
5/ This study is not required to support registration of the current use pattern of acephate as described in this Document.
6/ This study is required to assess the exposure of man to the residue remaining at the time of use of tobacco. The proposed protocol must be submitted within 6 months. The study must be submitted within 15 months from date of acceptance of the protocol by the Agency.
7/ The Agency will determine whether these studies are required based on an evaluation of the acute neurotoxicity study requested in 81-7 of this table. If required, the Agency will notify the registrant and will provide a time frame for submittal of the study which will be 15 months from date of notification.
8/ The proposed protocol must be submitted within 6 months. The study must be submitted within 6 months from date of acceptance of the protocol by the Agency.
9/ These data are not required to support registration of the current registered uses of acephate as described in this Document.
10/ Though a rat reproduction study has been submitted, it is not acceptable to support registration because a NOEL (non-observable-effect level) was not determined i.e., various effects on reproduction were observed in rats that were fed 50 ppm of the test material, the lowest dose level fed. Therefore, a new reproduction study using lower dose levels is needed in order to determine a definite NOEL for reproductive effects.
11/ Where there are more than one bibliographic data citation listed for a data requirement, each study by itself only partially satisfies that data requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Timeframe for Data Submission 3/
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B,C,G	Partially	00015241 05007862	Yes7/	27 Months
132-1 - Soil Dissipation	TEP	A	No	--	Yes4/	27 Months
133-3 - Dermal Exposure	TEP	A,B,C,G	Partially	00015241	Reserved8/	
133-4 - Inhalation Exposure	TEP	A,B,C,G	Partially	00015241	Reserved8/	
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP6/	A,B,C,G	No	--	Yes6/	6 Months
201-1 - Drift Field Evaluation	TEP6/	A,B,C,G	No	--	Yes6/	6 Months
Exposure Assessment Studies	TEP	B,F,G,H,I	No	--	Yes5/	6 Months (Protocol)
Glove Permeability Study	TEP9/	--	No	--	Yes9/	6 Months (Protocol)

1/ Composition: TEP = Typical end-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
° 6 Month Due Date is April 30, 1986 .
° 27 Month Due Date is January 31, 1988 .
4/ Soil dissipation data are required for use on peanuts because the registered use of acephate on peanuts as described in this Document involves human tasks that could cause human exposure to residue adsorbed to soil.

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Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/

§158.140 Reentry Protection - Continued

5/ Studies of potential applicator exposure must be conducted. Outdoor studies must include forestry application, application to tobacco, and to both home and commercial ornamentals. The material must be applied to home ornamentals using a hand compressed air or hose-end sprayer. In addition, studies of indoor exposure of applicators and inhabitants must be carried out for home, greenhouse, and commercial establishment applications. Home application must be by the use of a ready to use pressurized spray. Commercial building application must be by a "coarse spray technique." The postapplication decrease in exposure with time must be monitored.

The references cited below are to be used as guidelines for the exposure studies. The proposed protocol must be submitted within 6 months. The studies must be submitted within 27 months from date of acceptance of the protocol by the Agency.

The following general background documents are available to describe how monitoring studies and quantitative exposure assessments are carried out:

1. Davis, James E. (1980) "Minimizing Occupational Exposure to Pesticides: Personnel Monitoring." Residue Reviews 75: 33.

This review article describes state-of-the-art procedures for the actual field measurement of dermal and respiratory exposure.

2. Severn, David J. (1982) "Exposure Assessment for Agricultural Chemicals" in Genetic Toxicology - An Agricultural Perspective, R.D. Fleck and A. Hollaender, Eds., Plenum Press, New York, p. 235.

This paper presents an overview of how exposure assessments are carried out in EPA, including a discussion of the use of surrogate exposure studies for assessments when no data are available for a particular pesticide.

3. Severn, David J. (1984) "Use of Exposure Data for Risk Assessment." in Determination and Assessment of Pesticide Exposure, M. Siewierski, Ed., Elsevier Science Publishing Company, New York, p. 13

This paper describes in greater detail what assumptions are made and how exposure assessments are performed in EPA.

4. Reinert, Joseph C. and Severn, David J. (1985) "Dermal Exposure to Pesticides: EPA's Viewpoint." in Dermal Exposure Related to Pesticide Uses, R.C. Honeycutt, G. Zweig, and N.N. Ragsdale Eds., American Society, Washington, D.C., p. 357.

This paper is a synthesis of the methodologies and logistics used in preparing applicator exposure assessments in EPA.

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Exposure Assessment Studies - Continued

Protocols must be submitted to the Agency for review prior to conduct of the studies. If more detailed guidance is needed, or if specific questions related to any aspect of pesticide exposure assessment arise, contact:

Joseph C. Reinert, Ph.D., Chief
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)
(703) 557-3935

6/ The required studies may consist of either of the following or a combination thereof: (1) A reevaluation of existing published or unpublished data when chemical properties, use patterns, and general geographic/meteorological situations are similar to the proposed product, (2) An undertaking of the studies required in §158.142. Rather than conducting these studies on acephate, the Agency is currently encouraging the submittal of surrogate studies, i.e., published or unpublished information regarding spray drift patterns that would be expected to be similar to the acephate TEP. Refer to Subdivision R of the Pesticide Assessment Guidelines in section 200-1(d).

7/ Limited dislodgeable foliar data are available for cotton; dislodgeable residue (decline curve) data are required for cauliflower as a representative crop since, among the current crops registered for acephate as described in this document, cauliflower is considered to be representative of a worst case in regards to the liklihood of human exposure to residues by those involved in hand labor tasks.

8/ There are limited data available for use on cotton and it has been determined that this is sufficient given the Agency's current knowledge of acephate. Should the Agency determine that results of the studies required under 132-1 and the use-related exposure data warrant the need for these studies, they will be required. If required, the Agency will notify the registrant and will provide a time frame for submittal of the study which will be 27 months from date of notification. They may, however be submitted at the option of the registrant.

9/ Glove permeability studies are required for all liquid formulations of end-use products. The permeability studies are to be conducted as described in ASTM 739-81 Standard Test Method for Resistance of Protective Materials to Permeation by Hazard Liquid Chemicals. The proposed protocol must be submitted within 6 months. The studies must be submitted within 9 months from date of acceptance of the protocol by the Agency. Because the inerts could influence the permeability of a formulation, studies are required to be submitted on a typical end-use liquid formulation representative of a worse case scenario.

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
70-1 - Special Test					6 Months
- Avian Food Residue and Enzyme Monitoring	TEP	A,B	No	--	Yes 4/ (Protocol)
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,C,G,H	Yes	00014700* 00014701* 00015962**	No
71-2 - Avian Subacute Dietary Toxicity	TGAI				
- Upland Game Bird, and		A,B,C,G,H	Yes	00015956	No
- Waterfowl		A,B,C,G,H	Yes	00015957	No
71-3 - Wild Mammal Toxicity	TGAI	--	--	--	No 8/
71-4 - Avian Reproduction	TGAI				
- Upland Game Bird, and		A,B,C,G	Yes	00029692	No
- Waterfowl		A,B,C,G	Yes	00029691	No
71-5 - Simulated Field Testing	TEP				
- Mammals, and		A,B,G	No	--	Reserved 5/
- Birds		A,B,G	No	--	Reserved 5/
- Actual Field Testing	TEP				
- Mammals, and		A,B,G	No	--	Reserved 5/
- Birds		A,B,G	Partially	05014922 05017571 00014639 00014860 05019256 GS042019 05021173 GS042018 GS042017 GS042020 GS042022	Reserved 5/

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GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms - Continued					
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish Toxicity	TGAI				
- Cold water Fish Species, and		A,B,C,G,H	Yes	05018314* 00014705* GS0042016*	No
- Warm water Fish Species		A,B,C,G,H	Yes	00014705* GS0042016*	No
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,C,G,H	Yes	05012201* GS0042016* GS0042021*	No
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI				
- Fish		A,B,G	No	--	No 6/
- Mollusk		A,B,G	Partially	00014713	No 6/
- Shrimp		A,B,G	Partially	00014711	No 6/
72-4 - Fish Early Life Stage, and	TGAI				
- Aquatic Invertebrate Life-Cycle			--	--	No 7/

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms - Continued					
72-5 - Fish - Life-Cycle	TGAI				No7/
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product				
- Crustacean					No7/
- Fish					No7/
- Insect Nymph					No7/
- Mollusk					No7/
72-7 - Simulated Field Testing - Aquatic Organisms	TEP				No7/
- Actual Field Testing -Aquatic Organisms					No7/

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

§158.145 Wildlife and Aquatic Organisms - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood Crop; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
° 6 Month Due Date is April 30, 1986 .
4/ These data are necessary to support a hazard assessment for the multiple-application, high use-rate field crops. The data must: (1) address the occurrence of acephate-methamidophos in potential wildlife food items at maximum treatment rates under realistic repeat application conditions, and (2) monitor a biological index of toxic effects such as brain ChE in exposed birds. The proposed protocol must be submitted within 6 months. The study must be submitted within 19 months from date of acceptance of the protocol by the Agency. The following references may be useful in designing the monitoring study:
° Niethammer, K.R. and T.S. Basket. 1983. Cholinesterase Inhibition of Birds Inhabiting Wheat Fields Treated with Methyl Parathion. Arch. Environ. Contam. Toxicol.12, 471-475.
° Bunyan, P.J., M.J. Van Den Heuvel, P.I. Stanley, and E.N. Wright. 1981. An intensive field trial and a multi-site surveillance exercise on the use of aldicarb to investigate methods for the assessment of possible environmental hazards presented by new pesticides. Agro Ecoystems 7: 239-262.
5/ The Agency will determine whether these data are required based on an evaluation of the avian residue monitoring studies requested in 70-1 of this table. If required, the Agency will notify the registrant and will provide a timeframe for submittal of the data which will be from 24 to 48 months from date of notification, depending on testing required.
6/ These data are not required to support current registered uses of acephate based on the demonstrated low acute toxicity to fish. However, the two studies cited have been reviewed and used in the hazard assessment of acephate.
7/ Based on the demonstrated low acute toxicity to aquatic organisms and the current registered use patterns of acephate, these data are not required.
8/ This study is only required on a case-by-case basis. In the case with acephate, the rat toxicity data submitted under 40 CFR 158.135 are sufficient.

* Study by itself satisfies the data requirement.
** Study by itself only partially satisfies the data requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

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

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood Crop; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ These data not required in accordance with §158.150.

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honeybee acute contact toxicity	TGAI	A,B,C,G,H	Yes	00014714	No
141-2 - Honeybee - toxicity of residues on foliage	TEP	A,B,C,G,H	Yes	00014715	No
141-4 - Honeybee subacute feeding study	(Reserved) 5/				
141-5 - Field testing for pollinators	TEP	--	No	--	No 4/

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.155 Nontarget Insect - Continued					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved) 6/				
142-1 - Aquatic insect life-cycle study	(Reserved) 6/				
142-3 - Simulated or actual field testing for aquatic insects	(Reserved) 6/				
143-1 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES thru 143-3	(Reserved) 6/				

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop: D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
4/ Results from lower tier study do not indicate the need for field testing.
5/ This requirement is reserved pending development of test methodology.
6/ This requirement is reserved pending further evaluation to determine what and when data should be required, and to develop appropriate test methods.

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TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
Use Related-Exposure	TEP	A,B,F,G,H,I	No	--	Yes 4/ 6 Months

1/ Composition: TEP = Typical end-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop: D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
° 6-Month Due Date is April 30, 1986 .
4/ The following data are required for the uses of acephate in forests; on domestic and commercial ornamentals; cotton; lettuce; and for indoor uses in homes, greenhouses and commercial establishments.
a) Applicator types (homeowners, grower, PCO, etc.).
b) Rate ranges and most commonly used rate in active ingredient per unit.
c) Most commonly used formulations and package sizes with percentages of each.
d) Most commonly used carrier/diluent(s); report ratios.
e) Report methods of application (ground vs. air; band vs. broadcast; fixed boom vs. rope wick; etc.) and projected percentages of each.
f) Report application timing in relation to crop growth and pest growth (life cycle). Report number of applications and application intervals; report percent applied at each application (% preemergence vs. % postemergence vs. % layby). Report timing of field operations (cultivation, thinning, harvesting, etc.) in relation to pesticide application(s) timing.
g) For pesticide(s) of concern, describe typical equipment and factors such as width of boom, volume per unit application, speed of spraying equipment (MPH), tank size and type, normal operating pressure (PSI), nozzle types, percent use of open vs. closed cabs, percent use of closed system transfer. (If preemergence, describe if planting operation is commonly performed at the time of pesticide application.)

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE

Use Related Exposure - Continued

h) Describe if nurse tank is used; ferrying time and average distance to water source.
i) Calculate time required to spray out an average tank full of pesticide; and the total number of acres/unit that can be treated in a typical work day.
j) Describe mixing/loading procedures commonly employed and numbers of mixers/loaders/applications (number of each type) employed for the entire spray operation; describe if applicator and mixer/loader are the same person, if not, give percentages of each type. Calculate actual mixer-loader pesticide exposure time; excluding time spent to add diluent.
k) Describe preharvest; reentry intervals.
l) Describe proportion of grower vs. custom applicators and custom equipment types commonly employed.
m) Estimate total numbers of workers exposed per site/unit by type (applicators, mixer-loaders, flaggers, etc.). If there are fetotoxic or teratogenic concerns, estimate number of females employed.
n) Describe protective clothing, equipment, and other currently employed means of pesticide exposure avoidance.
o) Describe methods of pesticide and container disposal currently employed.
p) Estimate numbers of bystanders potentially exposed to spray or dust from treated fields.
q) Identify increased or reduced hazards associated with mixing-loading and applying alternative chemicals. Identify any other hazards to farmworkers, bystanders, fish and wildlife, water supplies, etc., associated with potential increased use if the review chemicals were not available.

TABLE B

31 PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ACEPHATE

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Timeframe Listed Below 1/
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	R	[x]	[ ]		6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	R	[x]	[ ]	6	6 Months
61-3 - Discussion of Formation of Impurities	MP	R	[x]	[ ]	6	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	CR	[x]	[ ]	7	12 Months
62-2 - Certification of Limits	MP	R	[x]	[ ]		12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	R	[x]	[ ]	7	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	R	[x]	[ ]		6 Months
63-3 - Physical State	MP	R	[x]	[ ]		6 Months
63-4 - Odor	MP	R	[x]	[ ]		6 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	[x]	[ ]		6 Months
63-12 - pH	MP	CR	[x]	[ ]		6 Months
63-14 - Oxidizing or Reducing Action	MP	CR	[x]	[ ]		6 Months

TABLE B

32 PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ACEPHATE

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Timeframe Listed Below 1/
§158.120 Product Chemistry (Continued) Physical and Chemical Characteristics (Continued)						
63-15 - Flammability	MP	CR	[x]	[ ]	2	6 Months
63-16 - Explodability	MP	R	[x]	[ ]	3	6 Months
63-17 - Storage Stability	MP	R	[x]	[ ]	8	15 Months
63-18 - Viscosity	MP	CR	[x]	[ ]	4	6 Months
63-19 - Miscibility	MP	CR	[x]	[ ]	5	6 Months
63-20 - Corrosion Characteristics	MP	R	[x]	[ ]		15 Months
Other Requirements:						
64- 1 - Submittal of samples	MP	CR	[ ]	[x]		

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

1/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
- 6 Month Due Date is April 30, 1986 .
- 12 Month Due Date is October 31, 1986 .
- 15 Month Due Date is January 31, 1987 .

2/ Data required for MP's that are combustible liquids.

3/ Data required for MP's that contain an explosive ingredient.

4/ Data required for liquid MP's.

5/ Data required for MP's that are emulsifiable liquids.

6/ A description of the new manufacturing process yielding methylthioacetate (MTA) as an impurity, including purities of starting materials, reaction conditions, and any purification and quality control steps must be submitted.

7/ Analysis of five or more representative batches from the altered process for any impurity present at ≥0.1% by weight, MTA, and any other highly toxic and/or mutagenic/oncogenic impurity whether above or below 0.1% (w:w) including descriptions and validation of the analytical procedures must be submitted. The 97%, 85% and 75% MP's derived from the new manufacturing process must all be analyzed. Confidential statements of formula must also be submitted for all three products.

8/ Storage stability data to determine if MTA forms (or declines) in the 97%, 85% and 75% MP's must be submitted.

TABLE B

33 PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ACEPHATE (97%)

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 3/ *	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 2/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity - Rat	MP	Yes	00014675 00029696	No
81-2 - Acute Dermal Toxicity - Rabbit	MP	Yes	00014681 GS0042023	No
81-3 - Acute Inhalation Toxicity - Rat	MP	Yes	00015307	No
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00014686	No
81-5 - Primary Dermal Irritation - Rabbit	MP	Yes	00015305	No
81-6 - Dermal Sensitization - Guinea Pig	MP	Yes	GS0042037	No

TABLE B

34 PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ACEPHATE (85%)

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 4/ *	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 2/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity - Rat	MP	Yes	GS0042042	No
81-2 - Acute Dermal Toxicity - Rabbit	MP	Yes	00014681 GS0042023	No 6/
81-3 - Acute Inhalation Toxicity - Rat	MP	Yes	00015307	No 6/
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	GS0042041	No
81-5 - Primary Dermal Irritation - Rabbit	MP	Yes	00015305 GS0042043	No 7/
81-6 - Dermal Sensitization - Guinea Pig	MP	Yes	GS0042037	No 6/

TABLE B

35 PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ACEPHATE (75%)

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 5/ *	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 2/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity - Rat	MP	Yes	GS0042042	No 9/
81-2 - Acute Dermal Toxicity - Rabbit	MP	Yes	00014681 GS0042023	No 8/
81-3 - Acute Inhalation Toxicity - Rat	MP	Yes	GS0042046	No
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	GS0042044	No
81-5 - Primary Dermal Irritation - Rabbit	MP	Yes	GS0042043	No
81-6 - Dermal Sensitization - Guinea Pig	MP	Yes	GS0042037	No 8/

TABLE B

36 PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ACEPHATE

§158.135 Toxicology - Continued

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
3/ These data are sufficient to support registration of the 97% MP currently registered.
4/ These data are sufficient to support registration of the 85% MP currently registered.
5/ These data are sufficient to support registration of the 75% MP currently registered.
6/ Though these studies were conducted with the 97% MP, they are sufficient to support registration of the 85% MP.
7/ Though these studies were conducted with the 97% MP (00015305) and 75% (GS0042043), they are sufficient, when taken together to support registration of the 85% MP.
8/ Though this study was conducted with the 97% MP, it is sufficient to support registration of the 75% MP.
9/ Though this study was conducted with the 85% MP, it is sufficient to support registration of the 75% MP.

* Where there are more than one bibliographic data citation listed for a data requirement, each study by itself only partially satisfies that data requirement.

TABLE C

37 PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING ACEPHATE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
Usage Data	TEP	A,B,F,G,H,I	No	---	Yes 4/ 6 Months

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

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

3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
° 6-Month Due Date is April 30, 1986 .

4/ The following data are required for the uses of acephate in forests; on domestic and commercial ornamentals; cotton; lettuce; and for indoor uses in homes, greenhouses, and commercial establishments.
a. Total acres/units treated by commodity (site) in U.S.
b. Lbs/gallon ai applied annually to each site and most commonly used application rate.
c. Geographic areas of use, by site.
d. Product end-use data. Describe commodity end-uses and estimate percentages of each. For example: Percent of apples sold for fresh fruit, percent sold for processing (broken down by juice vs. applesauce).
e. Sales and production records including container types and sizes and State sales.

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE'S IMPURITY, METHYLTHIOACETATE (MTA)

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Timeframe for Data Submission 3/
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	PI	A,B,C,F,G,H,I	No	--	Yes 4/	9 Months
- Rabbit			No	--	Yes 4/	9 Months
81-2 - Acute Dermal Toxicity - Rat	PI	A,B,C,F,G,H,I	No	--	Yes 5/	9 Months
- Rabbit			Partially	GS0042051	Yes 6/	9 Months
81-3 - Acute Inhalation Toxicity - Rat	PI	A,B,C,F,G,H,I	Partially	GS0042050	Yes 7/	9 Months
81-4 - Primary Eye Irritation - Rabbit	PI	A,B,C,F,G,H,I	Yes	GS0042054; GS0042055	No	
81-5 - Primary Dermal Irritiation - Rabbit	PI	A,B,C,F,G,H,I	Yes	GS0042052	No	
81-6 - Dermal Sensitization - Guinea Pig	PI	A,B,C,F,G,H,I	Yes	GS0042053	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE'S IMPURITY, METHYLTHIOACETATE (MTA)

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/	
§158.135 Toxicology - Continued						
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: - Rodent, and	PI	A,B,C,F,G,H,I	No	--	Reserved 8/	
- Nonrodent (Dog)			No	--	Reserved 8/	
82-3 - 90-Day Dermal - Rabbit	PI	A,B,C,F,G,H,I	No	--	Yes 9/	15 Months
82-4 - 90-Day Inhalation: - Rat	PI	A,B,C,F,G,H,I	No	--	Reserved 10/	
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	PI	A,B,C,F,G,H,I	Partially	GS0042056	Yes 12/	9 Months
84-2 - Structural Chromosomal Aberration	PI	A,B,C,F,G,H,I	No	--	Yes	12 Months
84-4 - Other Genotoxic Effects	PI	A,B,C,F,G,H,I	No	--	Yes	12 Months
SPECIAL TESTING						
- Neurophysiological Studies of the Visual System	PI	A,B,C,F,G,H,I	No	--	Yes 11/	6 Months (Protocol)

TABLE A
GENERIC DATA REQUIREMENTS FOR ACEPHATE'S IMPURITY, METHYLTHIOACETATE (MTA)

§158.135 Toxicology - Continued

1/ Composition: PI = Pure ingredient.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
- 6 Month Due Date is April 30, 1986 .
- 9 Month Due Date is July 31, 1986 .
- 15 Month Due Date is January 31, 1987 .

4/ These studies must be performed with histopathologic examinations of the visual system and pituitary.
5/ The rat acute dermal study referenced in the "Material Information Bulletin" for methylthioacetate received from Chevron Chemical Company must be submitted.
6/ Report Socal No. 2207 (GS0042049) is an interim report; the final report must be submitted.
7/ The available rat acute inhalation study is classified as core minimum. An additional study must be performed with histopathologic examinations of the visual system and pituitary.
8/ If blindness an/or lesions of the visual system or pituitary are observed in the acute oral studies (81-1), then 90-day feeding studies will be required. If required, the Agency will notify the registrant and will provide a time frame for submittal of the data which will be 15 months from date of notification.
9/ A no-observed effect level (NOEL) for blindness and related histopathologic lesions must be defined.
10/ If blindness and/or lesions of the visual system or pituitary are observed in the acute inhalation study required to be submitted, then a 90-day inhalation study will be required. If required, the Agency will notify the registrant and will provide a time frame for submittal of the data which will be 15 months from date of notification.
11/ A proposed protocol for these studies must be submitted within 6 months. The studies must be submitted within 12 months from date of acceptance of the protocol by the Agency.
12/ A mouse lymphoma mutagenicity screen test conducted on MTA has been received and is acceptable. Additional testing as specified in the 84-2 data guidelines are required.

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

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

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

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

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

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

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

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

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

C. Options Available for Complying With Requirements to Submit Data

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

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

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

OR

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

OR

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

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

(Footnote continued on next page)

OR

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

OR

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

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

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

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

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

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

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

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

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

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

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

IV. SUBMISSION OF REVISED LABELING

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

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

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

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

A. Label Contents

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 8C. PHYSICAL OR CHEMICAL HAZARD

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

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

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

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

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

i. The flame extension is zero inches;

ii. There is no flashback; and

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

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

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

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

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

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

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

Classification Labeling Requirements

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

1. Front panel statement of restricted use classification.

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

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

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

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

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

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

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

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

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

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

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

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

B. Collateral Labeling

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

V. INSTRUCTIONS FOR SUBMISSION

A. For Manufacturing Products (MP) containing (name of pesticide) as an active ingredient.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

William H. Miller
Product Manager (16)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460
Phone No. (703) 557-2600

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

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

Appendix II-1

Guide to Use of This Bibliography

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

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

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

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

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

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

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

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

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

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

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

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

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

MRID CITATION

00014219 Warnock, R.E. (1973) Metabolism of Orthene to Ortho 9006 Detected in Rats. (Unpublished study received Feb 17, 1977 under 6F1680; submitted by Chevron Chemical Co., Richmond, Calif.; CDL: 098473-C)

00014496 Tucker, B.V. (1972) Residues of Orthene and Ortho 9006 in a Marine Diatom Growing in Treated Water. (Unpublished study received Aug 7, 1972 under 239-2406; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:001571-U)

00014518 Cheng, H.M. (1974) Characterization of 14C in Liver and Urine from Rats Treated Orally with S-Methyl-14C-Orthene or S-Methyl-14C-Ortho 9006. (Unpublished study received Nov 10, 1976 under 239-2418; submitted by Chevron Chemical Co., Richmond, Calif.; CDL: 095570-L)

00014532 Rich, G.J.; Leary, J.B. (1975) Residue Data Sheet: Soybeans: Test No. T-3074. (Unpublished study including test nos. T-3075 and T-3197, received Sep 10, 1975 under 239-2418; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:195034-B)

00014533 Post, H.A.; Leary, J.B. (1975) Residue Data Sheet: Soybeans: Test No. T-3076. (Unpublished study received Sep 10, 1975 under 239-2418; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:195034-C)

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00014540 Sakamoto, S.S.; Slagowski, J.L. (1976) Residue Data Sheet: Beans: Test No. T-3682. (Unpublished study including test nos. T-3683 and T-3756, received Jun 7, 1977 under 239-2418; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:232596-H)

00014541 Ross, B.L.; Slagowski, J.L. (1976) Residue Data Sheet: Snapbeans: Test No. T-3743. (Unpublished study including test nos. T-3744, T-3780, T-3781..., received Jun 7, 1977 under 239-2418; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:232596-J)

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MRID CITATION

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00014635 O'Connor, T.F.; Galletta, T.A. (1975) Environmental Impact Study of Aerially Applied Orthene on a Forest and Aquatic Ecosystem: LOTEL Report 174. (Unpublished study received Jun 30, 1975 under 239-2443; prepared by State Univ. of New York--Oswego, Lake Ontario Environmental Laboratory, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:225768-A)

00014637 Bocsor, J.G.; O'Connor, T.F. (1975) Environmental Impact Study of Aerially Applied Orthene on a Forest and Aquatic Ecosystem: Impact on Aquatic Ecosystem: LOTEL Report 174. (Unpublished study received Jun 30, 1975 under 239-2443; prepared by State Univ. of New York--Oswego, Lake Ontario Environmental Laboratory, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:225768-C)

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00014639 Bart, J.; Streckewald, T.; Peakall, D. (1975) Environmental Impact Study of Aerially Applied Orthene on a Forest and Aquatic Ecosystem: Impact on Birds: LOTEL Report 174. (Unpublished study received Jun 30, 1975 under 239-2443; prepared by State Univ. of New York--Oswego, Lake Ontario Environmental Laboratory, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:225768-E)

00014642 Moore, R.B. (1975) Environmental Impact Study of Aerially Applied Orthene on a Forest and Aquatic Ecosystem: Effects of Orthene on Soil Microorganisms: LOTEL Report 174. (Unpublished study received Jun 30, 1975 under 239-2443; prepared by State Univ. of New York--Oswego, Lake Ontario Environmental Laboratory, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:225768-H)

00014659 Elliott, E.J.; Leary, J.B. (1978) Residue Analysis of Acephate and Methamidophos in Crops, Soil, Water and Milk. Method RM-12A-5 dated Jan 25, 1978. (Unpublished study received Apr 17, 1979 under 239-2464; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:238179-G)

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

00014675 Cavalli, R.D. (1970) Acute Oral Toxicity of Ortho RE 12,420: SOCO 127/III:39. (Unpublished study received Jun 21, 1972 under 239-EX-61; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:223505-F)

00014681 Cavalli, R.D. (1970) Acute Dermal Toxicity of RE 12,420: SOCO 134/III:35. (Unpublished study received Jun 21, 1972 under 239-EX-61; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:223505-L)

00014686 Narcisse, J.K.; Cavalli, R.D. (1971) Eye Irritation Potential of Orthene Technical, Orthene 75S (CC-2153), and Orthene 75S (CC-2152): SOCAL 273/VI:107. (Unpublished study received Jun 21, 1972 under 239-EX-61; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:223505-Q)

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

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

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

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

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

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

NAME OF OTHER REGISTRANT

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

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

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

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

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

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

(To qualify, certify ALL four items)

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

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

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

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

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

NAME OF FIRM	DATE OF OFFER

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

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

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[44 FR 27953, May 11, 1979]

§ 162.10 Labeling requirements.

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

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

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

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

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

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

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

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

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

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

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

(ii) All required label text must:

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

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

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

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

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

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

(i) Is false or misleading, or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

APPENDIX IV-1
(continued)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate 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. All other pressurized containers	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. Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) Nonpressurized Containers	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) Rotational crop restrictions.

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

(D) [Reserved]

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

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

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

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

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

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

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

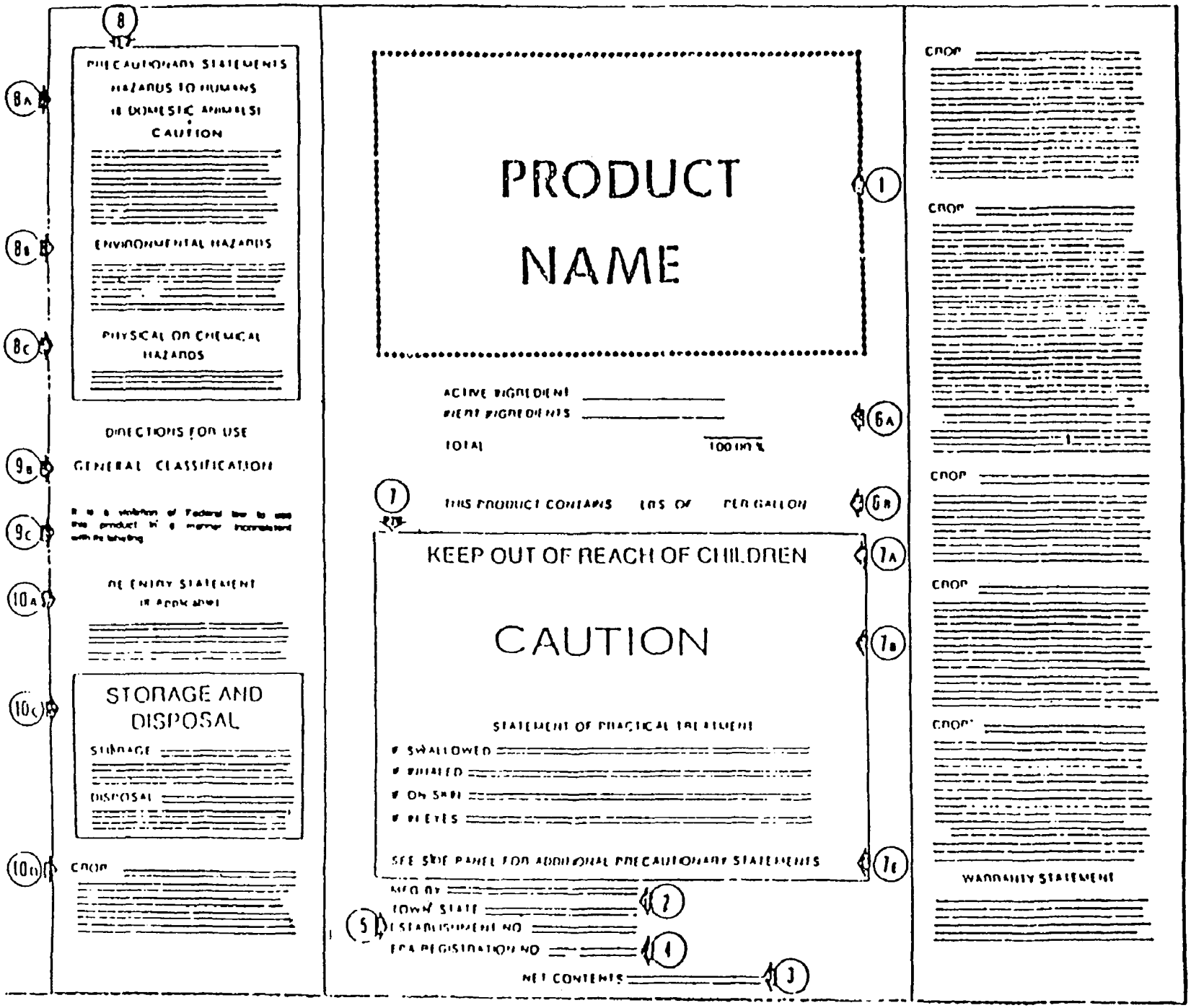
(k) Advertising. [Reserved]

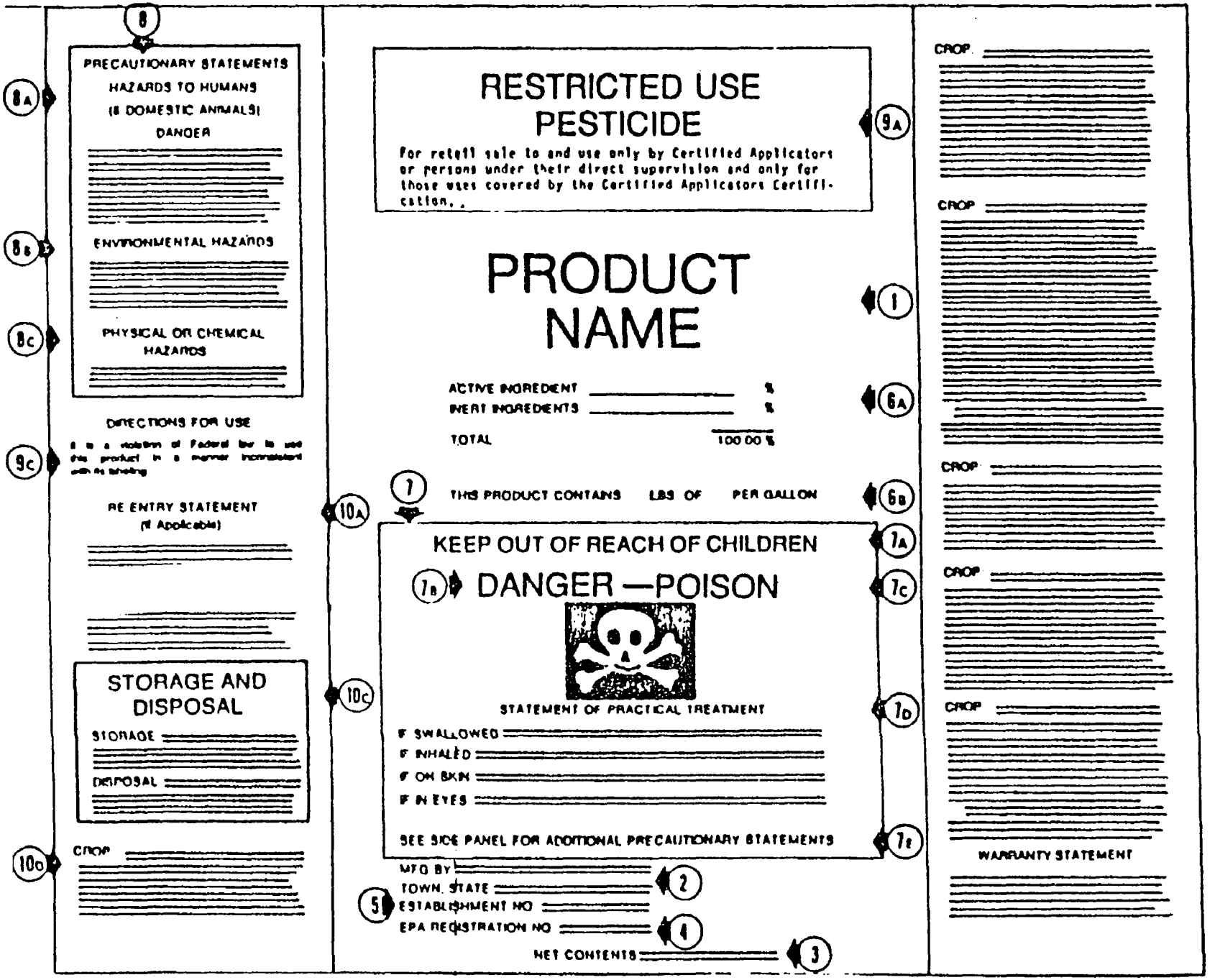
[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

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

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


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


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

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

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

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & 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 heading of directions for use		
10A	Reentry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

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

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

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

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

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

A. Storage Instructions:

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

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

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

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

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

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

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

B. Pesticide Disposal Instructions:

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

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

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

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

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

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

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

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

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

C. Container Disposal Instructions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6560-50

DRAFT

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

[OPP-36103;FRL]

PESTICIDE REGISTRATION STANDARDS; AVAILABILITY FOR COMMENT

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Availability of draft Standard for comment.

SUMMARY: This notice announces the availability of certain draft pesticide Registration Standard documents for comment. The Agency has completed a review of each listed pesticide and is making available a document describing its regulatory conclusions and actions.

DATE: Written comments on each Registration Standard should be submitted on or before [insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Three copies of comments identified with the docket number listed with each Registration Standard should be submitted to: By mail:

Information Services Section,
Program Management and Support Division (TS-757C),
Office of Pesticide Programs,
Environmental Protection Agency,
401 M St., SW.,
Washington, D.C. 20460.

85P-2132

In person, deliver comments to:

Rm. 236, CM#2,

1921 Jefferson Davis Highway,

Arlington, VA.

Information submitted as a comment in response to this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public docket. Information not marked confidential will be included in the public docket without prior notice. The public docket will be available for public inspection in Rm. 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. FOR FURTHER INFORMATION CONTACT: To request a copy of a Registration Standard, contact Frances Mann of the Information Services Section, in Rm. 236 at the address given above (703-557-3262). Requests should be submitted no later than [insert date 30 days after date of publication in FEDERAL REGISTER] to allow sufficient time for receipt before the close of the comment period.

For technical questions related to each Registration Standard, contact the Product Manager listed for that Standard, at the phone number given.

SUPPLEMENTARY INFORMATION: The Environmental Protection Agency conducts a systematic review of pesticides to determine whether they meet the criteria for continued registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). That review culminates in the issuance of a Registration Standard, a document describing the Agency's regulatory conclusions and positions on the continued registrability of the pesticide. In accordance with 40 CFR 155.34(c), published in the FEDERAL REGISTER on November 27, 1985 (50 FR 48998), before issuing certain Registration Standards, the Agency makes the draft document available for public comment.

Draft Registration Standards for the following pesticides are now available:

Name of pesticide	Docket number	Contact person
1. Acephate	30560-19-1	William H. Miller Product Manager 16 (703-557-2600)
2. Amitraz	33089-61-1	Jay Ellenberger Product Manager 12 (703-557-2386)
3. Chlordimeform	6164-98-3	Jay Ellenberger
4. Copper sulfate	1344-73-6	Richard Mountfort Product Manager 23 (703-557-1830)
5. Oryzalin	19044-88-3	Robert Taylor Product Manager 25 (703-557-1800)

Copies of each Registration Standard may be obtained from the Agency at the address listed under For Further Information Contact. Because of the length of each Standard and the limited number of copies available for distribution, only one copy can be provided by mail to any one individual or organization. Each Registration Standard is also available for inspection and copying in EPA Regional Offices at the addresses listed below after [insert date 30 days after date of publication in the FEDERAL REGISTER].

LIST OF EPA REGIONAL OFFICES

Pesticides Branch
EPA - Region I
JFK Federal Building
Boston, MA 02203
Contact person: ~~Harold Kazmaier~~ Andrew Triolo

Pesticides Branch
EPA - Region II
Woodbridge Avenue
Edison, NJ 08837
Contact person: ~~Fred Kozak~~ Dave Andreassen

EPA - Region III
Curtis Building
6th and Walnut Sts.
Philadelphia, PA 19106
Contact person: John Smith

Pesticide and Toxic Substances Branch
EPA - Region IV
345 Courtland St., NE
Atlanta, GA 30365
Contact person: Kent Williams

Toxic Materials Branch
EPA - Region V
230 South Dearborn St.
Chicago, IL 60604
Contact person: Lavarre Uhlken

Pesticide and Toxic Substances Branch
EPA - Region VI
1201 Elm St.
Dallas, TX 75270
Contact person: Norman Dyer

Pesticide and Toxic Substances Branch
EPA - Region VII
324 East 11th St.
Kansas City, MO 64106
Contact person: Leo Alderman

Toxic Substances Branch
EPA - Region VIII
1860 Lincoln St., Suite 900
Denver, CO 80295
Contact person: ~~Bob Harding~~ Dean Gillam

Hazardous Materials Branch
EPA - Region IX
215 Fremont St.
San Francisco, CA 94105
Contact person: ~~Nancy Frost~~ Laurie Perrot

Air & Water Division
EPA - Region X
1200 6th Ave.
Seattle, WA 98101
Contact person: ~~Lyn Frandsen~~ Chuck Shenk

Dated: _____

_____

Director,
Office of Pesticide Programs.